COSMETIC PRODUCT INFORMATION FILE

BIONIKS INTENSIVE CARE CREAM

Product Information File (R.1223/2009/EC, art. 11)
Cosmetic Product Safety Report (R.1223/2009/EC, art. 10, Annex I)
Safety Assessment (R.1223/2009/EC, art. 10, Annex I)
These information comply with (R.1223/2009/EC, art. 10, 11, Annex I)
These information comply with the 'UK Regulation: the EU Regulation as preserved in UK domestic law pursuant to the European Union (Withdrawal) Act 2018 and as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019'
Safety Assessment in Cosmetic Products (TR Cosmetics Law No. 5324)

Preparer: Dr. Pharm. Neslihan ŞAHİN
M.Sc. Cosmetology / PhD Toxicology

COSMETIC PRODUCT INFORMATION FILE

BIONIKS INTENSIVE CARE CREAM

R.1223/2009/EC Article 11, Product Information File:

The product information file shall contain the following information and data which shall be updated as necessary:

(a) a description of the cosmetic product which enables the product information file to be clearly attributed to the cosmetic product;

(b) the cosmetic product safety report referred to in Article 10 (1);

(c) a description of the method of manufacturing and a statement on compliance with good manufacturing practice referred to in Article 8;

(d) where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product;

(e) data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries.

R.1223/2009/EC Article 10 Safety assessment

The responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone a safety assessment on the basis of the relevant information and that a cosmetic product safety report is set up in accordance with Annex I.

R.1223/2009/EC Annex I Cosmetic Product Safety Report

The cosmetic product safety report shall, as a minimum, contain the following:

PART A – Cosmetic product safety information

1. Quantitative and qualitative composition of the cosmetic product
2. Physical/chemical characteristics and stability of the cosmetic product.
3. Microbiological quality
4. Impurities, traces, information about the packaging material
5. Normal and reasonably foreseeable use
6. Exposure to the cosmetic product

1) The site(s) of application;

2) The surface area(s) of application;

3) The amount of product applied;

4) The duration and frequency of use;

5) The normal and reasonably foreseeable exposure route(s);

6) The targeted (or exposed) population(s). Potential exposure of a specific population shall also be taken into account.

7. Exposure to the substances

8. Toxicological profile of the substances

9. Undesirable effects and serious undesirable effects.

10. Information on the cosmetic product

PART B – Cosmetic product safety assessment

1. Assessment conclusion
2. Labelled warnings and instructions of use
3. Reasoning
4. Assessor's credentials and approval of part B

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8. Toxicological profile of the substances

9. Undesirable effects and serious undesirable effects.

10. Information on the cosmetic product

PART B – Cosmetic product safety assessment

1. Assessment conclusion

2. Labelled warnings and instructions of use

3. Reasoning

4. Assessor's credentials and approval of part B

Annex I	Certificate of IFRA Compliance and Allergen Determination for Parfum Component
Annex II	Stability Forms
Annex III	Challenge Test Result
Annex IV	Microbiological Analysis Report
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III. Statement on Compliance With Good Manufacturing Practice

IV. Informations About Raw Materials

V. Finished product Certificate of Analysis

VI. Statement of Animal Testing

VII. Adverse and Serious Adverse Effect Declaration

VIII. Statement regarding to Nano Materials

IX. Statement regarding to claims

X. Finished product MSDS

I. INTRODUCTION

1. INFORMATION ON COSMETIC PRODUCT

Name of Cosmetic Product: BIONIKS INTENSIVE CARE CREAM - 50 ml 1.69 fl.oz
Category of Cosmetic Product: Leave on, Cosmetic Product, Cream.

2.MANUFACTURER AND PLACE OF MANUFACTURING

Name of Manufacturer	Bioniks Medikal Kozmetik Limited Şirketi
Adress of Manufacturer	Cevizli Mah. Mustafa Kemal Cad. Hukukçular İş Merkezı No: 34 İç Kapı No: 15 Kartal/ İstanbul
Contact Person & Phone No	Doğan TÜRKİSTANLI & -
Contact Person email adress:	-
Web Adress:	info@bioniks.com.tr

Name of Contract Manufacturer	Rk Kozmetik Ve Hijyen Ürünleri San. Dış Tic. A.Ş.
Adress of Manufacturer	İstanbul Deri Organize Sanayi Bölgesi Nokra Caddesi No:2/A Tuzla/Istanbul No:2 34957
Contact Person & Phone No	Ramazan KELEŞ & +90 555 152 88 01
Contact Person email adress:	ramazan@rkkozmetik.com
Web Adress:	https://www.rkkozmetik.com/

3.DESCRIPTION ON COSMETIC PRODUCT (R.1223/2009/EC Article 11, 2A-PIF)

BIONIKS INTENSIVE CARE CREAM is a leave-on cosmetic product formulated with Hyaluronic Acid Complex, Niacinamide, Panthenol, Betaine, Chamomilla Recutita Flower Extract and Aloe Barbadensis Leaf Juice to help maintain skin hydration, support the skin moisture barrier and provide a soothing effect to dry and sensitive skin. With regular use, the product helps maintain a balanced, healthy-looking and comfortable skin appearance.

The product belongs to the well-known category of skin care cosmetic products and is intended for use by the general adult population under normal and reasonably foreseeable conditions of use. The product is a cream and is placed on the market in a 50 ml size. The primary packaging consists of a cosmetic jar containing the product. The secondary packaging consists of a printed cardboard carton box containing the mandatory labeling information.

4.USE AND USERS (R.1223/2009/EC Article 11, 2A-PIF)

BIONIKS INTENSIVE CARE CREAM; Users Are Adults And Appropriate For All Types Of Skin

5. INTRODUCTION FOR USE

Cautions: Apply a sufficient amount of cream to clean, dry skin twice daily, morning and evening, massaging gently until absorbed. Suitable for both face and body. For external use only. Avoid direct contact with eyes. In case of contact, rinse thoroughly with plenty of water. Do not use on irritated or damaged skin. Keep out of reach of children.

II. COSMETIC PRODUCT SAFETY REPORT

bioniks

QUALITATIVE & QUANTITATIVE FORMULATION

PRODUCT NAME:	BIONIKS INSENTIVE CARE CREAM
PRODUCT FUNCTION:	SKIN PRODUCT
PRODUCT TYPE(LEAVE ON/RINSE OF)	LEAVE-ON
MANUFACTURER NAME	BİONİKS MEDİKAL KOZMETİK LİMİTED ŞİRKETİ
ADRESS	CEVİZLİ MAH. MUSTAFA KEMAL CAD. HUKUKÇULAR İŞ MERKEZI NO: 34 İÇ KAPI NO: 15 KARTAL/ İSTANBUL

No	Description (Raw Material INCI Name)	Blend Purpose	CAS Number	EINECS No	Range %	Spesification
1.	Aqua	Solvent	7732-18-5	231-791-2	72,704	INCI/CTFA
2.	Glycerin	Skin Conditioning - Humectant	56-81-5	200-289-5	10,125	INCI/CTFA
3.	Niacinamide	Smoothing	98-92-0	202-713-4	2,0000	INCI/CTFA
4.	Caprylic/Capric Triglyceride	Skin Conditioning - Occlusive	73398-61-5/ 65381-09-1	277-452-2/ 265-724-3	2,0000	INCI/CTFA
5.	Bis-Diglyceryl Polyacyladipate-2	Skin Conditioning - Emollient	82249-33-0	406-144-4	1,5000	INCI/CTFA
6.	Glyceryl Stearate	Skin Conditioning - Emollient	31566-31-1	250-705-4/286-490-9	1,5000	INCI/CTFA
7.	Panthenol	Skin Conditioning	81-13-0 / 16485-10-2	201-327-3 / 240-540-6	1,1385	INCI/CTFA
8.	Cetearyl Alcohol	Skin Conditioning - Emollient	267-008-6 / -	67762-27-0 / 8005-44-5	1,0000	INCI/CTFA
9.	1,2-Hexanediol	Skin Conditioning	6920-22-5	230-029-6	1,0000	INCI/CTFA
10.	Betaine	Skin Conditioning - Humectant	107-43-7/ 590-47-6	203-490-6/ 209-684-7	1,0000	INCI/CTFA
11.	Aloe Barbadensis Leaf Juice	Skin Conditioning	85507-69-3 / 94349-62-9	287-390-8 / 305-181-2	1,0000	INCI/CTFA
12.	Phenoxyethanol	Preservative	122-99-6	204-589-7	0,9320	INCI/CTFA
13.	Dimethicone	Skin Conditioning	63148-62-9 / 9006-65-9 / 9016-00-6	- / - / - /	0,8500	INCI/CTFA
14.	Polyacrylamide	Antistatic	9003-05-8	-	0,6000	INCI/CTFA
15.	Acrylates/C10-30 Alkyl Acrylate Crosspolymer	Emulsion Stabilising	-	-	0,5000	INCI/CTFA
16.	Saccharide İsomerate	Humectant	100843-69-4	-	0,5000	INCI/CTFA
17.	Laureth-7	Surfactant - Emulsifying	3055-97-8 / 68439-50-9 / 9002-92-0	221-283-9 / 500-213-3 / 500-002-6	0,3000	INCI/CTFA
18.	Sodium Stearoyl Lactylate	Surfactant - Emulsifying	25383-99-7 / 18200-72-1	246-929-7 / 242-090-6	0,3000	INCI/CTFA
19.	C13-14 İsoparaffin	Skin Conditioning - Emollient	246538-79-4	-	0,2500	INCI/CTFA
20.	Sodium Lauroyl Glutamate	Antistatic	29923-31-7 / 29923-34-0 / 42926-22-7 / 98984-78-2	249-958-3 / - / - / -	0,2000	INCI/CTFA
21.	Dimethicone Crosspolymer	Emulsion Stabilising	-	-	0,1500	INCI/CTFA
22.	Chamomilla Recutita Flower Extract	Skin Conditioning	84082-60-0	282-006-5	0,1250	INCI/CTFA
23.	Ethylhexylglycerin	Skin Conditioning	70445-33-9	408-080-2	0,1180	INCI/CTFA
24.	Squalane	Skin Conditioning - Emollient	111-01-3	203-825-6	0,1000	INCI/CTFA
25	Hyaluronic Acid	Skin Conditioning	9004-61-9	232-678-0	0,0225	INCI/CTFA
26.	Citric Acid	Buffering	77-92-9 / 5949-29-1	201-069-1	0,0200	INCI/CTFA
27.	Sodium Acetylated	Humectant	-	-	0,0180	INCI/CTFA

	Hyaluronate					
28.	Sodium Hyaluronate	Skin Conditioning	9067-32-7	-	0,0150	INCI/CTFA
29.	Sodium Citrate	Chelating	68-04-2 / 6132-04-3	200-675-3	0,0100	INCI/CTFA
30.	Sodium Hyaluronate Crosspolymer	Skin Conditioning	105524-32-1	-	0,0075	INCI/CTFA
31.	Hydroxypropyltrimonium Hyaluronate	Film Forming	-	-	0,0045	INCI/CTFA
32.	Hydrolyzed Hyaluronic Acid	Skin Conditioning	-	-	0,0030	INCI/CTFA
33.	Hydrolyzed Sodium Hyaluronate	Skin Conditioning	-	-	0,0030	INCI/CTFA
34.	Potassium Sorbate	Preservative	24634-61-5 / 590-00-1	246-376-1 / -	0,0020	INCI/CTFA
35.	Sodium Benzoate	Preservative	532-32-1	208-534-8	0,0010	INCI/CTFA
36.	Benzoic Acid	Preservative	65-85-0	200-618-2	0,0005	INCI/CTFA
37.	Dehydroacetic Acid	Preservative	520-45-6 / 771-03-9 / 16807-48-0	208-293-9 / 212-227-4 / -	0,0005	INCI/CTFA

İçindekiler / Ingredients (INCI): Aqua, Glycerin, Niacinamide, Caprylic/Capric Triglyceride, Bis-Diglyceryl Polyacyladipate-2, Glyceryl Stearate, Panthenol, Cetearyl Alcohol, 1,2-Hexanediol, Betaine, Aloe Barbadensis Leaf Juice, Phenoxyethanol, Dimethicone, Polyacrylamide, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Saccharide Isomerate, Laureth-7, Sodium Stearoyl Lactylate, C13-14 Isoparaffin, Sodium Lauroyl Glutamate, Dimethicone Crosspolymer, Chamomilla Recutita Flower Extract, Ethylhexylglycerin, Squalane, Hyaluronic Acid, Citric Acid, Sodium Acetylated Hyaluronate, Sodium Hyaluronate, Sodium Citrate, Sodium Hyaluronate Crosspolymer, Hydroxypropyltrimonium Hyaluronate, Hydrolyzed Hyaluronic Acid, Hydrolyzed Sodium Hyaluronate, Potassium Sorbate, Sodium Benzoate, Benzoic Acid, Dehydroacetic Acid.

Name: Dr.Pharm. Neslihan SAHİN
Position: Technical Director
Signed:

COSMETIC PRODUCT SAFETY ASSESSMENT REPORT

Name of Manufacturer	Bioniks Medikal Kozmetik Limited Şirketi
Adress of Manufacturer	Cevizli Mah. Mustafa Kemal Cad. Hukukçular İş Merkezı No: 34 İç Kapı No: 15 Kartal/ İstanbul
Contact Person & Phone No	Doğan TÜRKİSTANLI & -
Contact Person email adress:	-
Web Adress:	info@bioniks.com.tr

Name of Contract Manufacturer	Rk Kozmetik Ve Hijyen Ürünleri San. Dış Tic. A.Ş.
Adress of Manufacturer	İstanbul Deri Organize Sanayi Bölgesi Nokra Caddesi No:2/A Tuzla/Istanbul No:2 34957
Contact Person & Phone No	Ramazan KELEŞ & +90 555 152 88 01
Contact Person email adress:	ramazan@rkkozmetik.com
Web Adress:	https://www.rkkozmetik.com/

PART A – Cosmetic product safety information

1.Quantitative and qualitative composition of the cosmetic product

Raw materials components;

Raw Materials Chemical Name /or/ Trade Name	Raw Materials INCI Name	CAS Number	EINECS /ELINCS Number	Weight by % of raw material	Amount of concentration in raw material (% Concentration)	Amount of Use (% Concentration)	Amount of Raw Material in Finished Product (% Concentration)	Intended Use	Regulatory Compliance of 1223/2009 EC
WATER	Aqua	7732-18-5	231-791-2	72,7 04	100	72,704	Max. 72,704	Solvent	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/31959
EUXYL	Phenoxyethanol	122-99-6	204-	1,00	>88,5-	0,915000	Max. 0,915000	Preservative	**LIST OF PRESERVATIVES ALLOWED IN**

PE 9010			589-7		91,5 % >88,5				**COSMETIC PRODUCTS** **Annex / Ref #** V/29 **SCCS opinions** http://ec.europa.eu/health/ph_risk/committees/sccp/docshtml/sccp_out59_en.htm **Maximum concentration in ready for use preparation 1.0%** **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/28157
	Ethylhexylglycerin	70445-33-9	408-080-2		>8,5 - 11,5 %	0,115000	Max. 0,115000	Skin Conditioning	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/33896
CHT-BeauSil GEL 8014	Dimethicone	63148-62-9 / 9006-65-9 / 9016-00-6	- / - / - /	1,00	To 100	0,850000	Max. 0,850000	Skin Conditioning	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/33401
	Dimethicone Crosspolymer	-	-		10 - 15	0,150000	Max. 0,150000	Emulsion Stabilising	There is no any restriction for usage amount and usage area. **APPROPRIATE**

									REF. https://ec.europa.eu/growth/tools-databases/cosing/details/55749
Neossance Squalane	Squalane	111-01-3	203-825-6	0,1000	100	0,1000	Max. 0,1000	Skin Conditioning - Emollient	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/38226
Niacinamide	Niacinamide	98-92-0	202-713-4	2,0000	100	2,0000	Max. 2,0000	Smoothing	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/35499
D-panthenol %75	Aqua	7732-18-5	231-791-2	1,50	25	0,37500	Max. 0,37500	Solvent	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/31959
	Panthenol	81-13-0 / 16485-10-2	201-327-3 / 240-540-6		75,9	1,1385	Max. 1,1385	Skin Conditioning	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/35839
Lipestrol G-810	Caprylic/Capric Triglyceride	73398-61-5/ 65381-09-1	277-452-2/ 265-	2,0000	100	2,000	Max. 2,000	Skin Conditioning - Occlusive	There is no any restriction for usage amount and usage

			724-3						area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/74816	
SOFT ISAN 649	Bis-Diglyceryl Polyacyladipate-2	82249-33-0	406-144-4	1,50	100	1,50	Max. 1,50	Skin Conditioning - Emollient	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/74501	
Glycerin	Glycerin	56-81-5	200-289-5	10,00	100	10,00	Max. 10,00	Skin Conditioning - Humectant	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/34040	
Aevum Vita 500	Polyacrylamide	9003-05-8	-	1,00	50 - 60	0,60000	Max. 0,60000	Antistatic	**Annex / Ref #**	III / 66
									Product Type, body parts	(b) Other products
									Other	(b) Maximum residual acrylamide content 0.5mg/kg
									SCCS opinions	Opinion concerning Acrylamide Residues in Cosmetics

									APPROPRIATE REF. https://ec.europa.eu/growth/tools-databases/cosing/details/36687
	C13-14 Isoparaffin	246538-79-4	-		10 - 25	0,25000	Max. 0,25000	Skin Conditioning - Emollient	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/32236
	Laureth-7	3055-97-8 / 68439-50-9 / 9002-92-0	221-283-9 / 500-213-3 / 500-002-6		10 - 30	0,30000	Max. 0,30000	Surfactant - Emulsifying	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/34924
PROTELAN NMF	Glyceryl Stearate	31566-31-1	250-705-4/286-490-9	2,000	45,00 – 75,00	1,50000	Max. 1,50000	Skin Conditioning - Emollient	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/34103
	Cetearyl Alcohol	267-008-6 / -	67762-27-0 / 8005-44-5		30,00 – 50,00	1,00000	Max. 1,00000	Skin Conditioning - Emollient	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/75132

	Sodium Stearoyl Lactylate	25383-99-7 / 18200-72-1	246-929-7 / 242-090-6		5,00 – 15,00	0,300	Max. 0,300	Surfactant - Emulsifying	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/80101
	Sodium Lauroyl Glutamate	29923-31-7 / 29923-34-0 / 42926-22-7 / 98984-78-2	249-958-3 / - / - / -		5,00 – 10,00	0,200	Max. 0,200	Antistatic	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/79683
Carbopol®* Ultrez 21 Polymer	Acrylates/ C10-30 Alkyl Acrylate Crosspolymer	-	-	0,5000	100	0,500	Max. 0,500	Emulsion Stabilising	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/74162
NOVAGUARD HG	1, 2-Hexanediol	6920-22-5	230-029-6	1,0000	100	1,0000	Max. 1,0000	Skin Conditioning	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/54170
8D Hyaluronic Acid	Sodium Hyaluronate	9067-32-7	-	1,500	0,3 - 1,0	0,015	Max. 0,015	Skin Conditioning	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/detai

									ls/79556
	Hyaluronic Acid	9004-61-9	232-678-0		0,2 - 1,0	0,015	Max. 0,015	Skin Conditioning	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/34315
	Hydroxypropyltrimonium Hyaluronate	-	-		0,1 – 0,3	0,0045	Max. 0,0045	Film Forming	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/56838
	Sodium hyaluronate Crosspolymer	105524-32-1	-		0,2 - 0,5	0,0075	Max. 0,0075	Skin Conditioning	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/79557
	Sodium Acetylated Hyaluronate	-	-		0,5 - 1,2	0,018	Max. 0,018	Humectant	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/58706
	Hydrolyzed Sodium Hyaluronate	-	-		0,1 - 0,2	0,003	Max. 0,003	Skin Conditioning	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.**

									https://ec.europa.eu/growth/tools-databases/cosing/details/87175
	Hydrolyzed Hyaluronic Acid	-	-		0,05 - 0.2	0,003	Max. 0,003	Skin Conditioning	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/82209
	Hyaluronic Acid	9004-61-9	232-678-0		0,2 - 0,5	0,0075	Max. 0,0075	Skin Conditioning	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/34315
	Phenoxyethanol	122-99-6	204-589-7		0,1 – 0,8	0,012	Max. 0,012	Preservative	**LIST OF PRESERVATIVES ALLOWED IN COSMETIC PRODUCTS** **Annex / Ref #** V/29 **SCCS opinions** http://ec.europa.eu/health/ph_risk/committees/sccp/docshtml/sccp_out59_en.htm **Maximum concentration in ready for use preparation 1.0%** **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-

									databases/cosing/details/28157
	Ethylhexylglycerin	70445-33-9	408-080-2		0,05 - 0.2	0,003	Max. 0,003	Skin Conditioning	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/33896
	Aqua	7732-18-5	231-791-2		To 100	1,4115	Max. 1,4115	Solvent	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/31959
GENENCARE® OSMS CC	Betaine	107-43-7/ 590-47-6	203-490-6/ 209-684-7	1,0000	100	1,0000	Max. 1,0000	Skin Conditioning - Humectant	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/74520
CHAMOMILE GERMAN EXTRACT 20 GLY-LG	Chamomilla Recutita Flower Extract	84082-60-0	282-006-5	0,5	10 - 25	0,125	Max. 0,125	Skin Conditioning	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/55292

	Aqua	7732-18-5	231-791-2		>50	0,25	Max. 0,25	Solvent	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/31959
	Glycerin	56-81-5	200-289-5		10 - 25	0,125	Max. 0,125	Skin Conditioning - Humectant	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/34040
	Phenoxyethanol	122-99-6	204-589-7		0,1 - 1	0,005	Max. 0,005	Preservative	**LIST OF PRESERVATIVES ALLOWED IN COSMETIC PRODUCTS** **Annex / Ref #** V/29 **SCCS opinions** http://ec.europa.eu/health/ph_risk/committees/sccp/docshtml/sccp_out59_en.htm **Maximum concentration in ready for use preparation 1.0%** **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/28157
		65-85-0	200-618-2		<0,1 %	0,0005	Max. 0,0005	Preservative	**LIST OF PRESERVATIVES**

		Benzoic Acid								**ALLOWED IN COSMETIC PRODUCTS** **Annex / Ref #**: V / 1 **Product Type, body parts**: c) Leave-on products **Maximum concentration in ready for use preparation**: **c) 0.5% (acid)** **SCCS opinions**: Opinion on Benzoic Acid and Sodium Benzoate **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/32134
		Dehydroacetic Acid	520-45-6 / 771-03-9 / 16807-48-0	208-293-9 / 212-227-4 / -		<0,1 %	0,0005	Max. 0,0005	Preservative	**LIST OF PRESERVATIVES ALLOWED IN COSMETIC PRODUCTS** **Annex / Ref #**: V / 13 **Other**: Not to be used in aerosol dispensers (sprays) **Maximum concentration in ready for use preparation**: **0.6% (as acid)** **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-

									databases/cosing/details/33185
PENTAVITIN®	Saccharide Isomerate	100843-69-4	-	1,00	>50	0,5	Max. 0,5	Humectant	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/79971
	Aqua	7732-18-5	231-791-2		>25-50	0,5	Max. 0,5	Solvent	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/31959
	Citric Acid	77-92-9 / 5949-29-1	201-069-1		>0,10-1,0	0,01	Max. 0,01	Buffering	**SCCS opinions** Opinion on Citric acid (and) Silver Citrate **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/32858
	Sodium Citrate	68-04-2 / 6132-04-3	200-675-3		>0,10-1,0	0,01	Max. 0,01	Chelating	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/37816

Aloe Vera 10 to 1 Concantre	Aloe Barbadensis Leaf Juice	85507-69-3 / 94349-/ 62-9	287-390-8 / 305-181-2	1,00	> 98,0 to ≤	1,00	Max. 1,00	Skin Conditioning	There is no any restriction for usage amount and usage area. **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/54347
	Citric Acid	77-92-9 / 5949-29-1	201-069-1		≤ 1,0	0,01	Max. 0,01	Buffering	**SCCS opinions** Opinion on Citric acid (and) Silver Citrate **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/32858
	Sodium Benzoate	532-32-1	208-534-8		≤ 0,1	0,001	Max. 0,001	Preservative	**LIST OF PRESERVATIVES ALLOWED IN COSMETIC PRODUCTS** **Annex / Ref #** V / 1 **Product Type, body parts** c) Leave-on products **Maximum concentration in ready for use preparation** c) 0.5% (acid) **SCCS opinions** Opinion on Benzoic Acid and Sodium Benzoate **APPROPRIATE REF.** https://ec.europa.eu/growth/tools-databases/cosing/details/37735

	Potassium Sorbate	24634-61-5 / 590-00-1	246-376-1 / -		≤ 0,2	0,002	Max. 0,002	Preservative	**LIST OF PRESERVATIVES ALLOWED IN COSMETIC PRODUCTS**	
									Annex / Ref #	V / 4
									Maximum concentration in ready for use preparation	**0.6% (acid)**
									SCCS opinions	Opinion concerning Restrictions on Materials listed in annex VI of Directive 76/768/EEC on Cosmetic Products
									APPROPRIATE REF.	https://ec.europa.eu/growth/tools-databases/cosing/details/37025

Parfum component;

BIONIKS INTENSIVE CARE CREAM does not contain parfum components.

Parfum Components Name	Parfum Components Code Number	Identitiy of The Supplier	Amount of Use (% Concentration)
-	-	-	-

Aromatic component;

BIONIKS INTENSIVE CARE CREAM does not contain aromatic components.

Aromatic Components Name	Aromatic Components Code Number	Identitiy of The Supplier	Amount of Use (% Concentration)
-	-	-	-

Safety Assessor's Comment: BIONIKS INTENSIVE CARE CREAM is a leave-on cosmetic product formulated with Ceramides, Squalane, Hyaluronic Acid, Panthenol, Shea Butter and Vitamin E. The formulation does not contain added perfume, fragrance substances or aromatic ingredients. Consequently, an IFRA Certificate of Conformity and fragrance allergen identification documentation are not applicable for this product.

2. Physical/chemical characteristics and stability of the cosmetic product

a) Physical/chemical characteristics:

Parameter		Specifications	Result
Organoleptic Characteristics	**Appearance**	Cream	Approved
	Color	White	Approved
	Odor	Characteristic / Odorless	Approved
Flammability		Not Flammable	Approved
pH		6,0	Approved
Resolution / Homogeneity		Homogeneous	Approved

b) Stability: The **BIONIKS INTENSIVE CARE CREAM** product has been subjected to stability testing. The product was analyzed over a period of 45 days under different storage conditions, including 40°C. During the test period, parameters such as appearance, colour, odour, pH, and packaging integrity were evaluated. No significant changes were observed, and the product was found to be stable. The product is a cream and is placed on the market in a 50 ml size. The primary packaging consists of a cosmetic jar containing the product. The secondary packaging is a printed cardboard carton box. Stability test results are presented in **PIF Annex II**.

3. Microbiological quality

BIONIKS INTENSIVE CARE CREAM has been tested for microbiological quality. The presence of total mesophilic aerobic bacteria, yeast and mould, and specified pathogenic microorganisms including *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Escherichia coli* and *Candida albicans* were evaluated in the finished product. Microbiological analyses were performed according to relevant ISO standards (TS EN ISO 21149, 16212, 22717, 22718, 18416 and 21150). According to the test results, total mesophilic aerobic bacteria and total yeast and mould counts were found to be <10 cfu/g. Pathogenic microorganisms such as *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Escherichia coli* and *Candida albicans* were not detected in

the finished product. The results comply with the Cosmetic Regulation and the Guideline for Microbiological Control of Cosmetic Products. The microbiological test results are presented in **PIF Annex IV**.

BIONIKS INTENSIVE CARE CREAM contains a preservative system. The Challenge Test has been performed and evaluated separately. Challenge test results are presented in **PIF Annex III**.

4. Impurities, traces and the information about the packaging material

A- Impurities and Residues

Impurities originating from raw materials are documented in the raw material information section of the Product Information File (PIF). There are no impurities in the finished product that pose a risk under normal or reasonably foreseeable conditions of use. Furthermore, available supplier documentation including Safety Data Sheets (SDS), Technical Data Sheets (TDS) and Certificates of Analysis (CoA) were reviewed during the safety assessment. No specific concern regarding impurities, residues or contaminants was identified.

B – Packaging Material

BIONIKS INTENSIVE CARE CREAM;

• The product is a cream and is placed on the market in a 50 ml size. The primary packaging consists of a cosmetic jar containing the product. The product label is affixed to the primary container. The secondary packaging consists of a printed cardboard carton box containing the mandatory product information.

The packaging system has been selected to ensure compatibility with the cosmetic formulation under normal and reasonably foreseeable conditions of storage and use. Packaging compatibility has been evaluated and no incompatibility between the formulation and packaging materials has been identified. The packaging and the product consist of matching components suitable for the intended cosmetic application. Information about packaging materials is presented in Annex V.

5. Normal and reasonably foreseeable use

Product usage: Apply a sufficient amount of cream to clean, dry skin twice daily, morning and evening, massaging gently until absorbed. Suitable for both face and body. For external use only. Avoid contact with eyes. In case of contact, rinse thoroughly with plenty of water. Do not use on irritated or damaged skin. Keep out of reach of children.

Product use frequency: The frequency of application is specified on the product label. According to SCCS Notes of Guidance exposure data for body lotion products, the frequency of application is considered as **2.28/day**.

Label information

bioniks

INTENSIVE CARE CREAM

hyaluronic acid complex niacinamide
chamomile extract aloe barbadensis leaf juice

hydrate + soothe + comfort

Deep Moisture Reservoir
Utilizes a Multi-Hyaluronic
Complex to deliver intense,
long-lasting hydration.
Instant Botanical Calm
Harnesses Chamomile and Aloe
Vera to instantly soothe and
relieve dry skin.
Skin Equilibrium
Enriched with Niacinamide and
Panthenol to maintain a healthy
and balanced complexion.
50 ml 1.69 fl.oz

INTENSIVE CARE CREAM

Enriched with Hyaluronic Acid Complex, Niacinamide, Chamomile Extract, Aloe Barbadensis Leaf Water, Panthenol, and Betaine, this intense moisturizer deeply hydrates and soothes the skin. It helps maintain the skin's optimal moisture balance, keeping it soft and supple, all day long. Directions for use/Cautions: Apply a sufficient amount of cream to clean, dry skin twice daily, morning and evening, massaging it in. Suitable for both face and body. For external use only. Avoid contact with eyes. In case of contact, rinse thoroughly with plenty of water. Do not use on irritated or damaged skin. Keep out of reach of children.

YOĞUN BAKIM KREMİ

Hyaluronik Asit Kompleksi, Niasinamid, Papatya Özü, Aloe Barbadensis Yaprağı Suyu, Pantenol ve Betain ile zenginleştirilmiş yoğun nemlendirici, cildi derinlemesine nemlendirirken cildin sakinleşmesini destekler. Cildin optimum nem dengesinin korunmasına yardımcı olarak cildin gün boyu yumuşak ve esnek görünmesini destekler. Kullanım Şekli/Uyarılar: Günde iki kez sabah ve akşam, temiz ve kuru cildinize yeterli miktarda kremi masaj yaparak uygulayınız. Hem yüz hem de vücut için kullanımı uygundur. Harici kullanılır. Göz ile temasından kaçınınız. Temas halinde bol su ile durulayınız. Tahriş olmuş veya hasar görmüş cilt üzerinde kullanmayınız. Çocukların ulaşamayacağı yerde saklayınız.

İçindekiler / Ingredients (INCI): Aqua, Glycerin, Niacinamide, Caprylic/Capric Triglyceride, Bis-Diglyceryl Polyacyladipate-2, Glyceryl Stearate, Panthenol, Cetearyl Alcohol, 1,2-Hexanediol, Betaine, , Aloe Barbadensis Leaf Juice, Squalane, Hyaluronic Acid, Sodium Acetylated Hyaluronate, Sodium Hyaluronate, Saccharide Isomerate, Sodium Hyaluronate Crosspolymer, Hydroxypropyltrimonium Hyaluronate, Hydrolyzed Sodium Hyaluronate, Hydrolyzed Hyaluronic Acid, Phenoxyethanol, Dimethicone, Polyacrylamide, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Laureth-7, Sodium Stearoyl Lactylate, C13-14 Isoparaffin, Sodium Lauroyl Glutamate, Dimethicone Crosspolymer, Chamomilla Recutita Flower Extract, Ethylhexylglycerin, Citric Acid, Sodium Citrate, Benzoic Acid, Dehydroacetic Acid,
Sodium Benzoate, Potassium Sorbate.

Elevate your daily routine

SORUMLU KİŞİ:

BİONİKS MEDİKAL KOZMETİK LTD.ŞTİ.
Cevizli Mah. Mustafa Kemal Cad. Hukukçular İş Merkezi No: 34 İç Kapı No:15 Kartal/İstanbul
info@bioniks.com.tr

BARKOD: 8685221795120

Lot No: B0426IC01

Exp. Date: 04.2029

Made in TÜRKİYE

50 ml e / 1.69 fl.oz.

6. Exposure to the cosmetic product

Product Type: Cosmetic Leave-on skin care product (Face and Body Cream / Body Lotion)

1) The site(s) of application: area body – area head

2) The surface area(s) of application (cm2): 15670 cm² (SCCS Notes of Guidance, 12th Revision, Body Lotion)

3) The amount of product applied (g): 7.82 g (SCCS Notes of Guidance, 12th Revision, Body Lotion)

4) The duration and frequency of use: 2.28/day (SCCS Notes of Guidance, 12th Revision, Body Lotion)

Safety Assesor's Comment: The product label recommends application twice daily, morning and evening, and states that the product is suitable for both face and body. For safety assessment purposes, the exposure values established for body lotion products in the SCCS Notes of Guidance were used as a conservative worst-case approach.

5) The normal and reasonably foreseeable exposure route(s): Exposure with direct skin, dermal and Leave-on

6) The targeted (or exposed) population(s). Potential exposure of a specific population shall also be taken into account: The targeted population is adults.

7) Possibility of secondary exposure: There is no possibility of secondary exposure way.

Safety Assessor's Comment: As BIONIKS INTENSIVE CARE CREAM is a leave-on cosmetic product intended for application to both face and body, the exposure values established for body lotion products in the SCCS Notes of Guidance (12th Revision) were considered appropriate and were therefore used for the safety assessment as a conservative worst-case exposure scenario.

[Ref: The SCCS Notes of Guidance For The Testing Of Cosmetic Ingredients and Their Safety Evaluation, 12th Revision]

7. Exposure to the substances

SED = A (mg/kg body weight/day) × C(%) / 100 × DAp (%)/100

SED (mg/kg body weight/day): The Systemic Exposure Dosage of a cosmetic ingredient is the amount expected to enter the bloodstream (and therefore be systemically available) per kg body weight and per day. It is expressed in mg/kg body weight/day.

A (mg/kg body weight/day): Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application.

C(%): Concentration of the ingredient under study in the finished cosmetic product on the application site.

DAp (%): Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions.

DAp was considered as 100 in calculations.

For Body Lotion; A = 123.20 mg/kg bw/day for raw materials.

For preservative ingredients, aggregate exposure is considered in accordance with SCCS Notes of Guidance. Therefore, A = 269 mg/kg bw/day is accepted and used in the safety calculations for preservative substances.

Safety Assessor's Comment: As **BIONIKS INTENSIVE CARE CREAM** is a leave-on cosmetic product intended for application to both face and body, the exposure values established for body lotion products in the SCCS Notes of Guidance (12th Revision) were used for the safety assessment as a conservative worst-case approach.

Where ingredient-specific dermal absorption data are unavailable, a default dermal absorption value of **100%** may be applied as a conservative worst-case assumption.

Although complete dermal penetration is not expected under normal physiological conditions due to the barrier function of human skin, the use of **DAp = 100%** intentionally overestimates systemic exposure and therefore provides an additional margin of consumer protection.

Consequently, **DAp = 100%** represents a protective worst-case exposure scenario and does not reflect the actual expected dermal absorption of the ingredient.

[Ref: The SCCS Notes of Guidance For The Testing Of Cosmetic Ingredients and Their Safety Evaluation, 12th Revision]

SED calculations of the individual raw materials, excluding preservative and fragrance components, are presented below. The exposure parameters (A value and DAp) described in Section 7 have been applied consistently throughout all SED calculations.

- ***SED calculation for Aqua:***

A: 123,2 mg/kg bw/day
C: % 72,704
SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100
SED = 123,2 x 72,704/100 x 100/100
SED= 89,571328 mg/kg bw/day

- ***SED calculation for Glycerin:***

A: 123,2 mg/kg bw/day
C: % 10,125
SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100
SED = 123,2 x 10,125/100 x 100/100
SED= 12,474 mg/kg bw/day

- ***SED calculation for Niacinamide:***

A: 123,2 mg/kg bw/day
C: % 2
SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100
SED = 123,2 x 2/100 x 100/100
SED= 2,464 mg/kg bw/day

- ***SED calculation for Caprylic/Capric Triglyceride:***

A: 123,2 mg/kg bw/day
C: % 2
SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100
SED = 123,2 x 2/100 x 100/100
SED= 2,464 mg/kg bw/day

- ***SED calculation for Bis-Diglyceryl Polyacyladipate-2:***

A: 123,2 mg/kg bw/day
C: % 1,5
SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100
SED = 123,2 x 1,5/100 x 100/100
SED= 1,848 mg/kg bw/day

- ***SED calculation for Glyceryl Stearate:***

A: 123,2 mg/kg bw/day

C: % 1,5

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 1,5/100 x 100/100

SED= 1,848 mg/kg bw/day

- ***SED calculation for Panthenol:***

A: 123,2 mg/kg bw/day

C: % 1,1385

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 1,1385/100 x 100/100

SED= 1,402632 mg/kg bw/day

- ***SED calculation for Cetearyl Alcohol:***

A: 123,2 mg/kg bw/day

C: % 1

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 1/100 x 100/100

SED= 1,232 mg/kg bw/day

- ***SED calculation for 1,2-Hexanediol:***

A: 123,2 mg/kg bw/day

C: % 1

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 1/100 x 100/100

SED= 1,232 mg/kg bw/day

- ***SED calculation for Betaine:***

A: 123,2 mg/kg bw/day

C: % 1

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 1/100 x 100/100

SED= 1,232 mg/kg bw/day

- ***SED calculation for Aloe Barbadensis Leaf Juice:***

A: 123,2 mg/kg bw/day

C: % 1

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 1/100 x 100/100

SED= 1,232 mg/kg bw/day

- ***SED calculation for Dimethicone:***

A: 123,2 mg/kg bw/day

C: % 0,85

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 0,85/100 x 100/100

SED= 1,0472 mg/kg bw/day

- ***SED calculation for Polyacrylamide:***

A: 123,2 mg/kg bw/day

C: % 0,6

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 0,6/100 x 100/100

SED= 0,7392 mg/kg bw/day

- ***SED calculation for Acrylates/C10-30 Alkyl Acrylate Crosspolymer:***

A: 123,2 mg/kg bw/day

C: % 0,5

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 0,5/100 x 100/100

SED= 0,616 mg/kg bw/day

- ***SED calculation for Saccharide Isomerate:***

A: 123,2 mg/kg bw/day

C: % 0,5

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 0,5/100 x 100/100

SED= 0,616 mg/kg bw/day

- ***SED calculation for Laureth-7:***

A: 123,2 mg/kg bw/day

C: % 0,3

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 0,3/100 x 100/100

SED= 0,3696 mg/kg bw/day

- ***SED calculation for Sodium Stearoyl Lactylate:***

A: 123,2 mg/kg bw/day

C: % 0,3

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 0,3/100 x 100/100

SED= 0,3696 mg/kg bw/day

- ***SED calculation for C13-14 Isoparaffin:***

A: 123,2 mg/kg bw/day

C: % 0,25

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 0,25/100 x 100/100

SED= 0,308 mg/kg bw/day

- ***SED calculation for Sodium Lauroyl Glutamate:***

A: 123,2 mg/kg bw/day

C: % 0,2

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 0,2/100 x 100/100

SED= 0,2464 mg/kg bw/day

- ***SED calculation for Dimethicone Crosspolymer:***

A: 123,2 mg/kg bw/day

C: % 0,15

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 0,15/100 x 100/100

SED= 0,1848 mg/kg bw/day

- ***SED calculation for Chamomilla Recutita Flower Extract:***

A: 123,2 mg/kg bw/day

C: % 0,125

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 0,125/100 x 100/100

SED= 0,154 mg/kg bw/day

- ***SED calculation for Ethylhexylglycerin:***

A: 123,2 mg/kg bw/day

C: % 0,118

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 0,118/100 x 100/100

SED= 0,145376 mg/kg bw/day

- ***SED calculation for Squalane:***

A: 123,2 mg/kg bw/day

C: % 0,1

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 0,1/100 x 100/100

SED= 0,1232 mg/kg bw/day

- ***SED calculation for Hyaluronic Acid:***

A: 123,2 mg/kg bw/day

C: % 0,0225

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 0,0225/100 x 100/100

SED= 0,02772 mg/kg bw/day

- ***SED calculation for Citric Acid:***

A: 123,2 mg/kg bw/day

C: % 0,02

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 0,02/100 x 100/100

SED= 0,02464 mg/kg bw/day

- ***SED calculation for Sodium Acetylated Hyaluronate:***

A: 123,2 mg/kg bw/day

C: % 0,018

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 0,018/100 x 100/100

SED= 0,022176 mg/kg bw/day

- ***SED calculation for Sodium Hyaluronate:***

A: 123,2 mg/kg bw/day

C: % 0,015

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 0,015/100 x 100/100

SED= 0,01848 mg/kg bw/day

- ***SED calculation for Sodium Citrate:***

A: 123,2 mg/kg bw/day

C: % 0,01

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 0,01/100 x 100/100

SED= 0,01232 mg/kg bw/day

- ***SED calculation for Sodium Hyaluronate Crosspolymer:***

A: 123,2 mg/kg bw/day

C: % 0,0075

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 0,0075/100 x 100/100

SED= 0,00924 mg/kg bw/day

- ***SED calculation for Hydroxypropyltrimonium Hyaluronate:***

A: 123,2 mg/kg bw/day

C: % 0,0045

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 0,0045/100 x 100/100

SED= 0,005544 mg/kg bw/day

- ***SED calculation for Hydrolyzed Hyaluronic Acid:***

A: 123,2 mg/kg bw/day

C: % 0,003

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 0,003/100 x 100/100

SED= 0,003696 mg/kg bw/day

- ***SED calculation for Hydrolyzed Sodium Hyaluronate:***

A: 123,2 mg/kg bw/day

C: % 0,003

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 123,2 x 0,003/100 x 100/100

SED= 0,003696 mg/kg bw/day

For preservative ingredients, aggregate exposure is considered in accordance with SCCS Notes of Guidance. Therefore, A = 269 mg/kg bw/day has been accepted and used in the SED calculations for preservative components.

SED calculations for the preservative components are presented below.

- ***SED calculation for Phenoxyethanol:***

A: 269 mg/kg bw/day

C: % 0,932

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 269 x 0,932/100 x 100/100

SED= 2,50708 mg/kg bw/day

- ***SED calculation for Potassium Sorbate:***

A: 269 mg/kg bw/day

C: % 0,002

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 269 x 0,002/100 x 100/100

SED= 0,00538 mg/kg bw/day

- ***SED calculation for Sodium Benzoate:***

A: 269 mg/kg bw/day

C: % 0,001

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 269 x 0,001/100 x 100/100

SED= 0,00269 mg/kg bw/day

- ***SED calculation for Benzoic Acid:***

A: 269 mg/kg bw/day

C: % 0,0005

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 269 x 0,0005/100 x 100/100

SED= 0,001345 mg/kg bw/day

- ***SED calculation for Dehydroacetic Acid:***

A: 269 mg/kg bw/day

C: % 0,0005

SED = A (mg/kg bw/day) × C(%) / 100 × DAp (%)/100

SED = 269 x 0,0005/100 x 100/100

SED= 0,001345 mg/kg bw/day

SED Table for raw materials including preservatives except parfum components is below.

Raw Materials INCI Name	Amount of Use (% Concentration)	Amount of raw material in finished product (% Concentration)	Retention Factor (R)	Dermal Absorption DAa (µg/cm²)	Dermal Absorption DAp (%)	SED (mg/kg bw/day)	A (mg/kg bw/day)
Aqua	72,7040	Max. 72,7040	1,00	-	100	89,571328	123,20
Glycerin	10,1250	Max. 10,1250	1,00	-	100	12,474	123,20
Niacinamide	2,0000	Max. 2,0000	1,00	-	100	2,464	123,20
Caprylic/Capric Triglyceride	2,0000	Max. 2,0000	1,00	-	100	2,464	123,20
Bis-Diglyceryl Polyacyladipate-2	1,5000	Max. 1,5000	1,00	-	100	1,848	123,20
Glyceryl Stearate	1,5000	Max. 1,5000	1,00	-	100	1,848	123,20
Panthenol	1,1385	Max. 1,1385	1,00	-	100	1,402632	123,20
Cetearyl Alcohol	1,0000	Max. 1,0000	1,00	-	100	1,232	123,20
1,2-Hexanediol	1,0000	Max. 1,0000	1,00	-	100	1,232	123,20
Betaine	1,0000	Max. 1,0000	1,00	-	100	1,232	123,20
Aloe Barbadensis Leaf Juice	1,0000	Max. 1,0000	1,00	-	100	1,232	123,20
Phenoxyethanol	0,9320	Max. 0,9320	1,00	-	100	2,50708	269
Dimethicone	0,8500	Max. 0,8500	1,00	-	100	1,0472	123,20
Polyacrylamide	0,6000	Max. 0,6000	1,00	-	100	0,7392	123,20

Acrylates/C10-30 Alkyl Acrylate Crosspolymer	0,5000	Max. 0,5000	1,00	-	100	0,616	123,20
Saccharide Isomerate	0,5000	Max. 0,5000	1,00	-	100	0,616	123,20
Laureth-7	0,3000	Max. 0,3000	1,00	-	100	0,3696	123,20
Sodium Stearoyl Lactylate	0,3000	Max. 0,3000	1,00	-	100	0,3696	123,20
C13-14 Isoparaffin	0,2500	Max. 0,2500	1,00	-	100	0,308	123,20
Sodium Lauroyl Glutamate	0,2000	Max. 0,2000	1,00	-	100	0,2464	123,20
Dimethicone Crosspolymer	0,1500	Max. 0,1500	1,00	-	100	0,1848	123,20
Chamomilla Recutita Flower Extract	0,1250	Max. 0,1250	1,00	-	100	0,154	123,20
Ethylhexylglycerin	0,1180	Max. 0,1180	1,00	-	100	0,145376	123,20
Squalane	0,1000	Max. 0,1000	1,00	-	100	0,1232	123,20
Hyaluronic Acid	0,0225	Max. 0,0225	1,00	-	100	0,02772	123,20
Citric Acid	0,0200	Max. 0,0200	1,00	-	100	0,02464	123,20
Sodium Acetylated Hyaluronate	0,0180	Max. 0,0180	1,00	-	100	0,022176	123,20
Sodium Hyaluronate	0,0150	Max. 0,0150	1,00	-	100	0,01848	123,20
Sodium Citrate	0,0100	Max. 0,0100	1,00	-	100	0,01232	123,20
Sodium Hyaluronate Crosspolymer	0,0075	Max. 0,0075	1,00	-	100	0,00924	123,20

Hydroxypropyltrimonium Hyaluronate	0,0045	Max. 0,0045	1,00	-	100	0,005544	123,20
Hydrolyzed Hyaluronic Acid	0,0030	Max. 0,0030	1,00	-	100	0,003696	123,20
Hydrolyzed Sodium Hyaluronate	0,0030	Max. 0,0030	1,00	-	100	0,003696	123,20
Potassium Sorbate	0,0020	Max. 0,0020	1,00	-	100	0,00538	269
Sodium Benzoate	0,0010	Max. 0,0010	1,00	-	100	0,00269	269
Benzoic Acid	0,0005	Max. 0,0005	1,00	-	100	0,001345	269
Dehydroacetic Acid	0,0005	Max. 0,0005	1,00	-	100	0,001345	269

BIONIKS INTENSIVE CARE CREAM does not contain any parfum and aromatic components. For that reason, SED calculations for parfum and aromatic components are not calculated.

8. Toxicological profile of the substances

$$MoS = \frac{NO(A)EL}{SED}$$

MoS calculations for raw materials are below.

- *Mos Calculation For Aqua:*

NO(A)EL: Not Found.

SED: 89,571328 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= Not calculated.

***** Reasoning / Aqua / Safety Assessor Comment:**

Based on current Cosmetic legislation 1223/2009, MoS must be calculated for every ingredient according to the relevant NO(A)EL.

For ingredients without NO(A)EL values and total lack of safety reference, the calculation below is a "worst case approach", where, taking under consideration the pure maximum concentrated material of the formula, a minimum theoretical toxicological threshold is derived according to the Estimated Daily Exposure (A) of the product.

In this way "dangerous" ingredients are considered only those with hypothetical toxicological thresholds lower than the calculated minimum threshold value and concentrations, even not greater than the pure maximum concentrated material, but able to result (under Safety calculation) in MoS <100.

The combination above is statistically difficult to yield in MoS <100 as:

1. The existence in calculations of the maximum concentrated material of the formula (without NO(A)EL), minimizes the possibilities of any other material to be so potent (in view of a NO(A)EL value).

2. In this approach the calculated theoretical threshold is usually lower than 1000 mg/kg bw/day depending on the type of product. Toxicological reference values at these levels can generally be found only in ingredients such as preservatives and biocides.

3. Ingredients with low NO(A)EL values (<1000 mg/kg bw/day) are generally well defined in toxicological literature and exact toxicological data are usually available for calculation of the relevant MoS.

Calculation of the 'Worst Case Approach':

MoS ≥100, with:

SED (mg/kg bw/day) = Systemic Exposure Dosage

A (mg/kg bw/day) = Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application (123,20)

C (%) = The concentration of the ingredient under study in the finished cosmetic product on the application site (here Aqua %72,704)

DAp (%) = Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions (100%)

SED = A (mg/kg bw/day) × C (%) /100 × DAp (%) /100

SED = 123,20 x 72,704/100 x 100/100

SED = 89,571328 mg/kg bw/day

The minimum PODsys, according to the above suggested calculations for the pure maximum concentrated ingredient, should be:

Minimum PODsys = MoS × SED

Minimum PODsys = 100 × 89,571328

Minimum PODsys = 8957,1328 mg/kg bw/day

All calculations take into account the SCCS approach whereby, in the absence of specific oral absorption data, a default oral bioavailability of 50% may be assumed.

Therefore:

Equivalent Minimum Oral NO(A)EL = Minimum PODsys × 2

Equivalent Minimum Oral NO(A)EL = 8957,1328 × 2

Equivalent Minimum Oral NO(A)EL = 17914,2656 mg/kg bw/day

Result: SATISFACTORY

Conclusion: It is unlikely for ingredients of the specific formula, without identified NO(A)EL values and with total lack of toxicological reference data, to present toxicological thresholds lower than the equivalent minimum oral NO(A)EL calculated according to the "Worst Case Approach" and consequently, at the present concentrations, to yield a Margin of Safety below 100.

Furthermore,

Water is the major solvent of cosmetic formulations and has an established history of safe use in cosmetic products. No toxicological concern is expected from its use as the main vehicle of the formulation.

[Ref: General cosmetic safety assessment approach; Regulation (EC) No. 1223/2009; SCCS Notes of Guidance, 12th Revision.]

- *Mos Calculation For Glycerin:*

NOAEL: 1000 mg/kg bw/day

SED (DAp 100%): 12,474 mg/kg bw/day

MoS (initial)= 80,166747

MoS < 100

Since ingredient-specific dermal absorption data are not available and the initial calculation is below 100, DAp was refined to 50% as a conservative approach.

SED (DAp 50%): 6,237 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 160,333494

Mos ≥ 100

Safety Assessor's Comment: Since the dermal NOAEL value was not found for Glycerin, the calculation has been performed using the oral NOAEL value converted for dermal assessment by division by 2. The oral NOAEL value of 2000 mg/kg bw/day was therefore accepted as 1000 mg/kg bw/day. As the initial MoS calculated with DAp = 100% was below 100, an additional calculation was performed using DAp = 50% in line with the conservative oral absorption approach.

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: OECD SIDS, Glycerol; SCCS Notes of Guidance, 12th Revision.]

- *Mos Calculation For Niacinamide:*

NOAEL: 215 mg/kg bw/day

SED (DAp 100%): 2,464 mg/kg bw/day

MoS (initial)= 87,256494

MoS < 100

Since ingredient-specific dermal absorption data are not available and the initial calculation is below 100, DAp was refined to 50% as a conservative approach.

SED (DAp 50%): 1,232 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 174,512987

Mos ≥ 100

Safety Assessor's Comment: A repeated dose oral NOAEL of 215 mg/kg bw/day has been used. As the initial MoS calculated with DAp = 100% was below 100, an additional calculation was performed using DAp = 50% as a conservative refinement in the absence of ingredient-specific dermal absorption data.

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: Toxicological profile of Niacinamide; EPA/Nicotinamide assessment; SCCS Notes of Guidance, 12th Revision.]

- *Mos Calculation For Caprylic/Capric Triglyceride:*

NOAEL: 3500 mg/kg bw/day

SED: 2,464 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 1420,454545

Mos ≥ 100

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: CIR Safety Assessment of Caprylic/Capric Triglyceride and related cosmetic ingredients.]

- *Mos Calculation For Bis-Diglyceryl Polyacyladipate-2:*

NOAEL: 1800 mg/kg bw/day

SED: 1,848 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 974,025974

Mos ≥ 100

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: CIR Safety Assessment / toxicological information for Bis-Diglyceryl Polyacyladipate-2.]

- *Mos Calculation For Glyceryl Stearate:*

NO(A)EL: Not Found.

SED: 1,848 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= Not calculated.

***** Reasoning / Glyceryl Stearate / Safety Assessor Comment:**

Based on current Cosmetic legislation 1223/2009, MoS must be calculated for every ingredient according to the relevant NO(A)EL.

For ingredients without NO(A)EL values and total lack of safety reference, the calculation below is a "worst case approach", where, taking under consideration the pure maximum concentrated material of the formula, a minimum theoretical toxicological threshold is derived according to the Estimated Daily Exposure (A) of the product.

In this way "dangerous" ingredients are considered only those with hypothetical toxicological thresholds lower than the calculated minimum threshold value and concentrations, even not greater than the pure maximum concentrated material, but able to result (under Safety calculation) in MoS <100.

The combination above is statistically difficult to yield in MoS <100 as:

1. The existence in calculations of the maximum concentrated material of the formula (without NO(A)EL), minimizes the possibilities of any other material to be so potent (in view of a NO(A)EL value).

2. In this approach the calculated theoretical threshold is usually lower than 1000 mg/kg bw/day depending on the type of product. Toxicological reference values at these levels can generally be found only in ingredients such as preservatives and biocides.

3. Ingredients with low NO(A)EL values (<1000 mg/kg bw/day) are generally well defined in toxicological literature and exact toxicological data are usually available for calculation of the relevant MoS.

Calculation of the 'Worst Case Approach':

MoS ≥100, with:

SED (mg/kg bw/day) = Systemic Exposure Dosage

A (mg/kg bw/day) = Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application (123,20)

C (%) = The concentration of the ingredient under study in the finished cosmetic product on the application site (here Glyceryl Stearate %1,5)

DAp (%) = Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions (100%)

SED = A (mg/kg bw/day) × C (%) /100 × DAp (%) /100

SED = 123,20 x 1,5/100 x 100/100

SED = 1,848 mg/kg bw/day

The minimum PODsys, according to the above suggested calculations for the pure maximum concentrated ingredient, should be:

Minimum PODsys = MoS × SED

Minimum PODsys = 100 × 1,848

Minimum PODsys = 184,8 mg/kg bw/day

All calculations take into account the SCCS approach whereby, in the absence of specific oral absorption data, a default oral bioavailability of 50% may be assumed.

Therefore:

Equivalent Minimum Oral NO(A)EL = Minimum PODsys × 2

Equivalent Minimum Oral NO(A)EL = 184,8 × 2

Equivalent Minimum Oral NO(A)EL = 369,6 mg/kg bw/day

Result: SATISFACTORY

Conclusion: It is unlikely for ingredients of the specific formula, without identified NO(A)EL values and with total lack of toxicological reference data, to present toxicological thresholds lower than the equivalent minimum oral NO(A)EL calculated according to the "Worst Case Approach" and consequently, at the present concentrations, to yield a Margin of Safety below 100.

Furthermore,

Glyceryl Stearate is a glyceryl fatty acid ester. The CIR Expert Panel has concluded that glyceryl fatty acid esters are safe in cosmetics in the present practices of use and concentration when formulated to be non-irritating.

[Ref: CIR Safety Assessment of Glyceryl Stearate and related glyceryl fatty acid esters.]

- *Mos Calculation For Panthenol:*

NOAEL: 1000 mg/kg bw/day

SED: 1,402632 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 712,945377

Mos ≥ 100

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: Scientific Opinion on the safety and efficacy of pantothenic acid and D-panthenol; EFSA.]

- *Mos Calculation For Cetearyl Alcohol:*

NOAEL: 1000 mg/kg bw/day

SED: 1,232 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 811,688312

Mos ≥ 100

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: CIR Safety Assessment of Fatty Alcohols as Used in Cosmetics.]

- *Mos Calculation For 1,2-Hexanediol:*

NOAEL: 1000 mg/kg bw/day

SED: 1,232 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 811,688312

Mos ≥ 100

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: CIR Safety Assessment of 1,2-Glycols as Used in Cosmetics.]

- *Mos Calculation For Betaine:*

NO(A)EL: Not Found.

SED: 1,232 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= Not calculated.

***** Reasoning / Betaine / Safety Assessor Comment:**

Based on current Cosmetic legislation 1223/2009, MoS must be calculated for every ingredient according to the relevant NO(A)EL.

For ingredients without NO(A)EL values and total lack of safety reference, the calculation below is a "worst case approach", where, taking under consideration the pure maximum concentrated material of the formula, a

minimum theoretical toxicological threshold is derived according to the Estimated Daily Exposure (A) of the product.

In this way "dangerous" ingredients are considered only those with hypothetical toxicological thresholds lower than the calculated minimum threshold value and concentrations, even not greater than the pure maximum concentrated material, but able to result (under Safety calculation) in MoS <100.

The combination above is statistically difficult to yield in MoS <100 as:

1. The existence in calculations of the maximum concentrated material of the formula (without NO(A)EL), minimizes the possibilities of any other material to be so potent (in view of a NO(A)EL value).

2. In this approach the calculated theoretical threshold is usually lower than 1000 mg/kg bw/day depending on the type of product. Toxicological reference values at these levels can generally be found only in ingredients such as preservatives and biocides.

3. Ingredients with low NO(A)EL values (<1000 mg/kg bw/day) are generally well defined in toxicological literature and exact toxicological data are usually available for calculation of the relevant MoS.

Calculation of the 'Worst Case Approach':

MoS ≥100, with:

SED (mg/kg bw/day) = Systemic Exposure Dosage

A (mg/kg bw/day) = Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application (123,20)

C (%) = The concentration of the ingredient under study in the finished cosmetic product on the application site (here Betaine %1)

DAp (%) = Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions (100%)

SED = A (mg/kg bw/day) × C (%) /100 × DAp (%) /100

SED = 123,20 x 1/100 x 100/100

SED = 1,232 mg/kg bw/day

The minimum PODsys, according to the above suggested calculations for the pure maximum concentrated ingredient, should be:

Minimum PODsys = MoS × SED

Minimum PODsys = 100 × 1,232

Minimum PODsys = 123,2 mg/kg bw/day

All calculations take into account the SCCS approach whereby, in the absence of specific oral absorption data, a default oral bioavailability of 50% may be assumed.

Therefore:

Equivalent Minimum Oral NO(A)EL = Minimum PODsys × 2

Equivalent Minimum Oral NO(A)EL = 123,2 × 2

Equivalent Minimum Oral NO(A)EL = 246,4 mg/kg bw/day

Result: SATISFACTORY

Conclusion: It is unlikely for ingredients of the specific formula, without identified NO(A)EL values and with total lack of toxicological reference data, to present toxicological thresholds lower than the equivalent minimum oral NO(A)EL calculated according to the "Worst Case Approach" and consequently, at the present concentrations, to yield a Margin of Safety below 100.

Furthermore,

Betaine has a long history of use as a humectant and skin conditioning ingredient. Available safety information indicates low acute toxicity and no genotoxic concern under normal cosmetic use conditions.

[Ref: Toxicological information for Betaine; cosmetic ingredient safety data.]

- *Mos Calculation For Aloe Barbadensis Leaf Juice:*

NO(A)EL: Not Found.

SED: 1,232 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= Not calculated.

***** Reasoning / Aloe Barbadensis Leaf Juice / Safety Assessor Comment:**

Based on current Cosmetic legislation 1223/2009, MoS must be calculated for every ingredient according to the relevant NO(A)EL.

For ingredients without NO(A)EL values and total lack of safety reference, the calculation below is a "worst case approach", where, taking under consideration the pure maximum concentrated material of the formula, a minimum theoretical toxicological threshold is derived according to the Estimated Daily Exposure (A) of the product.

In this way "dangerous" ingredients are considered only those with hypothetical toxicological thresholds lower than the calculated minimum threshold value and concentrations, even not greater than the pure maximum concentrated material, but able to result (under Safety calculation) in MoS <100.

The combination above is statistically difficult to yield in MoS <100 as:

1. The existence in calculations of the maximum concentrated material of the formula (without NO(A)EL), minimizes the possibilities of any other material to be so potent (in view of a NO(A)EL value).

2. In this approach the calculated theoretical threshold is usually lower than 1000 mg/kg bw/day depending on the type of product. Toxicological reference values at these levels can generally be found only in ingredients such as preservatives and biocides.

3. Ingredients with low NO(A)EL values (<1000 mg/kg bw/day) are generally well defined in toxicological literature and exact toxicological data are usually available for calculation of the relevant MoS.

Calculation of the 'Worst Case Approach':

MoS ≥100, with:

SED (mg/kg bw/day) = Systemic Exposure Dosage

A (mg/kg bw/day) = Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application (123,20)

C (%) = The concentration of the ingredient under study in the finished cosmetic product on the application site (here Aloe Barbadensis Leaf Juice %1)

DAp (%) = Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions (100%)

SED = A (mg/kg bw/day) × C (%) /100 × DAp (%) /100

SED = 123,20 x 1/100 x 100/100

SED = 1,232 mg/kg bw/day

The minimum PODsys, according to the above suggested calculations for the pure maximum concentrated ingredient, should be:

Minimum PODsys = MoS × SED

Minimum PODsys = 100 × 1,232

Minimum PODsys = 123,2 mg/kg bw/day

All calculations take into account the SCCS approach whereby, in the absence of specific oral absorption data, a default oral bioavailability of 50% may be assumed.

Therefore:

Equivalent Minimum Oral NO(A)EL = Minimum PODsys × 2

Equivalent Minimum Oral NO(A)EL = 123,2 × 2

Equivalent Minimum Oral NO(A)EL = 246,4 mg/kg bw/day

Result: SATISFACTORY

Conclusion: It is unlikely for ingredients of the specific formula, without identified NO(A)EL values and with total lack of toxicological reference data, to present toxicological thresholds lower than the equivalent minimum oral NO(A)EL calculated according to the "Worst Case Approach" and consequently, at the present concentrations, to yield a Margin of Safety below 100.

Furthermore,

Aloe Barbadensis Leaf Juice is widely used in cosmetic products as a skin conditioning and soothing ingredient. Available cosmetic safety assessments support its use in topical products at typical cosmetic concentrations.

[Ref: CIR Safety Assessment of Aloe-derived ingredients as used in cosmetics.]

- *Mos Calculation For Dimethicone:*

NO(A)EL: Not Found.

SED: 1,0472 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= Not calculated.

***** Reasoning / Dimethicone / Safety Assessor Comment:**

Based on current Cosmetic legislation 1223/2009, MoS must be calculated for every ingredient according to the relevant NO(A)EL.

For ingredients without NO(A)EL values and total lack of safety reference, the calculation below is a "worst case approach", where, taking under consideration the pure maximum concentrated material of the formula, a minimum theoretical toxicological threshold is derived according to the Estimated Daily Exposure (A) of the product.

In this way "dangerous" ingredients are considered only those with hypothetical toxicological thresholds lower than the calculated minimum threshold value and concentrations, even not greater than the pure maximum concentrated material, but able to result (under Safety calculation) in MoS <100.

The combination above is statistically difficult to yield in MoS <100 as:

1. The existence in calculations of the maximum concentrated material of the formula (without NO(A)EL), minimizes the possibilities of any other material to be so potent (in view of a NO(A)EL value).

2. In this approach the calculated theoretical threshold is usually lower than 1000 mg/kg bw/day depending on the type of product. Toxicological reference values at these levels can generally be found only in ingredients such as preservatives and biocides.

3. Ingredients with low NO(A)EL values (<1000 mg/kg bw/day) are generally well defined in toxicological literature and exact toxicological data are usually available for calculation of the relevant MoS.

Calculation of the 'Worst Case Approach':

MoS ≥100, with:

SED (mg/kg bw/day) = Systemic Exposure Dosage

A (mg/kg bw/day) = Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application (123,20)

C (%) = The concentration of the ingredient under study in the finished cosmetic product on the application site (here Dimethicone %0,85)

DAp (%) = Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions (100%)

SED = A (mg/kg bw/day) × C (%) /100 × DAp (%) /100

SED = 123,20 x 0,85/100 x 100/100

SED = 1,0472 mg/kg bw/day

The minimum PODsys, according to the above suggested calculations for the pure maximum concentrated ingredient, should be:

Minimum PODsys = MoS × SED

Minimum PODsys = 100 × 1,0472

Minimum PODsys = 104,72 mg/kg bw/day

All calculations take into account the SCCS approach whereby, in the absence of specific oral absorption data, a default oral bioavailability of 50% may be assumed.

Therefore:

Equivalent Minimum Oral NO(A)EL = Minimum PODsys × 2

Equivalent Minimum Oral NO(A)EL = 104,72 × 2

Equivalent Minimum Oral NO(A)EL = 209,44 mg/kg bw/day

Result: SATISFACTORY

Conclusion: It is unlikely for ingredients of the specific formula, without identified NO(A)EL values and with total lack of toxicological reference data, to present toxicological thresholds lower than the equivalent minimum oral NO(A)EL calculated according to the "Worst Case Approach" and consequently, at the present concentrations, to yield a Margin of Safety below 100.

Furthermore,

Dimethicone is a high molecular weight silicone polymer with limited dermal penetration potential. The CIR Expert Panel has concluded that dimethicone and related silicone polymers are safe as used in cosmetics.

[Ref: CIR Safety Assessment of Dimethicone and related silicone polymers as used in cosmetics.]

- *Mos Calculation For Polyacrylamide:*

NO(A)EL: Not Found.

SED: 0,7392 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= Not calculated.

***** Reasoning / Polyacrylamide / Safety Assessor Comment:**

Based on current Cosmetic legislation 1223/2009, MoS must be calculated for every ingredient according to the relevant NO(A)EL.

For ingredients without NO(A)EL values and total lack of safety reference, the calculation below is a "worst case approach", where, taking under consideration the pure maximum concentrated material of the formula, a minimum theoretical toxicological threshold is derived according to the Estimated Daily Exposure (A) of the product.

In this way "dangerous" ingredients are considered only those with hypothetical toxicological thresholds lower than the calculated minimum threshold value and concentrations, even not greater than the pure maximum concentrated material, but able to result (under Safety calculation) in MoS <100.

The combination above is statistically difficult to yield in MoS <100 as:

1. The existence in calculations of the maximum concentrated material of the formula (without NO(A)EL), minimizes the possibilities of any other material to be so potent (in view of a NO(A)EL value).

2. In this approach the calculated theoretical threshold is usually lower than 1000 mg/kg bw/day depending on the type of product. Toxicological reference values at these levels can generally be found only in ingredients such as preservatives and biocides.

3. Ingredients with low NO(A)EL values (<1000 mg/kg bw/day) are generally well defined in toxicological literature and exact toxicological data are usually available for calculation of the relevant MoS.

Calculation of the 'Worst Case Approach':

MoS ≥100, with:

SED (mg/kg bw/day) = Systemic Exposure Dosage

A (mg/kg bw/day) = Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application (123,20)

C (%) = The concentration of the ingredient under study in the finished cosmetic product on the application site (here Polyacrylamide %0,6)

DAp (%) = Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions (100%)

SED = A (mg/kg bw/day) × C (%) /100 × DAp (%) /100

SED = 123,20 x 0,6/100 x 100/100

SED = 0,7392 mg/kg bw/day

The minimum PODsys, according to the above suggested calculations for the pure maximum concentrated ingredient, should be:

Minimum PODsys = MoS × SED

Minimum PODsys = 100 × 0,7392

Minimum PODsys = 73,92 mg/kg bw/day

All calculations take into account the SCCS approach whereby, in the absence of specific oral absorption data, a default oral bioavailability of 50% may be assumed.

Therefore:

Equivalent Minimum Oral NO(A)EL = Minimum PODsys × 2

Equivalent Minimum Oral NO(A)EL = 73,92 × 2

Equivalent Minimum Oral NO(A)EL = 147,84 mg/kg bw/day

Result: SATISFACTORY

Conclusion: It is unlikely for ingredients of the specific formula, without identified NO(A)EL values and with total lack of toxicological reference data, to present toxicological thresholds lower than the equivalent minimum oral NO(A)EL calculated according to the "Worst Case Approach" and consequently, at the present concentrations, to yield a Margin of Safety below 100.

Furthermore,

Polyacrylamide is a high molecular weight polymer used in cosmetics. Systemic exposure is expected to be limited due to polymeric structure; safety evaluation focuses on residual monomer control and use at low concentration.

[Ref: CIR Safety Assessment of Polyacrylamide and acrylamide polymers as used in cosmetics.]

- *Mos Calculation For Acrylates/C10-30 Alkyl Acrylate Crosspolymer:*

NO(A)EL: Not Found.

SED: 0,616 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= Not calculated.

***** Reasoning / Acrylates/C10-30 Alkyl Acrylate Crosspolymer / Safety Assessor Comment:**

Based on current Cosmetic legislation 1223/2009, MoS must be calculated for every ingredient according to the relevant NO(A)EL.

For ingredients without NO(A)EL values and total lack of safety reference, the calculation below is a "worst case approach", where, taking under consideration the pure maximum concentrated material of the formula, a minimum theoretical toxicological threshold is derived according to the Estimated Daily Exposure (A) of the product.

In this way "dangerous" ingredients are considered only those with hypothetical toxicological thresholds lower than the calculated minimum threshold value and concentrations, even not greater than the pure maximum concentrated material, but able to result (under Safety calculation) in MoS <100.

The combination above is statistically difficult to yield in MoS <100 as:

1. The existence in calculations of the maximum concentrated material of the formula (without NO(A)EL), minimizes the possibilities of any other material to be so potent (in view of a NO(A)EL value).

2. In this approach the calculated theoretical threshold is usually lower than 1000 mg/kg bw/day depending on the type of product. Toxicological reference values at these levels can generally be found only in ingredients such as preservatives and biocides.

3. Ingredients with low NO(A)EL values (<1000 mg/kg bw/day) are generally well defined in toxicological literature and exact toxicological data are usually available for calculation of the relevant MoS.

Calculation of the 'Worst Case Approach':

MoS ≥100, with:

SED (mg/kg bw/day) = Systemic Exposure Dosage

A (mg/kg bw/day) = Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application (123,20)

C (%) = The concentration of the ingredient under study in the finished cosmetic product on the application site (here Acrylates/C10-30 Alkyl Acrylate Crosspolymer %0,5)

DAp (%) = Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions (100%)

SED = A (mg/kg bw/day) × C (%) /100 × DAp (%) /100

SED = 123,20 x 0,5/100 x 100/100

SED = 0,616 mg/kg bw/day

The minimum PODsys, according to the above suggested calculations for the pure maximum concentrated ingredient, should be:

Minimum PODsys = MoS × SED

Minimum PODsys = 100 × 0,616

Minimum PODsys = 61,6 mg/kg bw/day

All calculations take into account the SCCS approach whereby, in the absence of specific oral absorption data, a default oral bioavailability of 50% may be assumed.

Therefore:

Equivalent Minimum Oral NO(A)EL = Minimum PODsys × 2

Equivalent Minimum Oral NO(A)EL = 61,6 × 2

Equivalent Minimum Oral NO(A)EL = 123,2 mg/kg bw/day

Result: SATISFACTORY

Conclusion: It is unlikely for ingredients of the specific formula, without identified NO(A)EL values and with total lack of toxicological reference data, to present toxicological thresholds lower than the equivalent

minimum oral NO(A)EL calculated according to the "Worst Case Approach" and consequently, at the present concentrations, to yield a Margin of Safety below 100.

Furthermore,

The CIR Expert Panel concluded that the acrylates copolymers named in the safety assessment are safe in cosmetics in the present practices of use and concentration described in the safety assessment when formulated to be nonirritating.

[Ref: Amended Safety Assessment of Acrylates Copolymers as Used in Cosmetics, December 3-4, 2018.]

- *Mos Calculation For Saccharide Isomerate:*

NO(A)EL: Not Found.

SED: 0,616 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= Not calculated.

***** Reasoning / Saccharide Isomerate / Safety Assessor Comment:**

Based on current Cosmetic legislation 1223/2009, MoS must be calculated for every ingredient according to the relevant NO(A)EL.

For ingredients without NO(A)EL values and total lack of safety reference, the calculation below is a "worst case approach", where, taking under consideration the pure maximum concentrated material of the formula, a minimum theoretical toxicological threshold is derived according to the Estimated Daily Exposure (A) of the product.

In this way "dangerous" ingredients are considered only those with hypothetical toxicological thresholds lower than the calculated minimum threshold value and concentrations, even not greater than the pure maximum concentrated material, but able to result (under Safety calculation) in MoS <100.

The combination above is statistically difficult to yield in MoS <100 as:

1. The existence in calculations of the maximum concentrated material of the formula (without NO(A)EL), minimizes the possibilities of any other material to be so potent (in view of a NO(A)EL value).

2. In this approach the calculated theoretical threshold is usually lower than 1000 mg/kg bw/day depending on the type of product. Toxicological reference values at these levels can generally be found only in ingredients such as preservatives and biocides.

3. Ingredients with low NO(A)EL values (<1000 mg/kg bw/day) are generally well defined in toxicological literature and exact toxicological data are usually available for calculation of the relevant MoS.

Calculation of the 'Worst Case Approach':

MoS ≥100, with:

SED (mg/kg bw/day) = Systemic Exposure Dosage

A (mg/kg bw/day) = Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application (123,20)

C (%) = The concentration of the ingredient under study in the finished cosmetic product on the application site (here Saccharide Isomerate %0,5)

DAp (%) = Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions (100%)

SED = A (mg/kg bw/day) × C (%) /100 × DAp (%) /100

SED = 123,20 x 0,5/100 x 100/100

SED = 0,616 mg/kg bw/day

The minimum PODsys, according to the above suggested calculations for the pure maximum concentrated ingredient, should be:

Minimum PODsys = MoS × SED

Minimum PODsys = 100 × 0,616

Minimum PODsys = 61,6 mg/kg bw/day

All calculations take into account the SCCS approach whereby, in the absence of specific oral absorption data, a default oral bioavailability of 50% may be assumed.

Therefore:

Equivalent Minimum Oral NO(A)EL = Minimum PODsys × 2

Equivalent Minimum Oral NO(A)EL = 61,6 × 2

Equivalent Minimum Oral NO(A)EL = 123,2 mg/kg bw/day

Result: SATISFACTORY

Conclusion: It is unlikely for ingredients of the specific formula, without identified NO(A)EL values and with total lack of toxicological reference data, to present toxicological thresholds lower than the equivalent minimum oral NO(A)EL calculated according to the "Worst Case Approach" and consequently, at the present concentrations, to yield a Margin of Safety below 100.

Furthermore,

Saccharide Isomerate is a carbohydrate-derived humectant. Based on its chemical nature, low use level, and history of cosmetic use, no systemic toxicological concern is expected under the intended conditions of use.

[Ref: Supplier toxicological information; carbohydrate-derived humectant safety support.]

- *Mos Calculation For Laureth-7:*

NOAEL: 50 mg/kg bw/day

SED: 0,3696 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 135,281385

Mos ≥ 100

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: CIR Safety Assessment of Alkyl PEG Ethers / Laureth ingredients as used in cosmetics.]

- *Mos Calculation For Sodium Stearoyl Lactylate:*

NOAEL: 1000 mg/kg bw/day

SED: 0,3696 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 2705,627706

Mos ≥ 100

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: Toxicological information for sodium lactate/lactylate derivatives; cosmetic ingredient safety support.]

- *Mos Calculation For C13-14 Isoparaffin:*

NOAEL: 500 mg/kg bw/day

SED: 0,308 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 1623,376623

Mos ≥ 100

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: ECHA/read-across toxicological data for isoparaffins / Isohexadecane.]

- *Mos Calculation For Sodium Lauroyl Glutamate:*

NO(A)EL: Not Found.

SED: 0,2464 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= Not calculated.

***** Reasoning / Sodium Lauroyl Glutamate / Safety Assessor Comment:**

Based on current Cosmetic legislation 1223/2009, MoS must be calculated for every ingredient according to the relevant NO(A)EL.

For ingredients without NO(A)EL values and total lack of safety reference, the calculation below is a "worst case approach", where, taking under consideration the pure maximum concentrated material of the formula, a minimum theoretical toxicological threshold is derived according to the Estimated Daily Exposure (A) of the product.

In this way "dangerous" ingredients are considered only those with hypothetical toxicological thresholds lower than the calculated minimum threshold value and concentrations, even not greater than the pure maximum concentrated material, but able to result (under Safety calculation) in MoS <100.

The combination above is statistically difficult to yield in MoS <100 as:

1. The existence in calculations of the maximum concentrated material of the formula (without NO(A)EL), minimizes the possibilities of any other material to be so potent (in view of a NO(A)EL value).

2. In this approach the calculated theoretical threshold is usually lower than 1000 mg/kg bw/day depending on the type of product. Toxicological reference values at these levels can generally be found only in ingredients such as preservatives and biocides.

3. Ingredients with low NO(A)EL values (<1000 mg/kg bw/day) are generally well defined in toxicological literature and exact toxicological data are usually available for calculation of the relevant MoS.

Calculation of the 'Worst Case Approach':

MoS ≥100, with:

SED (mg/kg bw/day) = Systemic Exposure Dosage

A (mg/kg bw/day) = Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application (123,20)

C (%) = The concentration of the ingredient under study in the finished cosmetic product on the application site (here Sodium Lauroyl Glutamate %0,2)

DAp (%) = Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions (100%)

SED = A (mg/kg bw/day) × C (%) /100 × DAp (%) /100

SED = 123,20 x 0,2/100 x 100/100

SED = 0,2464 mg/kg bw/day

The minimum PODsys, according to the above suggested calculations for the pure maximum concentrated ingredient, should be:

Minimum PODsys = MoS × SED

Minimum PODsys = 100 × 0,2464

Minimum PODsys = 24,64 mg/kg bw/day

All calculations take into account the SCCS approach whereby, in the absence of specific oral absorption data, a default oral bioavailability of 50% may be assumed.

Therefore:

Equivalent Minimum Oral NO(A)EL = Minimum PODsys × 2

Equivalent Minimum Oral NO(A)EL = 24,64 × 2

Equivalent Minimum Oral NO(A)EL = 49,28 mg/kg bw/day

Result: SATISFACTORY

Conclusion: It is unlikely for ingredients of the specific formula, without identified NO(A)EL values and with total lack of toxicological reference data, to present toxicological thresholds lower than the equivalent minimum oral NO(A)EL calculated according to the "Worst Case Approach" and consequently, at the present concentrations, to yield a Margin of Safety below 100.

Furthermore,

Sodium Lauroyl Glutamate belongs to amino acid-based surfactants. CIR safety assessments for related amino acid alkyl amides support their safety in cosmetics when formulated to be non-irritating.

[Ref: CIR Safety Assessment of Amino Acid Alkyl Amides as Used in Cosmetics.]

- *Mos Calculation For Dimethicone Crosspolymer:*

NO(A)EL: Not Found.

SED: 0,1848 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= Not calculated.

***** Reasoning / Dimethicone Crosspolymer / Safety Assessor Comment:**

Based on current Cosmetic legislation 1223/2009, MoS must be calculated for every ingredient according to the relevant NO(A)EL.

For ingredients without NO(A)EL values and total lack of safety reference, the calculation below is a "worst case approach", where, taking under consideration the pure maximum concentrated material of the formula, a minimum theoretical toxicological threshold is derived according to the Estimated Daily Exposure (A) of the product.

In this way "dangerous" ingredients are considered only those with hypothetical toxicological thresholds lower than the calculated minimum threshold value and concentrations, even not greater than the pure maximum concentrated material, but able to result (under Safety calculation) in MoS <100.

The combination above is statistically difficult to yield in MoS <100 as:

1. The existence in calculations of the maximum concentrated material of the formula (without NO(A)EL), minimizes the possibilities of any other material to be so potent (in view of a NO(A)EL value).

2. In this approach the calculated theoretical threshold is usually lower than 1000 mg/kg bw/day depending on the type of product. Toxicological reference values at these levels can generally be found only in ingredients such as preservatives and biocides.

3. Ingredients with low NO(A)EL values (<1000 mg/kg bw/day) are generally well defined in toxicological literature and exact toxicological data are usually available for calculation of the relevant MoS.

Calculation of the 'Worst Case Approach':

MoS ≥100, with:

SED (mg/kg bw/day) = Systemic Exposure Dosage

A (mg/kg bw/day) = Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application (123,20)

C (%) = The concentration of the ingredient under study in the finished cosmetic product on the application site (here Dimethicone Crosspolymer %0,15)

DAp (%) = Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions (100%)

SED = A (mg/kg bw/day) × C (%) /100 × DAp (%) /100

SED = 123,20 x 0,15/100 x 100/100

SED = 0,1848 mg/kg bw/day

The minimum PODsys, according to the above suggested calculations for the pure maximum concentrated ingredient, should be:

Minimum PODsys = MoS × SED

Minimum PODsys = 100 × 0,1848

Minimum PODsys = 18,48 mg/kg bw/day

All calculations take into account the SCCS approach whereby, in the absence of specific oral absorption data, a default oral bioavailability of 50% may be assumed.

Therefore:

Equivalent Minimum Oral NO(A)EL = Minimum PODsys × 2

Equivalent Minimum Oral NO(A)EL = 18,48 × 2

Equivalent Minimum Oral NO(A)EL = 36,96 mg/kg bw/day

Result: SATISFACTORY

Conclusion: It is unlikely for ingredients of the specific formula, without identified NO(A)EL values and with total lack of toxicological reference data, to present toxicological thresholds lower than the equivalent minimum oral NO(A)EL calculated according to the "Worst Case Approach" and consequently, at the present concentrations, to yield a Margin of Safety below 100.

Furthermore,

Dimethicone Crosspolymer is a high molecular weight silicone crosspolymer. Due to its polymeric structure, dermal absorption is expected to be negligible, and related silicone crosspolymers have been considered safe as used in cosmetics by CIR.

[Ref: CIR Safety Assessment of Dimethicone Crosspolymer and related silicone crosspolymers.]

- *Mos Calculation For Chamomilla Recutita Flower Extract:*

NO(A)EL: Not Found.

SED: 0,154 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= Not calculated.

***** Reasoning / Chamomilla Recutita Flower Extract / Safety Assessor Comment:**

Based on current Cosmetic legislation 1223/2009, MoS must be calculated for every ingredient according to the relevant NO(A)EL.

For ingredients without NO(A)EL values and total lack of safety reference, the calculation below is a "worst case approach", where, taking under consideration the pure maximum concentrated material of the formula, a minimum theoretical toxicological threshold is derived according to the Estimated Daily Exposure (A) of the product.

In this way "dangerous" ingredients are considered only those with hypothetical toxicological thresholds lower than the calculated minimum threshold value and concentrations, even not greater than the pure maximum concentrated material, but able to result (under Safety calculation) in MoS <100.

The combination above is statistically difficult to yield in MoS <100 as:

1. The existence in calculations of the maximum concentrated material of the formula (without NO(A)EL), minimizes the possibilities of any other material to be so potent (in view of a NO(A)EL value).

2. In this approach the calculated theoretical threshold is usually lower than 1000 mg/kg bw/day depending on the type of product. Toxicological reference values at these levels can generally be found only in ingredients such as preservatives and biocides.

3. Ingredients with low NO(A)EL values (<1000 mg/kg bw/day) are generally well defined in toxicological literature and exact toxicological data are usually available for calculation of the relevant MoS.

Calculation of the 'Worst Case Approach':

MoS ≥100, with:

SED (mg/kg bw/day) = Systemic Exposure Dosage

A (mg/kg bw/day) = Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application (123,20)

C (%) = The concentration of the ingredient under study in the finished cosmetic product on the application site (here Chamomilla Recutita Flower Extract %0,125)

DAp (%) = Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions (100%)

SED = A (mg/kg bw/day) × C (%) /100 × DAp (%) /100

SED = 123,20 x 0,125/100 x 100/100

SED = 0,154 mg/kg bw/day

The minimum PODsys, according to the above suggested calculations for the pure maximum concentrated ingredient, should be:

Minimum PODsys = MoS × SED

Minimum PODsys = 100 × 0,154

Minimum PODsys = 15,4 mg/kg bw/day

All calculations take into account the SCCS approach whereby, in the absence of specific oral absorption data, a default oral bioavailability of 50% may be assumed.

Therefore:

Equivalent Minimum Oral NO(A)EL = Minimum PODsys × 2

Equivalent Minimum Oral NO(A)EL = 15,4 × 2

Equivalent Minimum Oral NO(A)EL = 30,8 mg/kg bw/day

Result: SATISFACTORY

Conclusion: It is unlikely for ingredients of the specific formula, without identified NO(A)EL values and with total lack of toxicological reference data, to present toxicological thresholds lower than the equivalent minimum oral NO(A)EL calculated according to the "Worst Case Approach" and consequently, at the present concentrations, to yield a Margin of Safety below 100.

Furthermore,

Chamomilla Recutita Flower Extract is a botanical skin conditioning ingredient. Available cosmetic use history supports topical use at low concentrations; however, as with botanical extracts, potential individual sensitivity should be considered.

[Ref: Cosmetic safety information for Chamomilla Recutita Extract; botanical ingredient safety data.]

- *Mos Calculation For Ethylhexylglycerin:*

NOAEL: 100 mg/kg bw/day

SED: 0,145376 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 687,871451

Mos ≥ 100

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: CIR Safety Assessment of Ethylhexylglycerin and related ingredients.]

- *Mos Calculation For Squalane:*

NOAEL: 1000 mg/kg bw/day

SED: 0,1232 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 8116,883117

Mos ≥ 100

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: Cosmetic ingredient safety information for Squalane; hydrocarbon emollient safety data.]

- *Mos Calculation For Hyaluronic Acid:*

NOAEL: 40 mg/kg bw/day

SED: 0,02772 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 1443,001443

Mos ≥ 100

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: Final Report of the Safety Assessment of Hyaluronic Acid, Potassium Hyaluronate, and Sodium Hyaluronate.]

- *Mos Calculation For Citric Acid:*

NOAEL: 1200 mg/kg bw/day

SED: 0,02464 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 48701,298701

Mos ≥ 100

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: CIR Safety Assessment of Citric Acid, inorganic citrate salts and alkyl citrate esters as used in cosmetics.]

- *Mos Calculation For Sodium Acetylated Hyaluronate:*

NOAEL: 40 mg/kg bw/day

SED: 0,022176 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 1803,751804

Mos ≥ 100

Safety Assessor's Comment: Read-across from hyaluronic acid/sodium hyaluronate safety assessment was applied.

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: Final Report of the Safety Assessment of Hyaluronic Acid, Potassium Hyaluronate, and Sodium Hyaluronate.]

- *Mos Calculation For Sodium Hyaluronate:*

NOAEL: 40 mg/kg bw/day

SED: 0,01848 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 2164,502165

Mos ≥ 100

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: Final Report of the Safety Assessment of Hyaluronic Acid, Potassium Hyaluronate, and Sodium Hyaluronate.]

- *Mos Calculation For Sodium Citrate:*

NOAEL: 1200 mg/kg bw/day

SED: 0,01232 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 97402,597403

Mos ≥ 100

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: CIR Safety Assessment of Citric Acid, inorganic citrate salts and alkyl citrate esters as used in cosmetics.]

- *Mos Calculation For Sodium Hyaluronate Crosspolymer:*

NOAEL: 40 mg/kg bw/day

SED: 0,00924 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 4329,004329

Mos ≥ 100

Safety Assessor's Comment: Read-across from hyaluronic acid/sodium hyaluronate safety assessment was applied.

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: Final Report of the Safety Assessment of Hyaluronic Acid, Potassium Hyaluronate, and Sodium Hyaluronate.]

- *Mos Calculation For Hydroxypropyltrimonium Hyaluronate:*

NOAEL: 40 mg/kg bw/day

SED: 0,005544 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 7215,007215

Mos ≥ 100

Safety Assessor's Comment: Read-across from hyaluronic acid/sodium hyaluronate safety assessment was applied.

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: CIR Safety Assessment of Hyaluronic Acid and related hyaluronate ingredients.]

- *Mos Calculation For Hydrolyzed Hyaluronic Acid:*

NOAEL: 40 mg/kg bw/day

SED: 0,003696 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 10822,510823

Mos ≥ 100

Safety Assessor's Comment: Read-across from hyaluronic acid/sodium hyaluronate safety assessment was applied.

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: CIR Safety Assessment of Hyaluronic Acid and related hyaluronate ingredients.]

- *Mos Calculation For Hydrolyzed Sodium Hyaluronate:*

NOAEL: 40 mg/kg bw/day

SED: 0,003696 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 10822,510823

Mos ≥ 100

Safety Assessor's Comment: Read-across from hyaluronic acid/sodium hyaluronate safety assessment was applied.

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: CIR Safety Assessment of Hyaluronic Acid and related hyaluronate ingredients.]

MoS Table for raw materials except preservative and parfum components are below.

Raw Materials INCI Name	SED (mg/kg bw/day)	NOAEL (mg/kg bw/day)	MoS (NOAEL/SED)	Safety Data
Aqua	89,571328	-	-	Worst Case Approach: Result SATISFACTORY. Water is the major solvent of cosmetic formulations and has an established history of safe use in cosmetic products. No toxicological concern is expected from its use as the main vehicle of the formulation.
Glycerin	6,237	1000	160,333494	DAp refined to 50% after initial conservative calculation. The raw material is safe to use for this product at this concentration. Because of MoS ≥100.
Niacinamide	1,232	215	174,512987	DAp refined to 50% after initial conservative calculation. The raw material is safe to use for this product at this concentration. Because of MoS ≥100.
Caprylic/Capric Triglyceride	2,464	3500	1420,454545	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.
Bis-Diglyceryl Polyacyladipate-2	1,848	1800	974,025974	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.
Glyceryl Stearate	1,848	-	-	Worst Case Approach: Result SATISFACTORY. Glyceryl Stearate is a glyceryl fatty acid

				ester. The CIR Expert Panel has concluded that glyceryl fatty acid esters are safe in cosmetics in the present practices of use and concentration when formulated to be non-irritating.
Panthenol	1,402632	1000	712,945377	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.
Cetearyl Alcohol	1,232	1000	811,688312	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.
1,2-Hexanediol	1,232	1000	811,688312	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.
Betaine	1,232	-	-	Worst Case Approach: Result SATISFACTORY. Betaine has a long history of use as a humectant and skin conditioning ingredient. Available safety information indicates low acute toxicity and no genotoxic concern under normal cosmetic use conditions.
Aloe Barbadensis Leaf Juice	1,232	-	-	Worst Case Approach: Result SATISFACTORY. Aloe Barbadensis Leaf Juice is widely used in cosmetic products as a skin conditioning and soothing ingredient. Available cosmetic safety assessments support its use in

				topical products at typical cosmetic concentrations.
Dimethicone	1,0472	-	-	Worst Case Approach: Result SATISFACTORY. Dimethicone is a high molecular weight silicone polymer with limited dermal penetration potential. The CIR Expert Panel has concluded that dimethicone and related silicone polymers are safe as used in cosmetics.
Polyacrylamide	0,7392	-	-	Worst Case Approach: Result SATISFACTORY. Polyacrylamide is a high molecular weight polymer used in cosmetics. Systemic exposure is expected to be limited due to polymeric structure; safety evaluation focuses on residual monomer control and use at low concentration.
Acrylates/C10-30 Alkyl Acrylate Crosspolymer	0,616	-	-	Worst Case Approach: Result SATISFACTORY. The CIR Expert Panel concluded that the acrylates copolymers named in the safety assessment are safe in cosmetics in the present practices of use and concentration described in the safety assessment when formulated to be nonirritating.
Saccharide Isomerate	0,616	-	-	Worst Case Approach: Result

				SATISFACTORY. Saccharide Isomerate is a carbohydrate-derived humectant. Based on its chemical nature, low use level, and history of cosmetic use, no systemic toxicological concern is expected under the intended conditions of use.
Laureth-7	0,3696	50	135,281385	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.
Sodium Stearoyl Lactylate	0,3696	1000	2705,627706	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.
C13-14 Isoparaffin	0,308	500	1623,376623	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.
Sodium Lauroyl Glutamate	0,2464	-	-	Worst Case Approach: Result SATISFACTORY. Sodium Lauroyl Glutamate belongs to amino acid-based surfactants. CIR safety assessments for related amino acid alkyl amides support their safety in cosmetics when formulated to be non-irritating.
Dimethicone Crosspolymer	0,1848	-	-	Worst Case Approach: Result SATISFACTORY. Dimethicone Crosspolymer is a high molecular weight silicone crosspolymer. Due to its polymeric structure, dermal

				absorption is expected to be negligible, and related silicone crosspolymers have been considered safe as used in cosmetics by CIR.
Chamomilla Recutita Flower Extract	0,154	-	-	Worst Case Approach: Result SATISFACTORY. Chamomilla Recutita Flower Extract is a botanical skin conditioning ingredient. Available cosmetic use history supports topical use at low concentrations; however, as with botanical extracts, potential individual sensitivity should be considered.
Ethylhexylglycerin	0,145376	100	687,871451	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.
Squalane	0,1232	1000	8116,883117	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.
Hyaluronic Acid	0,02772	40	1443,001443	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.
Citric Acid	0,02464	1200	48701,298701	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.
Sodium Acetylated Hyaluronate	0,022176	40	1803,751804	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.

Sodium Hyaluronate	0,01848	40	2164,502165	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.
Sodium Citrate	0,01232	1200	97402,597403	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.
Sodium Hyaluronate Crosspolymer	0,00924	40	4329,004329	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.
Hydroxypropyltrimonium Hyaluronate	0,005544	40	7215,007215	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.
Hydrolyzed Hyaluronic Acid	0,003696	40	10822,510823	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.
Hydrolyzed Sodium Hyaluronate	0,003696	40	10822,510823	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.

MoS calculations for preservative components are below.

- *Mos Calculation For Phenoxyethanol:*

NOAEL: 500 mg/kg bw/day

SED: 2,50708 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 199,4352

Mos ≥ 100

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: SCCS / EPA toxicological information for 2-Phenoxyethanol.]

- *Mos Calculation For Potassium Sorbate:*

NOAEL: 1000 mg/kg bw/day

SED: 0,00538 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 185873,605948

Mos ≥ 100

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: Toxicological information for Potassium Sorbate / sorbic acid salts.]

- *Mos Calculation For Sodium Benzoate:*

NOAEL: 250 mg/kg bw/day

SED: 0,00269 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 92936,802974

Mos ≥ 100

Safety Assessor's Comment: Since dermal NOAEL value was not found, the oral NOAEL value for benzoate/benzoic acid was divided by 2 and accepted for dermal assessment.

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: SCCS Notes of Guidance, 12th Revision; toxicological information for benzoates.]

- *Mos Calculation For Benzoic Acid:*

NOAEL: 250 mg/kg bw/day

SED: 0,001345 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 185873,605948

Mos ≥ 100

Safety Assessor's Comment: Since dermal NOAEL value was not found, the oral NOAEL value of 500 mg/kg bw/day was divided by 2 and accepted as 250 mg/kg bw/day.

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: SCCS Notes of Guidance, 12th Revision; toxicological information for Benzoic Acid.]

- *Mos Calculation For Dehydroacetic Acid:*

NOAEL: 100 mg/kg bw/day

SED: 0,001345 mg/kg bw/day

Mos= NO(A)EL / SED

Mos= 74349,442379

Mos ≥ 100

* * The calculated Margin of Safety (MoS) is greater than 100. Therefore, the ingredient is considered safe for use at the present concentration and intended conditions of use.

[Ref: Toxicological information for Dehydroacetic Acid / Sodium Dehydroacetate.]

MoS Table for preservative components is below.

Raw Materials INCI Name	SED (mg/kg bw/day)	NOAEL (mg/kg bw/day)	MoS (NOAEL/SED)	Safety Data
Phenoxyethanol	2,50708	500	199,4352	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.
Potassium Sorbate	0,00538	1000	185873,605948	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.
Sodium Benzoate	0,00269	250	92936,802974	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.
Benzoic Acid	0,001345	250	185873,605948	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.

Dehydroacetic Acid	0,001345	100	74349,442379	The raw material is safe to use for this product at this concentration. Because of MoS ≥100.

BIONIKS INTENSIVE CARE CREAM does not contain any parfum and aromatic components. For that reason, MoS calculations for parfum and aromatic components are not calculated.

Toxicological Information About Raw Materials

No		Justification & the Toxicological Information
		AQUA
1.		**Concentration in formulation:** 72.704% **Function:** Solvent **Routes of Entry:** Dermal contact. Eye contact. **Toxicity to Animals:** Water is not classified as hazardous under normal conditions of cosmetic use. It has no known acute oral, dermal or inhalation toxicity and is considered physiologically compatible with human tissues. **Repeated Dose Toxicity:** No repeated-dose toxicity is associated with purified water under normal conditions of cosmetic exposure. **Irritation and Sensitization:** Purified water is not considered irritating to the skin or eyes and does not possess sensitization potential. **Safety Assessment:** Purified water complies with cosmetic quality requirements and is considered safe for use as a solvent in cosmetic products. At the concentration used in the formulation, no toxicological concern is expected. **[Ref: European Pharmacopoeia; Cosmetic Ingredient Review (CIR)]**
		GLYCERIN
2.		**Concentration in formulation:** 10.125% **Function:** Skin Conditioning – Humectant **Routes of Entry:** Dermal contact. Eye contact. **Toxicity to Animals:** Acute oral toxicity (LD50): 4090 mg/kg bw (Mouse). Acute dermal toxicity (LD50): 10000 mg/kg bw (Rabbit). Acute inhalation toxicity is considered negligible under normal cosmetic conditions. **Repeated Dose Toxicity:** Repeated-dose toxicity studies demonstrated very low systemic toxicity. Oral NOAEL values up to 2000 mg/kg bw/day have been reported. Glycerin is rapidly metabolized and naturally occurs within human metabolism. **Genotoxicity / Carcinogenicity:** Available toxicological studies demonstrated no evidence of mutagenic, genotoxic or carcinogenic potential.

Reproductive Toxicity:
No reproductive or developmental toxicity has been reported at concentrations relevant to cosmetic use.

Irritation and Sensitization:
Glycerin is not considered a skin sensitizer and is generally regarded as non-irritating when used in cosmetic formulations.

Safety Assessment:
Glycerin is widely used as a cosmetic humectant with a long history of safe use. At the concentration present in this formulation, no toxicological concern is expected.

[Ref: OECD SIDS Glycerol; CIR Safety Assessment of Glycerin]

NİACİNAMİDE

3.

Concentration in formulation: 2.000%

Function: Smoothing / Skin Conditioning

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Acute oral toxicity is low. Repeated-dose toxicity studies identified a NOAEL of **215 mg/kg bw/day**. Niacinamide exhibits low systemic toxicity and is an essential vitamin derivative.

Repeated Dose Toxicity:
Subchronic toxicity studies demonstrated good systemic tolerance without evidence of target organ toxicity at doses relevant for cosmetic exposure.

Genotoxicity / Carcinogenicity:
Niacinamide was not found to be mutagenic, genotoxic or carcinogenic.

Reproductive Toxicity:
No evidence of reproductive or developmental toxicity has been reported.

Irritation and Sensitization:
Niacinamide is considered non-sensitizing and generally well tolerated by human skin.

Safety Assessment:
Niacinamide is a well-established cosmetic active ingredient with extensive toxicological documentation and a long history of safe cosmetic use. At the concentration used in this formulation, it is considered safe.

[Ref: Cosmetic Ingredient Review (CIR); OECD; EFSA]

CAPRYLİC/CAPRİC TRİGLYCERİDE

4.

Caprylic/Capric Triglyceride

Concentration in formulation: 2.000%

Function: Skin Conditioning – Occlusive

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Acute oral toxicity (LD50): >5000 mg/kg bw.
Acute dermal toxicity (LD50): >2000 mg/kg bw.

Repeated Dose Toxicity:
Subchronic toxicity studies reported a NOAEL of **3500 mg/kg bw/day**. No significant adverse systemic effects were observed.

Genotoxicity / Carcinogenicity:
No evidence of mutagenicity, genotoxicity or carcinogenicity has been reported.

Reproductive Toxicity:
No reproductive or developmental toxicity concerns have been identified.

Irritation and Sensitization:
Caprylic/Capric Triglyceride is considered non-irritating and non-sensitizing.

Safety Assessment:
Caprylic/Capric Triglyceride is widely used as an emollient in cosmetic formulations. Based on the available toxicological information and long history of safe cosmetic use, it is considered safe under the intended conditions of use.

[Ref: CIR Safety Assessment of Caprylic/Capric Triglyceride]

BİS-DİGLYCERYL POLYACYLADİPATE-2

5.

Bis-Diglyceryl Polyacyladipate-2

Concentration in formulation: 1.500%

Function: Skin Conditioning – Emollient

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Acute oral and dermal toxicity are considered low. Available toxicological data indicate no significant acute systemic toxicity under cosmetic exposure conditions.

Repeated Dose Toxicity:
No substance-specific repeated-dose toxicity studies identifying a NO(A)EL were available. Available toxicological information together with structurally related emollient esters indicates a very low toxicological concern.

Genotoxicity / Carcinogenicity:
No evidence of mutagenicity, genotoxicity or carcinogenicity has been reported for this ingredient or structurally related cosmetic emollient esters.

Reproductive Toxicity:
No reproductive or developmental toxicity concerns have been reported at cosmetic exposure levels.

Irritation and Sensitization:
Bis-Diglyceryl Polyacyladipate-2 is considered non-irritating and non-sensitizing under intended cosmetic use conditions.

Safety Assessment:
No substance-specific NO(A)EL could be identified. Therefore, the safety evaluation was performed using a conservative worst-case approach supported by available toxicological data, published safety assessments and the documented history of safe cosmetic use. Based on the available evidence, Bis-Diglyceryl Polyacyladipate-2 is considered safe at the concentration used in this formulation.

Furthermore:
Bis-Diglyceryl Polyacyladipate-2 is widely used as an emollient in leave-on cosmetic products and has a long history of safe use. Available toxicological information and cosmetic exposure data do not indicate any safety concern under normal conditions of use.

[Ref: Cosmetic Ingredient Review (CIR); Supplier Safety Data Sheet; Available Toxicological Literature]

GLYCERYL STEARATE

6.

Glyceryl Stearate

Concentration in formulation: 1.500%

Function: Skin Conditioning – Emollient

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Acute toxicity is low. Oral LD50 values reported for structurally related glycerol esters exceed 5000 mg/kg bw.

Repeated Dose Toxicity:
No significant systemic toxicity has been observed in repeated-dose studies. Glyceryl Stearate is hydrolyzed to glycerin and stearic acid, both naturally occurring physiological substances.

Genotoxicity / Carcinogenicity:
No evidence of mutagenicity, genotoxicity or carcinogenicity has been reported.

Reproductive Toxicity:
No reproductive or developmental toxicity has been identified.

Irritation and Sensitization:
Glyceryl Stearate is considered non-irritating and non-sensitizing under normal cosmetic use conditions.

Safety Assessment:
Glyceryl Stearate is widely used in cosmetic emulsions and has an extensive history of safe cosmetic use. At the concentration present in this formulation, no toxicological concern is expected.

[Ref: Cosmetic Ingredient Review (CIR) Safety Assessment of Glyceryl Fatty Acid Esters]

PANTHENOL

7.

Concentration in formulation: 1.1385%

Function: Skin Conditioning

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Acute toxicity is low. Panthenol is rapidly converted into pantothenic acid (Vitamin B5) after dermal absorption and exhibits very low systemic toxicity.

Repeated Dose Toxicity:
Repeated-dose studies demonstrated no significant adverse effects at doses relevant to cosmetic exposure.

Genotoxicity / Carcinogenicity:
Panthenol is not considered mutagenic, genotoxic or carcinogenic.

Reproductive Toxicity:
No reproductive or developmental toxicity has been reported.

Irritation and Sensitization:
Panthenol is considered non-irritating and non-sensitizing and is widely used in products intended for sensitive skin.

Safety Assessment:
Panthenol has a long history of safe cosmetic use and is considered safe under the intended conditions of use at the concentration present in this formulation.

[Ref: Cosmetic Ingredient Review (CIR); EFSA; Scientific Literature]

CETEARYL ALCOHOL

8.

Concentration in formulation: 1.000%

Function: Skin Conditioning – Emollient

Routes of Entry:

Dermal contact. Eye contact.

Toxicity to Animals:

Acute oral toxicity is low, with reported LD50 values exceeding 5000 mg/kg bw.

Repeated Dose Toxicity:

Repeated-dose studies demonstrated low systemic toxicity. Long-chain fatty alcohols are extensively metabolized to naturally occurring fatty acids.

Genotoxicity / Carcinogenicity:

No evidence of mutagenic, genotoxic or carcinogenic potential has been reported.

Reproductive Toxicity:

No adverse reproductive or developmental effects have been identified.

Irritation and Sensitization:

Cetearyl Alcohol is considered non-irritating and non-sensitizing under intended cosmetic use conditions.

Safety Assessment:

The CIR Expert Panel concluded that fatty alcohols including Cetearyl Alcohol are safe in cosmetics in the present practices of use and concentration.

[Ref: CIR Final Report on Fatty Alcohols Used in Cosmetics]

1,2-HEXANEDİOL

9.

Concentration in formulation: 1.000%

Function: Skin Conditioning

Routes of Entry:

Dermal contact. Eye contact.

Toxicity to Animals:

Acute oral toxicity (LD50): >2000 mg/kg bw.

Acute dermal toxicity (LD50): >2000 mg/kg bw.

Repeated Dose Toxicity:

Repeated-dose toxicity studies identified a **NOAEL of 1000 mg/kg bw/day**. No significant systemic toxicity has been observed following repeated exposure.

Genotoxicity / Carcinogenicity:

1,2-Hexanediol was not found to be mutagenic, genotoxic or carcinogenic in available toxicological studies.

Reproductive Toxicity:

No reproductive or developmental toxicity has been reported.

Irritation and Sensitization:

1,2-Hexanediol is considered non-irritating and non-sensitizing under intended cosmetic use conditions.

Safety Assessment:

1,2-Hexanediol is widely used as a multifunctional cosmetic ingredient and preservative booster. Based on the available toxicological data and its long history of safe cosmetic use, the ingredient is considered safe at the concentration used in this formulation.

[Ref: Cosmetic Ingredient Review (CIR); Available Toxicological Literature]

BETAİNE

10.

Concentration in formulation: 1.000%

Function: Skin Conditioning – Humectant

Routes of Entry:

Dermal contact. Eye contact.

Toxicity to Animals:

Betaine exhibits very low acute oral and dermal toxicity. Acute toxicity studies demonstrated no significant systemic adverse effects at doses relevant to cosmetic exposure.

Repeated Dose Toxicity:

Repeated-dose studies demonstrated very low systemic toxicity. Betaine is a naturally occurring osmolyte and is rapidly metabolized within normal physiological pathways.

Genotoxicity / Carcinogenicity:

No evidence of mutagenicity, genotoxicity or carcinogenicity has been reported.

Reproductive Toxicity:

No reproductive or developmental toxicity concerns have been identified.

Irritation and Sensitization:

Betaine is considered non-irritating and non-sensitizing and is commonly used in formulations intended for sensitive skin.

Safety Assessment:

Betaine has an excellent toxicological profile and extensive history of safe cosmetic use. At the concentration present in this formulation, no toxicological concern is expected.

[Ref: Cosmetic Ingredient Review (CIR); EFSA; Scientific Literature]

ALOE BARBADENSİS LEAF JUİCE

11.

Concentration in formulation: 1.000%

Function: Skin Conditioning

Routes of Entry:

Dermal contact. Eye contact.

Toxicity to Animals:

Acute toxicity studies demonstrated very low toxicity following dermal and oral exposure. Cosmetic-grade Aloe Barbadensis Leaf Juice is considered safe under normal conditions of use.

Repeated Dose Toxicity:

Repeated-dose toxicity studies have demonstrated low systemic toxicity at cosmetic exposure levels. No significant target organ toxicity has been identified.

Genotoxicity / Carcinogenicity:

Purified Aloe Barbadensis Leaf Juice intended for cosmetic use is not considered mutagenic or carcinogenic.

Reproductive Toxicity:

No reproductive or developmental toxicity concerns have been identified for cosmetic-grade Aloe Barbadensis Leaf Juice.

Irritation and Sensitization:

Aloe Barbadensis Leaf Juice is generally regarded as non-irritating and is frequently incorporated into products formulated for dry and sensitive skin.

Safety Assessment:
Aloe Barbadensis Leaf Juice has a long history of safe cosmetic use. Based on available toxicological information and current cosmetic exposure levels, the ingredient is considered safe for its intended use.

[Ref: Cosmetic Ingredient Review (CIR) Safety Assessment of Aloe-Derived Ingredients]

PHENOXYETHANOL

12.

Concentration in formulation: 0.9320%

Function: Preservative

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Acute oral toxicity is low. Dermal LD50 values exceed 2000 mg/kg bw.

Repeated Dose Toxicity:
Repeated-dose dermal toxicity studies identified a **NOEL of 500 mg/kg bw/day**. No significant systemic toxicity was observed under cosmetic exposure conditions.

Genotoxicity / Carcinogenicity:
Phenoxyethanol is not considered mutagenic, genotoxic or carcinogenic.

Reproductive Toxicity:
No reproductive or developmental toxicity concerns have been identified at concentrations permitted for cosmetic use.

Irritation and Sensitization:
Phenoxyethanol is generally regarded as non-sensitizing. Mild eye irritation may occur at high concentrations; however, at the concentration used in this formulation it is considered safe.

Safety Assessment:
Phenoxyethanol is permitted as a preservative under Regulation (EC) No. 1223/2009 (Annex V) at concentrations up to 1.0%. The concentration used in this formulation complies with the regulatory limit and is considered safe.

[Ref: SCCS Opinion on Phenoxyethanol; Regulation (EC) No. 1223/2009 Annex V]

DIMETHICONE

13.

Concentration in formulation: 0.8500%

Function: Skin Conditioning

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Acute oral toxicity (LD50): >2000 mg/kg bw.
Acute dermal toxicity (LD50): >2000 mg/kg bw.

Repeated Dose Toxicity:
Repeated-dose toxicity studies demonstrated very low systemic toxicity. Dimethicone exhibits negligible dermal penetration due to its high molecular weight and physicochemical properties.

Genotoxicity / Carcinogenicity:
Dimethicone is not considered mutagenic, genotoxic or carcinogenic.

Reproductive Toxicity:
No reproductive or developmental toxicity concerns have been reported.

Irritation and Sensitization:
Dimethicone is considered non-irritating and non-sensitizing under intended cosmetic use conditions.

Safety Assessment:

Dimethicone has an extensive history of safe cosmetic use. Based on available toxicological data and Cosmetic Ingredient Review conclusions, the ingredient is considered safe at the concentration used in this formulation.

[Ref: Cosmetic Ingredient Review (CIR) Safety Assessment of Dimethicone and Related Ingredients]

POLYACRYLAMİDE

14.

Concentration in formulation: 0.6000%

Function: Antistatic

Routes of Entry:

Dermal contact. Eye contact.

Toxicity to Animals:

Acute toxicity studies demonstrated low systemic toxicity. High molecular weight polyacrylamide exhibits minimal dermal penetration.

Repeated Dose Toxicity:

No substance-specific NO(A)EL suitable for cosmetic exposure assessment could be identified. Due to its polymeric structure and negligible dermal absorption, systemic exposure is expected to be extremely low.

Genotoxicity / Carcinogenicity:

Polyacrylamide polymer itself is not considered genotoxic. Residual acrylamide monomer is controlled during manufacturing according to cosmetic quality requirements.

Reproductive Toxicity:

No reproductive toxicity concerns have been identified for cosmetic-grade polyacrylamide polymer.

Irritation and Sensitization:

Polyacrylamide is considered non-irritating and non-sensitizing under intended cosmetic use conditions.

Safety Assessment:

No substance-specific NO(A)EL could be identified. Therefore, a conservative worst-case approach supported by polymer toxicology principles and available cosmetic safety assessments was applied. Due to its high molecular weight and negligible dermal absorption, Polyacrylamide is considered safe at the concentration present in this formulation.

Furthermore:

Polyacrylamide is a high molecular weight polymer with extremely limited dermal penetration. Cosmetic-grade material contains strictly controlled residual acrylamide levels and has been widely used in cosmetic formulations with no significant safety concerns.

[Ref: Cosmetic Ingredient Review (CIR); Available Toxicological Literature]

ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER

15.

Concentration in formulation: 0.5000%

Function: Emulsion Stabilising

Routes of Entry:

Dermal contact. Eye contact.

Toxicity to Animals:

Acute toxicity is considered low. Due to its high molecular weight, dermal absorption is negligible.

Repeated Dose Toxicity:

No substance-specific NO(A)EL was identified. Toxicological evaluation is based on polymer safety and available Cosmetic Ingredient Review assessments.

Genotoxicity / Carcinogenicity:
No evidence of mutagenicity or carcinogenicity has been reported.

Reproductive Toxicity:
No reproductive toxicity concerns have been identified.

Irritation and Sensitization:
Generally regarded as non-irritating and non-sensitizing under intended cosmetic use conditions.

Safety Assessment:
No substance-specific NO(A)EL could be identified. Therefore, safety evaluation was performed using a conservative worst-case approach supported by available polymer toxicology data. The ingredient is considered safe under intended cosmetic use conditions.

Furthermore:
The Cosmetic Ingredient Review Expert Panel concluded that Acrylates Crosspolymers are safe in cosmetic products under the present practices of use and concentration.

[Ref: Cosmetic Ingredient Review (CIR) Safety Assessment of Acrylates Copolymers]

SACCHARİDE İSOMERATE

16.

Concentration in formulation: 0.5000%

Function: Humectant

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Acute toxicity studies indicate very low toxicity. Cosmetic exposure is not associated with systemic toxicological concern.

Repeated Dose Toxicity:
No substance-specific NO(A)EL was identified. Available toxicological information indicates excellent dermal compatibility.

Genotoxicity / Carcinogenicity:
No evidence of mutagenicity, genotoxicity or carcinogenicity has been reported.

Reproductive Toxicity:
No reproductive toxicity concerns have been identified.

Irritation and Sensitization:
Saccharide Isomerate is considered non-irritating and non-sensitizing.

Safety Assessment:
No substance-specific NO(A)EL could be identified. Therefore, a conservative worst-case toxicological assessment supported by available cosmetic safety data and the long history of cosmetic use was applied. The ingredient is considered safe under intended conditions of use.

Furthermore:
Saccharide Isomerate is widely used as a long-lasting moisturizing ingredient and demonstrates excellent skin compatibility in cosmetic formulations.

[Ref: Supplier Safety Data; Cosmetic Toxicological Literature]

LAURETH-7

17.

Concentration in formulation: 0.3000%

Function: Surfactant – Emulsifying

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Acute oral toxicity is low.

Repeated Dose Toxicity:
Repeated-dose toxicity studies for alcohol ethoxylates identified a conservative systemic **NOAEL of 37.5 mg/kg bw/day**.

Genotoxicity / Carcinogenicity:
Laureth compounds are not considered mutagenic, genotoxic or carcinogenic.

Reproductive Toxicity:
No reproductive toxicity concerns have been identified.

Irritation and Sensitization:
Concentrated material may cause irritation; however, cosmetic concentrations are considered safe and non-sensitizing.

Safety Assessment:
Laureth-7 has been extensively evaluated for cosmetic use and is considered safe when formulated to be non-irritating.

[Ref: Human & Environmental Risk Assessment on Alcohol Ethoxylates; Cosmetic Ingredient Review (CIR)]

SODİUM STEAROYL LACTYLATE

18.

Concentration in formulation: 0.3000%

Function: Surfactant – Emulsifying

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Acute toxicity studies demonstrated low oral and dermal toxicity. The ingredient is rapidly hydrolyzed into naturally occurring fatty acids, lactic acid and sodium salts following exposure.

Repeated Dose Toxicity:
No substance-specific NO(A)EL suitable for cosmetic safety assessment could be identified. Available toxicological information indicates low systemic toxicity.

Genotoxicity / Carcinogenicity:
No evidence of mutagenicity, genotoxicity or carcinogenicity has been reported.

Reproductive Toxicity:
No reproductive or developmental toxicity concerns have been identified.

Irritation and Sensitization:
Sodium Stearoyl Lactylate is considered non-irritating and non-sensitizing under intended cosmetic use conditions.

Safety Assessment:
No substance-specific NO(A)EL could be identified. Therefore, safety evaluation was performed using a conservative worst-case approach supported by available toxicological information and the long history of safe cosmetic use. The ingredient is considered safe under intended cosmetic use conditions.

Furthermore:
Sodium Stearoyl Lactylate is widely used as an emulsifier in cosmetic products and demonstrates excellent dermal compatibility and a long history of safe cosmetic use.

[Ref: Cosmetic Ingredient Review (CIR); Available Toxicological Literature]

C13-14 İSOPARAFFİN

19.

Concentration in formulation: 0.2500%

Function: Skin Conditioning – Emollient

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Acute oral toxicity is low. Available toxicological studies demonstrate low systemic toxicity following dermal exposure.

Repeated Dose Toxicity:
Repeated-dose toxicity studies identified a **NOAEL of 1000 mg/kg bw/day**.

Genotoxicity / Carcinogenicity:
No evidence of mutagenicity, genotoxicity or carcinogenicity has been reported.

Reproductive Toxicity:
No reproductive or developmental toxicity concerns have been identified.

Irritation and Sensitization:
C13-14 Isoparaffin is considered non-irritating and non-sensitizing under intended cosmetic use conditions.

Safety Assessment:
C13-14 Isoparaffin is widely used as an emollient in cosmetic products. Based on the available toxicological information and calculated Margin of Safety, the ingredient is considered safe at the concentration used in this formulation.

[Ref: ECHA Registration Dossier; Available Toxicological Literature]

SODİUM LAUROYL GLUTAMATE

20.

Concentration in formulation: 0.2000%

Function: Antistatic

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Acute oral toxicity is low. Available toxicological studies indicate low systemic toxicity under intended cosmetic exposure conditions.

Repeated Dose Toxicity:
No substance-specific NO(A)EL suitable for cosmetic assessment could be identified.

Genotoxicity / Carcinogenicity:
No evidence of mutagenicity or genotoxicity has been reported.

Reproductive Toxicity:
No reproductive or developmental toxicity concerns have been identified.

Irritation and Sensitization:
Sodium Lauroyl Glutamate is considered non-irritating, non-sensitizing and non-phototoxic under intended cosmetic use conditions.

Safety Assessment:
No substance-specific NO(A)EL could be identified. Therefore, a conservative worst-case approach supported by available toxicological information and cosmetic safety assessments was applied. The ingredient is considered safe at the concentration present in this formulation.

Furthermore:
The Cosmetic Ingredient Review Expert Panel concluded that amino acid alkyl amides, including Sodium Lauroyl Glutamate, are safe in cosmetic formulations when formulated to be non-irritating.

[Ref: Cosmetic Ingredient Review (CIR) Safety Assessment of Amino Acid Alkyl Amides]

DİMETHİCONE CROSSPOLYMER

21.

Concentration in formulation: 0.1500%

Function: Emulsion Stabilising

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Acute oral toxicity (LD50): >2000 mg/kg bw.
Acute dermal toxicity (LD50): >2000 mg/kg bw.

Repeated Dose Toxicity:
No substance-specific NO(A)EL suitable for cosmetic safety assessment was identified. Due to the highly cross-linked polymeric structure, dermal penetration is expected to be negligible.

Genotoxicity / Carcinogenicity:
No evidence of mutagenicity, genotoxicity or carcinogenicity has been reported.

Reproductive Toxicity:
No reproductive or developmental toxicity concerns have been identified.

Irritation and Sensitization:
Dimethicone Crosspolymer is considered non-irritating and non-sensitizing.

Safety Assessment:
No substance-specific NO(A)EL could be identified. Therefore, safety evaluation was performed using a conservative worst-case approach supported by polymer toxicology principles and Cosmetic Ingredient Review conclusions. The ingredient is considered safe under intended cosmetic use conditions.

Furthermore:
Due to its highly cross-linked silicone polymer structure, Dimethicone Crosspolymer exhibits negligible dermal absorption and has a long history of safe cosmetic use.

[Ref: Cosmetic Ingredient Review (CIR) Safety Assessment of Silicone Polymers]

CHAMOMİLLA RECUTİTA FLOWER EXTRACT

22.

Concentration in formulation: 0.1250%

Function: Skin Conditioning

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Available toxicological studies indicate low acute toxicity following dermal and oral exposure.

Repeated Dose Toxicity:
No substance-specific NO(A)EL suitable for cosmetic assessment could be identified.

Genotoxicity / Carcinogenicity:
No evidence of carcinogenicity has been reported. Genotoxicity data are considered acceptable for cosmetic use.

Reproductive Toxicity:
No reproductive toxicity concerns have been identified.

Irritation and Sensitization:
Chamomilla Recutita Flower Extract is generally well tolerated. However, individuals with known Asteraceae (Compositae) allergy may exhibit hypersensitivity reactions.

Safety Assessment:
No substance-specific NO(A)EL could be identified. Therefore, a conservative worst-case approach supported by published toxicological literature and the long history of cosmetic use was applied. At the concentration present in this formulation, the ingredient is considered safe.

Furthermore:
Chamomilla Recutita Flower Extract has been widely used in cosmetic formulations for its soothing properties and demonstrates excellent skin compatibility under normal conditions of use.

[Ref: Cosmetic Ingredient Review (CIR); Published Botanical Safety Literature]

ETHYLHEXYLGLYCERİN

23.

Concentration in formulation: 0.1180%

Function: Skin Conditioning

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Acute oral toxicity is low. Acute dermal toxicity studies demonstrated low systemic toxicity following dermal exposure.

Repeated Dose Toxicity:
Repeated-dose toxicity studies identified a **NOAEL of 100 mg/kg bw/day**. No significant systemic toxicity has been reported at cosmetic exposure levels.

Genotoxicity / Carcinogenicity:
Ethylhexylglycerin is not considered mutagenic, genotoxic or carcinogenic.

Reproductive Toxicity:
No reproductive or developmental toxicity concerns have been identified.

Irritation and Sensitization:
Ethylhexylglycerin is generally regarded as non-irritating and non-sensitizing under intended cosmetic use conditions.

Safety Assessment:
Ethylhexylglycerin is widely used as a multifunctional cosmetic ingredient and preservative booster. Based on available toxicological data and the calculated Margin of Safety, the ingredient is considered safe at the concentration used in this formulation.

[Ref: Cosmetic Ingredient Review (CIR); Available Toxicological Literature]

SQUALANE

24.

Concentration in formulation: 0.1000%

Function: Skin Conditioning – Emollient

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Squalane exhibits very low acute oral and dermal toxicity. No significant systemic toxicity has been observed in available toxicological studies.

Repeated Dose Toxicity:
No substance-specific NO(A)EL suitable for cosmetic safety assessment could be identified.

Genotoxicity / Carcinogenicity:
No evidence of mutagenicity, genotoxicity or carcinogenicity has been reported.

Reproductive Toxicity:
No reproductive or developmental toxicity concerns have been identified.

Irritation and Sensitization:
Squalane is considered non-irritating and non-sensitizing and demonstrates excellent dermal compatibility.

Safety Assessment:
No substance-specific NO(A)EL could be identified. Therefore, a conservative worst-case approach supported by available toxicological information and extensive cosmetic use history was applied. Squalane is considered safe under intended cosmetic use conditions.

Furthermore:
Squalane is a naturally occurring skin lipid analogue widely used in cosmetic products because of its excellent skin compatibility and long history of safe use.

[Ref: Cosmetic Ingredient Review (CIR); Available Toxicological Literature]

HYALURONİC ACİD

25.

Concentration in formulation: 0.0225%

Function: Skin Conditioning

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Acute toxicity studies demonstrated very low systemic toxicity. Hyaluronic Acid is a naturally occurring polysaccharide present in human connective tissues.

Repeated Dose Toxicity:
No substance-specific NO(A)EL suitable for cosmetic safety assessment could be identified.

Genotoxicity / Carcinogenicity:
No evidence of mutagenicity, genotoxicity or carcinogenicity has been reported.

Reproductive Toxicity:
No reproductive toxicity concerns have been identified.

Irritation and Sensitization:
Hyaluronic Acid is considered non-irritating and non-sensitizing.

Safety Assessment:
No substance-specific NO(A)EL could be identified. Therefore, safety evaluation was performed using a conservative worst-case approach supported by published toxicological data and extensive cosmetic use history. The ingredient is considered safe at the concentration present in this formulation.

Furthermore:
Hyaluronic Acid is naturally present in human skin and has a long history of safe cosmetic use as a moisturizing and skin conditioning ingredient.

[Ref: Cosmetic Ingredient Review (CIR) Safety Assessment of Hyaluronic Acid Ingredients]

CİTRİC ACİD

26.

Concentration in formulation: 0.0200%

Function: Buffering

Routes of Entry:

Dermal contact. Eye contact.

Toxicity to Animals:

Citric Acid exhibits low acute toxicity. It is a naturally occurring organic acid involved in normal cellular metabolism.

Repeated Dose Toxicity:

Repeated-dose toxicity studies demonstrated low systemic toxicity. Available toxicological information indicates a favorable safety profile under cosmetic exposure conditions.

Genotoxicity / Carcinogenicity:

Citric Acid is not considered mutagenic, genotoxic or carcinogenic.

Reproductive Toxicity:

No reproductive toxicity concerns have been identified.

Irritation and Sensitization:

Concentrated Citric Acid may cause irritation; however, at the concentration present in this formulation and with the finished product pH adjustment, no significant irritation is expected.

Safety Assessment:

Citric Acid is widely used as a buffering agent in cosmetic formulations and is considered safe under intended cosmetic use conditions.

[Ref: Cosmetic Ingredient Review (CIR) Safety Assessment of Citric Acid and Inorganic Citrate Ingredients]

SODİUM ACETYLATED HYALURONATE

27.

Concentration in formulation: 0.0180%

Function: Humectant

Routes of Entry:

Dermal contact. Eye contact.

Toxicity to Animals:

Available toxicological information indicates very low acute toxicity. Due to its polymeric polysaccharide structure, systemic exposure is expected to be negligible.

Repeated Dose Toxicity:

No substance-specific NO(A)EL suitable for cosmetic assessment could be identified.

Genotoxicity / Carcinogenicity:

No evidence of mutagenicity or carcinogenicity has been reported.

Reproductive Toxicity:

No reproductive toxicity concerns have been identified.

Irritation and Sensitization:

Sodium Acetylated Hyaluronate is considered non-irritating and non-sensitizing under intended cosmetic use conditions.

Safety Assessment:

No substance-specific NO(A)EL could be identified. Therefore, a conservative worst-case approach supported by the toxicological profile of hyaluronic acid derivatives and the long history of cosmetic use was applied. The ingredient is considered safe under intended cosmetic use conditions.

Furthermore:
Sodium Acetylated Hyaluronate is a modified Hyaluronic Acid derivative with excellent skin compatibility and is widely used in moisturizing cosmetic formulations.

[Ref: Cosmetic Ingredient Review (CIR); Available Toxicological Literature]

SODİUM HYALURONATE

28.

Concentration in formulation: 0.0150%

Function: Skin Conditioning

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Sodium Hyaluronate exhibits very low acute toxicity. It is a naturally occurring polysaccharide salt of Hyaluronic Acid and is present in human connective tissues.

Repeated Dose Toxicity:
Available repeated-dose studies on Hyaluronic Acid and Sodium Hyaluronate derivatives indicate low systemic toxicity. No significant adverse systemic effects have been reported under cosmetic exposure conditions.

Genotoxicity / Carcinogenicity:
Sodium Hyaluronate is not considered mutagenic, genotoxic or carcinogenic.

Reproductive Toxicity:
No reproductive or developmental toxicity concerns have been identified.

Irritation and Sensitization:
Sodium Hyaluronate is considered non-irritating and non-sensitizing.

Safety Assessment:
Sodium Hyaluronate is widely used in cosmetic formulations as a moisturizing and skin conditioning ingredient. Based on available toxicological information and its long history of safe cosmetic use, it is considered safe at the concentration used in this formulation.

[Ref: Cosmetic Ingredient Review (CIR) Safety Assessment of Hyaluronic Acid Ingredients]

SODİUM CİTRATE

29.

Concentration in formulation: 0.0100%

Function: Chelating

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Sodium Citrate exhibits low acute toxicity. It is a sodium salt of citric acid and is involved in normal physiological metabolic pathways.

Repeated Dose Toxicity:
Repeated-dose toxicity studies indicate low systemic toxicity. No significant toxicological concern is expected under cosmetic exposure conditions.

Genotoxicity / Carcinogenicity:
Sodium Citrate is not considered mutagenic, genotoxic or carcinogenic.

Reproductive Toxicity:
No reproductive or developmental toxicity concerns have been identified.

Irritation and Sensitization:
Sodium Citrate is considered non-irritating and non-sensitizing at cosmetic use concentrations.

Safety Assessment:
Sodium Citrate is widely used as a chelating, buffering and pH-adjusting ingredient in cosmetic formulations. At the concentration present in this formulation, no toxicological concern is expected.

[Ref: Cosmetic Ingredient Review (CIR) Safety Assessment of Citric Acid and Inorganic Citrate Ingredients]

SODİUM HYALURONATE CROSSPOLYMER

30.

Concentration in formulation: 0.0075%

Function: Skin Conditioning

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Available toxicological information indicates very low acute toxicity. Due to its crosslinked polysaccharide structure, systemic exposure is expected to be negligible.

Repeated Dose Toxicity:
No substance-specific NO(A)EL suitable for cosmetic assessment could be identified.

Genotoxicity / Carcinogenicity:
No evidence of mutagenicity or carcinogenicity has been reported.

Reproductive Toxicity:
No reproductive or developmental toxicity concerns have been identified.

Irritation and Sensitization:
Sodium Hyaluronate Crosspolymer is considered non-irritating and non-sensitizing under intended cosmetic use conditions.

Safety Assessment:
No substance-specific NO(A)EL could be identified. Therefore, a conservative worst-case approach supported by the toxicological profile of Hyaluronic Acid derivatives and the long history of cosmetic use was applied. The ingredient is considered safe under intended cosmetic use conditions.

Furthermore:
Sodium Hyaluronate Crosspolymer is a crosslinked derivative of Sodium Hyaluronate. Due to its high molecular weight and polymeric nature, dermal penetration is expected to be limited, and systemic exposure is considered negligible.

[Ref: Cosmetic Ingredient Review (CIR); Available Toxicological Literature]

HYDROXYPROPYLTRİMONİUM HYALURONATE

31.

Concentration in formulation: 0.0045%

Function: Film Forming

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Available toxicological information indicates very low acute toxicity. As a cationic derivative of Hyaluronic Acid, systemic exposure is expected to be very limited due to its polymeric structure.

Repeated Dose Toxicity:
No substance-specific NO(A)EL suitable for cosmetic assessment could be identified.

Genotoxicity / Carcinogenicity:
No evidence of mutagenicity, genotoxicity or carcinogenicity has been reported.

Reproductive Toxicity:
No reproductive or developmental toxicity concerns have been identified.

Irritation and Sensitization:
Hydroxypropyltrimonium Hyaluronate is considered non-irritating and non-sensitizing under intended cosmetic use conditions.

Safety Assessment:
No substance-specific NO(A)EL could be identified. Therefore, a conservative worst-case approach supported by Hyaluronic Acid derivative toxicology and cosmetic use history was applied. At the concentration present in this formulation, the ingredient is considered safe.

Furthermore:
Hydroxypropyltrimonium Hyaluronate is a high molecular weight Hyaluronic Acid derivative used in cosmetic formulations for skin conditioning and film forming properties. Dermal penetration and systemic exposure are expected to be negligible.

[Ref: Cosmetic Ingredient Review (CIR); Available Toxicological Literature]

HYDROLYZED HYALURONİC ACİD

32.

Concentration in formulation: 0.0030%

Function: Skin Conditioning

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Available toxicological studies indicate very low acute toxicity. Due to its reduced molecular weight, Hydrolyzed Hyaluronic Acid exhibits improved skin affinity while maintaining a favorable toxicological profile.

Repeated Dose Toxicity:
No substance-specific NO(A)EL suitable for cosmetic safety assessment could be identified. Available toxicological information indicates low systemic toxicity.

Genotoxicity / Carcinogenicity:
No evidence of mutagenicity, genotoxicity or carcinogenicity has been reported.

Reproductive Toxicity:
No reproductive or developmental toxicity concerns have been identified.

Irritation and Sensitization:
Hydrolyzed Hyaluronic Acid is considered non-irritating and non-sensitizing under intended cosmetic use conditions.

Safety Assessment:
No substance-specific NO(A)EL could be identified. Therefore, a conservative worst-case approach supported by available toxicological information and the extensive cosmetic use history of Hyaluronic Acid derivatives was applied. The ingredient is considered safe under intended cosmetic use conditions.

Furthermore:
Hydrolyzed Hyaluronic Acid is widely used as a skin conditioning and moisturizing ingredient. Available toxicological data and extensive cosmetic use demonstrate excellent dermal compatibility.

[Ref: Cosmetic Ingredient Review (CIR); Available Toxicological Literature]

HYDROLYZED SODİUM HYALURONATE

33.

Concentration in formulation: 0.0030%

Function: Skin Conditioning

Routes of Entry:

Dermal contact. Eye contact.

Toxicity to Animals:

Available toxicological studies demonstrate very low acute toxicity. Hydrolyzed Sodium Hyaluronate exhibits excellent biological compatibility and low systemic exposure under intended cosmetic use conditions.

Repeated Dose Toxicity:

No substance-specific NO(A)EL suitable for cosmetic safety assessment could be identified.

Genotoxicity / Carcinogenicity:

No evidence of mutagenicity, genotoxicity or carcinogenicity has been reported.

Reproductive Toxicity:

No reproductive or developmental toxicity concerns have been identified.

Irritation and Sensitization:

Hydrolyzed Sodium Hyaluronate is considered non-irritating and non-sensitizing.

Safety Assessment:

No substance-specific NO(A)EL could be identified. Therefore, a conservative worst-case approach supported by Hyaluronic Acid derivative toxicology and the documented history of safe cosmetic use was applied. The ingredient is considered safe at the concentration used in this formulation.

Furthermore:

Hydrolyzed Sodium Hyaluronate is commonly used in moisturizing cosmetic formulations and demonstrates excellent skin compatibility with negligible systemic exposure.

[Ref: Cosmetic Ingredient Review (CIR); Available Toxicological Literature]

POTASSİUM SORBATE

34.

Concentration in formulation: 0.0020%

Function: Preservative

Routes of Entry:

Dermal contact. Eye contact.

Toxicity to Animals:

Potassium Sorbate exhibits low acute oral and dermal toxicity. Cosmetic exposure levels are considerably below doses associated with systemic toxicity.

Repeated Dose Toxicity:

Repeated-dose toxicity studies demonstrated low systemic toxicity at cosmetic exposure levels.

Genotoxicity / Carcinogenicity:

Potassium Sorbate is not considered mutagenic, genotoxic or carcinogenic.

Reproductive Toxicity:

No reproductive or developmental toxicity concerns have been identified.

Irritation and Sensitization:

Potassium Sorbate may cause mild irritation at high concentrations. At the concentration used in this formulation, no significant irritation is expected.

Safety Assessment:
Potassium Sorbate is permitted for cosmetic use under Regulation (EC) No. 1223/2009 Annex V and is considered safe at the concentration present in this formulation.

[Ref: SCCS; Regulation (EC) No. 1223/2009 Annex V]

SODİUM BENZOATE

35.

Concentration in formulation: 0.0010%

Function: Preservative

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Acute toxicity studies indicate low systemic toxicity following dermal exposure.

Repeated Dose Toxicity:
Repeated-dose studies demonstrated acceptable safety under cosmetic exposure conditions.

Genotoxicity / Carcinogenicity:
No evidence of mutagenicity, genotoxicity or carcinogenicity has been reported.

Reproductive Toxicity:
No reproductive toxicity concerns have been identified.

Irritation and Sensitization:
Sodium Benzoate is generally considered non-sensitizing at cosmetic concentrations.

Safety Assessment:
Sodium Benzoate is permitted as a preservative under Regulation (EC) No. 1223/2009 Annex V and is considered safe at the concentration used in this formulation.

[Ref: SCCS; Regulation (EC) No. 1223/2009 Annex V]

BENZOIC ACID

36.

Concentration in formulation: 0.0005%

Function: Preservative

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Benzoic Acid exhibits low acute toxicity and has been extensively evaluated for cosmetic and food applications.

Repeated Dose Toxicity:
Repeated-dose toxicity studies indicate low systemic toxicity under intended cosmetic exposure conditions.

Genotoxicity / Carcinogenicity:
Benzoic Acid is not considered mutagenic, genotoxic or carcinogenic.

Reproductive Toxicity:
No reproductive toxicity concerns have been identified.

Irritation and Sensitization:
High concentrations may cause local irritation; however, at the concentration used in this formulation no toxicological concern is expected.

Safety Assessment:
Benzoic Acid is permitted as a preservative under Regulation (EC) No. 1223/2009 Annex V and is considered safe under intended cosmetic use conditions.

[Ref: SCCS; Regulation (EC) No. 1223/2009 Annex V]

DEHYDROACETİC ACİD

37.

Concentration in formulation: 0.0005%

Function: Preservative

Routes of Entry:
Dermal contact. Eye contact.

Toxicity to Animals:
Acute toxicity studies demonstrated low systemic toxicity following dermal exposure.

Repeated Dose Toxicity:
Repeated-dose studies indicate low systemic toxicity at cosmetic exposure levels.

Genotoxicity / Carcinogenicity:
No evidence of mutagenicity, genotoxicity or carcinogenicity has been reported.

Reproductive Toxicity:
No reproductive toxicity concerns have been identified.

Irritation and Sensitization:
Dehydroacetic Acid is generally considered non-irritating and non-sensitizing at cosmetic use concentrations.

Safety Assessment:
Dehydroacetic Acid is permitted as a preservative under Regulation (EC) No. 1223/2009 Annex V. At the concentration present in this formulation, it is considered safe for cosmetic use.

[Ref: SCCS; Regulation (EC) No. 1223/2009 Annex V]

9. Undesirable effects and serious undesirable effects

There are no any adverse reactions and serious adverse effects have been reported.

10. Information on the cosmetic product

Other relevant informationsare found in PIF.

The information contained in the PIF are as follows:

1. GMP compliance
2. Certificate of Analysis or Specifications of Final Product
3. English Label Information for Final Product
4. Production (Manufacturing) Method
5. Safety Data Sheets of Ingredients (MSDS)
6. Certification of Analysis of Ingredients
7. Microbiology Certificates of Ingredients
8. Formulation of the Product
9. Product Stability Follow-up Form
10. Microbiological and Challenge Test Report
11. Packaging Quality Certificate (TDS/MSDS)

PART B – Cosmetic product safety assessment

1. Assessment conclusion

The assessment was based on the qualitative and quantitative composition of the product, the toxicological profiles of the raw materials, the toxicological profile of the finished product, exposure assessment, stability evaluation, microbiological quality assessment, and packaging compatibility information.

BIONIKS INTENSIVE CARE CREAM is a leave-on cosmetic skin care product formulated with **Hyaluronic Acid Complex, Niacinamide, Panthenol, Betaine, Aloe Barbadensis Leaf Juice, Chamomilla Recutita Flower Extract and Squalane** to provide intensive moisturization, support the skin barrier, help maintain the skin moisture balance and improve the overall appearance and comfort of the skin.

The formulation contains raw materials, preservatives, emulsifiers, humectants, emollients and skin conditioning agents. The product does not contain fragrance, aromatic components or nanomaterials. Margin of Safety (MoS) calculations were performed for the relevant raw materials with available toxicological data. Calculated MoS values were found to be greater than 100.

All raw materials have been reviewed for compliance with Regulation (EC) No. 1223/2009 and the relevant supporting documentation has been evaluated. The raw materials are not considered toxic under normal or reasonably foreseeable conditions of use at the concentrations present in the formulation. The product does not contain prohibited substances listed in the Annexes of Regulation (EC) No. 1223/2009. Therefore, the raw materials, raw material components and their usage levels are considered acceptable and safe.

BIONIKS INTENSIVE CARE CREAM has been tested for microbiological quality. The presence of total mesophilic aerobic bacteria, yeast and mould, and specified pathogenic microorganisms was evaluated in the finished product. According to the test results, the product complies with the relevant microbiological quality requirements for cosmetic products. Microbiological test results are presented in **PIF Annex IV**.

The product contains a preservative system and has been subjected to a preservative efficacy (Challenge) test. According to the obtained results, the preservative system was found to be effective and suitable for protecting the product during normal use and storage conditions. Challenge test results are presented in **PIF Annex III**.

The **BIONIKS INTENSIVE CARE CREAM** product has been subjected to stability testing. The product was analyzed over a period of 45 days under different storage conditions, including 40°C. During the test period, parameters such as appearance, colour, odour, pH and packaging integrity were evaluated. No significant changes were observed, and the product was found to be stable. Stability test results are presented in **PIF Annex II**.

Impurities originating from raw materials are addressed through supplier documentation and certificates of analysis available in the Product Information File.

The product is claimed to be dermatologically tested. Relevant supporting documentation is included in the Product Information File.

The product is marketed in a **50 ml** size. The primary packaging consists of a cosmetic cream container and the secondary packaging consists of a printed carton box. Packaging compatibility and packaging material documentation have been evaluated and found suitable for the intended use.

Furthermore, all raw materials used in the formulation were reviewed for specific regulatory restrictions and warning requirements. No additional mandatory warning statements resulting from the raw materials were identified beyond the standard cosmetic precautions indicated on the label.

Following review of the information provided for the product and its ingredients, the product is considered safe for the intended application and complies with Regulation (EC) No. 1223/2009. This safety assessment is based upon information available at the date of preparation and shall be reviewed if new relevant information becomes available.

2.Labelled warnings and instructions of use

Directions for use/Cautions:

Apply a sufficient amount of cream to clean, dry skin twice daily, morning and evening, massaging gently until absorbed. Suitable for both face and body. For external use only. Avoid contact with eyes. In case of contact, rinse thoroughly with plenty of water. Do not use on irritated or damaged skin. Keep out of reach of children.

Kullanım Şekli/Uyarılar:

Günde iki kez sabah ve akşam, temiz ve kuru cildinize yeterli miktarda kremi masaj yaparak uygulayınız. Hem yüz hem de vücut için kullanımı uygundur. Harici kullanılır. Göz ile temasından kaçınınız. Temas halinde bol su ile durulayınız. Tahriş olmuş veya hasar görmüş cilt üzerinde kullanmayınız. Çocukların ulaşamayacağı yerde muhafaza ediniz.

3. Reasoning

The Safety Assessment Report prepared for **BIONIKS INTENSIVE CARE CREAM** is based on Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products together with the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation (12th Revision). Supporting documentation including Safety Data Sheets (SDS), Technical Data Sheets (TDS), Certificates of Analysis (CoA), Stability Test Reports, Microbiological Test Reports, Challenge Test Reports, Packaging Documentation and other available technical information have been taken into consideration during the safety assessment.

BIONIKS INTENSIVE CARE CREAM is a leave-on cosmetic skin care product formulated with moisturizing, humectant, emollient, skin conditioning and barrier-supporting ingredients including **Hyaluronic Acid Complex (Hyaluronic Acid, Sodium Acetylated Hyaluronate, Sodium Hyaluronate, Sodium Hyaluronate Crosspolymer, Hydroxypropyltrimonium Hyaluronate, Hydrolyzed Hyaluronic Acid and Hydrolyzed Sodium Hyaluronate), Niacinamide, Panthenol, Betaine, Aloe Barbadensis Leaf Juice, Chamomilla Recutita Flower Extract and Squalane**. These ingredients are commonly used in cosmetic products and are present at concentrations considered acceptable according to SCCS opinions, Cosmetic Ingredient Review (CIR) publications, scientific literature and other available toxicological references.

All ingredients included in the formulation have been reviewed individually with respect to their toxicological profiles, exposure levels and intended conditions of use. No prohibited substances listed in the Annexes of Regulation (EC) No. 1223/2009 are intentionally added to the formulation. No fragrance, aromatic components or nanomaterials are present in the product.

Margin of Safety (MoS) calculations were performed for ingredients for which suitable NO(A)EL values were available. For ingredients where a substance-specific NO(A)EL, Point of Departure (POD) or equivalent toxicological threshold could not be be identified, a conservative worst-case toxicological assessment approach was applied using estimated exposure levels, available toxicological information, published safety assessments, Cosmetic Ingredient Review (CIR) conclusions, SCCS guidance and the documented history of safe cosmetic use.

Exposure calculations were performed using the SCCS Notes of Guidance approach applicable to **body lotion / face and body leave-on products**, as the product is intended for application to both face and body. Where ingredient-specific dermal absorption data were unavailable, a default dermal absorption value of **100%** was used as a conservative worst-case assumption in accordance with the assessment methodology. Preservative ingredients were additionally evaluated using aggregate exposure principles described within SCCS guidance.

The product has been subjected to microbiological quality testing and challenge testing. The obtained results demonstrate that the preservative system is effective and that the product complies with the applicable microbiological quality requirements for cosmetic products. Stability studies performed under accelerated storage conditions demonstrated that the product remains stable under the tested conditions and no significant changes were observed in the evaluated parameters.

Packaging materials were assessed for suitability and compatibility with the formulation. Available packaging documentation and packaging compatibility information indicate that the packaging system is appropriate for the intended use of the product.

The formulation is not expected to be irritating to the skin, eyes or respiratory tract, phototoxic, photosensitizing, mutagenic, carcinogenic, reprotoxic or capable of causing systemic toxicity under normal and reasonably foreseeable conditions of use. At the concentrations present in the formulation, adverse effects are not expected to occur in the majority of consumers.

Considering the composition of the formulation, toxicological profiles of the ingredients, calculated exposure levels, Margin of Safety evaluations, available scientific literature, microbiological quality results, challenge test performance, stability studies, packaging suitability and intended conditions of use, the product can be considered safe for human health.

As a result of the evaluation of all available information and data provided, **BIONIKS INTENSIVE CARE CREAM** can be considered safe for its intended cosmetic use and complies with Regulation (EC) No. 1223/2009.

4. Assessor's credentials and approval of part B

Date: 25.05.2026

Safety Assessor's Name and Surname: Neslihan Şahin

Safety Assessor's Occupation: Dr. Pharmacist / Cosmetologist / PhD in Toxicology

Safety Assessor's Adress: KURŞUNLU MAH. SAHİLYOLU CAD. HALICIOĞLU SİTESİ GEMLİK / BURSA

Signature:

Safety Assessor's Credentials

DR. ECZ.
NESLIHAN
ŞAHIN

Mail : bilgi@dreczneslihansahin.com
dr.neslys@gmail.com

School

1999-2002	Private İlkbahar College , Bursa-Turkey
2002-2005	Atatürk Anadolu High School, Bursa - Turkey
2005-2006	Mc Daniel College , College International Pre-med, Budapest – Hungary

Studium

2006/7 -2011	Faculty of Pharmacy of Semmelweis Universty
2011-2012	Master science of Pharmacy Under the tittle of Pharmacy Doctor (Dr.Pharmacist) A Cum Laude Graduate - with honor, with academic distinction
2014- 2016	Yeditepe Unıversıty Master science of Cosmetology
2016- 2023	Doctoral Program in Pharmaceutical Toxicology Ph.D.

Professional Activities

Since 2006 - Kozas Cosmetic Chemical Industrial and Trade Company (Board Member)
Our company was founded in 1890 by our great grandfather in Plovdiv, an Ottoman city. Then in 1958 moved to Turkey and still have the title of the oldest cosmetic manufacturer in Turkey. As a 63-year stable company in such a beautiful city, we continue our activities in the country and abroad. Since 2013 I Have joined to our company as CEO but to be honest if ı say ı opened my eyes to the World in that cosmetic manfacturing company together with the billion different of cosmetic products and producing and formulating them wouldnt be a lie.
www.kontes.com.tr

2012-2013 - Angel Consulting – Italia
During my Unıversity years I have attend many of Seminers and Congress regarding to my interest of European Union Cosmetic Regulation, in one of the Seminer I had chance to met with an Italian Cosmetology Professor, gives the service as a Safety Assessor. Since then my direction in the cosmetic field expanded and became stronger. A week after my graduation he invited me to Italy and gave me the chance to work with him and his expert team who has years of experience in the cosmetic field. Briefly since the year of 2010 while ı was still a student , I have been educated by him regarding to EU Cosmetic regulation issue and from the 2012, professionally , in Italy, given training as an expert for the new EU Regulation.

2012-2013 - Ng Group International – Italia
After the victorious experience in Angel Consulting with Dr.Matteo Zanotti Russo , I have start working with NG Group International through the introduction of prof. This

wasnt an end to my education by him, it was a job likewise a bridge between the NG Group and the Angel consulting thereso ı start working parallels with two of the places. I had several different position as like project manager , in the scientific part of marketing, Research, Ar-ge, Foreign trade, Preperation of export certificates , Consulting regarding to products etc . After this intensive and a great work I had earn the years of experience only in one year.

2014 - I have opened my own consulting company called ' Vision Kozmetik Kimya ' and The other one which established in Budapest Hungary called ELNES COSMETIC CONSULTING KFT. since then ı am giving consulting services to the chemical , food agriculture and cosmetic companies for their regulatory papers , export to EU etc., As an Safety Assessor for the safety of Cosmetic products, Responsible Person in the Eu through ELNES company as well as CPNP notifications.

2021 Established a company in London-UK called ELNES COSMETIC CONSULTING LIMITED Which acting as a Responsible Person in the UK as well as UK portal cosmetic product notifications.

Certificates

2012- European Union Cosmetic production Seminar – Budapest – SOTE / Hungary

2011- European Cosmetics Regulation – EC 1223 /2009 - ECORE 7 –İstanbul / Turkey

2012- 2 nd Cosmetics Chemistry, Production and Standardization - Antalya / Turkey
2012- Safety Assessment and risk management of Cosmetic Products – P.İ.M , Istanbul / Turkey
2014- MSDS-Preparer (Material Safety Data Sheet Preparer) - İstanbul/Turkey
2014- Intensive Course in Dermato-Cosmetic Sciences – Vrije Universiteit Brussel/ Belgium
2015- Safety Assesment of Cosmetics in the EU- – Vrije Universiteit Brussel / Belgium
2016- Summer Universty- The art of French Perfumery and Cosmetics/Group ISIPCA France
2017- ICF Accredited Coach Training Program- Bursa/Turkey
2018- Clinical Aromatherapy Training – Bezmialem Vakıf Universty in İstanbul – Turkey.
2019- Visiting Professor in the İstinye University pharmacy Faculty in İstanbul-Turkey
2019- Holistic Approaches in Phytotherapy – Lokman Hekim Universty – Ankara-Turkey
2019- Basic Homeopathy Training- CHE (Center for Homeopathic Education)

Abilities

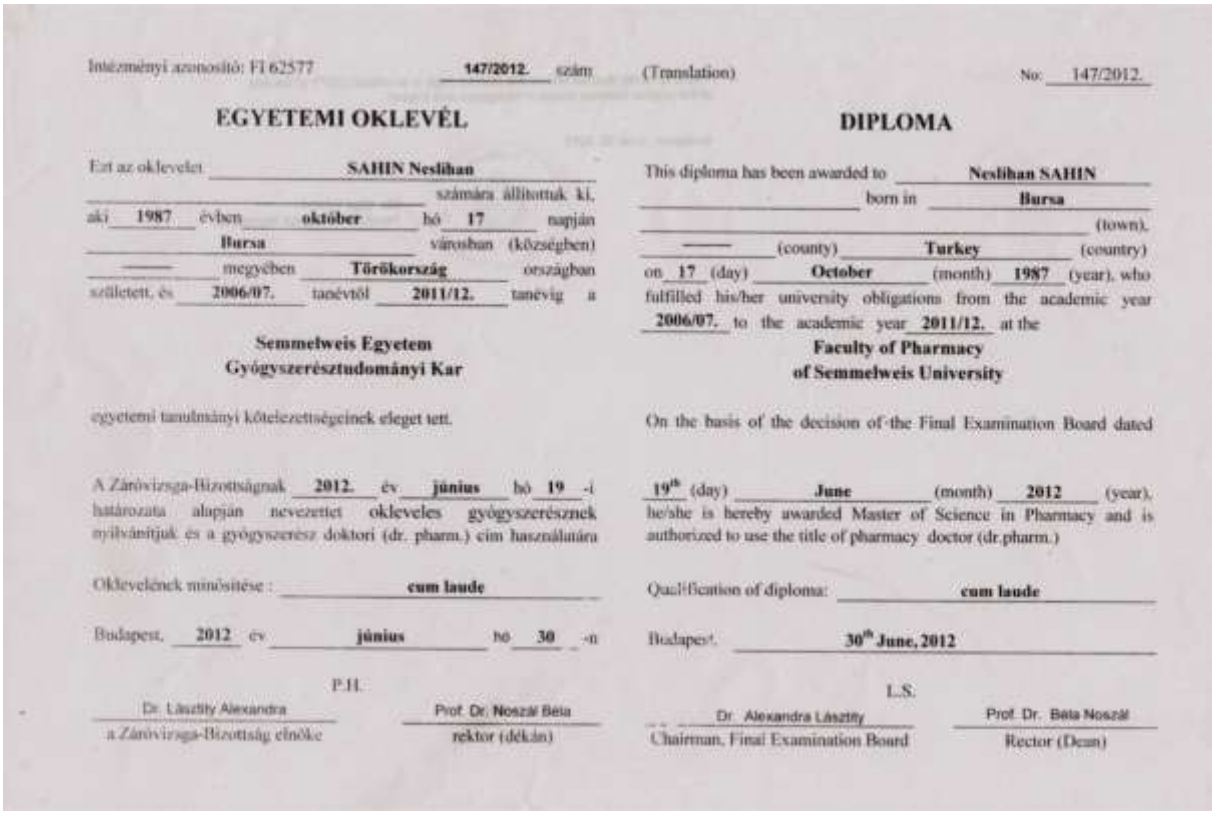
- Cosmetic production
- Formulation
- Simultaneous Translation
- GMP
- 1223/2009 Cosmetic Regulation ;
- Safety Assesment of Cosmetic Products
- Product Information File
- Responsible Person in the EU
- CPNP Notification
- MSDS-Preparer
- Writer

- Conculter
- Turkish Cosmetic Sector with Neslihan Şahin- Businesschannelturk TV- Programme maker and moderator

English	[Reading :10 Writing :10 Speaking :10] Advanced
Hungarian	[Reading :2 Writing :2 Speaking :2] Başlangıç
Italian	[Reading :2 Writing :2 Speaking :2] Başlangıç
French	[Reading :2 Writing :2 Speaking :2] Başlangıç

Owned websites

https://www.dreczneslihansahin.com/en/
www.kontes.com.tr
www.visionkimya.com
www.avrupayakozmetikihracati.com
http://www.milliyet.com.tr/dr--ecz--neslihan-sahin/saglik/pembenar-yazilari/
www.turkiyekozmetiksektoru.com



Intézményi azonosító: FI 62577 **147/2012.** szám (Translation) No: 147/2012.

EGYETEMI OKLEVÉL

Ezt az oklevelet **SAHIN Neslihan** számára állították ki, aki **1987** évben **október** hó **17** napján **Bursa** városban (községben) ——— megyében **Törökország** országban született, és **2006/07.** tanévtől **2011/12.** tanévig a

Semmelweis Egyetem
Gyógyszerésztudományi Kar

egyetemi tanulmányi kötelezettségeinek eleget tett.

A Záróvizsga-Bizottságnak **2012.** év **június** hó **19** -i határozata alapján nevezetlet okleveles gyógyszerésznek nyilvánítjuk és a gyógyszerész doktori (dr. pharm.) cím használatára

Oklevelének minősítése: **cum laude**

Budapest, **2012** év **június** hó **30** -n

P.H.

Dr. Lásztity Alexandra
a Záróvizsga-Bizottság elnöke

Prof. Dr. Noszál Béla
rektor (dékán)

DIPLOMA

This diploma has been awarded to **Neslihan SAHIN**
born in **Bursa** (town),
——— (county) **Turkey** (country)
on **17** (day) **October** (month) **1987** (year), who fulfilled his/her university obligations from the academic year **2006/07.** to the academic year **2011/12.** at the

Faculty of Pharmacy
of Semmelweis University

On the basis of the decision of the Final Examination Board dated

19th (day) **June** (month) **2012** (year), he/she is hereby awarded Master of Science in Pharmacy and is authorized to use the title of pharmacy doctor (dr.pharm.)

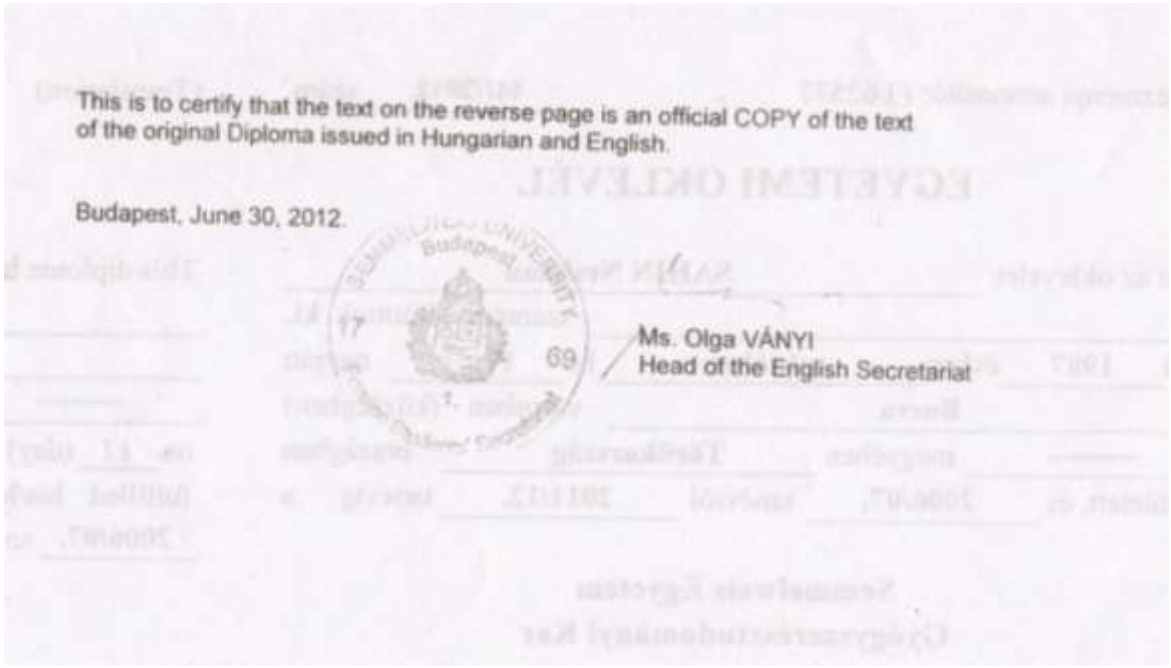
Qualification of diploma: **cum laude**

Budapest, **30th June, 2012**

L.S.

Dr. Alexandra Lásztity
Chairman, Final Examination Board

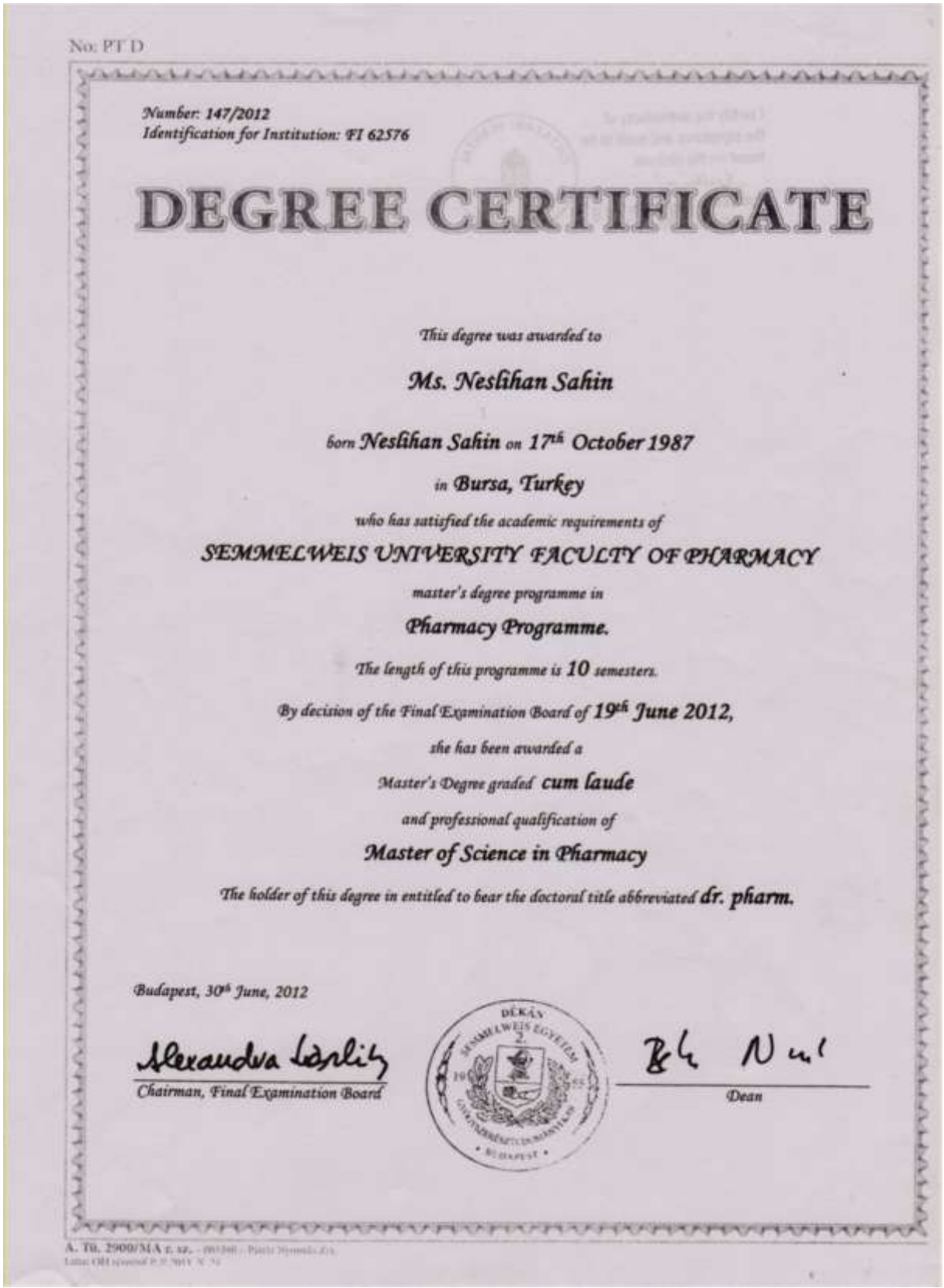
Prof. Dr. Béla Noszál
Rector (Dean)



This is to certify that the text on the reverse page is an official COPY of the text of the original Diploma issued in Hungarian and English.

Budapest, June 30, 2012.

Ms. Olga VÁNYI
Head of the English Secretariat



No: PT D

Number: 147/2012
Identification for Institution: FI 62576

DEGREE CERTIFICATE

This degree was awarded to

Ms. Neslihan Sahin

born **Neslihan Sahin** on **17th October 1987**

in **Bursa, Turkey**

who has satisfied the academic requirements of

SEMMELWEIS UNIVERSITY FACULTY OF PHARMACY

master's degree programme in

Pharmacy Programme.

The length of this programme is **10** semesters.

By decision of the Final Examination Board of **19th June 2012,**

she has been awarded a

Master's Degree graded **cum laude**

and professional qualification of

Master of Science in Pharmacy

The holder of this degree in entitled to bear the doctoral title abbreviated **dr. pharm.**

Budapest, 30th June, 2012

Alexandra Laslik
Chairman, Final Examination Board

DÉKÁN 2. SEMMELWEIS EGYETEM 1955 GYÓGYSZERÉSZTUDOMÁNYI KAR BUDAPEST

Dean

A. Tü. 2900/MA r. sz. -

İngilizce Aslından Türkçe'ye Tercüme Edilmiştir.

№36 188

(Çeviri)

No.: 147/2012

DİPLOMA

İşbu diploma, **2006/2007** Eğitim Öğretim yılından **2011/2012** Eğitim Öğretim yılına kadar

Semmelweis Üniversitesi

Eczacılık Fakültesi'nde

üniversite yükümlülüklerini yerine getirmiş olan, **17 Ekim 1987 Türkiye, Bursa** doğumlu Sn. **Neslihan ŞAHİN**'e verilmektedir.

Final Sınav Heyeti'nin **19 Haziran 2012** tarihli kararı esasında, kendisine işbu vesile ile Eczacılık Master Derecesi verilmekte olup, Eczacılık Doktoru (Dr. Ecz.) ünvanını kullanma yetkisine sahiptir.

Diploma derecesi: **Yüksek Şeref Derecesi**

Budapeşte, **30 Haziran 2012**

L. S.

Dr. Alexandra Lasztity
Başkan, Final Sınav Heyeti

Prof. Dr. Béla Noszal
Rektör (Dekan)

Arka Sayfa

İşbu belge ile, arka sayfada yer alan metnin, Macarca ve İngilizce dillerinde düzenlenmiş olan orijinal Diploma metninin resmi NÜSHASI olduğu onaylanmaktadır.

Budapeşte, 30 Haziran 2012

(Mühür Mevcuttur)

(İmza Mevcuttur)

Sn. Olga VANYI

İngilizce Sekreterliği Başkanı

u Tercüme dairemiz yeminli tercümanı VEDAT KULOĞLU
ngilizce aslından Türkçe'ye tercüme edildiğini tercüme evrakı
sının yeminli tercüman VEDAT KULOĞLU 'a ait olduğunu
binoniki yılı Eylül ayının yedinci günü 07.09.2012 SLN

İşbu Tercüme Evrakın
Tercümanından Tercüme Edilmiştir.
Vedat KULOĞLU
Noter Yeminli Tercüman

07 EYLÜL 2012

OFFICE OF HEALTH AUTHORISATION AND ADMINISTRATIVE PROCEDURES

DEPARTMENT OF MIGRATION AND MONITORING

22943/2012/BIZ **Consultant: Zsuzsa Nadicsán**

CERTIFICATE OF CONFORMITY

First name: Neslihan
Surname: Dr. Sahin
Registered address: Hungary, 1052 Budapest, Veress Pálné utca 14.
Nationality: Turkish
Gender: female
Place of birth: Bursa, Turkey
Date of birth: 17 October 1987
Basic registration number: 14444
Diploma in pharmacy
- **Number: 147/2012.**
- **Date: 30 June 2012**
- **Issuing body: Semmelweis University**

Pursuant to Section 60/C of Act C of 2001 on the recognition of foreign certificates and degrees and to Section 1 (5) a) of Government Decree 33/2008 (II. 21.) this is to attest that the **diploma in pharmacy** awarded to the aforementioned person satisfies the training requirements laid down in Article 44 and in Annex V.6. of European Parliament and Council Directive 2005/36/EC on the recognition of professional qualifications.

This certificate has been issued for use in the recognition of the diploma in another country by the request of the aforementioned person.

Done in Budapest, on the 8th of August 2012

On behalf of Rita Paphalmi
President

Nándor Rikker
Acting Head of Department

Street address: 1051 BUDAPEST V., ZRÍNYI U. 3. Mailing address: 1380 BUDAPEST, PF.: 1188
Tel: (36-1) 235-7965

Vrije Universiteit Brussel

CERTIFICATE

The Undersigned declare that

Sahin Neslihan

has followed the lessons and has successfully passed the exam of the

"Intensive Course in Dermato-Cosmetic Sciences 2014"

from Monday the 8th of September to Friday the 12th of September 2014
organized at the Vrije Universiteit Brussel

Brussels, November 7th, 2014

Prof. Dr. Pharm. V. Rogiers
Course organizer

Prof. Dr. Paul De Knop
Rector of Vrije Universiteit Brussel

Prof. Dr. D. Roseeuw
Course Organizer

Prof. Dr. A. Barel
Course organizer

iPAVUB • instituut voor PostAcademische Vorming • Pleinlaan 2 • 1050 Brussel • Tel.: 02-629 20 93 • Fax: 02-629 21 39 • www.vub.ac.be/PAVUB

Vrije Universiteit Brussel

CERTIFICATE

The Undersigned declare that

Neslihan SAHIN

Has attended the course and has successfully passed the exam of the

"Safety Assessment of Cosmetics in the EU - Training Course 2016"

from Monday the 1st of February to Saturday the 6th of February 2016
organized at the Vrije Universiteit Brussel

Brussels, March 8th, 2016

Prof. Dr. Pharm. V. Rogiers
Course organizer

Prof. Dr. Paul De Knop
Rector of Vrije Universiteit Brussel

Vrije Universiteit Brussel • Pleinlaan 2 • 1050 Brussel • Tel.: 02-629 20 93 • www.vub.ac.be/werken-studeren

T.C.
YEDİTEPE ÜNİVERSİTESİ
YEDİTEPE UNIVERSITY

NESLİHAN ŞAHİN

Sağlık Bilimleri Enstitüsü
Kozmetoloji
Yüksek Lisans Programı
mezuniyeti için gerekli çalışmaları başarıyla tamamlayarak
Yüksek Lisans
derecesini bütün onur, hak ve yetkileriyle almaya hak kazanmıştır.

having satisfactorily completed all the requirements of the
Master's Program in
Cosmetology
in the Graduate School of Health Sciences
has been awarded the degree of
Master of Science (MSc)
with all the honors, rights and privileges thereto.

22 Haziran 2016
June 22, 2016
Mezuniyet Tarihi / Graduation Date

Prof. Dr. Bayram Yılmaz
Enstitü Müdürü / Director of Graduate School

Prof. Dr. Canan Aykut Bingöl
Rektör / President

TÜRKİYE CUMHURİYETİ
YEDİTEPE ÜNİVERSİTESİ

REPUBLIC OF TURKEY
YEDİTEPE UNIVERSITY

NESLİHAN ŞAHİN

Gerekli çalışmaları başarı ile tamamlayarak,
Sağlık Bilimleri Enstitüsü
Farmasötik Toksikoloji
programından bütün onur ve yetkileriyle
Doktora
derecesini almaya hak kazanmıştır.

Having satisfactorily completed all the requirements of the program of
Pharmaceutical Toxicology
Graduate School of Health Sciences
has been awarded the degree of
Doctor of Philosophy (PhD)
with all the honors, rights and privileges thereto pertaining

28 Şubat / February 2023

Prof. Dr. Bayram YILMAZ
Enstitü Müdürü / Director of Graduate School

Prof. Dr. Canan AYKUT BİNGÖL
Rektör / Rector

ANNEX I.

Certificate of IFRA Compliance and Allergen Determination For Parfum Component

BIONIKS INTENSIVE CARE CREAM does not contain any fragrance, perfume, aromatic composition or fragrance raw materials in its formulation.

Therefore, no fragrance-related documentation including:

- IFRA Certificate of Conformity,
- Fragrance Allergen Declaration,
- Fragrance Safety Assessment,
- Fragrance Material Safety Data Sheet (MSDS/SDS),
- Allergen Identification Report,

is required for this product.

Consequently, IFRA compliance assessment and allergen determination regarding fragrance components are not applicable for **BIONIKS INTENSIVE CARE CREAM** .

ANNEX II.

Stability Forms

	STABİLİTE RAPORU/ STABILITY REPORT			
Ürün Adı/Product Name	BIONIKS INTENSIVE MOISTURIZING CREAM – 50 ml			
Esans Adı-Kodu/Fragrance Name-Code	-			
Ambalaj/ Package	Jar			
Numune Yapılış Tarihi / Sample Prepared Date	25.05.2026			
Test süresi/ Test Period	25.05.2026 - 09.07.2026			
Stabilite Sonuçları/ Stability Results	**Yapılan Testler/ Testing item**	**1. GÜN / DAY 1**	**28. GÜN / DAY 28**	**45. GÜN / DAY 45**
Oda Sıcaklığı/ Room Temperature (22-23 °C)	Görünüm/ Appearance	Krem / Cream	Krem / Cream	Krem / Cream
	Tortu-Dibe çökme/Settling	Yok / Nonexistence	Yok / Nonexistence	Yok / Nonexistence
	Koku / Odour	Karakteristik/Characteristic	Karakteristik /Characteristic	Karakteristik / Characteristic
	Ambalaj Sızıntı/Packaging Leakage	Yok / Nonexistence	Yok / Nonexistence	Yok / Nonexistence
	Ambalaj Deformasyon / Packaging Deformation	Yok / Nonexistence	Yok / Nonexistence	Yok / Nonexistence
	Ambalaj Bozukluğu / Packaging Distortion	Yok / Nonexistence	Yok / Nonexistence	Yok / Nonexistence
	Renk/Colour	Beyaz / White	Beyaz / White	Beyaz / White
	Toplam Mikroorganizma Sayımı / Total Microorganism Count	Yok / None	Yok / None	Yok / None
	Toplam Küf ve Maya Sayımı / Total Mold and Yeast Count	Yok / None	Yok / None	Yok / None
	Pseudomonas aeruginosa	Yok / None	Yok / None	Yok / None
	Staphylococcus aureus	Yok / None	Yok / None	Yok / None
	Escherichia coli	Yok / None	Yok / None	Yok / None
	Candida albicans	Yok / None	Yok / None	Yok / None
Soğutucu / Refrigerator (-6°C)	Görünüm/ Appearance	Krem / Cream	Krem / Cream	Krem / Cream
	Tortu-Dibe çökme/Settling	Yok / Nonexistence	Yok / Nonexistence	Yok / Nonexistence
	Koku / Odour	Karakteristik/Characteristic	Karakteristik /Characteristic	Karakteristik / Characteristic
	Ambalaj Sızıntı / Packaging Leakage	Yok / Nonexistence	Yok / Nonexistence	Yok / Nonexistence
	Ambalaj Deformasyon / Packaging Deformation	Yok / Nonexistence	Yok / Nonexistence	Yok / Nonexistence
	Ambalaj Bozukluğu / Packaging Distortion	Yok / Nonexistence	Yok / Nonexistence	Yok / Nonexistence
	Renk/Colour	Beyaz / White	Beyaz / White	Beyaz / White
	Toplam Mikroorganizma Sayımı / Total Microorganism Count	Yok / None	Yok / None	Yok / None
	Toplam Küf ve Maya Sayımı / Total Mold and Yeast Count	Yok / None	Yok / None	Yok / None
	Pseudomonas aeruginosa	Yok / None	Yok / None	Yok / None
	Staphylococcus aureus	Yok / None	Yok / None	Yok / None
	Escherichia coli	Yok / None	Yok / None	Yok / None
	Candida albicans	Yok / None	Yok / None	Yok / None
Güneş Işığı / Solar light	Görünüm/ Appearance	Krem / Cream	Krem / Cream	Krem / Cream
	Tortu-Dibe çökme/Settling	Yok / Nonexistence	Yok / Nonexistence	Yok / Nonexistence
	Koku / Odour	Karakteristik/Characteristic	Karakteristik / Characteristic	Karakteristik/ Characteristic
	Ambalaj Sızıntı / Packaging Leakage	Yok / Nonexistence	Yok / Nonexistence	Yok / Nonexistence
	Ambalaj Deformasyon / Packaging Deformation	Yok / Nonexistence	Yok / Nonexistence	Yok / Nonexistence
	Ambalaj Bozukluğu / Packaging Distortion	Yok / Nonexistence	Yok / Nonexistence	Yok / Nonexistence
	Renk/Colour	Beyaz / White	Beyaz / White	Beyaz / White
	Toplam Mikroorganizma Sayımı / Total Microorganism Count	Yok / None	Yok / None	Yok / None
	Toplam Küf ve Maya Sayımı / Total Mold and Yeast Count	Yok / None	Yok / None	Yok / None
	Pseudomonas aeruginosa	Yok / None	Yok / None	Yok / None
	Staphylococcus aureus	Yok / None	Yok / None	Yok / None
	Escherichia coli	Yok / None	Yok / None	Yok / None
	Candida albicans	Yok / None	Yok / None	Yok / None

NŞ GRUP DANIŞMANLIK
ARMUTKÖY MAH. 1.AYDINLIK SK. NO: 23
OSMANGAZİ/ BURSA
www.dreczneslihansahin.com

Termostat / Thermostat (40°C)	Görünüm/ Appearance	Krem / Cream	Krem / Cream	Krem / Cream
	Tortu-Dibe çökme/Settling	Yok / Nonexistence	Yok / Nonexistence	Yok / Nonexistence
	Koku / Odour	Karakteristik/Characteristic	Karakteristik / Characteristic	Karakteristik / Characteristic
	Ambalaj Sızıntı / Packaging Leakage	Yok / Nonexistence	Yok / Nonexistence	Yok / Nonexistence
	Ambalaj Deformasyon / Packaging Deformation	Yok / Nonexistence	Yok / Nonexistence	Yok / Nonexistence
	Ambalaj Bozukluğu / Packaging Distortion	Yok / Nonexistence	Yok / Nonexistence	Yok / Nonexistence
	Renk/Colour	Beyaz / White	Beyaz / White	Beyaz / White
	Toplam Mikroorganizma Sayımı / Total Microorganism Count	Yok / None	Yok / None	Yok / None
	Toplam Küf ve Maya Sayımı / Total Mold and Yeast Count	Yok / None	Yok / None	Yok / None
	Pseudomonas aeruginosa	Yok / None	Yok / None	Yok / None
	Staphylococcus aureus	Yok / None	Yok / None	Yok / None
	Escherichia coli	Yok / None	Yok / None	Yok / None
	Candida albicans	Yok / None	Yok / None	Yok / None
Genel Stabilite / Overall Stability:	APPROVAL			
Onaylayan/Approved by:	DR. PHARM. NESLİHAN ŞAHİN			
PAO 12M	NOTES: 45 days stability is equivalent to 1 years expiry date and 12 M for PAO			

BİONİKS MEDİKAL KOZMETİK LİMİTED ŞİRKETİ
Cevizli Mah. Mustafa Kemal Cad. Hukukçular İş Merkezi No: 34 İç Kapı No: 15 Kartal/ İstanbul

ANNEX III.

Challenge Test Result

The Challenge Test is currently in progress. The file will be updated upon receipt of the test report

ANNEX IV.

Microbiological Analysis Report

BİYO TEST LABORATUVARI

AB-1804-T

26-BYT-001453

06.26

DENEY RAPORU

Deneyin Amacı : Özel İstek		**Rapor No :**	26-BYT-001453
		Rapor Tarihi ve Saati :	1.06.2026 16:45
Numuneyi Gönderen Kurum ;		**Numunenin ;**	
Adı	BİONİKS MEDİKAL KOZMETİK LİMİTED ŞİRKETİ	**Adı**	: BIONIKS INTENSIVE CARE CREAM
Adresi	ESENTEPE MAH. ANADOLU CAD. YASAKULE NO: 14 İÇ KAPI NO: 20 KARTAL / İSTANBUL	**Miktarı - Sıcaklığı (C)**	: 2 Adet
		Ambalajı	: Firma Ambalajı
		ÜT. - SKT.	: -
		Parti - Seri No	: - B0426IC01
Telefon/Faks	:	**Marka**	:
Gönd. Firma	: BİONİKS MEDİKAL KOZMETİK LİMİTED ŞİRKETİ	**Diğer Bilgiler**	:
Üretici Firma	: BİONİKS MEDİKAL KOZMETİK LİMİTED ŞİRKETİ	**Geliş Tarihi**	: 21.05.2026
		Başlama Tarihi	: 21.05.2026
		Bitiş Tarihi	: 01.06.2026

SONUÇ

Deney Adı	Sonuç	Birim	Ö.B.	G.K.	Ö.L.	LDK	Limit Değ.	Metod	Değerlendirme
Aerobik Mezofilik Bakterilerin Tespiti ve Sayımı *	<10	kob/g-ml				1	<1000 (bakteri+maya+küf)	TS EN ISO 21149	Uygun
Maya Ve Küf Sayımı *	<10	kob/g-ml				1	< 1000 (bakteri+maya+küf)	TS EN ISO 16212	Uygun
Pseudomonas Aeruginosa Aranması *	Tespit Edilemedi.	g-ml				1	Bulunmamalı	TS EN ISO 22717	Uygun
Staphylococcus Aureus Aranması *	Tespit Edilemedi.	g-ml				1	Bulunmamalı	TS EN ISO 22718	Uygun
Candida Albicans Aranması *	Tespit Edilemedi.	g-ml				1	Bulunmamalı	TS EN ISO 18416	Uygun
Escherichia Coli Aranması *	Tespit Edilemedi.	g-ml				1	Bulunmamalı	TS EN ISO 21150	Uygun

AÇIKLAMA

- Kısaltmalar; G.K: Geri Kazanım, D: Değerlendirme, U: Uygun, UD: Uygun Değil, DY: Değerlendirme Yapılamadı

- Deney sonuçları ile ilgili uygunluk değerlendirmesi verildiğinde, varsa yönetmelik, tebliğ, standart, şartname, sözleşme vb. dokümanlarda belirtilen karar kuralı kullanılır. Eğer mevzuatta belirlenmiş bir karar kuralı yok ise, ölçüm belirsizliği dikkate alınmadan Basit Karar Kuralı uygulanır.
- Raporda belirtilen belirsizlikler k=2,%95 güven aralığında genişletilmiş belirsizliktir.
- Müşteri tarafından verilen bilgiler ve numunenin tarafımızdan alınmadığı durumlarda, sonuçlar numunenin teslim alındığı hali için geçerlidir ve tarafımızın numune alma aşamasına dair sorumluluğu bulunmamaktadır.

NOT:Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Candida albicans, Aerobik Mezofilik Bakteri ile Maya&Küf için başlangıç süspansiyonları 1/9 oranında hazırlanmıştır. Nötralizer diluent olarak Eugon LT 100 Broth kullanılarak ilgili mikroorganizmalar sırasıyla Cetrimide Agar, MacConkey Agar, Baird Parker Agar, Sabouraud Dextrose Chloramphenicol Agar, Tryptic Soy Agar ve Potato Dextrose Chloramphenicol Agar besiyerlerine ekilmiştir. Numunenin antimikrobiyal özelliklerinin nötralizasyonu ilgili mikroorganizmalarla kontrol edilerek doğrulanmış olup, yöntem uygundur.

*** İşaretli Analizler akreditasyon kapsamındadır.

1. Deney laboratuvarı olarak faaliyet gösteren Biyotest Laboratuvar ve Dan. Hiz. Ltd. Şti., TÜRKAK'tan AB-1804-T Dosya numarası ile TS_EN_ISO_IEC_17025 standardına göre akredite edilmiştir. Türk Akreditasyon Kurumu (TÜRKAK) deney raporlarının tanınırlığı konusunda Avrupa Akreditasyon Birliği (EA) ile çok taraflı Anlaşma ve Uluslararası Laboratuvar Akreditasyon Birliği (ILAC) ile karşılıklı tanıma anlaşması imzalamıştır.
2. Yapılan deneylerin sonuçları, laboratuvara firma/kurum/şahıs tarafından gönderilen yukarıdaki belirtilmiş olan numune için geçerlidir.
3. Deney raporunda yer alan ve sonuçların geçerliliğini etkileyen tanımsal bilgiler müşteri tarafından beyan edilmiştir. Bu bilgilerin doğruluğundan ve kullanımına bağlı oluşabilecek tüm kayıplardan / yasal zorunluluklardan laboratuvarımız sorumlu değildir.
4. Bu deney raporunun hiçbir bölümü tek başına veya ayrı ayrı kullanılamaz, laboratuvarın yazılı izni olmadan tamamen veya kısmen kopyalanıp çoğaltılamaz veya yayınlanamaz.
5. Bu rapor reklam amacıyla kullanılamaz, imzasız ve mühürsüz raporlar geçersizdir.

Biyotest Laboratuvarları ve Danışmanlık Hizmetleri Ltd. Şti. **Avcılar V.D. 781549767 - Tic. Sic. No: 327386-5**

Gümüşpala Mah. Kaynata Sok. No:2 Kat:6 Avcılar-İstanbul e-Posta : info@biyotestlab.com Tel : (0212) 591 90 92

BİYO TEST LABORATUVARI

AB-1804-T

26-BYT-001453

06.26

DENEY RAPORU

Deneyin Amacı : Özel İstek		**Rapor No :**	26-BYT-001453
		Rapor Tarihi ve Saati :	1.06.2026 16:45:
Numuneyi Gönderen Kurum ;		**Numunenin ;**	
Adı	: BİONİKS MEDİKAL KOZMETİK LİMİTED ŞİRKETİ	**Adı**	: BIONIKS INTENSIVE CARE CREAM
Adresi	: ESENTEPE MAH. ANADOLU CAD. YASAKULE NO: 14 İÇ KAPI NO: 20 KARTAL / İSTANBUL	**Miktarı - Sıcaklığı (C)**	: 2 Adet
		Ambalajı	: Firma Ambalajı
		ÜT. - SKT.	: -
		Parti - Seri No	: - B0426IC01
Telefon/Faks	:	**Marka**	:
Gönd. Firma	: BİONİKS MEDİKAL KOZMETİK LİMİTED ŞİRKETİ	**Diğer Bilgiler**	:
Üretici Firma	: BİONİKS MEDİKAL KOZMETİK LİMİTED ŞİRKETİ	**Geliş Tarihi**	: 21.05.2026
		Başlama Tarihi	: 21.05.2026
		Bitiş Tarihi	: 01.06.2026

Limit Değer Kaynağı (LDK)

1 - Uygunluk Değerlendirmesi 'Kozmetik Ürünlerin Mikrobiyolojik Kontrolüne İlişkin Kılavuz'a göre yapılmıştır.

REVİZYON BİLGİLERİ

:

Tuğba ÖZKAN

Numune Kabul ve Raporlama Sorumlusu

Tasdik Olunur
1.06.2026 16:45
Sema YUMAK
Yüksek Biyolog
Laboratuvar Müdürü

"*" İşaretli Analizler akreditasyon kapsamındadır.

1. Deney laboratuvarı olarak faaliyet gösteren Biyotest Laboratuvar ve Dan. Hiz. Ltd. Şti., TÜRKAK 'tan AB-1804-T Dosya numarası ile TS_EN_ISO_IEC_17025 standardına göre akredite edilmiştir. Türk Akreditasyon Kurumu (TÜRKAK) deney raporlarının tanınırlığı konusunda Avrupa Akreditasyon Birliği (EA) ile çok taraflı Anlaşma ve Uluslararası Laboratuvar Akreditasyon Birliği (ILAC) ile karşılıklı tanıma anlaşması imzalamıştır.
2. Yapılan deneylerin sonuçları, laboratuvara firma/kurum/şahıs tarafından gönderilen yukarıdaki belirtilmiş olan numune için geçerlidir.
3. Deney raporunda yer alan ve sonuçların geçerliliğini etkileyen tanımsal bilgiler müşteri tarafından beyan edilmiştir. Bu bilgilerin doğruluğundan ve kullanımına bağlı oluşabilecek tüm kayıplardan / yasal zorunluluklardan laboratuvarımız sorumlu değildir.
4. Bu deney raporunun hiçbir bölümü tek başına veya ayrı ayrı kullanılamaz, laboratuvarın yazılı izni olmadan tamamen veya kısmen kopyalanıp çoğaltılamaz veya yayınlanamaz.
5. Bu rapor reklam amacıyla kullanılamaz, imzasız ve mührüsüz raporlar geçersizdir.

Biyotest Laboratuvarları ve Danışmanlık Hizmetleri Ltd. Şti. **Avcılar V.D. 781549767 - Tic. Sic. No: 327386-5**

Gümüşpala Mah. Kaynata Sok. No:2 Kat:6 Avcılar-İstanbul e-Posta : info@biyotestlab.com Tel : (0212) 591 90 92

BİYO TEST LABORATUVARI

AB-1804-T

26-BYT-001453

06.26

ANALYSIS REPORT

Purpose of Analysis :	Private Request	**Report Number :**	26-BYT-001453
		Date and Time of Report :	1.06.2026 16:45:
Sample requested by:		**Sample Detail:**	
Name	: BİONİKS MEDİKAL KOZMETİK LİMİTED ŞİRKETİ	**Name**	: BIONIKS INTENSIVE CARE CREAM
Address	: ESENTEPE MAH. ANADOLU CAD. YASAKULE NO: 14 İÇ KAPI NO: 20 KARTAL / İSTANBUL	**Qty/Pcs - Temp. (C)**	: 2 Pcs
		Packing	: Company Packaging
		Date of Prod./Exp.	: -
Authorized Person	:	**Lot Number**	: - B0426IC01
Phone/Fax	:	**Brand**	:
Sender	: BİONİKS MEDİKAL KOZMETİK LİMİTED ŞİRKETİ		
Manufacturer	: BİONİKS MEDİKAL KOZMETİK LİMİTED ŞİRKETİ	**Date Received**	: 21.05.2026
		Date Started	: 21.05.2026
Offerr No	:	**Date Finished**	: 01.06.2026

RESULT

Name of Analysis	Result	Unit	U	Rec.	LOQ	LVS	D.R.	Reference Ranges	Method/s	Conformity
Detection and Enumeration of Aerobic Mesophilic Bacteria *	<10	cfu/g-ml				1		<1000 (bacteria+mold+yeast)	TS EN ISO 21149	Passed
Yeast and Mould *	<10	cfu/g-ml				1		< 1000 (bacteria+mold+yeast)	TS EN ISO 16212	Passed
Pseudomonas Aeruginosa *	Not Detected.	g-ml				1		Should not be	TS EN ISO 22717	Passed
Staphylococcus Aureus *	Not Detected.	g-ml				1		Should not be	TS EN ISO 22718	Passed
Candida Albicans *	Not Detected.	g-ml				1		Should not be	TS EN ISO 18416	Passed
Escherichia Coli *	Not Detected.	g-ml				1		Should not be	TS EN ISO 21150	Passed

DESCRIPTION

DECISION RULE (D.R.)

:

Limit Value Source (LVS)

1 - Conformity Assessment was carried out according to the 'Guideline on Microbiological Control of Cosmetic Products'.

"*" Analysis marked with "*" are within the scope of accreditation.

1. BİYOTEST Laboratory and Consulting Services Ltd., which operates as an Analysis laboratory. Şti. is accredited by TURKAK according to AB-1804-T and TS EN ISO/IEC 17025 standard. The Turkish Accreditation Agency (TURKAK) has signed a Multilateral Agreement with the European Accreditation Association (EA) and a mutual recognition agreement with the International Laboratory Accreditation Association (ILAC) on the recognition of test reports.
2. The results of the Analysis are valid for the above-mentioned sample sent to the laboratory by the company/institution/individual.
3. Descriptive information in the test report that affects the validity of the results has been declared by the customer. Our laboratory is not responsible for any losses/legal obligations that may occur due to the accuracy and use of this information.
4. No part of this test report can be used alone or separately, can not be copied, reproduced or published in whole or in part without the written permission of the laboratory.
5. This report cannot be used for advertising purposes, unsigned and unsealed reports are invalid.

Biyotest Laboratuvarları ve Danışmanlık Hizmetleri Ltd. Şti. **Avcılar V.D. 781549767 - Tic. Sic. No: 327386-5**

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BİYO TEST LABORATUVARI

AB-1804-T

26-BYT-001453

06.26

ANALYSIS REPORT

Purpose of Analysis :	Private Request	**Report Number :**	26-BYT-001453
		Date and Time of Report :	1.06.2026 16:45:
Sample requested by:		**Sample Detail:**	
Name	: BİONİKS MEDİKAL KOZMETİK LİMİTED ŞİRKETİ	**Name**	: BIONIKS INTENSIVE CARE CREAM
Address	: ESENTEPE MAH. ANADOLU CAD. YASAKULE NO: 14 İÇ KAPI NO: 20 KARTAL / İSTANBUL	**Qty/Pcs - Temp. (C)**	: 2 Pcs
		Packing	: Company Packaging
		Date of Prod./Exp.	: -
Authorized Person	:	**Lot Number**	: - B0426IC01
Phone/Fax	:	**Brand**	:
Sender	: BİONİKS MEDİKAL KOZMETİK LİMİTED ŞİRKETİ		
Manufacturer	: BİONİKS MEDİKAL KOZMETİK LİMİTED ŞİRKETİ	**Date Received**	: 21.05.2026
		Date Started	: 21.05.2026
Offerr No	:	**Date Finished**	: 01.06.2026

U. Uncertainty of Measurement **Rec. Recovery** **LOQ. Limit of Quantification**

- When the conformity assessment regarding the test results is given, the regulations, standards, specifications, contracts, etc., if any. The decision rule specified in the documents is used. If there is no decision rule specified in the legislation, the Simple Decision Rule is applied without considering the measurement uncertainty.
-The uncertainties specified in the report are k=2, expanded uncertainty at the 95% confidence interval.
-The results are valid as the sample is received and we are not responsible for the sampling phase. The laboratory cannot be held responsible for the information given by the customer.

NOTE: Initial suspensions for Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Candida albicans, Aerobic Mesophilic Bacteria and Yeast& Mold at a ratio of it is prepared. Cetrimide Agar, MacConkey Agar, Baird Parker Agar, Sabouraud Agar, related microorganisms using Eugon LT 100 Broth as the neutralizer diluent, respectively It was planted in Dextrose Chloramphenicol Agar, Tryptic Soy Agar and Potato Dextrose Chloramphenicol Agar media. Neutralization of antimicrobial properties of the sample it has been verified by checking with the relevant microorganisms and the method is suitable.

REVISION INFORMATION

:

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5. This report cannot be used for advertising purposes, unsigned and unsealed reports are invalid.

Biyotest Laboratuvarları ve Danışmanlık Hizmetleri Ltd. Şti. **Avcılar V.D. 781549767 - Tic. Sic. No: 327386-5**

Gümüşpala Mah. Kaynata Sok. No:2 Kat:6 Avcılar-İstanbul e-Mail : info@biyotestlab.com Phone : (0212) 591 90 92

BİYO TEST LABORATUVARI

AB-1804-T

26-BYT-001453

06.26

ANALYSIS REPORT

Purpose of Analysis :	Private Request	**Report Number :**	26-BYT-001453
		Date and Time of Report :	1.06.2026 16:45
Sample requested by:		**Sample Detail:**	
Name	: BİONİKS MEDİKAL KOZMETİK LİMİTED ŞİRKETİ	**Name**	: BIONIKS INTENSIVE CARE CREAM
Address	: ESENTEPE MAH. ANADOLU CAD. YASAKULE NO: 14 İÇ KAPI NO: 20 KARTAL / İSTANBUL	**Qty/Pcs - Temp. (C)**	: 2 Pcs
		Packing	: Company Packaging
		Date of Prod./Exp.	: -
Authorized Person	:	**Lot Number**	: - B0426IC01
Phone/Fax	:	**Brand**	:
Sender	: BİONİKS MEDİKAL KOZMETİK LİMİTED ŞİRKETİ		
Manufacturer	: BİONİKS MEDİKAL KOZMETİK LİMİTED ŞİRKETİ	**Date Received**	: 21.05.2026
		Date Started	: 21.05.2026
Offerr No	:	**Date Finished**	: 01.06.2026

Tuğba ÖZKAN

Head of Sample Submission ad
Reporting Department

Approved
1.06.2026 16:45
Sema YUMAK
Biologist
Manager Of Laboratory

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1. BİYOTEST Laboratory and Consulting Services Ltd., which operates as an Analysis laboratory, Şti. is accredited by TURKAK according to AB-1804-T and TS EN ISO/IEC 17025 standard. The Turkish Accreditation Agency (TURKAK) has signed a Multilateral Agreement with the European Accreditation Association (EA) and a mutual recognition agreement with the International Laboratory Accreditation Association (ILAC) on the recognition of test reports.
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Biyotest Laboratuvarları ve Danışmanlık Hizmetleri Ltd. Şti. Avcılar V.D. 781549767 - Tic. Sic. No: 327386-5

Gümüşpala Mah. Kaynata Sok. No:2 Kat:6 Avcılar-İstanbul e-Mail : info@biyotestlab.com Phone : (0212) 591 90 92

Annex V.

Packaging Materials

PRODUCT ANALYSIS CERTIFICATE

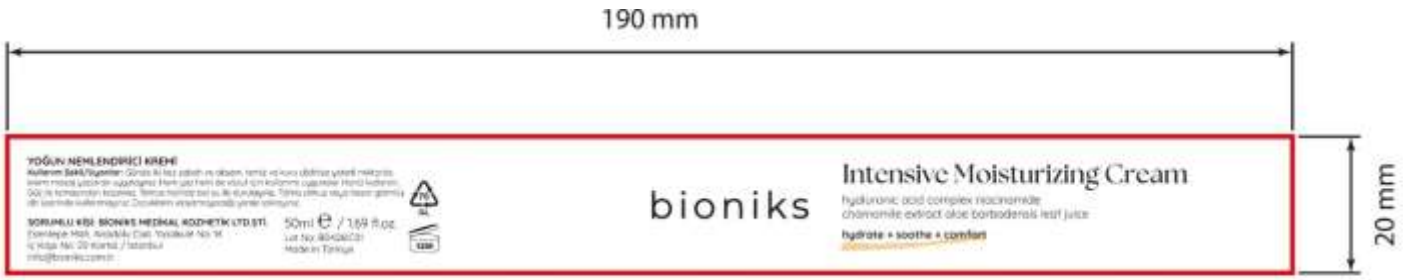
BIONIKS INTENSIVE CARE CREAM

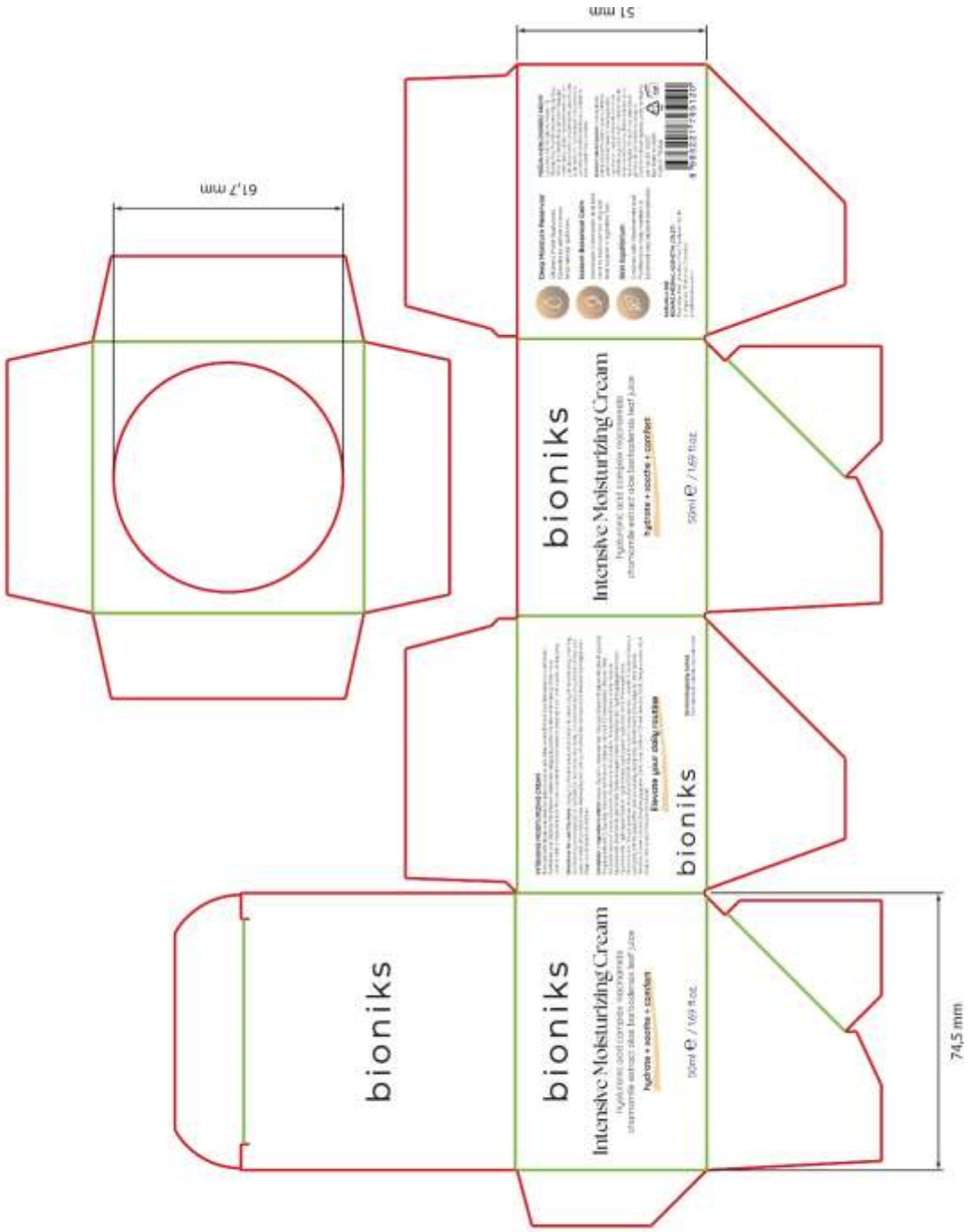
• The product is a leave-on cosmetic skin care cream and is placed on the market in a 50 ml size. The primary packaging consists of a cosmetic cream jar with a closure system suitable for cosmetic use. The secondary packaging consists of a printed carton box containing the mandatory cosmetic labeling information.

Packaging materials have been analyzed and the relevant packaging documentation has been reviewed. Packaging compatibility has been evaluated and no incompatibility between the formulation and the packaging materials has been identified. No evidence of leakage, cracking, deformation, discoloration or packaging deterioration was observed under the evaluated conditions.

The packaging system and the formulation consist of compatible components suitable for the intended cosmetic application. Furthermore, all raw materials included in the formulation were reviewed with respect to specific regulatory restrictions, mandatory warnings and labeling requirements. No additional mandatory warning statement resulting from the raw materials was identified beyond the standard cosmetic precautions indicated on the product label.

Based on the available packaging documentation, packaging compatibility evaluation and intended conditions of use, the packaging system is considered suitable for BIONIKS INTENSIVE CARE CREAM .





Certificate of Analysis

Invoice No:	220126	Batch No:	Quantity:140000
Commodity: Material: Color:	50G CREAM JAR CAP PP Plastic White	Destination Delivery date:	Turkey August 11th 2022

PHYSICAL TEST Dimension in mm.

TEST DESCRIPTIONS	STANDARD	N/Ac(pcs)	Result	IL	AQL
Total height	13±0.5	500	0	I	
Intramural diameter	44±0.3	500	0		
Extermal diameter	45.5±0.3	500	0		
Screw diameter	39.8±0.3	500	0		
Verticality	Less than 3.0	500	0		
Final result			Qualified		

This certificate is issued by FOSHAN GOODPACK MANUFACTURING CO.,LTD.
For and on behalf of
FOSHAN GOODPACK MANUFACTURING CO.,LTD.
Quality Assurance Department Manager: Cherry Hu

FOSHAN GOODPACK MANUFACTURING CO., LTD

Certificate of Analysis

Invoice No: 0361-23 Batch No: Quantity:80000

Commodity:	50G FROSTED CREAM JAR	Destination:	Istanbul, Turkey
Glass type:	SODA-LIME GLASS,TYPEIII	Delivery date:	November 1st 2021
Glass Color	Clear		

PHYSICAL TEST Dimension in mm.

TEST DESCRIPTIONS	STANDARD	N/Ac(pcs)	Result	IL	AQL
Total height	41±0.8	500	0	I	
Intramural diameter	42±0.5	500	0		
External diameter	49.3±0.5	500	0		
Finish height	9.5±0.3	500	0		
Screw diameter	51±0.5	500	0		
Body diameter	56±0.8	500	0		
Verticality	Less than 3.0	500	0		
Mass weight	≈93g	500	Fitness		
Brimful capacity	55±3ML	500	/	S-3	1.5
Light transmission	USP 25		Fitness		
Final result			Qualified		

CHEMICAL TEST

Glass container hydrolytic resistance (YBB00242003)	N/Ac	15
	Classification	HC3, COMPLIES WITH USP TYPE III
Thermal shock resistance (YBB00182003) Equal to ISO7459-1984	N/Ac(15/0)	15
	Min42℃ glass type III	
	Result	0
Internal pressure resistance (YBB00172003)	N/Ac(20/0)	Withstand the pressure of 6bar
	Result	0
Residual stress (YBB00162003)	N/Ac(20/0)	0
Final result		Qualified
Glass composition	SIO2: 71.58% Fe2O3: 0.378% Al2O3: 1.76% R2O: 14.27% RO:11.6%	

This certificate is issued by FOSHAN GOODPACK MANUFACTURING CO.,LTD.
For and on behalf of FOSHAN GOODPACK MANUFACTURING CO.,LTD.
Assurance Quality Department Manager: Cherry Hu

This certificate is approved by Assurance Quality Department. Page 1/1

Certificate of Analysis

Invoice No:	220126 Batch No:		Quantity:250000
Commodity: Material: Color:	50G CREAM JAR LID PP Plastic White	Destination Delivery date:	Turkey August 11th 2022

PHYSICAL TEST Dimension in mm.

TEST DESCRIPTIONS	STANDARD	N/Ac(pcs)	Result	IL	AQL
Total height	4±0.05	500	0	I	
Intramural diameter	36.15±0.3	500	0		
Extermal diameter	40.8±0.3	500	0		
Upper depth	3±0.03	500	0		
Verticality	Less than 3.0	500	0		
Final result			Qualified		

This certificate is issued by FOSHAN GOODPACK MANUFACTURING CO.,LTD.
For and on behalf of
FOSHAN GOODPACK MANUFACTURING CO.,LTD.
Quality Assurance Department Manager: Cherry Hu

III. A Statement on Compliance With Good Manufacturing Practice

QUALITY CERTIFICATE

QUALITY MANAGEMENT SYSTEM CERTIFICATE

This certificate is granted to the organization,

RK KOZMETIK VE HIJYEN URUNLERI SANAYI DIS TICARET A.S.

ISTANBUL DERI ORGANIZE SANAYI BOLGESI NOKRA CAD. NO:2/A TUZLA/ISTANBUL/TURKIYE

by review of IA2-2-8026 numbered report for the scope

MANUFACTURE OF COSMETICS, PERSONAL CARE AND HOUSEHOLD CLEANER PRODUCTS, DOMESTIC AND INDUSTRIAL CLEANING, BIOCIDAL, DISINFECTANT, HYGIENE PRODUCTS AND SOAP

to certify that a management system in accordance with standard's clauses is established and being implemented

ISO 9001:2015

Certificate No : QMS 0925 0011145
Original Certification Date : 11.09.2025
Revised Date : 11.09.2025
Expiry Date : 10.09.2026
Certification Period : 3 years (1st year)

EUROTECH CERTIFICATION

AMERICAN QUALITY

IAQS International Association of Quality and Sustainability

Eurotech Certification Approval

Eurotech LLC
1309 Coffeen Avenue Suite 2435 Sheridan,Wyoming 82801/ USA
www.eurotechcertification.com, email:info@eurotechcertification.com
The validity of this certificate can be confirmed by e-mail to info@eurotechcertification.com

QUALITY CERTIFICATE

KALİTE YÖNETİM SİSTEMİ SERTİFİKASI

Bu sertifika,

RK KOZMETİK VE HİJYEN ÜRÜNLERİ SANAYİ DIŞ TİCARET A.Ş.

İSTANBUL DERİ ORGANİZE SANAYİ BÖLGESİ NOKRA CAD. NO:2/A TUZLA/İSTANBUL/TÜRKİYE

kuruluşunun,

KOZMETİK, KİŞİSEL BAKIM VE TEMİZLİK ÜRÜNLERİ, EV VE ENDÜSTRİYEL TEMİZLİK ÜRÜNLERİ, BİOSİDAL, DEZENFEKTAN VE SABUN İMALATI VE SATIŞI

Kapsamında, IA2-2-8026 sayılı rapordaki inceleme ile

ISO 9001:2015

standardının şartlarına uyan bir yönetim sistemi kurduğunu ve uyguladığını onaylamak üzere verilmiştir.

Sertifika No : QMS 0925 0011145
İlk Yayın Tarihi : 11.09.2025
Revizyon Tarihi : 11.09.2025
Geçerlilik Tarihi : 10.09.2026
Belge Periyodu : 3 yıl (1. yıl)

EUROTECH CERTIFICATION

EUROTECH CERTIFICATION

AMERICAN QUALITY

IAQS International Association of Quality and Sustainability

Eurotech Certification Approval

Eurotech LLC
1309 Coffeen Avenue Suite 2435 Sheridan,Wyoming 82801/ USA
www.eurotechcertification.com, email:info@eurotechcertification.com
The validity of this certificate can be confirmed by e-mail to info@eurotechcertification.com

QUALITY CERTIFICATE

MEDICAL QUALITY MANAGEMENT SYSTEM CERTIFICATE

This certificate is granted to the organization,

RK KOZMETIK VE HIJYEN URUNLERI SANAYI DIS TICARET A.S.

ISTANBUL DERI ORGANIZE SANAYI BOLGESI NOKRA CAD. NO:2/A TUZLA/ISTANBUL/TURKIYE

by review of IA2-2-8026 numbered report for the scope

MANUFACTURE OF COSMETICS, PERSONAL CARE AND HOUSEHOLD CLEANER PRODUCTS, DOMESTIC AND INDUSTRIAL CLEANING, BIOCIDAL, DISINFECTANT, HYGIENE PRODUCTS AND SOAP

to certify that a management system in accordance with standard's clauses is established and being implemented

ISO 13485:2016

Certificate No : MDMS 0925 0011147
Original Certification Date : 11.09.2025
Revised Date : 11.09.2025
Expiry Date : 10.09.2026
Certification Period : 3 years (1st year)

EUROTECH CERTIFICATION

EUROTECH CERTIFICATION
AMERICAN QUALITY

IAQS International Association of Quality and Sustainability

Eurotech Certification Approval

Eurotech LLC
1309 Coffeen Avenue Suite 2435 Sheridan,Wyoming 82801/ USA
www.eurotechcertification.com, email:info@eurotechcertification.com
The validity of this certificate can be confirmed by e-mail to info@eurotechcertification.com

QUALITY CERTIFICATE

MEDİKAL KALİTE YÖNETİM SİSTEMİ SERTİFİKASI

Bu sertifika,

RK KOZMETİK VE HİJYEN ÜRÜNLERİ SANAYİ DIŞ TİCARET A.Ş.

İSTANBUL DERİ ORGANİZE SANAYİ BÖLGESİ NOKRA CAD. NO:2/A TUZLA/İSTANBUL/TÜRKİYE

kuruluşunun,

KOZMETİK, KİŞİSEL BAKIM VE TEMİZLİK ÜRÜNLERİ, EV VE ENDÜSTRİYEL TEMİZLİK ÜRÜNLERİ, BİOSİDAL, DEZENFEKTAN VE SABUN İMALATI VE SATIŞI

Kapsamında, IA2-2-8026 sayılı rapordaki inceleme ile

ISO 13485:2016

standardının şartlarına uyan bir yönetim sistemi kurduğunu ve uyguladığını onaylamak üzere verilmiştir.

Sertifika No : MDMS 0925 0011147
İlk Yayın Tarihi : 11.09.2025
Revizyon Tarihi : 11.09.2025
Geçerlilik Tarihi : 10.09.2026
Belge Periyodu : 3 yıl (1. yıl)

EUROTECH CERTIFICATION

EUROTECH CERTIFICATION
AMERICAN QUALITY

IAQS International Association of Quality and Sustainability

Eurotech Certification Approval

Eurotech LLC
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www.eurotechcertification.com, email:info@eurotechcertification.com
The validity of this certificate can be confirmed by e-mail to info@eurotechcertification.com

QUALITY CERTIFICATE

ENVIRONMENTAL MANAGEMENT SYSTEM CERTIFICATE

This certificate is granted to the organization,

RK KOZMETIK VE HIJYEN URUNLERI SANAYI DIS TICARET A.S.

ISTANBUL DERI ORGANIZE SANAYI BOLGESI NOKRA CAD. NO:2/A TUZLA/ISTANBUL/TURKIYE

by review of IA2-2-8026 numbered report for the scope

MANUFACTURE OF COSMETICS, PERSONAL CARE AND HOUSEHOLD CLEANER PRODUCTS, DOMESTIC AND INDUSTRIAL CLEANING, BIOCIDAL, DISINFECTANT, HYGIENE PRODUCTS AND SOAP

to certify that a management system in accordance with standard's clauses is established and being implemented

ISO 14001:2015

Certificate No : EMS 0925 0011146
Original Certification Date : 11.09.2025
Revised Date : 11.09.2025
Expiry Date : 10.09.2026
Certification Period : 3 years (1st year)

EUROTECH CERTIFICATION

AMERICAN QUALITY

IAQS International Association of Quality and Sustainability

Eurotech Certification Approval

Eurotech LLC
1309 Colleen Avenue Suite 2435 Sheridan,Wyoming 82801/ USA
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QUALITY CERTIFICATE

ÇEVRE YÖNETİM SİSTEMİ SERTİFİKASI

Bu sertifika,

RK KOZMETİK VE HİJYEN ÜRÜNLERİ SANAYİ DIŞ TİCARET A.Ş.

İSTANBUL DERİ ORGANİZE SANAYİ BÖLGESİ NOKRA CAD. NO:2/A TUZLA/İSTANBUL/TÜRKİYE

kuruluşunun,

KOZMETİK, KİŞİSEL BAKIM VE TEMİZLİK ÜRÜNLERİ, EV VE ENDÜSTRİYEL TEMİZLİK ÜRÜNLERİ, BİOSİDAL, DEZENFEKTAN VE SABUN İMALATI VE SATIŞI

Kapsamında, IA2-2-8026 sayılı rapordaki inceleme ile

ISO 14001:2015

standardının şartlarına uyan bir yönetim sistemi kurduğunu ve uyguladığını onaylamak üzere verilmiştir.

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QUALITY CERTIFICATE

COSMETICS - GOOD MANUFACTURING PRACTICES (GMP) CERTIFICATE

This certificate is granted to the organization,

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ISTANBUL DERI ORGANIZE SANAYI BOLGESI NOKRA CAD. NO:2/A TUZLA/ISTANBUL/TURKIYE

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to certify that a management system in accordance with standard's clauses is established and being implemented

ISO 22716:2007

Certificate No : CGMP 0925 0011148
Original Certification Date : 11.09.2025
Revised Date : 11.09.2025
Expiry Date : 10.09.2026
Certification Period : 3 years (1st year)

EUROTECH CERTIFICATION
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QUALITY CERTIFICATE

KOZMETİKLER - İYİ ÜRETİM UYGULAMALARI (GMP) SERTİFİKASI

Bu sertifika,

RK KOZMETİK VE HİJYEN ÜRÜNLERİ SANAYİ DIŞ TİCARET A.Ş.

İSTANBUL DERİ ORGANİZE SANAYİ BÖLGESİ NOKRA CAD. NO:2/A TUZLA/İSTANBUL/TÜRKİYE

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GOOD MANUFACTURING PRACTICES DECLARATION

To whom it may concern,

I, the undersigned, legal representative of **RK KOZMETİK HİJYEN ÜRÜNLERİ SAN. DIŞ. TİC. A.Ş**, certify that all products under the brand name "**BIONIKS**" are registered and marketed in Turkey and are manufactured in accordance with the Good Manufacturing Practices (G.M.P.) conditions.

We also declare that all the ingredients and materials used in manufacturing the products are of the highest quality and are effective and safe to use.

In faith,

President
RK KOZMETİK HİJYEN ÜRÜNLERİ SAN. DIŞ. TİC. A.Ş.

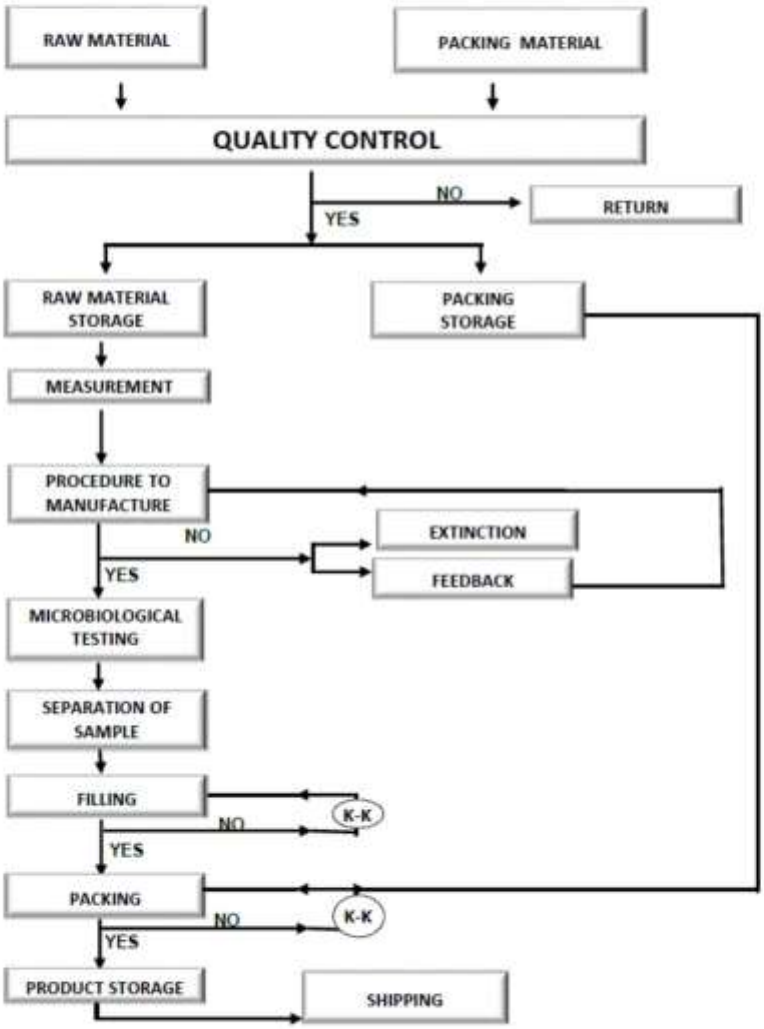
RK KOZMETİK HİJYEN ÜRÜNLERİ SAN. DIŞ. TİC. A.Ş
İstanbul Deri Organize Sanayi Bölgesi Nokra Caddesi. No: 2/A 3495
TUZLA / İSTANBUL

MANUFACTURING PROCESS

PRODUCT NAME: BIONIKS INTENSIVE MOISTURIZING CREAM

PRODUCT SIZE: 50 ml e

GENERAL MANUFACTURING SCHEMA



RK KOZMETİK HİJYEN ÜRÜNLERİ SAN. DIŞ. TİC. A.Ş.
İstanbul Deri Organize Sanayi Bölgesi Nokra Caddesi.No:2/A No:2 3495
TUZLA / İSTANBUL

IV. Informations About Raw Materials

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : euxyl® PE 9010

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Preservative for cosmetics & toiletries

1.3 Details of the supplier of the safety data sheet

Manufacturer/ Supplier : Schülke & Mayr GmbH
Robert-Koch-Str. 2

22851 Norderstedt
Germany
Telephone: +49 (0)40/ 52100-0
Telefax: +49 (0)40/ 52100318
mail@schuelke.com
www.schuelke.com

E-mail address of person responsible for the SDS/Contact person : SAI/AT +49 40 52100 100 or S&M UK +44 114 254 3500
sai-at@schuelke.com

1.4 Emergency telephone number

Emergency telephone number : UK Poisons Emergency number: 0870 600 6266

Emergency telephone number : +49 (0)40 / 52 100 –0

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Serious eye damage, Category 1 H318: Causes serious eye damage.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Danger

Hazard statements : H318 Causes serious eye damage.

Precautionary statements : P280 Wear eye protection/ face protection.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with wa-

ter for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER/doctor.

Hazardous components which must be listed on the label:
70445-33-9 3-(2-ethylhexyloxy)propane-1,2-diol

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature : solution

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
2-phenoxyethanol	122-99-6 204-589-7 603-098-00-9 01-2119488943-21-XXXX	Acute Tox. 4; H302 Eye Irrit. 2; H319	88,5 - 91,5
3-(2-ethylhexyloxy)propane-1,2-diol	70445-33-9 408-080-2 603-168-00-9 01-0000015745-65-0001	Eye Dam. 1; H318 Acute Tox. 4; H332 Aquatic Chronic 3; H412	8,5 - 11,5

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : Take off all contaminated clothing immediately.

If inhaled : If symptoms persist, call a physician.

In case of skin contact : Wash off immediately with plenty of water.

In case of eye contact : In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

If swallowed : Obtain medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : Risk of serious damage to eyes.

Risks : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : No information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water
Dry powder
Foam
Carbon dioxide (CO2)

Unsuitable extinguishing media : No information available.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : No information available.

5.3 Advice for firefighters

Further information : Standard procedure for chemical fires.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions : Do not flush into surface water or sanitary sewer system.
Avoid subsoil penetration.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).
Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).

6.4 Reference to other sections

see Section 8 + 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling	:	Handle and open container with care.
Advice on protection against fire and explosion	:	No special protective measures against fire required.
Hygiene measures	:	Take off all contaminated clothing immediately.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	:	Store in original container.
Further information on storage conditions	:	Keep away from direct sunlight. Limited stability - see label on pack. Keep container tightly closed.
Advice on common storage	:	Keep away from food and drink.

7.3 Specific end use(s)

Specific use(s)	:	none

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
2-phenoxyethanol	Workers	Inhalation	Long-term systemic effects, Long-term local effects	8,07 mg/m3
	Workers	Skin contact	Long-term systemic effects	34,72 mg/kg
	Consumers	Inhalation	Long-term exposure, Short-term exposure, Local effects	2,5 mg/m3
	Consumers	Skin contact	Long-term local effects	20,83 mg/kg
	Consumers	Ingestion	Short-term exposure, Long-term exposure, Systemic effects	17,43 mg/kg
3-(2-ethylhexyloxy)propane-1,2-diol	Workers	Inhalation	Acute systemic effects	1,55 mg/m3
	Workers	Inhalation	Long-term systemic effects	0,875 mg/m3
	Workers	Skin contact	Long-term systemic effects	1 mg/kg

	Consumers	Inhalation	Long-term systemic effects	0,109 mg/m3
	Consumers	Skin contact	Long-term systemic effects	0,5 mg/kg

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
2-phenoxyethanol	Fresh water	0,943 mg/l
	Marine water	0,0943 mg/l
	Fresh water sediment	7,2366 mg/kg
	Marine sediment	0,7237 mg/kg
	Soil	1,26 mg/kg
	Intermittent use/release	3,44 mg/l
	Sewage treatment plant	24,8 mg/l
3-(2-ethylhexyloxy)propane-1,2-diol	Fresh water	0,15 mg/l
	Marine water	0,015 mg/l
	Fresh water sediment	0,19 mg/kg
	Marine sediment	0,019 mg/kg
	Soil	0,894 mg/kg
	Sewage treatment plant	5,6 mg/l

8.2 Exposure controls

Personal protective equipment

Eye protection : Safety glasses with side-shields conforming to EN166

Hand protection : Impervious glovesSplash protection: disposable nitrile rubber gloves e.g. Dermatril (layer thickness: 0.11 mm) made by KCL or gloves from other manufacturers offering the same protection.Prolonged contact: Butyl rubber gloves e.g. Butoject (>480 Min., layer thickness: 0.70 mm) made by KCL or gloves from other manufacturers offering the same protection.

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Protective measures : Avoid contact with skin and eyes.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : liquid

Colour : nearly colourless

Odour : characteristic

Odour Threshold : not determined

pH : 6 - 8 (20 °C)
Concentration: 10 g/l

Freezing point	:	ca. 5 °C
Boiling point/boiling range	:	> 100 °C
Flash point	:	> 100 °C Method: ISO 2719
Evaporation rate	:	not determined
Flammability (solid, gas)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	Not applicable
Lower explosion limit / Lower flammability limit	:	Not applicable
Vapour pressure	:	not determined
Vapour density	:	not determined
Relative density	:	ca. 1,087 - 1,092 g/ml (20 °C)
Solubility(ies)		
Water solubility	:	10 g/l (20 °C)
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	Not applicable
Viscosity		
Viscosity, dynamic	:	28 mPa*s Method: Rheo WIN RS 600
Flow time	:	< 15 s at 20 °C Method: DIN 53211
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

9.2 Other information

Surface tension	:	34 mN/m
Refractive index	:	1,522 - 1,534 at 20 °C
Self-ignition	:	Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity

Stable under recommended storage conditions.

10.2 Chemical stability

No decomposition if stored normally.

10.3 Possibility of hazardous reactions

Hazardous reactions : None reasonably foreseeable.

10.4 Conditions to avoid

Conditions to avoid : Protect from frost, heat and sunlight.

10.5 Incompatible materials

Materials to avoid : No data available

10.6 Hazardous decomposition products

None reasonably foreseeable.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Components:

2-phenoxyethanol:

Acute oral toxicity : LD50 (Rat): 1.850 mg/kg
Assessment: Harmful if swallowed.

Acute inhalation toxicity : (Rat): Exposure time: 8 h
Remarks: An LC50/ inhalation could not be determined because no mortality of rats was observed at the maximum achievable concentration.

Acute dermal toxicity : LD50: > 2.000 mg/kg
Remarks: Based on available data, the classification criteria are not met.

3-(2-ethylhexyloxy)propane-1,2-diol:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 401
Remarks: Based on available data, the classification criteria are not met.

Acute inhalation toxicity : LC50 (Rat): 3,07 mg/l
Method: OECD Test Guideline 403
Assessment: Harmful if inhaled.

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on available data, the classification criteria are not met.

Skin corrosion/irritation

Components:

2-phenoxyethanol:

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation

3-(2-ethylhexyloxy)propane-1,2-diol:

Method	:	OECD Test Guideline 404
Result	:	slight irritation
Remarks	:	Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation

Components:

2-phenoxyethanol:

Species	:	Rabbit
Assessment	:	Causes serious eye irritation.
Method	:	OECD Test Guideline 405

3-(2-ethylhexyloxy)propane-1,2-diol:

Method	:	OECD Test Guideline 405
Result	:	Risk of serious damage to eyes.
Test substance	:	concentrate

Respiratory or skin sensitisation

Components:

2-phenoxyethanol:

Test Type	:	Maximisation Test
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	Did not cause sensitisation on laboratory animals.

3-(2-ethylhexyloxy)propane-1,2-diol:

Method	:	OECD Test Guideline 406
Result	:	Did not cause sensitisation on laboratory animals.

Germ cell mutagenicity

Components:

2-phenoxyethanol:

Germ cell mutagenicity- Assessment	:	Tests on bacterial or mammalian cell cultures did not show mutagenic effects.

3-(2-ethylhexyloxy)propane-1,2-diol:

Genotoxicity in vitro	:	Method: OECD Test Guideline 471 Result: Not mutagenic in Ames Test
Genotoxicity in vivo	:	Method: OECD 474 Remarks: Micronucleus test: not mutagenic

Carcinogenicity

Components:

2-phenoxyethanol:

Carcinogenicity - Assessment	:	No data available

Reproductive toxicity

Components:

2-phenoxyethanol:

Reproductive toxicity - Assessment	:	Animal testing did not show any effects on fertility.

3-(2-ethylhexyloxy)propane-1,2-diol:

Effects on foetal development	:	Species: Rat Application Route: Oral General Toxicity Maternal: NOAEL: 800 mg/kg body weight Method: OECD Test Guideline 414

STOT - single exposure

Components:

2-phenoxyethanol:

Remarks	:	Based on available data, the classification criteria are not met.

STOT - repeated exposure

Components:

2-phenoxyethanol:

Remarks	:	No data available

Repeated dose toxicity

Components:

2-phenoxyethanol:

Species	:	Rat
NOAEL	:	400 mg/kg
Application Route	:	Oral
Remarks	:	Based on available data, the classification criteria are not met.

3-(2-ethylhexyloxy)propane-1,2-diol:

Species	:	Rat
NOAEL	:	100 mg/kg
Application Route	:	Oral
Exposure time	:	28-day
Method	:	OECD Test Guideline 407
Remarks	:	Based on available data, the classification criteria are not met.

Species	:	Rat
NOAEL	:	50 mg/kg
Application Route	:	Oral
Exposure time	:	90-day

Aspiration toxicity

No data available

SECTION 12: Ecological information

12.1 Toxicity

Components:

2-phenoxyethanol:

Toxicity to fish	:	LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 : > 500 mg/l Exposure time: 48 h
Toxicity to algae	:	EC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l Exposure time: 72 h
Toxicity to fish (Chronic toxicity)	:	NOEC: 23 mg/l Exposure time: 34 d Species: Pimephales promelas (fathead minnow)
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 9,43 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea)

3-(2-ethylhexyloxy)propane-1,2-diol:

Toxicity to fish	:	LC50 (Brachidanio rerio): 60,2 mg/l Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna): 78,3 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae	:	IC50 (Desmodesmus subspicatus (green algae)): 48,3 mg/l Exposure time: 72 h Method: OECD Test Guideline 201

Toxicity to microorganisms	:	EC50 : 560 mg/l Method: OECD 209
Toxicity to fish (Chronic toxicity)	:	NOEC: 1,5 mg/l Exposure time: 35 d Species: Brachidanio rerio Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 20 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

12.2 Persistence and degradability

Components:

2-phenoxyethanol:

Biodegradability	:	Biodegradation: 90 - 100 % Exposure time: 15 d Method: OECD Test Guideline 301A Remarks: According to the results of tests of biodegradability this product is considered as being readily biodegradable.

3-(2-ethylhexyloxy)propane-1,2-diol:

Biodegradability	:	Result: According to OECD criteria, the product is inherently biodegradable. Method: OECD 302B/ ISO 9888/ EEC 88/302C

12.3 Bioaccumulative potential

Components:

2-phenoxyethanol:

Bioaccumulation	:	Bioconcentration factor (BCF): 0,35 Remarks: No bioaccumulation is to be expected (log Pow <= 4).
Partition coefficient: n-octanol/water	:	log Pow: 1,16

3-(2-ethylhexyloxy)propane-1,2-diol:

Partition coefficient: n-octanol/water	:	log Pow: 2,53

12.4 Mobility in soil

Product:

Mobility	:	Remarks: No data available

Components:

2-phenoxyethanol:

Mobility : Remarks: Mobile in soils

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher..

12.6 Other adverse effects

Product:

Adsorbed organic bound halogens (AOX) : Remarks: Product does not contain any organic halogens.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of as hazardous waste in compliance with local and national regulations.
The product should not be allowed to enter drains, water courses or the soil.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

Waste key for the unused product(Group) : The waste producer itself must, in consultation with the appropriate authorities and a waste disposal company, obtain a waste code from the EWC (European Waste Catalogue)

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable
For personal protection see section 8.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Volatile organic compounds : none, Directive 2010/75/EC on the limitation of emissions of volatile organic compounds

15.2 Chemical safety assessment

Exempt

SECTION 16: Other information

Full text of H-Statements

H302	:	Harmful if swallowed.
H318	:	Causes serious eye damage.
H319	:	Causes serious eye irritation.
H332	:	Harmful if inhaled.
H412	:	Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Eye Dam.	:	Serious eye damage
Eye Irrit.	:	Eye irritation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equip-

ment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) No. 1272/2008

Eye Dam. 1, H318 : Calculation method

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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euxyl® PE 9010

Preservative for cosmetics & toiletries

Use-concentration	Leave-on (i.e. creams, lotions)	Rinse-off (i.e. shampoos, bath preparations)
acc. schülke-recommendation	0.5 - 1.0 %	0.5 - 1.0 % [1]
acc. EU Cosmetics Regulation	max. 1.11 %	max. 1.11 %
acc. CIR (USA)	max. 1.11 %	max. 1.11 %
acc. ASEAN Cosmetic Directive	max. 1.11 %	max. 1.11 %
acc. Hygienic Standard for Cosmetics 2007 (China)	max. 1.11 %	max. 1.11 %
acc. MERCOSUR	max. 1.11 %	max. 1.11 %

Recommended use-concentrations are based on average active content. Please pay attention to the corresponding certificate of analysis.

1) A high load of ethoxylated surfactants result in a loss of efficacy.

EU-INCI-declaration
Phenoxyethanol, Ethylhexylglycerin *

* Stabilised with synthetic alpha-tocopherol

Active substance			
INCI name	**EINECS-Name:**	**CAS-No.**	**EC-No.**
Phenoxyethanol	2-phenoxyethanol	122-99-6	204-589-7

Physico-chemical properties	
Colour	nearly colourless
Form	liquid
Odour	characteristic
Density (20 °C)	1.087 - 1.092 g/ml
Refractive index (20 °C)	1.522 - 1.534
Boiling point/boiling range	> 100 °C
Flash point (ISO 2719)	> 100 °C
Flow time (DIN 53211 - 20 °C)	< 15 s
Viscosity (Rheo WIN RS 600 -)	28 mPa*s
Water solubility (20 °C)	10 g/l
Water solubility (60 °C)	15 g/l
Foaming characteristics (DIN 53902)	non foaming (1.0 % in water)
Colour index (Hazen)	< 50

Fields of application

The recommended use levels relate to the total formulation in each case. The values given are recommended guidelines. The optimum use level should be evaluated by means of a repeated challenge test (e.g. at schülke Customer Support and Microbiological department).

	Recommended dosage
Leave-on (i.e. creams, lotions)	0.5 - 1.0 %
Rinse-off (i.e. shampoos, bath preparations)	0.5 - 1.0 %
Wet wipes	0.5 - 1.0 %
Other uses	Kindly contact us.

Indications for use	
General Information	Effective in pH ranges up to 12.
Solubility(ies)	In water and non-polar solvents only limitedly soluble. Highly soluble in organic solvents like alcohols, ethers, esters and ketones.
Compatibility with surfactants	euxyl® PE 9010 proved to have good chemical compatibility with anionic surfactants such as sulphates, ether sulphates and sulphosuccinates, as well as with non-ionogenic surfactants. Ethoxylated surfactants may lead to loss of effectiveness.
Compatibility with sulphite ions	euxyl® PE 9010 exhibits no interaction with sulphite ions.
Discolouration	In general euxyl® PE 9010 displays good compatibility with cosmetic ingredients. No discolouration has been observed.
Maximum use temperature	> 100 °C

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euxyl® PE 9010

Microbiological efficacy

euxyl® PE 9010 is equally effective against bacteria, yeasts and mould. For euxyl® PE 9010 to perform effectively in destroying organisms in products already contaminated, a minimum contact time of 48 hours is necessary. Since the effect of euxyl® PE 9010 takes place through chemical reactions with the microorganisms, when it is used in heavily contaminated products loss of active ingredient must be taken into account. Good production hygiene, as well as the use of raw materials with low microorganism levels as a result of correct raw material control, are of course vital prerequisites for the production of microbiologically faultless finished products.

MIC

The efficacy of the product has been tested against the following microorganisms according to DGHM (German Society for Hygiene and Microbiology). Determination of the minimum inhibitory concentration in the serial dilution test produced the following values (MIC in % of the product):

Bacteria (gram-negative)	MIC	Bacteria (gram-positive)	MIC	Yeasts	MIC
Enterobacter gergoviae	0.50	*Staphylococcus aureus*	0.50	*Candida albicans*	0.25
Escherichia coli	0.50	*Staphylococcus epidermidis*	0.50		
Klebsiella pneumoniae	0.25			**Moulds**	**MIC**
Pseudomonas aeruginosa	0.50			*Aspergillus niger*	0.25
Pseudomonas fluorescens	0.25			*Penicillium pinophilum*	0.25
Pseudomonas putida	0.50				

Compatibility*

	compatible	to be avoided
concentrate	stainless steel, brass, copper, zinc, aluminium, polyethylene, PVC (hard), ethylene-propylene-terpolymer (EPDM), polytetrafluoroethylene (PTFE), Polyoxymethylene (POM), polyamide (PA 6), fluorinated rubber (FKM)	polycarbonate (PC), polymethyl methacrylate (PMMA), acrylo-nitrile butadiene styrene polymer (ABS), sealants and plastics other than mentioned
aqueous dilution (1.0 %)	no significant difference to water	water incompatible materials

*Compatibility has to be proved in each case.

Environmental information

Dilutions of euxyl® PE 9010 normally do not interfere with the operation of waste water treatment plants. The canisters and drums used by schülke are made of polyethylene (HDPE) and are labelled accordingly. The 1000 kg containers are covered by a return scheme that ensures collection of the used containers free of charge and appropriate reuse all over Europe. The labels are made of PE. schülke packaging materials contain no PVC and can be recycled. For further information please ask for our detailed environmental report.

Labelling

Hazard statements	H318
Precautionary statements	P280, P305 + P351 + P338, P310
Labelling	Danger GHS05 (Corrosion)

Transport & Storage

Dangerous goods	No
UN number	-
Packaging group	-
Package sizes	10 kg, 200 kg, 1000 kg
Shelf life	36 months
Storage	Keep away from direct sunlight. Limited stability - see label on pack. Keep container tightly closed.

*For further hazard instructions and safety advice please refer to the actual material safety data sheet.

schülke subsidiaries:

Certified acc. to DIN EN ISO 14001

China
Schülke & Mayr GmbH
Shanghai Representative Office
Shanghai 200041
Tel. +86-21-62 17 29 95
mail.cn@schuelke.com

France
Schülke France SARL
92806 Puteaux Cedex
Tel. +33-1-42 91 42 42
schuelkefrance.info@schuelke.com

Italy
Schülke & Mayr Italia S.r.l.
20158 Milano
Tel. +39-02-40 26 590
info-italia@schuelke.com

Netherlands
Schülke & Mayr Benelux B.V.
2031 CC Haarlem
Tel. +31-23-535 26 34
salesbenelux@schuelke.com

Switzerland
Schülke & Mayr AG
8003 Zürich
Tel. +41-44-466 55 44
mail.ch@schuelke.com

United Kingdom
Schülke & Mayr UK Ltd.
Sheffield S9 1 AT
Tel. +44-1142 54 35 00
mail.uk@schuelke.com

United States of America (USA)
schülke inc.
Fairfield, NJ 07004
Tel. +1-973 770 7300
sales@schuelke.com

Other Distributors:
Argentina · Australia · Austria · Belarus · Benin · Brazil · Bulgaria · Canada · Croatia · Czech Republic · Denmark · Egypt · Estonia · Finland · Ghana · Greece · Hong Kong · Hungary · India · Indonesia · Iran · Israel · Japan · Jordan · Korea · Kuwait · Latvia · Lebanon · Lithuania · Macedonia · Malaysia · New Zealand · Nigeria · Norway · Oman · Philippines · Poland · Portugal · Russia · Saudi Arabia · Singapore · Slovakia · Slovenia · South Africa · Spain · Sweden · Syria · Taiwan · Thailand · Turkey · Ukraine · United Arab Emirates · USA · Vietnam · Yemen

Air Liquide HEALTHCARE
A company of the Air Liquide Group

Schülke & Mayr GmbH
22840 Norderstedt
Germany
Tel. +49 40 52100-0
Fax +49 40 52100-244
www.schuelke.com
sai@schuelke.com

EN/Version 06.00/Revision Date: 22.02.2019/This product information is not automatically updated

Safety Data Sheet

Regulation (EC) No. 1907/2006 and
Regulation (EC) No. 1272/2008

CHT
SMART CHEMISTRY
WITH CHARACTER.

Issuing Date 19-Jul-2019 **Revision date** 23-Jul-2021 **Version** 3

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name BeauSil GEL 8014

Pure substance/mixture Mixture

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended use Cosmetics

Application No information available

1.3. Details of the supplier of the safety data sheet

Supplier
CHT USA, Inc.
805 Wolfe Avenue
Cassopolis, MI 49031
For further information, please contact

E-mail address info.usa@cht.com

1.4. Emergency telephone number

Emergency telephone +1 (703) 527-3887 CHEMTREC

Emergency telephone - §45 - (EC)1272/2008	
Europe	112

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Chronic aquatic toxicity	Category 3 - (H412)

2.2. Label elements

Hazard statements
H412 - Harmful to aquatic life with long lasting effects

Precautionary Statements - EU (§28, 1272/2008)
P262 - Do not get in eyes, on skin, or on clothing
P264 - Wash face, hands and any exposed skin thoroughly after handling
P280 - Wear protective gloves and protective clothing
P310 - Immediately call a POISON CENTER or doctor
P321 - Specific treatment (see supplemental first aid instructions on this label)
P361 + P364 - Take off immediately all contaminated clothing and wash it before reuse

Additional information

This product requires tactile warnings if supplied to the general public. This product requires child resistant fastenings if supplied to the general public.

2.3. Other hazards

May be harmful in contact with skin.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH registration number
isopropyl alcohol	200-661-7	67-63-0	<0.1	Eye Irrit. 2 (H319) STOT SE 3 (H336) Flam. Liq. 2 (H225)	No data available
Dihydrogen hexachloroplatinate(IV) hydrate	-	26023-84-7	<0.1	Acute Tox. 3 (H301) Eye Dam. 1 (H318) Resp. Sens. 1 (H334) Skin Sens. 1 (H317)	No data available

Full text of H- and EUH-phrases: see section 16

This product contains one or more candidate substance(s) of very high concern (Regulation (EC) No. 1907/2006 (REACH), Article 59)

Chemical name	CAS No	SVHC candidates
Decamethylcyclopentasiloxane	541-02-6	X
Dodecamethylcyclohexasiloxane	540-97-6	X
Octamethylcyclotetrasiloxane	556-67-2	X

Section 4: First aid measures

4.1. Description of first aid measures

General advice Show this safety data sheet to the doctor in attendance. Immediate medical attention is required.

Inhalation Remove to fresh air.

Eye contact Get immediate medical advice/attention. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing.

Skin contact Get immediate medical advice/attention. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Ingestion Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.

Self-protection of the first aider Wear personal protective clothing (see section 8). Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms	No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	No information available.

5.3. Advice for firefighters

Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas.
Other information	Refer to protective measures listed in Sections 7 and 8.
For emergency responders	Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions	Prevent further leakage or spillage if safe to do so.

6.3. Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Take up mechanically, placing in appropriate containers for disposal.
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections	See section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Take off contaminated clothing and

wash before reuse.

General hygiene considerations Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up.

7.3. Specific end use(s)

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

Chemical name	European Union	Austria	Belgium	Bulgaria	Croatia
isopropyl alcohol 67-63-0	-	TWA: 200 ppm TWA: 500 mg/m³ STEL 800 ppm STEL 2000 mg/m³	-	STEL: 1225.0 mg/m³ TWA: 980.0 mg/m³	TWA: 400 ppm TWA: 999 mg/m³ STEL: 500 ppm STEL: 1250 mg/m³
Dihydrogen hexachloroplatinate(IV) hydrate 26023-84-7	-	TWA: 0.002 mg/m³	-	-	TWA: 0.002 mg/m³
Chemical name	**Cyprus**	**Czech Republic**	**Denmark**	**Estonia**	**Finland**
isopropyl alcohol 67-63-0	-	-	TWA: 200 ppm TWA: 490 mg/m³	TWA: 150 ppm TWA: 350 mg/m³ STEL: 250 ppm STEL: 600 mg/m³	TWA: 200 ppm TWA: 500 mg/m³ STEL: 250 ppm STEL: 620 mg/m³
Dihydrogen hexachloroplatinate(IV) hydrate 26023-84-7	-	-	TWA: 0.002 mg/m³	-	TWA: 0.002 mg/m³
Chemical name	**France**	**Germany**	**Germany MAK**	**Greece**	**Hungary**
isopropyl alcohol 67-63-0	STEL: 400 ppm STEL: 980 mg/m³	TWA: 200 ppm TWA: 500 mg/m³	TWA: 200 ppm TWA: 500 mg/m³ Ceiling / Peak: 400 ppm Ceiling / Peak: 1000 mg/m³	-	TWA: 500 mg/m³ STEL: 1000 mg/m³ b*
Dihydrogen hexachloroplatinate(IV) hydrate 26023-84-7	-	-	-	-	TWA: 0.002 mg/m³
Chemical name	**Ireland**	**Italy**	**Italy REL**	**Latvia**	**Lithuania**
isopropyl alcohol 67-63-0	TWA: 200 ppm STEL: 400 ppm Sk*	-	-	TWA: 350 mg/m³ STEL: 600 mg/m³	-
Dihydrogen hexachloroplatinate(IV) hydrate 26023-84-7	TWA: 0.002 mg/m³ STEL: 0.006 mg/m³	-	-	-	-
Chemical name	**Luxembourg**	**Malta**	**Netherlands**	**Norway**	**Poland**
isopropyl alcohol 67-63-0	-	-	-	TWA: 100 ppm TWA: 245 mg/m³	STEL: 1200 mg/m³ TWA: 900 mg/m³

				STEL: 150 ppm STEL: 306.25 mg/m³	
Dihydrogen hexachloroplatinate(IV) hydrate 26023-84-7	-	-	-	TWA: 0.002 mg/m³ STEL: 0.006 mg/m³	-

Chemical name	Portugal	Romania	Slovakia	Slovenia	Spain
isopropyl alcohol 67-63-0	TWA: 200 ppm STEL: 400 ppm	TWA: 81 ppm TWA: 200 mg/m³ STEL: 203 ppm STEL: 500 mg/m³	TWA: 200 ppm TWA: 500 mg/m³	TWA: 200 ppm TWA: 500 mg/m³ STEL: STEL ppm STEL: STEL mg/m³	TWA: 200 ppm TWA: 500 mg/m³ STEL: 400 ppm STEL: 1000 mg/m³
Dihydrogen hexachloroplatinate(IV) hydrate 26023-84-7	TWA: 0.002 mg/m³	-	TWA: 0.001 mg/m³	-	-

Chemical name	Sweden	Switzerland	United Kingdom
isopropyl alcohol 67-63-0	-	TWA: 200 ppm TWA: 500 mg/m³ STEL: 400 ppm STEL: 1000 mg/m³	TWA: 400 ppm TWA: 999 mg/m³ STEL: 500 ppm STEL: 1250 mg/m³
Dihydrogen hexachloroplatinate(IV) hydrate 26023-84-7	-	TWA: 0.002 mg/m³	TWA: 0.002 mg/m³

Biological occupational exposure limits

Chemical name	Denmark	Finland	France	Germany	Germany MAK
isopropyl alcohol 67-63-0	-	-	-	-	25 mg/L

Chemical name	Slovenia	Spain	Switzerland	United Kingdom
isopropyl alcohol 67-63-0	-	40	25	-

Derived No Effect Level (DNEL) No information available.
Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Personal Protective Equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Hand protection Wear suitable gloves. Impervious gloves.

Skin and body protection Impervious clothing. Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product.

Environmental exposure controls No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Gel
Color	Clear Colorless
Odor	Negligible
Odor threshold	No data available

Property	Values	Remarks • Method
pH	No data available	None known
pH (as aqueous solution)	No data available	None known
Melting point / Freezing point	No data available	None known
Boiling point / boiling range °C	> 150 °C	
Flash point	> 102 °C	
Evaporation rate		None known
Flammability (solid, gas)		None known
Flammability limit in air		None known
Upper flammability limit:	No data available	
Lower flammability limit:	No data available	
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Relative density	0.98	
Water solubility	No data available	None known
solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
Kinematic viscosity		None known
Dynamic viscosity	No data available	None known
Explosive properties	No data available	
Oxidizing properties	No data available	

9.2. Other information

Molecular weight	No data available
Density	No data available
Bulk density	No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion Data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials None known based on information supplied.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute Toxicity

Product information

Product does not present an acute toxicity hazard based on known or supplied information.

INHALATION	No data available.
Eye Contact	No data available.
Skin Contact	No data available.
INGESTION	No data available.

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral)	17,019.00 mg/kg
ATEmix (dermal)	2,002.00 mg/kg

Unknown Acute Toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
isopropyl alcohol	= 1870 mg/kg (Rat)	= 4059 mg/kg (Rabbit)	> 10000 ppm (Rat) 6 h

Skin Corrosion/Irritation	No information available.
Serious eye damage/eye irritation	No information available.
sensitization	No information available.
Germ Cell Mutagenicity	No information available.
carcinogenicity	No information available.
Reproductive Toxicity	No information available.
STOT - Single Exposure	No information available.
STOT - Repeated Exposure	No information available.
Aspiration Hazard	No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity Harmful to aquatic life with long lasting effects.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
isopropyl alcohol	1000: 72 h Desmodesmus subspicatus mg/L EC50 1000: 96 h Desmodesmus subspicatus mg/L EC50	11130: 96 h Pimephales promelas mg/L LC50 static 9640: 96 h Pimephales promelas mg/L LC50 flow-through 1400000: 96 h Lepomis macrochirus µg/L LC50	-	13299: 48 h Daphnia magna mg/L EC50

12.2. Persistence and degradability

Persistence and Degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation There is no data for this product.

Component Information

Chemical name	Partition coefficient
isopropyl alcohol	0.05

12.4. Mobility in soil

Mobility in Soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Other adverse effects

Other Adverse Effects No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

Section 14: Transport information

IMDG

14.1 UN/ID no	NOT REGULATED
14.2 Proper Shipping Name	NOT REGULATED
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	NOT REGULATED
14.5 Marine pollutant	Not applicable
14.6 Special precautions for user	
Special Provisions	None
14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code	No information available

RID

14.1 UN/ID no	NOT REGULATED
14.2 Proper Shipping Name	NOT REGULATED
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	NOT REGULATED
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	
Special Provisions	None

ADR

14.1 UN number	Not regulated
14.2 Proper Shipping Name	NOT REGULATED
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	NOT REGULATED
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	
Special Provisions	None

IATA

14.1 UN number	Not regulated
14.2 Proper Shipping Name	NOT REGULATED
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	
Special Provisions	None

Section 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations

France
Occupational Illnesses (R-463-3, France)

Chemical name	French RG number	Title
isopropyl alcohol 67-63-0	RG 84	-

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
isopropyl alcohol - 67-63-0	75.	

Persistent Organic Pollutants

Not applicable

Dangerous substance category per Seveso Directive (2012/18/EU)

H1 - ACUTE TOXIC

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventories

TSCA	Exempt
DSL/NDSL	Complies
EINECS/ELINCS	Complies
ENCS	Complies
IECSC	Complies
KECL	Complies
PICCS	Not listed
AICS	Complies
NZIoC	Complies
TCSI	Complies

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances
NZIoC - New Zealand Inventory of Chemicals
TCSI - Taiwan Chemical Substance Inventory

15.2. Chemical safety assessment

Chemical Safety Report No information available

SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3
H225 - Highly flammable liquid and vapor
H301 - Toxic if swallowed
H317 - May cause an allergic skin reaction
H318 - Causes serious eye damage
H319 - Causes serious eye irritation
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H336 - May cause drowsiness or dizziness

Legend
SVHC: Substances of Very High Concern for Authorization:

Legend SECTION 8: Exposure controls/personal protection

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapor	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitization	Calculation method
Skin sensitization	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

Key literature references and sources for data used to compile the SDS
Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AEGL(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
World Health Organization

Issuing Date 19-Jul-2019

Revision date 23-Jul-2021

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006
Disclaimer
The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet

1. Identity and Registrations

INCI Name

Dimethicone (and) Dimethicone Crosspolymer

Chemical description

Crosslinked silicone polymer in dimethicone

Composition

INCI-breakdown

INCI Name	CAS No.	Target wt %
Dimethicone	63148-62-9	To 100
Dimethicone Crosspolymer	213629-14-2	10 - 15

Compliance with Chemical Inventories

Compliance with the European Union's Chemicals Legislation (REACH), Regulation (EC) 1907/2006

☒ We hereby confirm that the raw material marketed by CHT Group fully comply with the related requirements of European Union Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)*

***Only if taken from CHT Germany GmbH or appropriate REACH certificate issued**

Compliance with Global Chemical Inventories & Regulatory Status

Country	Inventory	Yes/No
Europe	EINECS / ELINCS	Yes / Exempt
United States	TSCA	Yes
Canada	DSL	No
Australia	AICS	Yes
China	IECSC	Yes
Japan	ENCS (former METI)	No
Korea	KECL	Yes
New Zealand	NZIoC	Yes
Philippines	PICCS	No
Taiwan	NECI	Yes

Product Information

BeauSil GEL 8014

INCI Name – Dimethicone and Dimethicone Crosspolymer

Description
BeauSil GEL 8014 is a high molecular weight specialty silicone elastomer carried in low molecular weight dimethicone fluid (5 cst). BeauSil GEL 8014 features a non-tacky, ultra-smooth exquisite feel with haze-free, near-perfect clarity.

Applications
- Skin Care
- Color Cosmetics
- Sun Care
- Hair Care
- Shower Gels
- Antiperspirants and Deodorants

Benefits and Features
- Water white in color, completely haze free
- Easier dispersibility when formulating
- Reduces tackiness of formulations
- Easily colored with pigment
- Silky skin feel that is non-greasy
- No balling effect when rubbed on skin
- Quick absorption
- Improves fragrance retention

Typical Properties
- Appearance: Clear Gel
- Viscosity: @25 °C (cSt.) 400,000
- % Elastomer 10-15%

Limitations
This product is not intended for pharmaceutical use.

How to Use
BeauSil GEL 8014can be incorporated directly into the oil phase of the final formulation.

BeauSil GEL 8014 has been used at any weight percent in a final formulation and will disperse easily in non-aqueous diluents with minor agitation.

Safe Handling Information
Read product and safety data sheets before handling this product for physical and health hazard information. The safety data sheet is available from your CHT representative.

Storage and Shelf Life
This product is stable for 18 months from the original production date when stored in the original unopened container and below 40 °C.

Packaging Information
This product is available for sale as 35 lb. pails and 410 lb. drums.

Limited Warranty
The information presented in this document is accurate to the best of our knowledge, however no warranty is expressed or implied other than the quality of the product as described. No recommendation to infringe upon any patented or proprietary procedures is intended. Each user of CHT products should review this information and these recommendations to determine their relevance and applicability in the specific context in which the products are to be used.

Contact Information
Phone: 269-445-0847
Email: consumer-care@cht.com

REV 1 14-APRIL-2021

APRINNOVA

A Joint Venture of Amyris & NIKKOL GROUP

SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Aprinnova, LLC
5885 Hollis St., Ste 100
Emeryville, CA 94608
Main: +1 (510) 450-0761
Fax: +1 (510) 225-2645
E-mail: SDS@amyris.com

EU contact:
Penman Consulting BVBA
+32(0)2 305 0698
OR.SDS@penmanconsulting.com
Avenue des Artes 10, 1210 Brussels
Belgium

Emergency telephone number (Chemtrec):
+1(800) 424-9300 (US and Canada)
+1(703) 741-5970 (outside US and Canada)

Product identifier	Squalane
Synonyms	Tetracosane, 2,6,10,15,23-hexamethyl-Dodecahydrosqualene; Perhydrosqualene; Cosbiol, Robane, Spinacane, Vitabiosol, Renewable Squalane
Trade names	Neossance™ Squalane
Chemical family	Paraffinic hydrocarbons
REACH Registration No.:	01-2120014832-65-0007
Relevant identified uses of the substance or mixture and uses advised against	Used as a natural emollient, lubricant, and humectant in cosmetics.
Note	This SDS is written to address the handling of this chemical during manufacturing under industrial use conditions. If further information becomes available, this SDS will be updated.
Issue Date	11 March 2019

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Regulation (EC) 1272/2008
OSHA HCS 2012 Not classified as hazardous under these regulations.

Label elements

CLP/GHS hazard pictogram	None required
CLP/GHS signal word	None required

CLP/GHS hazard statements	None required
CLP/GHS precautionary statements	None required.
Other hazards	No information identified for squalane.
NFPA Classification:	Health Hazard: 1; Fire Hazard: 1; Reactivity Hazard; 0
Note	None

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS #	EC#	Amount	GHS/CLP Classification
Squalane	111-01-3	203-825-6	>92%	Not classified

Note This substance is not considered hazardous under EU and US criteria. It contains minor isomeric byproducts which are not considered hazardous. The GHS classification is based on Regulation (EC) 1272/2008 (EU CLP) and OSHA 29 CFR 1910.1200, (United Nations ST/SG/AC 10/30 rev 3).

SECTION 4 - FIRST AID MEASURES

Description of first aid measures

Immediate Medical Attention Needed	No. If exposed and concerned: Get medical advice/attention.
Eye Contact	If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.
Skin Contact	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
Inhalation	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.
Ingestion	If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.
Protection of first aid responders	See Section 8 for Exposure Controls/Personal Protection recommendations.
Most important symptoms and effects, both acute and delayed	See Sections 2 and 11

Indication of immediate medical attention and special treatment needed, if necessary	Treat symptomatically and supportively. If accidental exposure occurs to an individual who is also taking one or more concomitant medications, consult the respective package or prescribing information for potential drug interactions.

SECTION 5 - FIREFIGHTING MEASURES

Extinguishing media	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
Specific hazards arising from the substance or mixture	No information identified. May emit toxic gasses such as carbon monoxide and carbon dioxide.
Flammability/Explosivity	High airborne concentrations of finely divided organic particles can potentially explode if ignited.
Advice for firefighters	Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated.
Environmental precautions	Do not empty into drains. Avoid release to the environment.
Methods and material for containment and cleaning up	For small spills (such as in a laboratory), soak up material with absorbent pads and wash spill area thoroughly with soap and water. For large spills in manufacturing, absorb liquid with an appropriate adsorbent. Do not raise dust. Eliminate ignition sources. Use only equipment suitable for use with combustible liquids. Place spill materials into a leak-proof container suitable for disposal. Dispose of material in a manner that is compliant with federal, state and local laws
Reference to other sections	See Sections 8 and 13 for more information.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling	Avoid contact with eyes and other mucous membranes. Wash thoroughly after handling. Use personal protective equipment. Avoid breathing vapor. Do not eat, drink or smoke while handling this product. Avoid prolonged or repeated exposure. Provide sufficient air exchange and/or exhaust in workrooms. Use normal preventative fire protection measures. Keep away from sources of ignition. Keep away from incompatible materials such as oxidizing agents.
Conditions for safe storage including any incompatibilities	Keep container tightly closed in a cool and well ventilated area. To maintain product quality, do not store in heat or direct sunlight.
Specific end use(s)	Cosmetic ingredient.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters/Occupational Exposure Limit Values

Compound	Issuer	Type	OEL
Squalane	--	--	--

DNEL/PNEC Limits

In the chemical safety assessment performed according to Article 14 in connection with Annex 1(Health, environmental and PBT/vPvB assessments), no hazard was identified. Therefore according to REACH, an exposure estimation is not necessary. Consequently all identified uses of the substance are assessed as safe for human health and environment.

Exposure/Engineering controls

Provide ventilation. Use local exhaust and/or enclosure at mist/ aerosol/spray-generating points. High-energy operations such as spraying should be done within an approved emission control or containment system. Remove ignition sources.

Respiratory protection

If adequate ventilation is unavailable, use a NIOSH approved N95 or P95 dust mask or an approved and properly fitted air-purifying respirator with organic vapor cartridge based on an assessment of risk and exposure level. Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls.

Hand protection

Wear nitrile or other impervious gloves if skin contact is possible as squalane may act as a vehicle for skin absorption of other toxic substances in the workplace.

Skin protection

Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Environmental Exposure Controls

Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release and to prevent inadvertent contact by personnel.

Other protective measures

Wash hands after handling substance especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors). Decontaminate all protective equipment following use.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance

Liquid

Color	Clear to Colorless
Odor	Odorless.
Odor threshold	No information identified.
pH	No information identified.
Melting point/freezing point	-38°C (-36.4°F) literature
Initial boiling point and boiling range	176°C (348°F) at 0.05 mm Hg; 210-215°C at 1.0 mm Hg, literature
Flash point	218 °C (424 °F) – closed cup
Evaporation rate	No information identified.
Flammability (solid, gas)	No information identified.
Upper/lower flammability or explosive limits	No information identified.
Vapor pressure	No information identified
Vapor density	No information identified.
Relative density	0.81 g/mL
Water solubility	Insoluble.
Solvent solubility	Soluble in alcohols.
Partition coefficient (*n-octanol/water*)	No information identified.
Auto-ignition temperature	No information identified.
Decomposition temperature	No information identified.
Viscosity	34 cP at 20°C, literature
Explosive properties	Non explosive.
Oxidizing properties	No information identified.
Other information	
Molecular weight	422.83
Molecular formula	$C_{30}H_{62}$

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	No information identified.
Chemical stability	Stable under recommended storage conditions.
Possibility of hazardous reactions	Not expected to occur.
Conditions to avoid	Keep away from heat, sparks, and open flame.

Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No information identified.

SECTION 11 - TOXICOLOGICAL INFORMATION

Information on toxicological effects

Route of entry	May be absorbed by inhalation, skin contact and ingestion.
Acute toxicity	Squalane is not considered acutely toxic. No adverse effects were noted in repeat dose studies on rats (Wistar) at dose rates >1000 mg/kg bw for up to 28 days.
Irritation/Corrosion	Squalane is considered non-irritating based on results from both skin and eye irritation testing carried out according to EPA OPPTS 870.2500 and 870.2400, respectively.
Sensitization	Squalane is not a dermal sensitizer based on results from Local Lymph Node Assay and Human Repeat Insult Patch Test with 100% squalane which showed no adverse effects.
STOT-single exposure	No studies identified.
STOT-repeated exposure/Repeat-dose toxicity	Squalane is not considered toxic from repeated exposure.
Reproductive toxicity	No adverse effect observed; NOAEL 1000 mg/kg bw/day (chronic; rat).
Developmental toxicity	No adverse effect observed; NOAEL 1000 mg/kg bw/day (chronic; rat).
Genotoxicity	Negative in an Ames bacterial cell mutagenicity assay.
Carcinogenicity	No studies identified. This substance is not listed by NTP, IARC, ACGIH or OSHA as a carcinogen.
Aspiration hazard	No
Human health data	See "Section 2 - Other Hazards"
Additional information	None available.

SECTION 12 - ECOLOGICAL INFORMATION

Toxicity

Compound	Type	Species	Concentration
Squalane	LC50 (96h)	*Danio rerio*	>100 mg/L
	NOEC (72h)	*Pseudokirchnerella subcapitata*	>100 mg/L
	LC50 (48h)	*Daphnia magna*	>100 mg/L

Additional toxicity information	No data available for the minor components.
Persistence and Degradability	Squalane is considered inherently biodegradable.
Bioaccumulative potential	No data available.

Mobility in soil	No data available.
Results of PBT and vPvB assessment	Based on the results of the chemical safety assessment, squalane is not a PBT/vPvB substance. It is inherently biodegradable and not toxic to aquatic species.
Other adverse effects	No data available.
Note	The environmental characteristics of this substance have not been fully investigated. Releases to the environment should be avoided.

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste treatment methods	Used product should be disposed of according to local, state, and federal regulations. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.

SECTION 14 - TRANSPORT INFORMATION

Transport	Based on the available data, this substance is not regulated as a hazardous material/ dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.
UN number	None assigned.
UN proper shipping name	None assigned.
Transport hazard classes and packing group	None assigned.
Environmental hazards	Based on the available data, this substance is not regulated as an environmental hazard or a marine pollutant.
Special precautions for users	Avoid release to the environment.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

SECTION 15 - REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture	This SDS complies with the requirements under US, EU and GHS (EU CLP - Regulation EC No 1272/2008) guidelines. Consult your local or regional authorities for more information.
Chemical safety assessment	Conducted.
OSHA Hazardous	Not hazardous.

WHMIS classification	This SDS contains the information required by WHMIS 2015 regulations.
US TSCA status	Listed on the TSCA inventory, 2016.
EU REACH status	Reach registration number: 01-2120014832-65-0007
Canada DSL	On DSL Supplement to Canada Gazette, Part I, January 26, 1991
China 2014 IECIC	Squalane
SARA section 313	Not listed.
California proposition 65	Not listed.

SECTION 16 - OTHER INFORMATION

Full text of R phrases and EU Classifications	Not applicable.
Full text of H phrases, P phrases and GHS classification	Not applicable.
Sources of data	Information from published literature and internal company data.
Abbreviations	ACGIH - American Conference of Governmental Industrial Hygienists ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail AIHA - American Industrial Hygiene Association CAS# - Chemical Abstract Services Number DNEL - Derived No Effect Level DOT - Department of Transportation EINECS - European Inventory of New and Existing Chemical Substances ELINCS - European List of Notified Chemical Substances EU - European Union GHS - Globally Harmonized System of Classification and Labelling of Chemicals IARC - International Agency for Research on Cancer IDLH - Immediately Dangerous to Life or Health IATA - International Air Transport Association IMDG - International Maritime Dangerous Goods LOEL - Lowest Observed Effect Level LOAEL - Lowest Observed Adverse Effect Level NIOSH - The National Institute for Occupational Safety and Health NOEL - No Observed Effect Level NOAEL - No Observed Adverse Effect Level NTP - National Toxicology Program OEL - Occupational Exposure Limit OSHA - Occupational Safety and Health Administration PBT - Persistent, Bioaccumulative and Toxic PNEC - Predicted No Effect Concentration SARA - Superfund Amendments and Reauthorization Act STEL - Short Term Exposure Limit TDG - Transport Dangerous Goods TSCA - Toxic Substances Control Act TWA - Time Weighted Average WHMIS - Workplace Hazardous Materials Information System
Revisions	This is the third version of this SDS.

Disclaimer

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a chemical product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.

APRINNOVA

A Joint Venture of Amyris & NIKKOL GROUP

Neossance™ Squalane – Certificate of Origin

Neossance Squalane is derived from farnesene that is produced from fermentation of sugar-based feedstock using an engineered, non-pathogenic, common strain of yeast, *Saccharomyces cerevisiae*, or *S. cerevisiae*. The wildtype strain of *S. cerevisiae* is engineered by Amyris in a targeted fashion to over-express the native yeast mevalonate pathway and produce farnesene, a sesquiterpene which is naturally occurring in some plants and insects. Our biotechnology process has been designed from plant to product to meet current environmental and health standards.

- **Non-GMO feedstock:** The feedstock we use to produce farnesene to make Neossance Squalane comes from non-GMO sources – for example, non-GMO sugarcane from Brazil and non-GMO sugar beets from Europe.

- **S. cerevisiae is regarded as safe to human health and the environment:** *S. cerevisiae* has an extensive history of industrial use and is considered a Risk Group 1 organism (not likely to cause adverse health effects in normal health adults; World Health Organization). It has been used for millennia in the manufacture of bread, beer, wine and other fermented beverages. Given its use in food, the United States Food and Drug Administration has classified *S. cerevisiae* and its extracts as "Generally Recognized as Safe" (FDA, 1986). Under the US Toxic Substance Control Act (TSCA), the *S. cerevisiae* as engineered by Amyris to produce farnesene has exempt status because, based on our assessment of the relevant regulatory criteria, these strains are considered to have low potential impact on human health and the environment.

- **Fully contained facilities:** All fermentation and processing operations involving Amyris-engineered *S. cerevisiae* are carried out in contained facilities. Any by-products or wastes from the process are fully deactivated prior to release to the environment.

- **Physical separation of product from our bio-process:** Our farnesene product is secreted by the modified yeast and easily separated from the cells and sugar fractions during processing. The farnesene is then further purified by distillation before use in the production of subsequent products such as Neossance Squalane. Tests for DNA from the modified yeast in the purified farnesene using polymerase chain reaction (PCR) have confirmed that the farnesene contains none of the Amyris-engineered yeast at or above 0.01%, the detection limit of the test.

5885 Hollis St. Emeryville, CA 94608
(510) 450-0761 info@aprinnova.com

Version 3, August 2017

F363(GC)v07en
Issued the: **20/12/2018**

Attestation n°: 846964

ATTESTATION OF CONFORMITY
- RAW MATERIALS -
ECOCERT COSMETICS

This attestation has been granted by ECOCERT Greenlife to the company:

APRINNOVA, LLC

5885 Hollis Street, Ste. 100
CA 94608 EMERYVILLE
UNITED STATES OF AMERICA

whose non-organic raw materials (listed hereafter) have been assessed as compliant to the current version of the ECOCERT standard:

NATURAL AND ORGANIC COSMETICS

This attestation of conformity has been issued on the basis of the terms and conditions for the verification of raw materials according to the ECOCERT standard defining Natural and Organic Cosmetics available on the ECOCERT website: http://www.ecocert.com and the conformity has been established according to the requirements related to the raw materials contained in this standard.

Issued in : L'Isle Jourdain,
the: 20/12/2018,

by: Matthieu Bouffartigue
Raw materials service manager

Valid until: 31/12/2019

ECOCERT Greenlife S.A.S. - Capital 50 000 € - BP 47 - 32600 L'ISLE JOURDAIN - FRANCE
TVA Intracommunautaire n° FR 55 509 534 095
Phone: +33 5 62 07 50 16 - Fax: +33 5 62 07 74 96 - Mail: mpgreenlife@ecocert.com

ECOCERT

ATTESTATION OF CONFORMITY - ECOCERT COSMETICS

List of the approved raw materials of: **APRINNOVA, LLC**

Nat : Natural or from natural origin
Veg: Physically processed vegetal ingredients
Synth: Synthetic (petrochemical)

Unless an exception, the following references are published on the ECOCERT raw materials online database for approved raw materials available at the following link: http://ap.ecocert.com/ecoproduits

Commercial name / INCI / Function	%Nat	%Veg	%Synth	Restriction	Approved since
Neossance™ Squalane *Squalane* Emollient	100	0	0		01/01/2019

Valid until: 31/12/2019

WARNING: The sole purpose of the present attestation is to allow the raw material(s) to be used in finished products to be certified as compliant to the standard specified in the first page. In no event this attestation should constitute proof of the actual certification of the conformity of the raw material(s) to this standard. In that context, the raw material(s) listed in this attestation must not be qualified and / or marketed as «organic» raw material(s) certified in accordance with the abovementioned standard.
The approval of the raw material (s) listed in the present attestation is personally addressed to the above-mentioned beneficiary. It is the beneficiary' s liability to ensure that its own customers are aware of the requirements and prohibitions defined in the terms and conditions and governing any reference to and use of the approval of the raw material(s) and that they abide by it.

ECOCERT Greenlife S.A.S. - Capital 50 000 € - BP 47 - 32600 L'ISLE JOURDAIN - FRANCE
TVA Intracommunautaire n° FR 55 509 534 095
Phone: +33 5 62 07 50 16 - Fax: +33 5 62 07 74 96 - Mail: mpgreenlife@ecocert.com

F363(GC)v09en
Issued the: **13/01/2020**

Attestation n°: 1004216

ATTESTATION OF CONFORMITY
- RAW MATERIALS -
ECOCERT COSMETICS

This attestation has been granted by ECOCERT Greenlife to the company:

APRINNOVA, LLC

5885 Hollis Street, Ste. 100
CA 94608 EMERYVILLE
UNITED STATES OF AMERICA

whose non-organic raw materials (listed hereafter) have been assessed as compliant to the current version of the ECOCERT standard:

NATURAL AND ORGANIC COSMETICS

This attestation of conformity has been issued on the basis of the terms and conditions for the verification of raw materials according to the ECOCERT standard defining Natural and Organic Cosmetics available on the ECOCERT website: http://www.ecocert.com and the conformity has been established according to the requirements related to the raw materials contained in this standard.

Issued in: L'Isle Jourdain,
the: 13/01/2020,

Emilie CHERHAL
ECOCERT Greenlife General Manager

Valid until: 31/12/2020

ECOCERT Greenlife S.A.S. - Capital 50 000 € - BP 47 - 32600 L'ISLE JOURDAIN - FRANCE
TVA Intracommunautaire n° FR 55 509 534 095
Phone: +33 5 62 07 50 16 - Fax: +33 5 62 07 74 96 - Mail: mpgreenlife@ecocert.com

ECOCERT

ATTESTATION OF CONFORMITY - ECOCERT COSMETICS

List of the approved raw materials of: **APRINNOVA, LLC**

Nat: Natural or from natural origin
Veg: Physically processed vegetal ingredients
Synth: Synthetic (petrochemical)

Unless an exception, the following references are published on the ECOCERT raw materials online database for approved raw materials available at the following link: http://ap.ecocert.com/ecoproduits

Commercial name / INCI / Function	%Nat	%Veg	%Synth	Restriction	Approved since
Neossance™ Squalane *Squalane* Emollient	100	0	0		01/01/2020

Valid until: 31/12/2020

WARNING: The sole purpose of the present attestation is to allow the raw material(s) to be used in finished products to be certified as compliant to the standard specified in the first page. In no event this attestation should constitute proof of the actual certification of the conformity of the raw material(s) to this standard. In that context, the raw material(s) listed in this attestation must not be qualified and / or marketed as «organic» raw material(s) certified in accordance with the abovementioned standard.
The approval of the raw material (s) listed in the present attestation is personally addressed to the above-mentioned beneficiary. It is the beneficiary' s liability to ensure that its own customers are aware of the requirements and prohibitions defined in the terms and conditions and governing any reference to and use of the approval of the raw material(s) and that they abide by it.

ECOCERT Greenlife S.A.S. - Capital 50 000 € - BP 47 - 32600 L'ISLE JOURDAIN - FRANCE
TVA Intracommunautaire n° FR 55 509 534 095
Phone: +33 5 62 07 50 16 - Fax: +33 5 62 07 74 96 - Mail: mpgreenlife@ecocert.com

APRINNOVA

A Joint Venture of Amyris & NIKKOL GROUP

Halal Statement

Emeryville, August 1st, 2017

Manufacturer: Neossance® Squalane is manufactured on behalf of:

Aprinnova, LLC.
5885 Hollis Street, Suite 100
Emeryville, CA 94608, USA
(510) 450-0761

Neither Aprinnova, LLC. nor any part of the supply chain have allowed contact with animals, animal-derived ingredients (i.e. milk, cheese, egg), grape or ethyl alcohol based ingredients. The equipment used to manufacture the product is not used for the manufacture of products containing animal or animal-derived ingredients.

Neossance Squalane is free of all the following:

- Swine/pork and its by-products
- Animals improperly slaughtered or dead before slaughtering
- Animals killed in the name of anyone other than ALLAH (God)
- Alcohol and intoxicants
- Carnivorous animals, birds of prey and land animals without external ears
- Blood and blood by-products
- Foods contaminated with any of the above products

APRINNOVA, LLC.

Signature _____

Howard T. Fuller – PhD, Vice President of Quality

Date 06-07-2017

5885 Hollis St. Emeryville, CA 94608
(510) 450-0761 info@aprinnova.com

Version 1, August 2017

APRINNOVA

A Joint Venture of Amyris & NIKKOL GROUP

Neossance® Squalane INCI Statement

Manufacturer:

Neossance Squalane is manufactured on behalf of:

Aprinnova, LLC.
5885 Hollis Street, Suite 100
Emeryville, CA 94608
(510) 450-0761

Product name: Neossance Squalane
INCI name: Squalane
IUPAC name: 2,6,10,15,19,23-Hexamethyltetracosane
CAS Number: 111-01-3

Neossance Squalane contains low levels of technically unavoidable byproducts, including isosqualane, monocyclosqualane, sesquisqualane, and hemisqualane. Since these low-level byproducts are not intentionally added, their INCI names are not specified.

APRINNOVA, LLC.

Signature _____
Howard T. Fuller – PhD, Vice President of Quality

Date AUG-02-2017

5885 Hollis St. Emeryville, CA 94608
(510) 450-0761 info@aprinnova.com

Version 2, August 2017

APRINNOVA

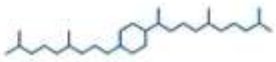
A Joint Venture of Amyris & NIKKOL GROUP

Neossance™ Squalane Indicative Compositional Breakdown

Manufacturer:
Neossance™ Squalane is manufactured on behalf of:

Aprinnova, LLC.
5885 Hollis Street, Suite 100
Emeryville, CA 94608
(510) 450-0761

The table below lists the indicative compositional breakdown of Neossance® Squalane.

COMPOUND	APPROXIMATE % COMPOSITION	STRUCTURE
SQUALANE	Average: 94.5% Maximum: 95.0%	
ISO-SQUALANE IMPURITY	Average: 4.2% Maximum: 4.3%	
MONOCYCLO-SQUALANE IMPURITY	Average: 1.2% Maximum: 1.7%	
SQUALANE RELATED OTHER IMPURITIES	<0.1%	

APRINNOVA, LLC.

Signature _____

Howard T. Fuller – PhD, Vice President of Quality

Date AUG-02-2017

5885 Hollis St. Emeryville, CA 94608
(510) 450-0761 info@aprinnova.com

Version 4, August 2017

APRINNOVA

A Joint Venture of Amyris & NIKKOL GROUP

Neossance Squalane ISO 16128 Compliance & Natural Origin Index

Neossance Squalane is compliant with IS0 16128-1 and has a natural origin index of 1.00 per ISO 16128-2, determined by renewable carbon content.

Aprinnova confirms that Neossance Squalane adheres to International Standard ISO 16128-1 (1st edition/2016-02-15), Guidelines on technical definitions and criteria for natural and organic cosmetics ingredients and products – Part 1: Definitions for Ingredients and ISO 16128-2 (1st edition/2017-09), Cosmetics – Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients – Part 2: Criteria for ingredients and products

ISO 16128-1 provides international guidelines on definitions and criteria for natural and organic cosmetic ingredients and products which are fully applicable to Neossance Squalane.

ISO 16128-2 provides international guidelines on the calculation of natural and organic origin index for cosmetic ingredients and products which are fully applicable to Neossance Squalane.

Stephanie Muni

Manager, Scientific & Regulatory Affairs

5885 Hollis St. Emeryville, CA 94608
(510) 450-0761 info@aprinnova.com

Version 2, July 2019

APRINNOVA

A Joint Venture of Amyris & NIKKOL GROUP

Neossance Squalane ISO 16128 Compliance & Natural Origin Index

Neossance Squalane is compliant with IS0 16128-1 and has a natural origin index of 1.00 per ISO 16128-2, determined by renewable carbon content.

Aprinnova confirms that Neossance Squalane adheres to International Standard ISO 16128-1 (1st edition/2016-02-15), Guidelines on technical definitions and criteria for natural and organic cosmetics ingredients and products – Part 1: Definitions for Ingredients and ISO 16128-2 (1st edition/2017-09), Cosmetics – Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients – Part 2: Criteria for ingredients and products

ISO 16128-1 provides international guidelines on definitions and criteria for natural and organic cosmetic ingredients and products which are fully applicable to Neossance Squalane.

ISO 16128-2 provides international guidelines on the calculation of natural and organic origin index for cosmetic ingredients and products which are fully applicable to Neossance Squalane.

Stephanie Muni

Manager, Scientific & Regulatory Affairs

5885 Hollis St. Emeryville, CA 94608
(510) 450-0761 info@aprinnova.com

Version 2, July 2019

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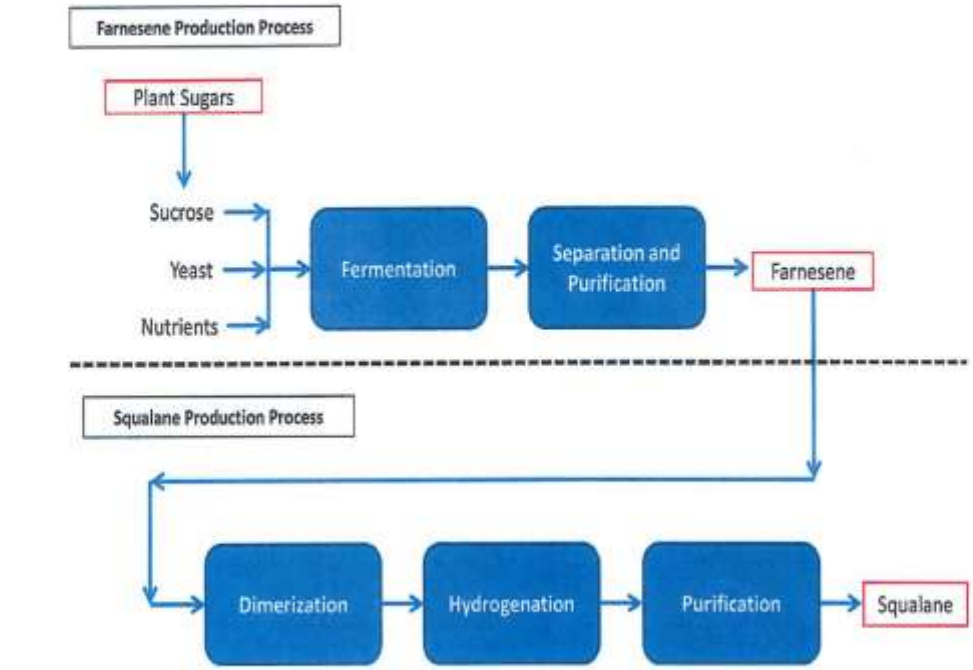
Neossance™ Squalane Manufacturing Process



Signature _____ Date Aug-02-2017

5885 Hollis St. Emeryville, CA 94608
(510) 450-0761 info@aprinnova.com

Version 3, August 2017

APRINNOVA

A Joint Venture of Amyris & NIKKOL GROUP

Product Declaration Statement

Product: Neossance™ Squalane

The undersigned attests to the accuracy of the Product composition as follows:
The Product;

- is derived from ingredients of plant sugars and does not contain or come into contact with any ingredients of animal origin. It is therefore considered to be non-animal derived and BSE/TSE free. The product does not contain any sugars.
- is not a fragrance and does not contain any of the 26 fragrance allergens as listed in the EU Cosmetic Directive.
- is manufactured in the United States of America.
- is in compliance with the European Union Cosmetic Directive for no animal testing.
- does not contain any California Proposition 65 listed chemicals.
- does not contain any GMO (Genetically Modified Organisms).
- does not contain any wheat proteins and is gluten-free.
- does not contain any food allergens.
- does not contain any pesticides.
- does not contain any paraben substances, nor any other preservatives.
- does not contain any Carcinogens, Mutagens, nor Reprotoxic (CMR) substances.
- does not contain metals.
- does not contain any Nano-particles.

Fernando J. Garcia

Senior Director, Scientific and Regulatory Affairs

5885 Hollis St. Emeryville, CA 94608
(510) 450-0761 info@aprinnova.com

Version 2, August 2017

APRINNOVA

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Product Requirements Statement for Neossance® Squalane

Aprinnova, LLC. confirms that Neossance Squalane meets the following requirements:

- **Animal-Derived Material (ADM) / HALAL / KOSHER**
  Neither Aprinnova, LLC. nor any part of the supply chain have allowed contact with animals, animal-derived ingredients (i.e. milk, cheese, egg), grape or ethyl alcohol based ingredients. The equipment used to manufacture the product is not used for the manufacture of products containing animal or animal-derived ingredients.

- **Animal Testing**
  Aprinnova has not conducted testing of this product as a cosmetic ingredient on animals in compliance with 7th Amendment to the European Cosmetics Directive 76/768/EEC related to the replacement of animal tests, and its following recast: Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products – Chapter V – Art. 18.

- **Bovine Spongiform Encephalopathy (BSE) / Transmissible Spongiform Encephalopathy (TSE)**
  Neither the product nor any raw material used in the process contains any ingredient or component made of ruminant extracts or ruminant derivatives.

- **Carcinogens, Mutagens, and Reproductive toxins**
  This product is in compliance with CMR regulation (Compliance Regulation (EC) No 1223/2009 of the European Parliament and the Council of 30 November 2009 on cosmetics products (recast) Chapter IV restrictions for certain substances – Article 15 Substances classified as CMR substances and subsequent amendment (EU) 2019/831). By the criteria outlined in CLP 1272/2008, this product does not contain any substances classified as 1A, 1B or 2 CMRs.

  The Chain of Custody is known and the presence of carcinogens are not expected in the materials from which the product is derived.

- **Conflict Minerals**
  The product does not contain any of the elements present in Conflict Minerals (cassiterite, wolframite, columbite-tantalite and gold), also known as, tin, tungsten, tantalum, and gold.

- **Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) and IUCN Red List**
  The product does not contain any species listed in CITES or listed in IUCN Red list.

- **Environmental Endocrine Disrupters (EDD)**
  Environmental Endocrine Disrupters such as alkylphenol & alkylphenol ethoxylates and nonylphenol & nonylphenol ethoxylates are not expected to be present, based on our production process, raw materials and equipment used. However, we do not test this product for EDD.

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- **Food Allergens in the EU** (Directive 2007/68/EC of 27 November 2007 amending Annex IIIa of Directive 2000/13/EC of the European Parliament)
  Food Allergens analysis was performed to determine the presence or absence of allergens listed in the European Union Directive mentioned above (Almonds, Brazil nut, Cashew nut, Celery, Crustaceans, Fish, Gluten, Hazelnut, Lupin, Macadamia nut or Queensland nut, Mollusks, Mustard, Peanut, Pecan nut, Pistachio, Sesame, Soya, Walnut, Sulphites expressed in sulphur dioxide, Lactose, Egg proteins, Caseins and serum proteins). None of these allergens were detected (detection limit varies, depending on the allergen, from 0.4 to 10 ppm) with the exception of Lactose which did not report a detection limit and was reported as <0.01%, which is below the quantitation limit.

- **Fragrance Allergens in the EU** (Annex III part 1 and Annex VIII, 7th Amendment Cosmetic Directive, 2003/715/EC, on the basis of the SCCNFP/0017/98 publication and subsequent amendment 1223/2009/EC).
  Allergens analysis was performed by gas chromatography/mass spectrometry to determine the presence or absence of 26 allergens listed in the European Union Directive mentioned above. None of the 26 listed allergens were detected with limit of detection of 5 ppm.

- **General compliance with US and EU cosmetic laws**
  Sales of this product are allowed in the EU in compliance with the Council directive 76/768/EEC of 27 July 1976 & Regulation (EC) No 1223/2009 of European Parliament and of the Council of 30 November 2009 on cosmetic products. Sales of this product are allowed in the US in compliance with the Federal Food, Drugs and Cosmetics Act (FDA&C Act) and its subsequent amendments on or before the date this statement was prepared.

- **Genetically Modified Organism (GMO)**
  The product is not a Genetically Modified Organism and does not contain any GMOs.

- **Irradiation / Ionization**
  This product is neither irradiated nor ionized.

- **Metals**
  Aprinnova's manufacturing specification sets limits for the following metals:

Arsenic:	1 mg/L
Nickel:	1 mg/L
Cadmium, Chromium, Lead, Mercury:	Combined limit of 10 mg/L

To ensure we are within these specification limits and to verify the robustness of our quality processes, Aprinnova routinely analyzes for the following metals, with the detection limits indicated as follows:

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(510) 450-0761 info@aprinnova.com

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Metal	Detection Limit (units = mg/L, unless otherwise indicated)
Aluminum	50
Antimony	0.5
Arsenic	0.5
Barium	5
Beryllium	0.5
Cadmium	0.25
Chromium	0.5
Cobalt	0.5
Copper	0.5
Iron	20
Lead	0.5
Mercury	0.05
Molybdenum	0.5
Nickel	0.5
Selenium	0.5
Palladium	0.01 (mg/Kg)
Silver	0.5
Sodium	100
Thallium	0.5
Vanadium	0.5
Zinc	5

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- **Microbiological properties**

Bacteria/organisms	Specifications
Total Aerobic Bacteria	< 100 CFU/g
Total Yeast and Molds	< 100 CFU/g
Staphylococcus aureus	Absent
Pseudomonas aeruginosa	Absent
Candida albicans	Absent

- **Nanoparticles** (*Cosmetics Regulation (EC) No 1223/2009/CE, French Decree n°2012-232, European recommendations 2011/696/UE)*
  Nanoparticles are not expected to be present, based on our production process, raw materials and equipment used. However, we do not analyze for nanoparticles.

- **Natural/Biobased**
  Neossance Squalane, a product of fermentation, comes entirely from bio-based feedstock: plant sugars, such as sugarcane. It is certified as 100% bio-based by the United States Department of Agriculture BioPreferred® Program and conforms to ECOCERT's natural cosmetic standard.

- **Non-comedogenicity**
  This product has been dermatologist-tested to determine tendency to form sebum plugs (comedones/blackheads) in openings of the sebaceous glands. Neossance Squalane has been determined to be non-comedogenic (does not clog pores).

- **Palm Oil and Palm Oil Derivatives**
  Neossance Squalane does not contain palm oil or palm oil derivatives. Palm oil and its derivatives are not used in any part of the manufacturing process.

- **Pesticides**
  Pesticides analysis was performed using US Environmental Protective Agency (EPA) methods 8081A (Organochlorine Pesticides by GC-ECD), 8041Am (Organophosphorous Pesticides by GC-MS), 8151A (Chlorinated Herbicides by GC-ECD), 8270 (Semi-Volatile Organics) and 8318 (Carbamates by HPLC). Pesticides were not detected (detection limits vary depending on the method used; 0.1- 5000 mg/L).

- **Phthalates**
  Phthalates are not expected to be present based on our production process, raw material and equipment used. However, we do not test this product for phthalates. The container for transportation is a High Density Polyethylene – natural tank. Phthalates are not used in the manufacture of or the formulation of the container. However, the supplier does not test this product for phthalates.

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- **Polycyclic Aromatic Hydrocarbons (PAHs)**
  The presence of polycyclic aromatic hydrocarbons (PAHs) is not expected based on our production process, raw materials and equipment used.

- **Preservatives and Formaldehyde Releasers**
  This product contains no preservatives, specifically no formaldehyde releasing preservative listed in the Annex VI of the European Cosmetic Directive or Annex V of the European Cosmetic Regulation.

- **Sulfate Compounds/Sulfates**
  Sulfate compounds/Sulfates are not expected to be present based on our production process, raw materials and equipment used.

- **REACH Registration**
  The European Union regulates import and manufacture of chemicals under the Registration, Evaluation, Authorisation and Restriction of Chemicals regulation, or REACH. Neossance Squalane is registered for Aprinnova by Amyris's Only Representative, Penman Consulting bvba, for quantities of 100 to < 1000 tonnes per year for use in cosmetic formulations.

- **REACH Substances of Very High Concern**
  As of the revision date of this document, the product does not contain any of the substances of very high concern listed on the most current candidate or intentions lists published on ECHA's websites (http://echa.europa.eu/candidate-list-table;http://echa.europa.eu/fr/registry-of-current-svhc-intentions).

- **Residual Solvents**
  Isopropanol residual solvent analysis was performed by derivatization followed by HPLC. Isopropanol was not detected with limit of detection of 0.5 mg/L.

- **Volatile Organic Compounds** (VOC according directive 1999/13/EC amended 2004/42/EC & Switzerland Ordinance RS 814.018)
  Volatile Organic Compounds are not expected to be present, based on our production process, raw materials and equipment used. However, we do not test this product for VOCs.

The following substances are not expected to be present, based on our production process, raw materials and equipment used:

➢ **Chemicals**

Oxides	Butylene oxide
	Ethylene oxide
	Propylene oxide
Amines	Free amines
	Melamine
	Nitrosamines

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	Halogens	Iodine and derivatives
	Other chemicals	1,4 – Butanediol 1,4 – Dioxane Butylated hydroxyanisole (BHA) Butylated hydroxytoluene (BHT) Camphor, Menthol, Eucalyptol Dimethyl sulfoxide (DMSO) Dioxin Dyes Essential oils Ethanol Formaldehyde Fragrances Furfural Glycol ethers Hydroquinone Iodopropynyl Butyl Carbamate (IPBC) Musk Xylene; Musk Xylol Oxybenzone Parabens Phenoxyethanol pH adjusters Polyaminopropyl Biguanide (PHMB) Retinyl Palmitate Titanium dioxide (TiO2/CI 77891) Triclosan (TCS), Triclocarban UV Filters
➢	**Materials and minerals**	Asbestos Coal Mineral Oil Nanomaterial Natural Rubber Latex Palladium Silicone Tar
➢	**Food Allergens**	Apple Banana Buckwheat Corn

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Version 28, August 2019

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	Dioscorea japonica Kiwi Fruit Orange Peach Rice Rye Wheat
➢ **Fragrance Allergens**	Hydroxyl- Isohexylcyclohexene Carboxaldehyde (HICC) Atranol Chloroatranol
➢ **Biological Molecules and Organisms**	Aflatoxins, Mycotoxins, Ochratoxins and organisms Antibiotics Antineoplastic agents Fungi Growth promoters Hormones Melanin Mycoplasmas Narcotics Polyunsaturated Fatty Acids Proteins and wheat proteins Psychotropic agents Steroids

5885 Hollis St. Emeryville, CA 94608
(510) 450-0761 info@aprinnova.com

Version 28, August 2019

APRINNOVA

A Joint Venture of Amyris & NIKKOL GROUP

November 2017

Regarding: REACH Registration

Dear Neossance ™ Squalane Customers:

Please be advised that Neossance™ Squalane has been REACH-registered by Aprinnova's Only Representative, Penman Consulting BVBA, for quantities of greater than 100 tonnes for use in cosmetic formulations. The registration number is 17-2120602193-69-0000.

Thank you for choosing Neossance ™ Squalane.

Sincerely,

Fernando J. Garcia
Senior Director, Scientific and Regulatory Affairs

5885 Hollis St. Emeryville, CA 94608
(510) 450-0761 info@aprinnova.com

Version 4, November 2017

APRINNOVA

A Joint Venture of Amyris & NIKKOL GROUP

Neossance® Squalane Regulatory Status

Manufacturer:

Neossance Squalane is manufactured on behalf of:

Aprinnova, LLC.
5885 Hollis Street, Suite 100
Emeryville, CA 94608
(510) 450-0761

Product name: Neossance Squalane
INCI name: Squalane
IUPAC name: 2,6,10,15,19,23-Hexamethyltetracosane
CAS Number: 111-01-3

There are no known regulatory restrictions of Neossance Squalane. Neossance Squalane appears on the following regulatory inventories:

Country/List	Identifier	Comments
Australia: Present on AICS	Tetracosane, 2,6,10,15,19,23-hexamethyl-	
Canada: Present on DSL	Tetracosane, 2,6,10,15,19,23-hexamethyl-	
China: Present on IECSC	角鲨烷	
China: Present on IECIC (2015)	角鲨烷 (Squalane)	
European Union: REACH registered	CAS 111-01-3 Registration number: 17-2120602193-69-0000	Registered by Aprinnova's Only Representative for >100 tonnes/year
Japan: Present on ENCS	(9)-1317	
Korea: Present on KFDA	스쿠알란	
Korea: Present on KECI/KECL	KE-18620	
Mercosur: List of substances that cannot be used in personal hygiene products, cosmetics and perfumes		No known restrictions
Mexico: Present on INSQ Inventory		2012
New Zealand: Present on NZIoC	Tetracosane, 2,6,10,15,19,23-hexamethyl-	
Phillippines: Present on PICCS	Tetracosane, 2,6,10,15,19,23-hexamethyl-	
Russia: *TR TS 009/2011*		No known restrictions
United States: Present on TSCA inventory	CAS 111-01-3	

APRINNOVA, LLC.

Signature Fernando J. Garcia

Fernando J. Garcia, Senior Director, Scientific and Regulatory Affairs

Date 2 August 2017

5885 Hollis St. Emeryville, CA 94608
(510) 450-0761 info@aprinnova.com

Version 2, August 2017

APRINNOVA

A Joint Venture of Amyris & NIKKOL GROUP

Sales Specification[1]

Neossance Squalane

Product name: Neossance Squalane
Product CAS number: 111-01-3
IUPAC name: 2,6,10,15,19,23-hexamethyltetracosane

Test Description	Specification Limits Minimum	Maximum	Unit of Measure	Test Method
Purity by Gas Chromatography	92		Area %	SOP00188A
Density @ 20 °C	0.806	0.811	g / cm^3	SOP00222A
Refractive Index @ 20 °C	1.449	1.453		SOP00222A
Iodine Value		2	g I_2 / 100 g	SOP00218A
Acid Value		0.5	mg KOH / g	SOP00195A
Odor	Nearly odorless			SOP00194A
Total Ash		0.1	Percent	SOP00223A
Appearance and Color	Colorless liquid			SOP00221A

Notes:
Note 1 - These tests will be run on all commercial lots of Neossance Squalane and are required for product release for shipment.

Specification Revision Number: 8
Specification Revision Date: 18 August 2017

5885 Hollis St. Emeryville, CA 94608
(510) 450-0761 info@aprinnova.com

APRINNOVA

A Joint Venture of Amyris & NIKKOL GROUP

Neossance® Squalane Statement of Continuity

Manufacturer:

Neossance Squalane is manufactured by:

Aprinnova, LLC.
5885 Hollis Street, Suite 100
Emeryville, CA 94608
(510) 450-0761

The manufacturing entity has changed to Aprinnova, LLC. Aprinnova is a joint venture between Amyris and Nikkol Group. Neossance Squalane is being manufactured at the same facility in Leland, NC, with no changes to the manufacturing or quality processes.

AMYRIS, INC.

Signature _____

Howard T. Fuller – PhD, Vice President of Quality

Date July-27-2017

APRINNOVA, LLC.

Signature _____

Ro Oteri, General Manager

Date July 25, 2017

5885 Hollis St. Emeryville, CA 94608
(510) 450-0761 info@aprinnova.com

Version 2, July 2017

APRINNOVA

A Joint Venture of Amyris & NIKKOL GROUP

Technical Data Sheet - Neossance™ Squalane

Product name: Neossance™ Squalane
CAS number: 111-01-3
EINECS number: 203-825-6
IUPAC name: 2,6,10,15,19,23-hexamethyltetracosane
INCI name: Squalane

Molecular formula: $C_{30}H_{62}$
Molecular weight: 422.81

Product Description

Neossance™ Squalane is sustainably sourced from sugarcane. It is one of the highest quality and most versatile emollients on the market due to its sensorial profile, biocompatibility and consistently robust composition. It is a non-polar, fully saturated and very stable hydrocarbon that is easily incorporated into emulsions, and is compatible with most cosmetic ingredients. It is an excellent moisturizer, keeping your skin and your hair properly hydrated and imparting suppleness and flexibility to the skin.

Typical Properties

Test Description	Typical Value	Unit of Measurement
Squalane Content by GC	96	weight %
Density @ 20 °C	0.810	g/cm^3
Refractive Index @ 20 °C	1.452	
Iodine Value	< 0.2	g I_2/100 g
Acid Value	< 0.1	mg KOH/g
Total Ash	< 0.1	%
Appearance and Color	Colorless liquid	
Odor	Nearly odorless	
Saponification Value	< 0.2	
Viscosity @ 20°C	35	cP
Surface Tension @ 20°C	28.9	mN/m
Flash Point	218	°C
Pour Point	< -55	°C

The typical properties and ranges shown are typical values, not for specification purposes. For sales specifications, please contact your local sales representative.

Quality Compliance

5885 Hollis St. Emeryville, CA 94608
(510) 450-0761 info@aprinnova.com

Version 3, August 2017

APRINNOVA

A Joint Venture of Amyris & NIKKOL GROUP

Neossance Squalane is manufactured in accordance with ISO 22716 Cosmetics Good Manufacturing Practices (GMP).

Peace of Mind Ingredient

Sustainability	Features and Benefits	Proven Performance**
· Derived from plant sugar · Renewable source · Biodegradable · ECOCERT-approved · USDA certified 100% Bio-based	· Consistent composition · Non-polar, fully saturated · Stable to heat, cold, oxidation · Chemically inert · Non-comedogenic · Non-irritating · Non-sensitizing	· Increases cell turnover · Provides long-lasting moisturization · Decreases skin roughness · Reduces the appearance of fine lines and wrinkles · Improves skin elasticity · Provides heat protection and strengthens hair · Penetrates the hair shaft

Applications

Skin, hair, sun and body care, makeup, cleansers

Recommended Usage	up to 100%
Required HLB	12 ± 1
Solubility	Oil soluble; water insoluble
Spreadability	Good
Compatibility	Compatible with silicones, lipophilic ingredients
Polarity	Non-polar

Storage and Packaging

Shelf-life and Storage	36 months in unopened, original packaging; stored in a dry and mild environment at ambient temperature, and away from heat sources and light
Packaging	17 kg (Jerricans), 164 kg (Drums), 832 kg (Totes)

Regulatory Status

There are no known regulatory restrictions of Neossance Squalane. Squalane appears on the following regulatory inventories:

Country/List	
Australia: AICS	Mexico: INSQ
Canada: DSL	New Zealand: NZIoC
China: IECSC, IECIC (2015)	Philippines: PICCS
European Union: REACH registered	Russia: TR TS 009/2011
Japan: ENCS	United States: TSCA
Korea: KFDA, KECI/KECL	

5885 Hollis St. Emeryville, CA 94608
(510) 450-0761 info@aprinnova.com

Version 3, August 2017

APRINNOVA

A Joint Venture of Amyris & NIKKOL GROUP

**Purchasers of Neossance Squalane from Aprinnova are solely responsible for ensuring compliance of their cosmetic products with all applicable regulatory requirements, including claims regarding the effect of Squalane on skin and hair.

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Vegan and Vegetarian Certificate

Aprinnova guarantees that our Neossance™ range of products does not and will not contain ingredients or sourced raw materials that contain animal products or animal by-products. Our products and sourced raw materials are not and will not be processed using processing aids that contain animal products or animal by-products.

For the purposes of this statement, the word "animal" refers to the entire Animal Kingdom, that is all vertebrates and all multi-cellular invertebrates.

APRINNOVA, LLC.

Signature _____

Howard T. Fuller – PhD, Vice President of Quality

Date 04 January 2019

5885 Hollis St. Emeryville, CA 94608
(510) 450-0761 info@aprinnova.com

Version 2, January 2019

201

Niacinamide
Safety Data Sheet
According to the federal final rule of hazard communication revised on 2012 (HazCom 2012)

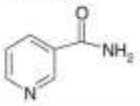
Date of compilation	:	March 06, 2012
File Name	:	0014Bh Ghs11 Div.4 sds Niacinamide
Revision Number	:	11
Date of Issue of SDS	:	January 15, 2018
Revision Due Date	:	December, 2019
Supersedes date	:	February 3, 2017
Supersedes version	:	0014Bh Ghs10 Div.4 sds Niacinamide

Niacinamide
Safety Data Sheet
According to the federal final rule of hazard communication revised on 2012 (HazCom 2012)

SECTION 1: PRODUCT IDENTIFICATION

1.1. Identification

PRODUCT NAME	: Niacinamide
CAS RN	: 98-92-0
EC#	: 202-713-4
SYNONYMS	: 3-Pyridinecarboxamide, Niacinamide, Nicotinamide , 3-Carbamoylpyridine, 3-Pyridinecarboxamide, Vitamin B, beta-Pyridinecarboxamidem-(Aminocarbonyl)pyridine
SYSTEMATIC NAME	: 3-Pyridinecarboxamide
MOLECULAR FORMULA	: $C_6H_6N_2O$
STRUCTURAL FORMULA	



1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Niacinamide is used as a nutrient supplement in Pharmaceutical products. It has been used in the enrichment of bread, flour, and other grain-derived products. Animal feed is routinely supplemented with nicotinamide. It is also used in multi-vitamin preparations and dietary supplement. It is used in the treatment of pellagra.

Uses advised against: None

1.3. Details of the supplier of the safety data sheet

Jubilant Life Sciences Limited
FACTORY & REGISTERED OFFICE: Jubilant Life Sciences Ltd.Unit-1Plot No. P1-L1 within Jubilant Sector Specific SEZ for Chemicals at Plot No-5 Vilayat GIDC, Tal-Vagra,Dist.-Bharuch-392012Gujarat,IndiaTel: +91-2641-281500, 281507 Fax: +91-2641-281515

HEAD OFFICE: Jubilant Life Sciences Ltd., Plot 1-A, Sector 16-A, Institutional Area, Noida, Uttar Pradesh, 201301 – India
T +91-120-4361000 - F +91-120-4234881 / 84 / 85 / 87 / 95 / 96 support@jubl.com-www.jubl.com

1.4. Emergency telephone number

CHEMTEL 24-HOUR EMERGENCY TELEPHONE NUMBERS (Contract No. MIS9454477):
North America: 1-800-255-3924
International: +1-813-248-0585
India: 000-800-100-4086
Brazil: 0-800-591-6042
Mexico: 01-800-099-0731

SECTION 2: HAZARD(S) IDENTIFICATION

2.1. Classification of the substance or mixture
GHS-US classification
Serious Eye Damage/ Eye Irritation: Category 2A

2.2. Label Elements

Hazard Pictogram: GHS 07.

Signal Word: Warning!

HAZARD AND PRECAUTIONARY STATEMENTS:
HAZARD STATEMENTS

- H319: Causes serious eye irritation.

PRECAUTIONARY STATEMENTS

- P264: Wash hands, eyes and face thoroughly after handling.
- P280: Wear protective gloves/clothing and eye/face protection.

- P305 + P351 + P338: IF IN EYES, Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rising.
- P337 + P313: If eye irritation persists: Get medical advice/attention
- P405: Store locked up
- P501: Dispose of contents/container in accordance with local/regional/national/ international regulations.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical	CAS #	Purity	GHS-US classification
Niacinamide	98-92-0	~100%	Serious Eye Damage/ Eye Irritation: Category 2A

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Key symptoms

Acute effects:

- In contact with eyes, it causes serious eye irritation and redness of eyes.

Chronic effects:

- Affects the kidneys, eyes & liver.

FIRST AID:

- **Eyes**: If in eyes rinse cautiously with water for at least 15 minutes. Remove contact lenses if easy to do so. Continue rinsing. Seek medical attention.
- **Skin:** Immediately take off all contaminated clothing. Wash thoroughly with water for at least 15 minutes. Wash contaminated clothes before reuse. Seek immediate medical attention.
- **Inhalation**: Remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if you feel unwell. Monitor for respiratory distress. Apply artificial respiration if not breathing. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Toxic vapours may be released on thermal decomposition including nitrogen oxides, carbon monoxide and cyanide.
- **Ingestion**: If swallowed call a poison center if you feel unwell. Rinse mouth. Do NOT induce vomiting by use of emetics. Seek medical attention.

SECTION 5 : FIRE-FIGHTING MEASURES

Extinguishing media

- *Appropriate extinguishing media*: Dry chemical powder, carbon dioxide, and alcohol resistant foam. Water may be in effective. Water sprays can be effective in cooling down the fire-exposed containers and knocking down the vapours. Water jets may be used to flush spills away and dilute the same to non-flammable mixtures fog or alcohol-resistant foam by directing streams to the periphery of the fires to prevent spread.Do not permit water to get inside containers.

Special Protective Equipment and Precautions for Fire Fighter

- Evacuate the area and fight fires from a safe distance.
- If tank, rail car or tank truck is involved in a fire, ISOLATE for 800 meters (1/2 mile) in all directions; also, consider initial evacuation for 800 meters (1/2 mile) in all directions or as per locally valid procedures.
- Fire fighters must wear Self Contained Breathing Apparatus (SCBA) and full protective clothing. The chemical is harmful in contact with skin.
- Report any run-off of fire waters contaminated with this chemical as per local and federal procedures applicable.

Unusual fire and explosion hazard

- Toxic vapors may be released on thermal decomposition including nitrogen oxides, carbon monoxide and cyanide.
- High vapor concentration may result in an explosion hazard.
- Vapors are heavier than air. May travel considerable distance from source and flashback.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

- **Minor Spills**
- Clean up all spills immediately following relevant Standard Operating Procedures.
- Avoid breathing vapors and contact with skin and eyes.
- Shut off leak source if possible.
- Shut off all possible sources of ignition.
- Wear protective clothing, boots, impervious gloves and safety glasses.
- Wipe up.
- Decontaminate all equipment.
- Use non-sparking tools.

Major Spill

- Alert Emergency Responders and tell them location and nature of hazard.
- Shut off all possible sources of ignition and increase ventilation.
- Wear protective clothing, full boots, impervious gloves, safety glasses and Self Contained Breathing Apparatus (SCBA), as may be deemed appropriate.
- Clear area of personnel and move upwind.
- Stop leaks if possible.
- Prevent, by any means available, spillage from entering drains or water and watercourses.
- Collect recoverable product into labeled containers for recycling, recovery or disposal.
- Contain spill with sand, earth or vermiculite.
- Spread area with lime or absorbent material, and leave for at least 1 hour before washing.
- Clean up all tools and equipment.
- Inform authorities in event of contamination of any public sewers, drains or water bodies.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling

- Do not breathe vapor or mist.
- Wear protective gloves/clothing and eye/face protection.
- Wash thoroughly after handling.
- Ground and secure containers when dispensing or pouring product.
- Avoid contact with incompatible materials.
- When handling, DO NOT eat, drink or smoke.
- Launder contaminated clothing before re-use.
- If on skin or hair, IMMEDIATELY remove all contaminated clothing and rinse/shower with plenty of water.
- Use in a well-ventilated place/Use protective clothing commensurate with exposure levels.
- Use non-sparking tools.

Storage

- Store in a cool, well ventilated place.
- Store in a flame proof area.
- Store away from incompatible materials.
- Keep only in original container.
- Keep securely closed when not in use.

SECTION 8 : EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

- **Exposure Limits Values**

Chemical name	ACGIH	NIOSH	OSHA-Final PELs
Niacinamide	None Listed	None Listed	None Listed

Exposure Limits (International):

- **OEL-RUSSIA:** STEL 1 mg/m^3

Exposure Controls

- Provide exhaust ventilation or other engineering controls to keep the relevant airborne concentrations below their respective occupational exposure limits. Local ventilation is usually preferred. Ensure that eyewash stations and safety showers are close to the workstation location.

Personal Protection:

- Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled. The resistance of the protective clothing to chemicals should be ascertained with the respective supplier.
- **Eyes**: Safety goggles/ Chemical Safety glasses and Face shield.
- **Clothing**: Boots and clothing to prevent contact.
- **Respirator**: Follow the OSHA respirator regulations found in 29CFR 1910.134 or European Standard EN 149. Always use a NIOSH or European Standard EN 149 approved respirator when necessary.
- For emergency situations, wear a positive pressure, pressure-demand, full face piece self- contained breathing apparatus (SCBA) or pressure-demand supplied air respirator with escape SCBA and a fully-encapsulating, chemical resistant suit. (EPA, 1998).
- **Hand protection:**
  - **In full contact:**
    - Glove material: nitrile rubber
    - Layer thickness: 0.11 mm
    - Breakthrough time: > 480 Min.

In Splash contact:
Glove material: nitrile rubber
Layer thickness: 0.11 mm
Breakthrough time: > 480 Min.

The protective gloves to be used must comply with the specifications of EC directive 89\686/EEC and the resultant standard EN374, for example KCL 740 Dermatril® (full contact), 740 Dermatril® (splash contact).

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

- **Information on basic physical and chemical properties.**

Sr.No.	Parameter	Typical value
1	Appearance	White crystalline powder
2	Odor	Odorless
3	Odor Threshold	Not available
4	Melting point	128-131°C
5	Boiling point	157 deg C at $5X10^{-4}$ mm Hg
6	Flash point	182°C
7	Evaporation rate (n-BuAc=1)	Not available
8	Explosive limits	Not available
9	Vapor pressure	$4.2X10^{-4}$ mm Hg at 25 deg C (est)
10	Vapor density (air=1)	Not available
11	Specific gravity (water=1)	1.400 at 25 deg C
12	Solubility	Freely soluble in water and in alcohol. Soluble in Glycerin.
13	PH @ 5%aq solution water at 25°C	5.35 to 5.5
14	Log Kow (octonol/water)	-0.37 (estimated)
15	Auto-ignition temperature	480°C
16	Decomposition temperature	>140°C
17	Viscosity	Not available
18	Bulk density	~360 Kg/m^3
19	Molecular Weight	122.12
20	pKa (@20°C)	3.35
21	Koc	51.56 (estimated)
22	Flammable material	No
23	Oxidizer	No
24	Pyrophoric material	No
25	Explosive material	No

SECTION 10: STABILITY AND REACTIVITY

- **Reactivity:** It is a crystalline white solid. It is odorless and soluble in water.
- **Stability:** Stable under normal temperatures and conditions.
- **Conditions to avoid:** Dust generation.
- **Incompatible chemicals:** Strong acids and bases, strong oxidizing agents.
- **Hazardous decomposition:** Burning may produce hazardous combustion gases like Nitrogen oxides, carbon monoxide, carbon dioxide.
- **Hazardous Polymerization**: Not expected.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

- ***Acute toxicity:*** In contact with eyes, it causes serious eye irritation and redness of eyes.
- ***Chronic Effects:*** Affects the kidneys, eyes & liver.
- **RTECS#:** QS3675000
- **LD50/LC50:**

Test	Species	Result
Acute Oral LD50	Rat	3530-3540mg/kg
Acute Dermal LD50	Rabbit	>2000 mg/kg

- Skin irritation: rabbit, Patch test OECD 404, 1981: Not irritating
- Eye irritation: rabbit, OECD Guideline 405: moderately irritating

Skin corrosion/irritation : Not irritating to skin. Causes marginal skin irritation on long exposure.

Serious eye damage/irritation : Causes serious eye irritation.

Respiratory or skin sensitization : Not sensitizing.

- **Type:** Beuhler test.
- **Species**: Guinea pig.
- **Method**: OECD Guideline- 408 "Skin sensitization", 1981.
- **Result:** not sensitizing.

Germ cell Mutagenicity : Non mutagenic.

Carcinogenicity : Not a carcinogen

Route of administration	Species	Exposure period	Doses	Result	Source
oral feed	Mouse (swiss)	life span study (110 weeks)	1%, average daily intake, m: 100.5 mg, f: 66.3 mg.	Consumption of nicotinamide caused no apparent carcinogenic action	Degussa Antwerpen N.V. Antwerpen 4

Reproductive toxicity : No reproductive and developmental toxicity.

STOT-single exposure : No data is available.

STOT- repeated exposure

- **Species:** Rat (Wistar)
- **Route of administration:** oral feed
- **Exposure period:** 28 days
- **Doses:** 215 and 1000 mg/kg
- **Method**: OECD Guideline- 407 " Repeated dose oral toxicity- Rodent"
- **Year:** 1981
- **GLP:** yes
- **Remark:** Effects: decreased body weight and food consumption in males; increased transaminases; spleen weight reduced in males liver, weight increased in females; minimal to mild hypertrophy in liver; reduced extramedullary hematopoiesis, all findings were reversible.

Aspiration Hazards : No data available.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

- **Ecotoxicity:**
- Fish toxicity: P.reticulataLC$_{50}$: 4200 mg/l/96h.
- Daphnia magna EC50: >1000 mg/L/24 hr.
- Algeal toxicity: Desmodesmussubspicatus NOEC: 560 mg/l/72h.

12.2. Persistence and degradability

- **AEROBIC:** Nicotinamide was determined to be readily biodegradable in an aerobic screening test recommended by the Department of Environment, Standing Committee of Analysts, UK(1).
- **ANAEROBIC**: Nicotinamide was not degraded using an anaerobic spore-forming rod (Clostridia sp.) bacteria isolated from Potamac River mud(1).

12.3. Bioaccumulative potential (Predicted)

- BCF = 3
- Log Kow = -0.37

Based on the Log Kow and Bio concentration factor value it is expected to have low potential to concentrate in fatty tissue of fish and aquatic organisms.

12.4. Mobility in soil

- Log Koc = 15 (If released to soil, nicotinamide is expected to have very high mobility based upon estimated KOC value.)
- Henry's Law Constant = 2.9X10-12 atm-cu m/mole. (Volatilization from moist soil surfaces is not expected to be an important fate process based upon an estimated Henry's Law constant)
- Log Kow = -0.37 (Very Low bioaccumulation is expected).

12.5. Other adverse effects

Environment Fate:

- Nicotinamide's production and use as a medication and dietary supplement may result in its release to the environment through various waste streams.
- If released to air, an estimated vapor pressure of 4.2X10-4 mm Hg at 25 deg C indicates nicotinamide will exist in both the vapor and particulate phases in the atmosphere.
- Vapor-phase nicotinamide will be degraded in the atmosphere by reaction with photo chemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 7 days.
- If released to soil, nicotinamide is expected to have very high mobility based upon an estimated Koc of 15.
- Volatilization from moist soil surfaces is not expected to be an important fate process based upon an estimated Henry's Law constant of 2.9X10-12 atm-cu m/mole.
- If released into water, nicotinamide is not expected to adsorb to suspended solids and sediment based upon the estimated Koc.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

- Burn in a chemical incinerator equipped with an afterburner and scrubber.
- Exert extra care in igniting, as this material is combustible.
- Dispose of this material in accordance with standard practice for disposal of potentially hazardous materials as required by applicable federal, state or local laws. Note that disposal regulations may also apply to empty containers and equipment reinstates.

SECTION 14: TRANSPORT INFORMATION

- This substance is considered to be Non-Hazardous for transport by Air/Rail/Road and Sea and thus not regulated by IATA/ICAO/ IMO/IMDG/US DOT.

S.No	Agency	Status
Land Transport	DOT	Not Regulated
Maritime Transport	IMDG	Not Regulated
Air Transport	IATA	Not Regulated

Environmental hazards

- It is expected that this chemical is not a marine pollutant and is not Harmful to the Aquatic environment.

SECTION 15: REGULATORY INFORMATION

- **European Union Information**

Classification as per CLP Regulation 1272/2008:

- Eye Irrit Cat.2
- Hazard Statements: : H319

US information

TSCA

- CAS# 98-92-0 is listed on the TSCA inventory.

WGK (Water Danger/Protection)

- CAS# 98-92-0: 0

Canada

- CAS# 98-92-0 is listed on Canada's DSL List.
- CAS# 98-92-0 is not listed on Canada's Ingredient Disclosure List.

SECTION 16: OTHER INFORMATION

a) Compilation information of safety data sheet

Date of compilation	: March 06, 2012
Chemical	: Niacinamide
CAS #	: 98-92-0
File Name	: 0014Bh Ghs11 Div.4 sds Niacinamide
Revision Number	: 11
Date of Issue of SDS	: January 15, 2018
Revision Due Date	: December, 2019
Supersedes date	: February 3, 2017

b) A key or legend to aberrations and acronyms used in the safety data sheet

- PBT =Persistent Bio accumulative and Toxic.
- vPvB= Very Persistent and Very Bio accumulative.
- SCBA= Self Contained Breathing Apparatus.

- NIOSH REL= National Institute for Occupational Safety and Health Recommended Exposure Limit.
- OSHA PEL=Occupational Safety and Health Administration Permissible Exposure Limit.
- OELTWA= Occupational Exposure Limit Time Weighted Averages.
- IDLH= Immediately Dangerous to Life or Health.
- UEL= Upper Explosive Limit.
- LEL= Lower Explosive Limit.
- RTECS= Registry of Toxic Effects of Chemical Substances.
- NTP=National Toxicology Program
- IARC= International Agency for Research on Cancer.
- EPA=Environmental Protection Agency.
- TSCA= Toxic Substances Control Act.
- CERCLA= Comprehensive Environmental Response, Compensation, and Liability Act.
- SARA= Superfund Amendments and Reauthorization Act.
- NFPA= National Fire Protection Association.
- WHIMS= Workplace Hazardous Materials Information System.
- DSL/NDSL= Domestic/Non-Domestic Substances List.
- CSR=Chemical Safety Report.
- BCF = Bio Concentration Factor.
- DNEL = Derived No Effect Level.
- PNEC = Predicted No Effect Concentration.
- TLV = Threshold Limit Value.
- ACGIH = American Conference of Governmental Industrial Hygienists.
- REACH = Registration, Evaluation ,Authorization and Restriction of Chemicals.
- CLP = Classification, Labeling and Packaging.
- LD / LC = Lethal Doses / Lethal Concentration.
- GHS = Globally Harmonized System.
- ADR = Accord European relative au transport international de merchandises.
- IMDG-Code = International Maritime Code for Dangerous Goods.
- EmS = Emergency measures on Sea.
- ICAO = International Civil Aviation Organization.
- IATA/DGR= International Air Transport Association/Dangerous Goods Regulation.

c) Key Literature reference and sources for data

Biographical reference and data sources

- CLP REG (regulation) (EC) no. 1272/2008, last modification by regulation (EC) no. 790/2009
- DIR 67/548/EWG, last modification by DIR 2009/2/EC
- REG (EC) no. 1907/2006, last modification by REG (EC) Nr. 453/2009.
- OECD Guideline- 407 " Repeated dose oral toxicity- Rodent" **Year:** 1981
- Degussa Antwerpen N.V, Antwerpen 4
- Department of Environment, Standing Committee of Analysts, UK(1).

SDS US (GHS HazCom 2012)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

(End of Safety Data Sheet)

Material Safety Data Sheet

XINFA D-Panthenol 75% W

1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND OF THE COMPANY / UNDERTAKING

Commercial product name:	Xinfa D-Panthenol 75% W
Manufacturer:	Huangdian Village, Kenli Town, Kenli County, Dongying City, Shandong Province, China 257500
Emergency telephone number:	+86 546 7398789

2. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical characterization:	D-Panthenol 75% W
Synonyms:	(R)-（+）-2,4-Dihydroxy-N-(3-hydroxypropyl) - 3,3-dimethylbutyramide Dexpanthenol Provitamin B (R)-2,4-Dihydroxy-3,3-dimethylbutyric 3-hydroxypropylamide D-pantothenyl alcohol
Labelling according to EU statutory	
Order on dangerous substances:	None
Hazardous components:	None
Empirical Formula:	$C_9H_{19}NO_4$
Molar Mass:	205.25 g/mol
CAS number:	81-13-0
EINECS number:	201-327-3

3. HAZARDS IDENTIFICATION

Most important hazards no particular hazards known.

4. FIRST-AID MEASURES

Eye contact:	-Wash immediately with tap water for 15 minutes-open eyelids forcibly

-consult physician

Skin contact: -remove contaminated clothes,

-wash affected skin with water and Soap.

Inhalation: -remove the casualty to fresh air and keep him/her calm.

Ingestion: -Rinse mouth and then drink plenty of water.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: -water spray jet, dry powder, foam, carbon dioxide

Specific hazards: -formation of toxic and corrosive combustion gases (nitrogen oxides (NOx)) possible

-when using lots of water on burning open containers，a burning water product mix. may overflow, possibly spreading the fire.

Protection of fire-fighters: -precipitate gases/vapors/mists with water spray

6. ACCIDENTAL RELEASE MEASURES

Methods for cleaning up -collect spills with inert absorbent and hand over to waste removal

-flush afterwards with plenty of water

7. HANDLING AND STORAGE

Handing

Technical measure: -processing in closed systems, if possible superposed by inert gas (e.g. nitrogen)

-local exhaust ventilation necessary

-take precautionary measures against electrostatic charging

Suitable material: -stainless steel, glass, polyethylene, enamel

Storage

Storage conditions: -keep container tightly closed and dry;

-store in a cool place

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

General safety and hygiene measures:

Handle in accordance with good industrial hygiene and safety practice

Hand protection: -suitable chemical resistant safety gloves,

Eye protection: -safety glasses with side-shields (frame goggles)

9. PHYSICAL AND CHEMICAL PROPERTIES

Color: colorless to slightly yellow

Form: liquid

Odor: none to faint, With slightly bitter taste

Solubility in water: fully soluble

10. STABILITY AND REACTIVITY

Stability: -stable under the conditions mentioned in chapter7
-fairly stable to air and light

Conditions to avoid: -humidity
-warming

Materials to avoid: -bases, acids, carbon dioxide, alkali metals

11. TOXICOLOGICAL INFORMATION

RTECS Number :ES4316000

Acute Toxicity

LD50:ORL-MUS 15g/kg

12. ECOLOGICAL INFORMATION

Inherent biodegradability: -well inherently biodegradable

Ecotoxicity: -barely toxic for fish
-barely toxic for algae
-barely toxic for plankton and shellfish

13. DISPOSAL CONSIDERATIONS

Waste from residues: -drain into wastewater treatment plant, observe local/national regulations regarding waste disposal

14. TRANSPORT INFORMATION

UN No. Not applicable

Sea	Not applicable
Road/rail	Not applicable
Air	Not applicable

15. REGULATORY INFORMATION

Note: -no classification and labeling according to EU directives.

16. OTHER INFORMATION

Biological activity: -no biological activity has been defined for L-pantothenic acid
only the D form has biological activity.
-1.000g D-panthenol 75W is equivalent to 0.750g D-panthenol
-1.000g D-panthenol 75W is equivalent to 0.801g D-pantothenol acid
-1.000g D-panthenol 75W is equivalent to 0.871g D-calcium Pantothenate

XINFA PHARMACEUTICAL CO.,LTD

CERTIFICATE OF ANALYSIS

Product name：D－Panthenol (75W) **Expiry：2 years** **Standard: enterprise standard**
Batch No.：171020C16 **Quantity：1000KG**
MFG. date: OCT.20,2017 **EXP.date: OCT.19,2019**

Items of analysis	Specification	Results
Appearance	Colorless or faintly yellow transparent liquid	Conform
Identification	Positive reaction	Positive reaction
Assay（HPLC）	75.0%～78.5%	75.9%
Water（Karl Fischer）	≤ 25.0%	22.0%
Specific optical rotation (on dried basis)	+29.0°～+31.5°	+31.1°
Limit of aminopropanol	≤ 1.0%	conform
Heavy metals	≤20ppm	conform

XINFA PHARMACEUTICAL CO.,LTD 李新发

Conclusion: **Conform to enterprise standard**

Approval: **Checker:** **Reviewer:**

XINFA PHARMACEUTICAL CO.,LTD.
新发药业有限公司
Add: No 1, Tongxing Road, Kenli county, Dongying city, Shandong province, PR China
地址：山东省东营市垦利县同兴路 1 号　邮编：257500

PRODUCT DATA SHEET

Product Name: D-panthenol 75%

Product Expiry Date: 2 years

Product Characteristics:

(2R)-2,4-dihydroxy-N-(3-hydroxypropyl)-3,3-dimethylbutanamide,

Appearance: A colourless or slightly yellowish, viscous hygroscopic liquid, or a white or almost white,crystalline powder

Chemical Formula: $C_9H_{19}NO_4$

Molecular Weight: 205.25

CAS number: 81-13-0

Specificatons:

Items	Standard enterprise standard	Test Data
1.Appearance	Colorless or faintly yellow transparent liquid	Meets
2.Identification	Positive reaction	Meets
3.Specific optical rotation (on dried basis)	+29.0° ~+31.5°	Meets
4. Heavy metals	≤20ppm	Meets
5.Assay（HPLC）	75.0%~78.5%	Meets
6. Water（Karl Fischer）	≤ 25.0%	Meets
7.Limit of aminopropanol	≤ 1.0%	Meets

XINFA PHARMACEUTICAL CO.,LTD

CERTIFICATE OF ANALYSIS

Product name：D-Panthenol 75% **Expiry：2 years**
Batch No.: 2016062101 **Quantity:850KG** **Manufacturing date:JUN.21,2016**
Expiry date:JUN.20,2018 **Sampling date: JUN.21 ,2016** **Analytical date:JUN.21 ,2016**

Items of analysis	Specification	Results
Appearance	Colorless or faintly yellow transparent liquid	Conform
Identification	Positive reaction	Positive reaction
Assay	75.0%~78.5%	76.60%
Water	≤ 25.0%	19.20%
Specific optical rotation (on dried basis)	+29.0° ~+31.5°	+30.00°
Limit of aminopropanol	≤ 1.0%	conform
Heavy metals	≤20ppm	conform
Organic volatile impurities	Meets the requirements	Meetsthe requirements

XINFA PHARMACEUTICAL CO.,LTD 李新发

Conclusion: **Conform to enterprise standard**

Approval: **Checker:** **Analyst:**

XINFA PHARMACEUTICAL CO.,LTD

CERTIFICATE OF ANALYSIS

Product name：D-Panthenol 75% **Expiry：2 years**
Batch No.: 2016070901 **Quantity:3150KG** **Manufacturing date:JUL.09,2016**
Expiry date:JUL.08,2018 **Sampling date: JUL.09 ,2016** **Analytical date:JUL.09 ,2016**

Items of analysis	Specification	Results
Appearance	Colorless or faintly yellow transparent liquid	Conform
Identification	Positive reaction	Positive reaction
Assay	75.0%~78.5%	76.20%
Water	≤ 25.0%	19.90%
Specific optical rotation (on dried basis)	+29.0° ~+31.5°	+30.00°
Limit of aminopropanol	≤ 1.0%	conform
Heavy metals	≤20ppm	conform
Organic volatile impurities	Meets the requirements	Meetsthe requirements

XINFA PHARMACEUTICAL CO.,LTD 李新发

Conclusion: **Conform to enterprise standard**

Approval: **Checker:** **Analyst:**

Provitamin B5 (d-panthenol)

Safety Data Sheet according to Federal Register / Vol. 77, No. 58 / March 26, 2012 / Rules and Regulation

Revision Date: 10-20-2015
Supersedes: 11-13-2012

1 PRODUCT & COMPANY IDENTIFICATION

Product Name: Provitamin B5 (d-panthenol)
Synonyms:
INCI Name: d-panthenol, water
CAS Number: 81-13-0, 7732-18-5
Formula: C9H19NO4
Product Form: Liquid
Product Use: Cosmetic use

Distributor: MakingCosmetics.com Inc.
Address: 10800 231st Way NE
Redmond, WA 98053 (USA)
Phone / Fax: 425-292-9502 / 425-292-9601
Web: www.makingcosmetics.com

Emergency Telephone Number: 1-800-424-9300 (Chemtrec)

2 HAZARDS IDENTIFICATION

GHS Classification: Not classified
GHS Labeling: Not classified
GHS Hazard Pictograms: None
GHS Hazard Statements: None
GHS Precautionary Statements: None
Potential Health Hazards: Eyes: May be irritant.
Inhalation: Not expected to be irritant.
Skin: Not irritant.
Ingestion: Not expected to be irritant.

NFPA Ratings (704):

Health	1	Slight
Flammability	1	Slight
Reactivity	0	Minimal
Specific Hazard	n/a	

3 COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No.	Weight %	Molecular Weight
d-panthenol	81-13-0	75%	205.25 g/mol
Water	7732-18-5	25%	18.02 g/mol

4 FIRST AID MEASURES

Eyes: Flush eyes with water or standard eye wash solution. Consult physician.
Inhalation: Move to fresh air. If breathing is difficult, give oxygen. Call a physician if symptoms develop or persist.
Skin: Wash off skin with soap and water. Get medical attention if irritation develops or persists.
Ingestion: May cause nausea, vomiting, diarrhea, constipation, cramps and loss of appetite. Contact physician.

5 FIRE-FIGHTING MEASURES

Suitable (and unsuitable) extinguishing media: Water spray, dry powder, foam, carbon dioxide
Special protective equipment & precautions for firefighters: Firefighters should wear full firefighting turn-out gear (full Bunker gear) including NIOSH-approved self-contained breathing apparatus with full face piece operated in the pressure demand or other positive pressure mode.
Flash Points: Undetermined
Specific hazards arising from the chemical: Not available.

6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment & emergency procedures: See section 8 for recommendations on the use of personal protective equipment.

Environmental precautions:	Prevent further leakage or spillage if safe to do so. Do not contaminate surface water.
Methods and material for containment and cleaning up:	Eliminate all sources of ignition or flammables that may come into contact with a spill of this material. Prevent entry into waterways, sewers, basements or confined areas. Vacuum or sweep up material and place in a disposal container. Avoid dust formation.

7 HANDLING & STORAGE

Precautions for safe handling:	Process in closed systems, if possible superposed by inert gas (e.g. nitrogen), local exhaust ventilation is recommended, take precautionary measures against electrostatic charging, avoid dust; very high dust explosion hazard.
Conditions for safe storage, incl. any incompatibilities:	Store in stainless steel, aluminum, enamel glass or polyethylene. Store below 25°C protected from light and humidity.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Component	Exposure Limits	Basis	Entity
d-panthenol	No data	No data	No data

TWA: Time Weighted Average over 8 hours of work.
TLV: Threshold Limit Value over 8 hours of work.
REL: Recommended Exposure Limit
PEL: Permissible Exposure Limit

STEL: Short Term Exposure Limit during x minutes.
IDLH: Immediately Dangerous to Life or Health
WEEL: Workplace Environmental Exposure Levels
CEIL: Ceiling

Personal Protection:

Eyes:	Wear safety glasses
Inhalation:	In case of open handling of larger quantities wear particle mask or respirator.
Body:	Wear protective gloves.
Other:	Employees must practice good personal hygiene, washing exposed areas of skin several times daily and laundering contaminated clothing before re-use.

9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance, Physical State:	Viscous liquid	**Vapor Pressure:**	Undetermined
Odor:	Faint odor	**Vapor Density:**	Undetermined
Taste:	Not available	**Evaporation Rate:**	Undetermined
Color:	Clear	**Flammability:**	Undetermined
Molecular Weight:	205.25 g/mol	**Upper/lower Explosive Limit:**	Undetermined
pH (1% sol. in water)	8.0-9.0 (10% aqueous solution)	**Solubility:**	Soluble in water
Boiling Point:	118-120°C	**Flash Point:**	Undetermined
Melting Point:	Not applicable	**Density (kg/m3):**	1200

10 STABILITY AND REACTIVITY

Reactivity:	Product is stable under normal conditions
Chemical Stability:	Product is stable under normal conditions
Hazardous Polymerization:	Undetermined
Conditions to Avoid:	Undetermined
Incompatible Materials:	Acids, bases (hydrolysis)
Hazardous Decomposition Products:	Readily biodegradable; formation of toxic and corrosive combustion gasses possible.

11 TOXICOLOGICAL INFORMATION

Acute Toxicity:	Oral : LD50 (mouse) : > 10.000 mg/kg Dermal : LD50 (rat) : No data available. Inhalation : LC50 (rat) : No data available.
Skin:	Non-irritant
Eyes:	Irritant
Respiratory:	Inhaling vapor may be irritating to the respiratory system.
Ingestion:	Do not ingest; product may cause gastrointestinal irritation.
Carcinogenicity:	Not available

Teratogenicity:	Not available
Germ Cell Mutagenicity:	Not available
Embryotoxicity:	Not available
Specific Target Organ Toxicity:	Not available
Reproductive Toxicity:	Not available
Respiratory/Skin Sensitization:	Not available

12 ECOLOGICAL INFORMATION

Ecotoxicity	
Aquatic Vertebrate:	Not available
Aquatic Invertebrate:	Not available
Terrestrial:	Not available
Persistence and Degradability:	Not available
Bioaccumulative Potential:	Not available
Mobility in Soil:	Not available
PBT and vPvB Assessment:	Not available
Other Adverse Effects:	Not available

13 DISPOSAL CONSIDERATIONS

Waste Residues: Users should review their operations in terms of the applicable federal/national or local regulations and consult with appropriate regulatory agencies if necessary before disposing of waste product container.

Product Containers: Users should review their operations in terms of the applicable federal/national or local regulations and consult with appropriate regulatory agencies if necessary before disposing of waste product container.

The information in section 13 is for the product as shipped. Use and/or alterations to the product may change the characteristics of the material and alter the waste classification and proper disposal methods

14 TRANSPORT INFORMATION

DOT (Dept. of Transportation, USA):	Not regulated
TDG (Transportation of Dangerous Goods, Canada):	Not regulated
IMDG (International Maritime Dangerous Goods):	Not regulated
IATA (International Air Transport Association):	Not regulated
ICAO (International Civil Aviation Organization):	Not regulated

15 REGULATORY INFORMATION

TSCA Inventory Status:	Listed as d-panthenol
DSCL (EEC):	This product is not classified according to the EU regulations. Not applicable.
WHMIS (Canada):	Not controlled under WHMIS (Canada)

16 OTHER INFORMATION

Revision Date: 10-20-2015

Compliance: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

Disclaimer: This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process. Such information is to be the best of the company's knowledge and believed accurate and reliable as of the date indicated. However, no representation, warranty or guarantee of any kind, express or implied, is made as to its accuracy, reliability or completeness and we assume no responsibility for any loss, damage or expense, direct or consequential, arising out of use. It is the user's responsibility to satisfy himself as to the suitableness & completeness of such information for his own particular use.

Safety Data Sheet dated 12/5/2017, version 1 (Reg. 830/2015/UE)

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Identification of the substance

Trade name:	LIPESTROL G-810
SdS n°:	EV14046-EV
CAS number:	73398-61-5
EC number:	277-452-2

The transition time according to REACH Regulation, Article 23 is still not expired.

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended use:

Industrial use - Cosmetic Industry

1.3. Details of the supplier of the safety data sheet

Supplier:
EIGENMANN & VERONELLI S.p.A.
Via della Mosa, 6 - 20017 Rho (MI) Italy
Tel. +39 02935391 - Fax +39 02935361

Competent person responsible for the safety data sheet:
stg@eigver.it

1.4. Emergency telephone number

Poison Control Center Pavia - via Maugeri 10, Pavia (Italy) - Tel. +39 (0)382 24444 - http://www.cavpavia.it/
World Health Organization - World directory of poison centres - http://apps.who.int/poisoncentres/

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

EC regulation criteria 1272/2008 (CLP):

The product is not classified as dangerous according to Regulation EC 1272/2008 (CLP).

Adverse physicochemical, human health and environmental effects:

No other hazards

2.2. Label elements

Hazard pictograms:

None

Hazard statements:

None

Precautionary statements:

None

Special Provisions:

None

Special provisions according to Annex XVII of REACH and subsequent amendments:

None

2.3. Other hazards

vPvB Substances: None - PBT Substances: None

Other Hazards:

No other hazards

SECTION 3: Composition/information on ingredients

3.1. Substances

Identification of the substance

Chemical Identity:	Glycerides, mixed decanoyl and octanoyl
INCI:	Caprylic/Capric triglyceride
CAS number:	73398-61-5
EC number:	277-452-2

3.2. Mixtures

N.A.

SECTION 4: First aid measures

4.1. Description of first aid measures

In case of skin contact:

Wash with plenty of water and soap.

In case of eyes contact:

Wash immediately with water for at least 10 minutes.

In case of Ingestion:

In case of accidental ingestion rinse the mouth with water.

GET IMMEDIATE MEDICAL ADVICE, showing the emergency card.

In case of Inhalation:

Remove casualty to fresh air and keep warm and at rest.

Self-protection of the first aider

Wear personal protective equipment when required (see par. 8.2)

4.2. Most important symptoms and effects, both acute and delayed

None

4.3. Indication of any immediate medical attention and special treatment needed

Special treatment: None

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

Water.

Carbon dioxide (CO_2).

Extinguishing media which must not be used for safety reasons:

None in particular.

5.2. Special hazards arising from the substance or mixture

Do not inhale explosion and combustion gases.

Burning produces heavy smoke.

5.3. Advice for firefighters

Use suitable breathing apparatus .

Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

Move undamaged containers from immediate hazard area if it can be done safely.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel:

Wear personal protection equipment.

Remove persons to safety.

See protective measures under point 7 and 8.

For emergency responders:
Check the compatibility of protective clothing materials with what is stated in par. 8

6.2. Environmental precautions
Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.
Retain contaminated washing water and dispose it.
In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.
Suitable material for taking up: absorbing material, organic, sand

6.3. Methods and material for containment and cleaning up
Wash with plenty of water.

6.4. Reference to other sections
See also section 8 and 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling
Avoid contact with skin and eyes, inhalation of vapours and mists.
Do not eat or drink while working.
See also section 8 for recommended protective equipment.

7.2. Conditions for safe storage, including any incompatibilities
Incompatible materials:
Keep away from strong oxidizing agents.
Keep away from food, drink and feed.
Instructions as regards storage premises:
Adequately ventilated premises.

7.3. Specific end use(s)
None in particular

SECTION 8: Exposure controls/personal protection

8.1. Control parameters
No occupational exposure limit available
DNEL Exposure Limit Values
N.A.
PNEC Exposure Limit Values
N.A.

8.2. Exposure controls
Eye protection:
Eye glasses with side protection [EN 166].
Protection for skin:
Overall.
Protection for hands:
Butyl caoutchouc (butyl rubber).
Respiratory protection:
Not needed for normal use.
Thermal Hazards:
None
Environmental exposure controls:
None
Appropriate engineering controls:
None

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Notes:
Appearance:	Clear liquid	--
Colour :	--	--
Odour:	Fatty, weak	--
Odour threshold:	N.D.	--
pH:	--	--
Melting point / freezing point:	N.D.	--
Initial boiling point and boiling range:	N.D.	--
Flash point:	>150 °C.	--
Evaporation rate:	N.D.	--
Solid/gas flammability:	N.D.	--
Upper/lower flammability or explosive limits:	N.D.	--
Vapour pressure:	N.D.	--
Vapour density:	N.D.	--
Relative density:	0,94-0,95 g/cm3	--
Solubility in water:	insoluble	--
Solubility in oil:	N.D.	--
Partition coefficient (n-octanol/water):	N.D.	--
Auto-ignition temperature:	N.D.	--
Decomposition temperature:	N.D.	--
Viscosity:	28-32 mPa.s	(20°C)
Explosive properties:	None	--
Oxidizing properties:	None	--

9.2. Other information

Properties	Value	Notes:
Miscibility:	N.D.	--
Fat Solubility:	N.D.	--
Conductivity:	N.D.	--
Substance Groups relevant properties	Not Relevant	--

SECTION 10: Stability and reactivity

10.1. Reactivity
Stable under normal conditions
10.2. Chemical stability
Stable under normal conditions
10.3. Possibility of hazardous reactions
None
10.4. Conditions to avoid
Stable under normal conditions.
10.5. Incompatible materials
None in particular.
10.6. Hazardous decomposition products
None.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicological information of the substance:

Acute Toxicity:

Oral: LD50(Mouse):	>5000 mg/kg bw (OECD 401)
Inhalaton: LC50(Rat):	> 1,86mg/l/6h (OECD 403)
Dermal: LD50(Rat):	>2000 mg/kg(79/831/EWG, Annex V, Part B) [Read-across]

Serious eye damage/irritation:
Not irritant (Rabbit - EPA OPP 81-4)

Skin corrosion/irritation:
Not irritant (Rabbit - EPA OPP 81-5)

Respiratory or skin sensitisation:
Not sensitising (Guinea Pig - OECD 406) [Read-across]

Carcinogenicity:
No data available

Cerm cell mutagenicity:
Not mutagenic. (EU Method B.13/14)

Reproductive toxicity:
NOAEL: 1 000 mg/kg bw/day (OECD Guideline 422)

Summary of evaluation of the CMR properties:
Not classifiable as CMR.

STOT-repeated exposure:
No data available

STOT-single exposure:
No data available

Aspiration hazard:
No data available

SECTION 12: Ecological information

12.1. Toxicity

Adopt sound working practices, so that the product is not released into the environment.

Acute (short-term) toxicity:

Fish:
LC0(Danio rerio): >= 53 mg/l/96h (EU Method C.1)

Crustacea:
EC50(Daphnia Magna): >100 mg/l/48h (Nominal - EU Method C.2)

Algae/aquatic plants:
EC50(Desmodesmus subspicatus): >0,449 mg/l/72h (EU Method C.3 - Algal Inhibition test)

Other organisms:
No data available

Chronic (long-term) toxicity:

Fish:
No data available

Crustacea:
No data available

Algae/aquatic plants:
No data available

Other organisms:
No data available

12.2. Persistence and degradability

Readly Biodegradable. (>80%) OECD 301 B

12.3. Bioaccumulative potential
N.A.
12.4. Mobility in soil
N.A.
12.5. Results of PBT and vPvB assessment
vPvB Substances: None - PBT Substances: None
12.6. Other adverse effects
None

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Recover if possible. In so doing, comply with the local and national regulations currently in force.

SECTION 14: Transport information

Not a dangerous material under the amended E.E.C. Council Directives
14.1. UN number
N.A.
14.2. UN proper shipping name
N.A.
14.3. Transport hazard class(es)
N.A.
14.4. Packing group
N.A.
14.5. Environmental hazards
Environmental/Marine pollution: No
N.A.
14.6. Special precautions for user
N.A.
14.7. Transport in bulk according to Annex II of Marpol and the IBC Code
N.A.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
Dir. 98/24/EC (Risks related to chemical agents at work)
Dir. 2000/39/EC (Occupational exposure limit values)
Regulation (EC) n. 1907/2006 (REACH)
Regulation (EC) n. 1272/2008 (CLP)
Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013
Regulation (EU) 2015/830
Regulation (EU) n. 286/2011 (ATP 2 CLP)
Regulation (EU) n. 618/2012 (ATP 3 CLP)
Regulation (EU) n. 487/2013 (ATP 4 CLP)
Regulation (EU) n. 944/2013 (ATP 5 CLP)
Regulation (EU) n. 605/2014 (ATP 6 CLP)
Regulation (EU) n. 2015/1221 (ATP 7 CLP)

Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006 (REACH) and subsequent modifications:

Restrictions related to the product:

No restriction.

Restrictions related to the substances contained:

No restriction.

Where applicable, refer to the following regulatory provisions :

Directive 2012/18/EU (Seveso III)
Regulation (EC) nr 648/2004 (detergents).
Dir. 2004/42/EC (VOC directive)

Provisions related to directive EU 2012/18 (Seveso III):

N.A.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for the substance.

SECTION 16: Other information

Product code : 14046

Main bibliographic sources:

- ECHA Registered Substances site:
http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances
- ACGIH - Threshold Limit Values - 2004 edition

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality.
It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS:	Chemical Abstracts Service (division of the American Chemical Society).
CLP:	Classification, Labeling, Packaging.
DNEL:	Derived No Effect Level.
EINECS:	European Inventory of Existing Commercial Chemical Substances.
GefStoffVO:	Ordinance on Hazardous Substances, Germany.
GHS:	Globally Harmonized System of Classification and Labeling of Chemicals.
IATA:	International Air Transport Association.
IATA-DGR:	Dangerous Goods Regulation by the "International Air Transport Association" (IATA).
ICAO:	International Civil Aviation Organization.
ICAO-TI:	Technical Instructions by the "International Civil Aviation Organization" (ICAO).
IMDG:	International Maritime Code for Dangerous Goods.
INCI:	International Nomenclature of Cosmetic Ingredients.
KSt:	Explosion coefficient.
LC50:	Lethal concentration, for 50 percent of test population.
LD50:	Lethal dose, for 50 percent of test population.
PNEC:	Predicted No Effect Concentration.
RID:	Regulation Concerning the International Transport of Dangerous Goods by Rail.
STEL:	Short Term Exposure limit.
STOT:	Specific Target Organ Toxicity.
TLV:	Threshold Limiting Value.
TWA:	Time-weighted average
WGK:	German Water Hazard Class.

Eigenmann & Veronelli

Rev. 11/2017

TECHNICAL DATA SHEET

LIPESTROL G-810

INCI NAME: Caprylic/Capric Triglyceride
CAS number: 73398-61-5

SPECIFICATIONS

	UM	Limits	Methods
Appearance at 25°C		Clear liquid	*MA001*
Colour	Apha range	100 max.	*MA188*
1 Acid value	mg KOH/g	0,20 max.	*MA040*
Saponification value	mg KOH/g	310 - 360	*MA042*
Refractive index (25°C)		1.4400 - 1.4520	*MA039*
Specific gravity (25°C)	g/ml	0,930 - 0,960	*MA149*
Hydroxyl value	mg KOH/g	10,00 max.	*MA043*
Iodine number	g I/100g	1,00 max.	*MA044*
Water (K.F.)	%	0,10 max.	*MA013*
Peroxides number	mg O/Kg	1,00 max.	*MA046*
Unsaponifiable content	%	0,50 max.	*MA234*
Viscosity (25°C)	cPs	25 - 33	*MA022*

Uffici – *Office*
Via della Mosa, 6
I-20017 Rho (MI) – Italy
Tel +39 02 93539.1
Fax +39 02 93539.300

Unità Produttiva – *Production Unit*
Via Vigevano, 63/a
28069 S. Martino di Trecate (Novara)
ppetrella@eigver.it
Tel +39 02 93539.292
Fax +39 02 93539.613

EIGVER.COM

Eigenmann & Veronelli

LIPESTROL G-810

SPECIFICATIONS

		UM	Limits	Methods
Content	C_6	%	0 - 2	*MA205*
	C_8	%	50 - 80	
	C_{10}	%	20 - 50	
	C_{12}	%	0 - 3	
	C_{14}	%	0 - 1	

2 **APPLICATIONS**

LIPESTROL G-810 is a triglyceride obtained by esterification of glycerin with caprylic and capric acids. LIPESTROL G-810 is used in Personal Care market as a low viscous oil. It has a high degree of oxidation and ageing stability and excellent softening and penetrating properties.

STORAGE

If stored at a temperature between 5° and 35°C, the product is stable for 36 months.

Uffici – *Office*
Via della Mosa, 6
I-20017 Rho (MI) – Italy
Tel +39 02 93539.1
Fax +39 02 93539.300

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Via Vigevano, 63/a
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IOI OLEOCHEMICAL

PERSONAL CARE

TECHNICAL DATA SHEET

SOFTISAN® 649

INCI: Bis-Diglyceryl Polyacyladipate-2

THE VEGAN, ALL-PURPOSE FILM-PROTECTOR

The water-resistant/water-binding vegan film former for safe formulas offering caring smooth sensoriality, and providing barrier protecting effect

IOI Oleo GmbH

DESCRIPTION

SOFTISAN® 649 is a vegan, pure multifunctional ester in pasty form, offered only in RSPO MB certified quality and produced exclusively in Germany.

Due to its pasty consistency SOFTISAN® 649 is able to adjust the viscosity and spreading properties of an oil phase. It underlines the caring properties of your emulsion by enhancing the skin softness and providing a caring smooth skin feel that supports your signature touch. SOFTISAN® 649 has a unique relationship with water. Its complex and unique chemical 3D-structure traps water inside. This makes it both water-resistant and water binding (up to 200%), resulting in a strong and highly substantive protecting film that can reduce skin water loss (TEWL). This all-purpose ingredient is used for high performance products like moisturizing & skin barrier protecting formulas, long-lasting color care, effective hair care or water-resistant sun or baby care.

SOFTISAN® 649 is based on 85% renewable sources and has a natural origin index (NOI) of 0.85 according to ISO 16128. Proven skin compatibility, its vegan nature, biodegradability and safe toxicological profile round off the great assets of this chemically inert product.

It is a partial ester of natural diglycerin with medium chain fatty acids, isostearic acid, stearic acid, 12-hydroxystearic acid and adipic acid. SOFTISAN® 649 is a slight yellowish viscous paste with characteristic odor and neutral, non-rancid taste. It is stable against air oxidation and does not change its appearance during storage. It is free from any additives, pesticides or impurities.

APPLICATION

SOFTISAN® 649 is the perfect fit for all formulas and is especially suitable for baby care, sun care and color cosmetics. The neutral taste combined with glossiness and film-forming properties make SOFTISAN® 649 a staple product for lip care and color cosmetics.

☒ Skin Care	☒ Body Care	☒ Sun Care	☒ Color Cosmetics
☒ Baby Care	☒ Hair Care	☐ Bath Care	☐ Wet Wipes
☒ Self-Tanning	☒ Beard Care	☐ Deodorants	☒ Intimate Hygiene

SOFTISAN® 649 is miscible with all fats, oils and paraffin.

FORMULATION HINTS

- Recommended dosage of **SOFTISAN® 649**: 0.5 – 30%
  - Skin care: 1 – 5% for smooth, moisturized skin and decreased TEWL readings
  - Hair care: 2 – 4%, clear formulas possible
  - Sun care: 2 – 5% for enhanced water resistance, clear formulas possible
- Can also be used as 1:1 vegan replacement of lanolin
- Applicable for hot and cold processes
  - Melting up to 80°C (bulk container) does not change the performance
- Add SOFTISAN® 649 to the oil phase or to the surfactant phase in rinse-off formulas
- Recommended pH level: pH 4.0 – 7.0
- No anti-oxidant needed

FORMULATION GUIDE

SOFT & SILKY W/O CREAM #740

Who says that W/O creams are always oily and take ages to get absorbed?
This silky W/O cream protects the skin from moisture loss during cold winter times for a strengthened skin barrier. Unlike other W/O emulsions, it also has a pleasant soft and silky touch without being oily.
SOFTISAN® 649 moisturized and contributes to the skin barrier effect by lowering the TEWL and provides, in combination with MIGLYOL® T-C7 and SOFTISAN® 378 a caring smooth sensoriality.

	Trade Name	INCI	%
PHASE A	**IMWITOR® 600**	**Polyglyceryl-3 Polyricinoleate**	**4.5**
	MIGLYOL® T-C7	**Triheptanoin**	**5.0**
	WITARIX® MCT 60/40	**Caprylic/Capric Triglyceride**	**8.0**
	SOFTISAN® 378	**Caprylic/Capric/Myristic/Stearic Triglyceride**	**3.0**
	Argan Oil	Argania Spinosa Kernel Oil	2.5
	Baobab Oil	Adansonia Digitata Seed Oil	2.6
	Sweet Almond Oil	Prunus Amygdalus Dulcis Oil	5.0
	Beeswax	Cera Alba	2.0
	Tocopherol	Tocopherol	0.5
	SOFTISAN® 649	Bis-Diglyceryl Polyacyladipate-2	2.0
PHASE B	Water demin.	Aqua	63.3
	SOFTISAN® GC8	**Glyceryl Caprylate**	**0.4**
	Zinc Sulfate Heptahydrate	Zinc Sulfate	1.2

PREPARATION:

1. Heat (60°C) and stir SOFTISAN® 378 prior use.
2. Heat phase A and B to 75°C.
3. Add phase B to phase A in small amounts while homogenize at low/medium speed.
4. Cool phase A/B with stirring to approx. 25°C.

SUPPLIERS:

IOI Oleo GmbH: IMWITOR®, MIGLYOL®, SOFTISAN®, WITARIX®

MARBLE KISS LIPSTICK #844

This masterpiece is more than its glossy and marbled surface. Marble Kiss combines red color with white creamy color for an arty look with additional benefits. Thanks to long-lasting & moisture loss reducing (SOFTISAN® 649) and shine (SOFTISAN® PG2 C10) agents, the red reveals a radiant color that lingers on the lips. The white creamy phase combines unlimited hydration (SOFTISAN® conditionHAIR) with repairing oils (WITARIX® MCT C8 and MIGLYOL® OE). Each application on the lips is unique, as is the hydration and care mix, and the fusion of the two colors into one showcases the unique personality of the wearer.

	Trade Name	INCI	%	%
PHASE A	**WITARIX® MCT C8**	**Tricaprylin**	**27.0**	**23.6**
	MIGLYOL® OE	**Oleyl Erucate**	**12.5**	**16.5**
	Castor Oil	Ricinus Communis Seed Oil	25.1	29.5
	SOFTISAN® conditionHAIR	**PCA Glyceryl Oleate**	**5.0**	-
	SOFTIGEN® 701 ECO	**Glyceryl Ricinoleate (and) Tocopherol**	**2.0**	-
	SOFTISAN® PG2 C10	**Polyglyceryl-2 Caprate**	-	**2.0**
	6642 Carnauba Wax	Copernicia Cerifera Cera	8.0	7.5
	2039 L Candelilla Wax	Euphorbia Cerifera Cera	8.0	8.0
	Tocopherol	Tocopherol	1.0	0.5
	Ecoperse White W 47051	CI 77891 (and) Octyldodecyl Oleate	8.0	-
	SOFTISAN® 649	**Bis-Diglyceryl Polyacyladipate-2**	-	**2.0**
	SWD 4512 D&C Red 6 Ba Lake	Synthetic Wax (and) CI 15850	-	10.0
	SOFTISAN® 378	**Caprylic/Capric/Myristic/Stearic Triglyceride**	**3.0**	-
PHASE B	Raspberry Lips 6800026	Parfum (EU)/ Fragrance (US)	0.4	0.4

PREPARATION:

1. Heat (60°C) and stir SOFTISAN® 378 prior use.
2. Mix all components of Caring Cream Stick (white) phase A and Color Stick (red) phase A and heat to 75-80°C.
3. Add parfum to both lipstick masses.
4. Pour both lipstick masses into the mold at the same time to create the marble swirl. Make sure that about the same amount runs out.
5. Let allow to cool down (30 min @ refrigerator), then remove the sticks from the molds.

SUPPLIERS:

IOI Oleo GmbH: MIGLYOL®, SOFTIGEN®, SOFTISAN®, WITARIX®
KahlWax: Carnauba Wax, Candelilla Wax
Sandream Impact: Ecoperse
SunChemical: D&C Red
Bell: Parfum

HANDLING AND SHELF LIFE

The shelf life for SOFTISAN® 649 is at least twenty-four months if the product is stored below 25°C in a dry place in original, tightly closed containers, protected from light and moisture.

PACKAGING UNITS

Hobbock with 25 kg, 600 kg on CP3 pallet
Drum with 180 kg, 720 kg on CP3 pallet

IOI Oleo GmbH

Hamburg, Germany | +49 40 28 00 31-0
personalcare@ioioleo.de | www.ioioleo.de

IOI OLEOCHEMICAL

Composition Statement

SOFTISAN® 649

This is to confirm that the above mentioned product comprises of

Bis-Diglyceryl Polyacyladipate-2	100%

Date: 15 November 2021

Signature:

Y. Harjes
Quality Assurance

B. Akacha
Quality Assurance

Production Site Witten **IOI Oleo GmbH, Arthur-Imhausen-Str. 92, D-58453 Witten**
M quality-witten@ioioleo.de W www.ioioleo.de

Vance Bioenergy Sdn. Bhd.
Co Reg: 709163 K

PLO 668 / PLO 669 Jalan Keluli 5
Kawasan Perindustrian Pasir Gudang
81700 Pasir Gudang
Johor Darul Takzim
MALAYSIA

tel +607 254 3668
fax +607 254 3778

www.vancebioenergy.com

MATERIAL SAFETY DATA SHEET

REFINED GLYCERINE

1. Product and Company Identification

Product Name	Refined Glycerine
Commercial Description	Refined Glycerine 99.5% Min Refined Glycerine 99.7% Min
Material / Origin	Crude Glycerine
Manufacturer Name **Address**	Vance Bioenergy Sdn. Bhd. PLO 668 / 669 Jalan Keluli 5 Kawasan Perindustrian Pasir Gudang 81700 Pasir Gudang Johor Darul Takzim MALAYSIA
Telephone Number	+607 254 3668
Facsimile Number	+607 254 3778
Emergency Mobile Number	+6012 712 7356

2. Composition / Information on Ingredients

Chemical Name	1,2,3 – propanetriol Glycerol $C_3H_8O_3$
CAS No.	56-81-5
EC-No.	2002895
EC Symbols	Not Applicable
EC R-phrases	None

3. Hazards Identification

European Hazard classification	This product is not classified as dangerous according to Directive 67/548/EEC
Potential Health Effect	***Eye*** – Concentrated solutions may cause mild transient irritation ***Skin*** – Unlikely to be irritant. Heated product may cause thermal burns if contacted ***Inhalation*** – Not applicable at ambient temperature. Glycerine mist may be irritative to respiratory tract ***Ingestion*** – Unlikely to be harmful unless excessive amount

Physical / Chemical Hazards	Contact of glycerine with strong oxidizing agent such as Nitric Acid or other strong acids, Chromium Trioxide, Potassium Chlorate or Potassium Permanganate may cause an explosion
Environmental Hazards	Product is biodegradable

4. First-Aid Measures

General	In all cases of doubt, or when symptoms persist, seek medical attention
Inhalation	Use self-contained breathing equipment if in confined place. Remove to fresh air. If suffocation is serious, take to a doctor
Skin Contact	Use gloves. Remove contaminated clothing. Wash skin thoroughly with plenty of water. Take to a doctor if necessary
Eye Contact	Wash out with plenty of water. Get medical attention if any sensations persist
Ingestion	Remove material from mouth. Drink plenty of water. No typical symptoms and effects known. However, if large amount swallowed or symptoms develop, get medical attention

5. Fire Fighting Measures

Flash Point (Method Used)	198.9°C (PMCC)
Auto-ignition temperature	Approx 400°C
LEL	N.A.
UEL	N.A.
Extinguishing Media	Use water spray, alcohol resistant foam, CO_2 or dry chemical
Special Fire Fighting Procedure	Use water spray to cool drums exposed to fire
Special Fire Fighting Equipment	Firefighters should use self-contained breathing apparatus and full protective clothing
Other Fire Fighting Consideration	Contact of glycerine with strong oxidizing agent such as Nitric Acid or other strong acids, Chromium Trioxide, Potassium Chlorate, or Potassium Permanganate may cause explosion
Hazardous decomposition/ combustion products	At elevated temperatures there is a risk of exothermic polymerization (>200°C). At temperature >280°C, acrolein may be formed

6. Accidental Release Measures

Personal Precautions	The usual precautions for handling chemicals should be observed
Environmental Precautions	Minimize contamination of drains, surface and ground waters
Procedure for Spill / Leak Clean-up	Transfer product to suitably labeled containers for disposal at an approved site. Residues and small spillages may be washed away with water and detergent

7. Handling and Storage

Handling	No special precautions required, but avoid eye and skin contact as part of normal industrial hygiene. Prevent formation of mist. Eye and skin contact should be avoided if handling at elevated temperatures
Storage	Store in clean tight containers to prevent moisture pick up from air. Can be stored in clean aluminum, stainless steel, fiberglass or suitable resin-lined steel vessels. In bulk, store at ambient temperature. For pumping, heat up to not more than 45°C
Other Recommendations	Avoid contact with strong oxidizing agent such as Nitric Acid or other strong acids, Chromium Trioxide, Potassium Chlorate or Potassium Permanganate

8. Exposure Control / Personal Protection

General Precaution	Good industrial hygiene should be followed. Avoid breathing mist
Exposure Limit Values - glycerine	Refer to respective countries' established limits (*if any*)
Engineering Controls	**Ventilation:** Local exhaust – preferred Mechanical (general) – acceptable Provide ventilation to meet exposure limits
Personal Protective Equipment	***Eye*** – Not required, although eye protection is recommended as part of good industrial hygiene ***Skin*** – Protective gloves : None required with normal use ***Inhalation*** – An appropriate NIOSH/MSHA approved respirator should be used if a mist or vapor is generated. A NIOSH/MSHA approved self-contained breathing apparatus or air-supplied respirator is recommended if the concentration exceeds the capacity of cartridge respirator. WARNING: Air purifying respirator does not protect workers in oxygen-deficient atmospheres

9. Physical and Chemical Properties

Boiling Point @ 760 mmHg (101.3 kPa)	290°C
Specific Gravity (H_20 = 1)	Approx. 1.26
Vapor Pressure	0.0025 mmHg @ 50°C
Vapor Density, Air = 1	Not Available
Appearance and Odor	Water white clear liquid and odorless
Volatiles, % by Volume	Not volatile
Solubility in H_20	Soluble
pH	Neutral
Flash Point , method	198.9°C (PMCC)
Melting Point	Approx. 18°C (solidifies at a much lower temperature)
Viscosity	1410mPa.s at 20°C

Auto ignition temperature	Approx 400°C
Flammability (solid, gas)	Not Determined
Explosive properties	Not to be expected
Oxidizing properties	Not to be expected

10. Stability and Reactivity

Stability

Stable under normal operational procedures

Conditions to avoid	Temp >200°C (Polymerization, Decompose) Keep away from sources of ignition and naked flames
Dangerous Decomposition Products	Acrolein (>280°C)
Decomposition Advices	No decomposition if used according to specification

Reactivity

Material to avoid	Contact of glycerine with strong oxidizing agent such as Nitric Acid or other strong acids, Chromium Trioxide, Potassium Chlorate, or Potassium Permanganate may cause explosion
Hazardous polymerization	Will not occur

11. Toxicological Information

Acute Toxicity

Oral LD_{50}	>2000 mg/kg (rat)

Irritation

Skin	Mildly irritating
Eye	Mildly irritating
Chronic Toxicity	No additional adverse health effects noted

12. Ecological Information

Ecotoxicity	
- Fish	96h-LC_{50}: >5000 mg/l
- Algae	48h-EC_{50}: > 2900 mg/l
- Bacteria	72h-IC_{50}: > 10,000 mg/l
Mobility	Low potential for sorption to soil. Glycerine will partition primarily to water.
Persistence and degradability	Readily biodegradable (OECD 301)
Bioavailability	Low bioaccumulation potential and is not expected to bioaccumulate

13. Disposal Considerations

Disposal is to be performed in compliance with all federal, state/provincial and local regulations. Do not dispose of via sinks, drains or into immediate environment

14. Transportation Requirements

U.S DOT Not regulated for transport

Not a hazardous material according to RID/ADR, IMDG, ICAO-TI/IATA-DGR

15. Regulatory Information

Country(s) or region	Inventory Name	On Inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes
Switzerland	Switzerland FOPH	No

Note: A "Yes" indicates that all components of the product comply with the inventory requirements administered by the governing country(s).

WGK water endangering class 1, low hazard to water

EU Classification This product is not classified as dangerous according to Directive 67/548/EEC.

US Regulations This product is not classified as dangerous according to CERCLA Hazardous Substances (40 CFR 302.4), SARA Section 302 and 311.

16. Other Information

This MSDS only concerns the above mentioned product and does not need to be valid if used with other products or in any process. This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this product. The information contained here is offered in good faith but without warranty, and has been compiled from sources considered by Vance Bioenergy to be dependable and is accurate to the best of the Company's knowledge. It remains the user's own responsibility to make sure the information is appropriate and complete for his special use of this product. Vance Bioenergy assumes no responsibility for injury to the recipient or third persons or for any damage to any property resulting from misuse of this product.

Any Other Information	*None*
Date of printing	*19/08/2013*
Revision	*6*
Composed By	*Khairul@Khairil Anuar Bin Abdul Samad*

Vance Bioenergy Sdn. Bhd.
Co Reg: 709163 K

PLO 668 / PLO 669 Jalan Keluli 5
Kawasan Perindustrian Pasir Gudang
81700 Pasir Gudang
Johor Darul Takzim
MALAYSIA

tel +607 254 3668
fax +607 254 3778

www.vancebioenergy.com

REFINED GLYCERINE 99.7% MIN

Allergens

The crude glycerine feedstocks used in the production of **REFINED GLYCERINE 99.7% MIN.** are derived from various oleochemical processes involving vegetable oils. These vegetable oils may themselves be of allergenic concern. In the glycerine refining process, the glycerine feedstock is subjected to high temperature distillation processes to produce the high purity refined glycerine. **REFINED GLYCERINE 99.7% MIN.** is highly processed, distilled and purified. Any protein residue in the glycerine feedstock is removed by this processing, thus removing the allergens.

We certify that none of the following potential allergens are present in **REFINED GLYCERINE 99.7% MIN.** :

- Gluten/wheat
- Corn
- Dairy
- Egg
- Fish/shellfish
- Yeast
- Starch
- Nuts (any including peanut)
- Rice
- Sugar
- Soy
- Sesame
- Sulphite
- Tartazine
- Coconut
- MSG
- Hydrolysed Plant Protein

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email sales@vancebioenergy.com

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Refined Glycerine 99.7% USP Grade

Parameters	Test Method	Specification	Typical Result
Glycerin, % Assay ($C_3H_8O_3$, calculated on the anhydrous basis)	USP 36	99.0 - 101.0	99.89
Water Content, % w/w	USP 36	5.0 max	0.11
Specific Gravity @ 25°C	USP 36	1.249 min	1.2617
Color	USP 36	Passed	Passed
Residue on Ignition, %	USP 36	0.01 max	<0.01
Chlorides, ppm	USP 36	10 max	<10
Sulphates, ppm	USP 36	20 max	<20
Heavy Metals (as Pb), ppm	USP 36	5 max	<0.1
Limit of Chlorinated Compounds, ppm	USP 36	30 max	<30
FA & E as ml of 0.5 NaOH max	USP 36	1 max	0.5 ml of 0.5N NaOH was consumed
Identification - A (IR) - B (Limit of Diethylene Glycol & Ethylene Glycol) - Diethylene Glycol, % - Ethylene Glycol, % - C (RT of Glycerine's peak)	USP 36	 Passed 0.1 max 0.1 max Meet test requirement	 Passed <0.025 <0.025 Meet test requirement
Related Compounds - Individual impurities (Excluding any solvent peak & diethylene glycol), % - Total Impurities, %	USP 36	 0.1 max 1.0 max	 All the individual impurities are <0.1 <1.0
Glycerol, %	APAG-GL-008	99.7 % min	99.89
Color, APHA	AOCS Ea 9-65 : 1997	10 max	5
Arsenic, ppm	USP 32 <231>	1.5 max	<0.1

IMPORTANT NOTE: This information is offered in good faith. While it is believed to be accurate and reliable, it is given without guarantee or warranty of any kind expressed or implied. User assumes all risk in acting on this information provided by Vance Bioenergy.

בס"ד

KOSHER CERTIFICATE

KOSHER CERTIFICATION
Rabbi Don Yoel Levy
Kashruth Administrator

KC# 3105051 - 1
7 Teves, 5774
December 10, 2013

Vance Bioenergy Sdn Bhd
PLO 668, Jalan Keluli 5,
Kawasan Perindustrian Pasir Gudang
Pasir Gudang, Johor 81700, MALAYSIA
Tel: 011 607 254 3668 Fax: 011 607 254 3778

The following products sold by Vance Bioenergy Sdn Bhd are certified Kosher with the listed restrictions.

Name	K-ID	Status	Restriction	Size
Refined Glycerine 99.5% or 99.7% Min Usp Grade	TQV-PVRX	Pareve	® SYMBOL	

This certificate is VALID UNTIL December 31, 2014

Verify authenticity by entering K-ID at
www.digitalkosher.com

11 Tevet / 13

Powered by: K-ID DIGITALKOSHER.COM

RABBI DON YOEL LEVY, Kashruth Administrator

391 Troy Avenue, Brooklyn, New York 11213 U.S.A. • Tel: 718-756-7500 Fax: 718-756-7503 • E-Mail: info@ok.org

Vance Bioenergy Sdn. Bhd.
Co Reg: 709163 K

PLO 668 / PLO 669 Jalan Keluli 5
Kawasan Perindustrian Pasir Gudang
81700 Pasir Gudang
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REFINED GLYCERINE 99.7% MIN

Animal Testing

This is to certify that **REFINED GLYCERINE 99.7% MIN.** manufactured by Vance Bioenergy Sdn. Bhd. does not undergo any animal testing.

Vance Bioenergy Sdn. Bhd.
Co Reg: 709163 K

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REFINED GLYCERINE 99.7% MIN

Palm-Based – Non GMO

According to the Malaysian Palm Oil Board ("MPOB"), the leading authority on Palm Oil in Malaysia, Palm Oil is not genetically modified. Based on this statement by the MPOB (see attached certificate from MPOB), and our best knowledge that there is no other information that contradicts this statement, we provide the concomitant assurance that **REFINED GLYCERINE 99.7% MIN.** derived from Palm Oil manufactured by Vance Bioenergy does not contain any genetic modification.

Vance Bioenergy Sdn. Bhd.
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81700 Pasir Gudang
Johor Darul Takzim
MALAYSIA

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fax +607 254 3778

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MPOB

MALAYSIAN PALM OIL BOARD

To Whom It May Concern

Re : Malaysian Palm and Palm Kernel Oils

This is to certify that palm and palm kernel oils from Malaysia are derived from oil palm trees which are not genetically modified (GM) by the techniques of modern biotechnology.

Malaysian Palm and Palm Kernel Oils are 100% GM-free

(DATUK DR. CHOO YUEN MAY)
Director-General, MPOB

12 MARCH 2013

Vance Bioenergy Sdn. Bhd.
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Kawasan Perindustrian Pasir Gudang
81700 Pasir Gudang
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REFINED GLYCERINE 99.7% MIN

Vegetable Derivation – BSE & TSE

This is to certify that **REFINED GLYCERINE 99.7% MIN.** manufactured by Vance Bioenergy Sdn. Bhd. is of vegetable source only. It does not contain, nor is it manufactured using, any raw material of animal origin.

This product is manufactured in a closed process. Consequently, Vance Bioenergy Sdn. Bhd. certifies that there are no Bovine Spongiform Encephalopathy (BSE) / Transmissible Spongiform Encephalopathy (TSE) concerns with the use of **REFINED GLYCERINE 99.7% MIN.**

ISCA UK Ltd
Nine Mile Point Industrial Estate
Crosskeys, Newport, NP11 7HZ
Tel: +44 (0) 1495 200747
Fax: +44 (0) 1495 200757
Email: enquiries@iscauk.com
www.iscauk.com

INCI Declaration – Aevum Vita 500

We confirm that Aevum Vita 500 contains the following ingredients which are listed in the Inventory of Cosmetic Ingredients:

INCI Name	CAS Number	Contains (by weight)
Polyacrylamide	9003-05-8	50 - 60 %
C13-14 Isoparaffin	246538-79-4	10 - 25 %
Laureth-7	3055-97-8	10 - 30 %

ISCA UK Ltd
Nine Mile Point Industrial Estate
Crosskeys, Newport, NP11 7HZ
Tel: +44 (0) 1495 200747
Fax: +44 (0) 1495 200757
Email: enquiries@iscauk.com
www.iscauk.com

Vegan Statement – Aevum Vita 500

To Whom It May Concern:

This is to certify that Aevum Vita 500 (INCI name: Polyacrylamide / C13-14 Isoparaffin / Laureth-7) complies with the requirements for use in vegan products. No material of animal origin is used in the manufacture and the product is manufactured in a facility that is free from animal products and derivatives. Aevum Vita 500 is therefore suitable for use in products intended for vegans.

Antony Hudson

Technical Director
ISCA UK Ltd

ZSCHIMMER & SCHWARZ

PERSONAL CARE

PROTELAN NMF

Oil / water emulsifier

Chemical composition

Blend of nonionic and anionic surfactants

INCI name:	Glyceryl Stearate (and) Cetearyl Alcohol (and) Sodium Lauroyl Glutamate (and) Sodium Stearoyl Lactylate
Appearance:	white ivory to yellowish flakes

Typical data

Active ingredient:	98 %
Water content:	2 %
pH value (1 %):	6.5
Acid value:	20
Melting point:	48 - 64 °C

Application

PROTELAN NMF is an O/W self-emulsifying base made from vegetable raw materials without ethoxylated compounds.
PROTELAN NMF can be used in emulsions of high cosmetic elegance. It is able to provide a very nice and silky skin feeling to any type of emulsion. By variation of the used concentration both creams and loitons can be produced.
Furthermore an excellent moisturizing effect is provided.

Storage

Protect from heat and humidity.

Zschimmer & Schwarz Italiana S.p.A. Via Angelo Ariotto, 1/C 13038 Tricerro (VC) | IT T +39 0161 808 111 F +39 0161 801 002 care@zschimmer-schwarz.com zschimmer-schwarz.com

Product Specification active

Specification Nr. 3 **Active** þ **Months Validity** 12

Product 20275#000XXX

PROTELAN NMF

Emission Date 30/03/2020 **Modified Date** 31/03/2020

INCI Name	CAS nr.	Einecs nr.	Range
NOTES			
GLYCERYL STEARATE	85251-77-0	286-490-9	45% - 75%
CETEARYL ALCOHOL	67762-27-0	267-008-6	30% - 50%
SODIUM STEAROYL LACTYLATE	25383-99-7	246-929-7	5% - 15%
SODIUM LAUROYL GLUTAMATE	29923-31-7	249-958-3	5% - 10%

PARAMETER	EXPECTED VALUE
METHOD	
NOTES	
Appearance at 20°C zsi-am-53	flakes
Colour zsi-am-53	white ivory
Water content % zsi-am-05	0,0 - 5,0
Nitrogen % zsi-am-40	0,15 min
Acidity mg KOH/g zsi-am-02	10,0 - 30,0
Iodine number g I2/100 g zsi-am-77	0,0 - 4,0
Melting point °C zsi-am-62	52 - 62

ZSCHIMMER & SCHWARZ ITALIANA S.p.A.
Via Angelo Anelio No. 1/C
13038 TRICERRO (VC) / ITALY
Tel.: +39 - 0161 80 81 11
Fax: +39 - 0161 80 73 38

Lubrizol

PARKOTEKS KIMYA SAN VE TIC LTD
SALIH TOZAN SOK
34394 ISTANBUL
TURQUIE

Subject: Material Safety Data Sheets
(18-2009)

Date: 09/07/2009

Dear Sirs and Madams,

Please find enclosed the MSDS's sent to you in accordance to the regulations of the sending country relative to the products(s).

CARBOPOL® ULTREZ 21 POLYMER

This information is provided to you for the following reason:

The MSDS has been revised since the product was last ordered by your company.

Thanking you in advance for your cooperation, please accept our best regards,

LUBRIZOL EUROPE COODINATION CENTER, BVBA
BRUSSELS COORDINATION CENTER
CHAUSSÉE DE WAVRE, 1945
BRUSSELS, BELGIUM
+32 (0) 2 678 19 11
+32 (0) 2 678 20 03
0065 0001028671

Log on to www.mylubrizol.com to get the most up to date MSDS. You can also view the MSDS Change Report online that lists MSDS with changes in the last 30 days.

Lubrizol

Safety Data Sheet
CARBOPOL® ULTREZ 21 POLYMER

Prepared according to Annex II of EC Regulation 1907/2006.

1 Substance/Product Identification

Product Trade Name **CARBOPOL® ULTREZ 21 POLYMER**

Company *LUBRIZOL EUROPE COODINATION CENTER, BVBA*
BRUSSELS COORDINATION CENTER
CHAUSSÉE DE WAVRE, 1945
BRUSSELS, BELGIUM
+32 (0) 2 678 19 11
+32 (0) 2 678 20 03

E-mail contact EUSDS@lubrizol.com

CAS Number Not determined.

Synonyms Acrylates/C10-30 Alkyl Acrylate Crosspolymer

Preparation/Revision Date 14 August 2009

Generic Chemical Name Modified acrylic polymer

Product Type Base Carbopol-Personal Care

Emergency Phone Number FOR TRANSPORT EMERGENCY call CHEMTREC: (+1) 703-527-3887 (outside the U.S.), 1-800-424-9300 (in the U.S.)

MSDS No. 98854616-1211718-2091920-102103

2 Hazards Identification

Symbol(s)

Product Classification R36 -- Irritating to eyes.
R52/53 -- Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

3 Composition/Information on Ingredients

Hazardous Ingredients

Comp	Percentage (by wt.)	Symbol(s)	Risk Phrase(s)	EU Number
Alcohol ethoxylate	From 1 to 4.9 percent	N Xi	R38 R41 R51/53	Polymer
Cyclohexane	From 0.1 to 0.9 percent	F N Xi	R11 R38 R50/53 R65 R67	203-806-2

4 First Aid Measures

Ingestion Treat symptomatically. Get medical attention.

Eyes Immediately flush eyes with plenty of one percent (1%) physiological saline solution for five

	(5) minutes while holding eyelids open. If no saline is available, flush with plenty of clean water for fifteen (15) minutes. See a physician. If eye irritation persists, get medical attention. Water (moisture) swells this product into a gelatinous film which may be difficult to remove from the eye using only water.
Skin	Wash with soap and water. Get medical attention if irritation develops. Launder contaminated clothing before reuse.
Inhalation	Remove exposed person to fresh air if adverse effects are observed. If breathing is labored, administer oxygen. If breathing has stopped, apply artificial respiration. If irritation persists or if toxic symptoms are observed, get medical attention.
Additional Information	Note to physician: Treat symptomatically.

5	**Fire Fighting Measures**

Flash Point	Not applicable.
Extinguishing Media	CO2, dry chemical, foam, water spray, water fog. Carbon dioxide may be ineffective on larger fires due to a lack of cooling capacity which may result in reignition. Avoid hose stream or any method which will create dust clouds.
Firefighting Procedures	Wear full protective firegear including self-containing breathing apparatus operated in the positive pressure mode with full facepiece, coat, pants, gloves and boots.
Unusual Fire & Explosion Hazards	Solid does not readily release flammable vapors. Material can form an explosive organic dust air mixture.

-- Fire and Explosive Properties --

Min. Explosive Concentration	115 g/m3 (0.115 oz/ft3)
Min. Ignition Energy	0.25 joules
Volume Resistivity	4.58 x 10+15 ohm-cm
	This product has a high volume resistivity and a propensity to build up static electricity which may be discharged as a spark. A spark can be an ignition source for solvent vapor/air mixtures. If you add this product to a solvent, ensure appropriate safe handling practices such as provision for inerting flammable vapors. As with all organic dusts, fine particles suspended in air in critical proportions and in the presence of an ignition source may ignite and/or explode. Dust may be sensitive to ignition by electrostatic discharge, electrical arcs, sparks, welding torches, cigarettes, open flame, or other significant hear sources. As a precaution, implement standard safety measures for handling finely divided organic powders.

6	**Accidental Release Measures**

Spill Procedures	Personal Protective Equipment must be worn, see Personal Protection Section for PPE recommendations. Prevent entry into sewers and waterways, dispose of in accordance with all federal, state and local environmental regulation. Pick up free solid for recycle and/or disposal. Avoid raising a dust. Wash spill area with detergent. Material is slippery when wet.

7	**Handling and Storage**

Pumping Temperature	Not applicable.
Maximum Handling Temperature	Not determined.
Handling Procedures	Keep material away from heat, sparks, pilot lights, static electricity and open flame. Avoid creating dust. Maintain good housekeeping practices. Do not discharge into drains or the environment, dispose to an authorized waste collection point. Use appropriate containment to avoid environmental contamination. Avoid drinking, tasting, swallowing or ingesting this product. Avoid breathing dust, fume, gas, mist, vapors or spray. Avoid inhalation of dust, aerosol, mist, spray, fume, or vapor. Use with appropriate and adequate ventilation. Ground

and bond containers when transferring material. Avoid prolonged skin contact.

Maximum Storage Temperature Not determined.

Storage Procedures Store in a cool, dry, well-ventilated area. Keep container closed when not in use.

Loading Temperature Not determined.

8 Exposure Controls/Personal Protection

Exposure Limits

EU

Comp	CAS No.	Long Term (8 Hours T.W.A.)	Short Term (15 mins.)
Cyclohexane	110-82-7	200 ppm	N/E

UK
Not applicable.

Ireland

Comp	CAS No.	Long Term (8 Hours T.W.A.)	Short Term (15 mins.)
Cyclohexane	110-82-7	100 ppm	300 ppm

India
Not applicable.

Cyprus

Comp	CAS No.	Long Term (8 Hours T.W.A.)	Short Term (15 mins.)
Cyclohexane	110-82-7	200 ppm	N/E

(s) - Skin exposure
(p) - Proposed limit
(c) - Ceiling exposure
(l) - Recommended exposure limit
(u) - Supplier recommended exposure limit
(N/E) - None established

Other Exposure Limits The industry-recommended permissible exposure limit for respirable polyacrylate dusts is 0.05 mg/m3

Engineering Controls If use generates a dust, local exhaust ventilation is recommended. Additional ventilation or exhaust may be required to maintain air concentrations below recommended exposure limits. Prevent inhalation by providing effective general and, when necessary, local exhaust ventilation to draw dust away from workers. Avoid high concentrations of dust in air and accumulation of dust on equipment.

Hand Protection Use good industrial hygiene practices to avoid skin contact. If contact with the material may occur wear chemically protective gloves.

Eye Protection Safety glasses or goggles.

Respiratory Protection Use respirator with a High Efficiency Particulate Air (HEPA) filter if the recommended exposure limit is exceeded Consult with an industrial hygienist to determine the appropriate respiratory protection for your specific use of this material. A respiratory protection program compliant with all applicable regulations must be followed whenever workplace conditions require the use of a respirator.

Clothing Recommendation Long sleeve shirt is recommended.

9 Physical and Chemical Properties

Flash Point	Not applicable.
Upper Flammable Limit	Not determined.
Lower Flammable Limit	Not determined.
Autoignition Point	– 520 °C, – 968 °F
Explosion Data	Dust can form explosive mixtures in the air.
Vapour Pressure	Not determined.
pH	2.5 - 3.5 at 1% in water
Specific Gravity	1.4 (20 °C)
Bulk Density	< 0.24 Kg/L, < 2 Lb/gal
Water Solubility	Material will swell in water.
Percent Solid	Not determined.
Percent Volatile	Not determined.
Volatile Organic Compound	< 0.6%
Vapour Density	Not determined.
Evaporation Rate	Not determined.
Odour	Mild acrylic
Appearance	White powder.
Viscosity	Not determined.
Odour Threshold	Not determined.
Boiling Point	Not determined.
Pour Point Temperature	Not determined.
Melting / Freezing Point	Not determined.

The above data are typical values and do not constitute a specification.

10	**Stability and Reactivity**

Stability	Material is normally stable at moderately elevated temperatures and pressures.
Decomposition Temperature	Not determined.
Incompatibility	Heat may be generated if polymer comes in contact with strong basic materials like ammonia, sodium hydroxide or strong basic amines.
Polymerization	Will not occur.
Thermal Decomposition	Smoke, carbon monoxide, carbon dioxide, aldehydes and other products of incomplete combustion.

11	**Toxicological Information**

-- ACUTE EXPOSURE --

Eye Irritation	Moderate to strong eye irritant. Based on data from components or similar materials. Particulates may cause mechanical irritation. Solid particles (powder or dust) on the eye may cause pain and irritation.
Skin Irritation	Not expected to be a primary skin irritant. Based on data from components or similar mateials. Prolonged or repeated contact may cause dermatitis. Contact dermatitis may occur in sensitive individuals under extreme and unusual conditions of prolonged and repeated contact, such as high exposure accompanied by elevated temperature and occlusion by clothing. This effect may be the result of the product's hygroscopic properties, abrasion, or pH.
Respiratory Irritation	May cause nose, throat, and lung irritation. Based on data from components or similar materials. Exposure to a dust may be irritating. Breathing of dust may cause coughing, mucous production, and shortness of breath.

Dermal Toxicity	The LD50 in rabbits is > 2000 mg/Kg. Based on data from components or similar materials.
Inhalation Toxicity	Avoid inhalation of dust. Animal studies indicate the inhalation of respirable polyacrylate dust may cause inflammatory changes in the lung.
Oral Toxicity	The LD50 in rats is > 2000 mg/Kg. Based on data from components or similar materials. Swallowing material may cause irritation of the gastrointestinal lining, nausea, vomiting, diarrhea, and abdominal pain.
Dermal Sensitization	Not expected to cause skin sensitization. Based on data from components or similar materials.
Inhalation Sensitization	No data available to indicate product or components may be respiratory sensitizers.

-- CHRONIC EXPOSURE --

Chronic Toxicity	A two-year inhalation study in rats exposed to a respirable, water-absorbent sodium polyacrylate dust resulted in lung effects such as inflammation, hyperplasia, and tumors. There were no observed adverse effects at exposures of 0.05 mg/m3. In addition, long-term medical monitoring of potentially exposed workers has not revealed lung effects such as those observed in the rat. However, the inhalation of respirable dusts should be avoided by implementing respiratory protection measures and observing the recommended permissible exposure limit of 0.05 mg/m3.
Carcinogenicity	Not listed as a carcinogen or suspect carcinogen by NTP, IARC or OSHA.
Mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Reproductive Toxicity	No data available to indicate either product or components present at greater than 0.1% that may cause reproductive toxicity.
Teratogenicity	No data available to indicate product or any components contained at greater than 0.1% may cause birth defects.
Other	Pre-existing skin conditions may be aggravated by prolonged or repeated exposure. Persons with sensitive airways (e.g., asthmatics) may react to vapors. This material readily absorbs moisture and may become thick and gelatinous upon contact with mucous membranes of the eye, or upon inhalation into the nasal passages.

12 Ecological Information

-- ENVIRONMENTAL TOXICITY --

Freshwater Fish Toxicity	The acute LC50 is 10 - 100 mg/L based on component data.
Freshwater Invertebrates Toxicity	The acute EC50 is 10 - 100 mg/L based on component data.
Algae Toxicity	Not determined.
Saltwater Fish Toxicity	Not determined.
Saltwater Invertebrates Toxicity	Not determined.
Bacteria Toxicity	Not determined.
Miscellaneous Toxicity	Not determined.

-- ENVIRONMENTAL FATE --

Biodegradation	At least 25% of the components in this product show limited biodegradation based on OECD 301-type test data. At least 25% of the components in this product show limited biodegradation based on OECD 302-type test data.
Bioaccumulation	Less than 1.0% of the components potentially bioconcentrate, based on measured octanol/water partition coefficients.
Soil Mobility	Not determined.
WGK	WGK = 1 according to the Water Hazardous Directive, VwVwS, dated May 17, 1999.

13	Disposal Considerations

Waste Disposal This material, if discarded, should be considered a European hazardous waste in accordance with European Law. H4, H14.

14	Transport Information

ICAO/IATA II Not regulated
IMDG Not regulated
IMDG EMS Fire Not applicable.
IMDG EMS Spill Not applicable.
IMDG MFAG Not applicable.
MARPOL Annex II Not determined.
USCG Compatibility Not determined.
ADR/RID Not regulated
ADR/RID Hazard ID No. Not applicable.
South Africa Not regulated

Review classification requirements before shipping materials at elevated temperatures.

15	Regulatory Information

Symbol(s)

Indication of Danger Irritant
Precautionary Labels R36 -- Irritating to eyes.
R52/53 -- Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
S26 -- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S33 -- Take precautionary measures against static discharges.
S39 -- Wear eye/face protection.
S61 -- Avoid release to the environment. Refer to special instructions/Safety data sheets.
Other Label Information None.

-- Global Chemical Inventories --

USA All components of this material are on the US TSCA Inventory or are exempt.
EU All components are in compliance with the EC Seventh amendment Directive 92 /32/EEC.
Japan All components are in compliance with the Chemical Substances Control Law of Japan.
Australia All components are in compliance with chemical notification requirements in Australia.
New Zealand May require notification before sale under New Zealand regulations.
Canada All components are in compliance with the Canadian Environmental Protection Act and are present on the Domestic Substances List.
Switzerland All components are in compliance with the Environmentally Hazardous Substances Ordinance in Switzerland.
Korea All components are in compliance in Korea.
Philippines All components are in compliance with the Philippines Toxic Substances and Hazardous and

	Nuclear Wastes Control Act of 1990 (R.A. 6969).
China	All components of this product are listed on the Inventory of Existing Chemical Substances in China.

-- Product Registrations --

Finnish Registration Number	Not Registered
Swedish Registration Number	Not Registered
Norwegian Registration Number	Not Registered
Danish Registration Number	Not Registered
Swiss Registration Number	Not Registered
Italian Registration Number	Not Registered
Korean Registration Number	This product is registered in Korea with the Ministry of the Environment.
U.S. Dept of Agriculture	This product has not been filed with the USDA to support H2 approvals.
NSF Nonfood Compounds Registration	This product has not been filed with the NSF to support H1 or H2 approvals.

-- Other / International --

FDA Approval	Not applicable.

16 Other Information

HMIS Codes

Health	Fire	Reactivity
2	1	0

Relevant R Phrases

R11 -- Highly flammable.
R36 -- Irritating to eyes.
R38 -- Irritating to skin.
R41 -- Risk of serious damage to eye.
R50/53 -- Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R51/53 -- Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R52/53 -- Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R65 -- Harmful: may cause lung damage if swallowed.
R67 -- Vapors may cause drowsiness or dizziness.

Revision Indicators

Section	Changed
1 Cas registry number.	25 March 2009
1 Product type.	3 December 2008
1 Synonyms.	25 March 2009
3 EU hazardous ingredients.	31 March 2009
4 Oral first aid.	29 March 2009
4 Skin first aid.	29 March 2009
8 Clothing recommendations.	29 March 2009
8 Other Exposure Limits	27 March 2009
8 Ventilation procedures.	29 March 2009

9 Odor threshold.	3 December 2008
9 Percent volatile.	3 December 2008
9 Viscosity.	3 December 2008
11 Cacinogenicity.	30 March 2009
11 Oral toxicity.	19 May 2009
12 WGK.	3 December 2008
13 Waste disposal.	29 March 2009
16 HMIS codes.	29 March 2009

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TECHNICAL DATA SHEET

TDS-297
Edition: November 6, 2002
Original Date: February 13, 2002

Carbopol®* Ultrez 21 Polymer

INCI name: Acrylates/C10-30 alkyl acrylate crosspolymer

Technical Data Sheet

Product Overview

Carbopol® Ultrez 21 Polymer is a hydrophobically modified crosslinked polyacrylate polymer designed to efficiently impart thickening, stabilizing, and suspending properties to a variety of personal care applications. The polymer incorporates patented technology, which allows it to quickly and easily self-wet – without any mixing required. (Please note that typical mixing/agitation is needed to make a final product).

Physical Properties

Physical properties of Carbopol® Ultrez 21 polymer are listed in Table 1 and indicate typical values and properties; they are not intended to be used as product specifications.

Table 1

Carbopol® Ultrez 21 Polymer
Typical Properties
(not to be used as specification)

• Appearance	white powder
• Odor	mild acrylic odor
• Total solids	100%
• pH (in water)	3
• 0.5% mucilage* viscosity at 20 rpm	55,000 mPa·s
• 0.5% dispersion wetting time	3 minutes
• 0.5% mucilage* clarity (% Transmission):	~ 95

** A mucilage is defined as an active polymer dispersion in water neutralized with a base, preferably NaOH, to a specified pH.*

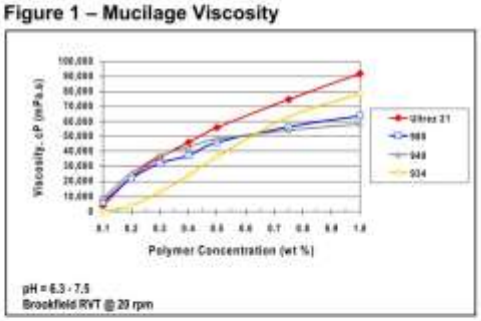
Benefits

In addition to the benefits that all powdered Carbopol® polymers provide, which include thickening, yield value, shear thinning rheology and favorable toxicology profile, Carbopol® Ultrez 21 polymer offers the following benefits:

- **Rapid wetting …**
Carbopol® Ultrez 21 polymer has self-wetting properties similar to Carbopol® Ultrez 10 polymer. Dispersion of 0.5% Carbopol® Ultrez 21 polymer can self-wet within minutes without any mixing.

- **High thickening efficiency …**
Carbopol® Ultrez 21 polymer provides more efficient thickening than other Carbopol® polymers, such as Carbopol® 934, Carbopol® 940 and Carbopol® 980 polymers (see Figure 1). For instance, a reduction of about 15% polymer is recommended when using Carbopol® Ultrez 21 polymer to achieve a similar viscosity in most emulsion formulas.

Figure 1 – Mucilage Viscosity



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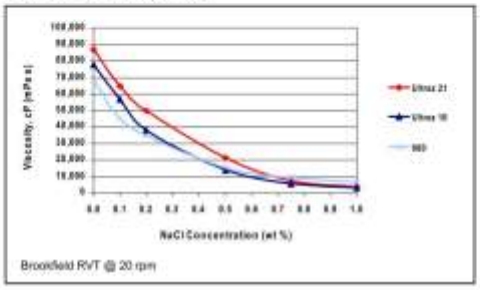
For further information, please visit www.personalcare.noveon.com

- **Improved electrolyte tolerance …**

Carbopol® Ultrez 21 polymer provides superior electrolyte tolerance compared to most Carbopol® polymers, resulting in improved clarity and higher viscosity in electrolyte containing systems.

Figure 2 – Salt Tolerance



- **Excellent clarity …**

Carbopol® Ultrez 21 polymer provides excellent clarity to applications such as hair gels and hand sanitizers.

- **Smooth aesthetic appearance …**

Carbopol® Ultrez 21 polymer provides a non-grainy glossy appearance to gels and emulsions similar to gels and emulsions made with Carbopol® 940 and 934 polymers.

- **Superior skin feel …**

Carbopol® Ultrez 21 polymer is less tacky than other Carbopol® polymers.

- **Broad application use …**

Carbopol® Ultrez 21 polymer has the best overall performance in a wide variety of applications when compared with other Carbopol® polymers.

Suggested Applications

Carbopol® Ultrez 21 polymer can be used in a wide variety of applications, such as:

- Hair Styling Gels
- Hand and Body Lotions
- Baby Lotions
- Hand Sanitizers
- Moisturizing Gels
- Sunscreen Lotions
- Bath Gels
- Shampoos

Processing Guidelines

The development of the self-wetting technology has greatly improved the dispersability of Carbopol® polymers - especially in water. These polymers behave differently in their dispersion as well as hydration rates and need to be processed and handled in a slightly different manner.

Using No Agitation (Self-Wetting) - Preferred

This is the preferred method of dispersion and will result in less entrapped air.

In most situations, Carbopol® Ultrez 21 polymer can simply be "sprinkled" onto the surface of the water without any special equipment or handling.

The powder will wet and drop below the surface in minutes. When there is no visible white powder on the water surface, mixing can begin.

Using Moderate to High Agitation

Dispersions can also be prepared by slowly sifting the polymer into the vortex of a rapidly stirred solution, although this technique may entrap more air.

Techniques or devices which sprinkle the powder as discrete particles are the most effective. The ideal method should efficiently sprinkle the polymer at a controlled rate as well as break-up the soft agglomerates of dry powder formed by static electricity or humid conditions. This allows each particle to completely wet out in the water vortex.

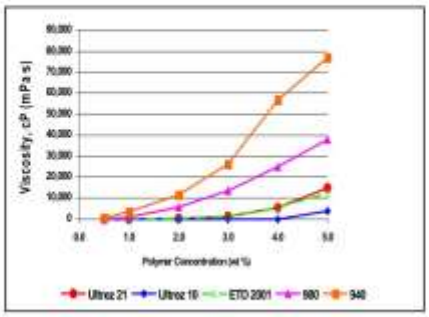
In general, high shear rates disperse the polymer very rapidly; however, extremely high shear mixers or homogenizers should be carefully employed because they can break down the polymer molecule - resulting in permanent viscosity loss. Moderate agitation equipment is the preferred choice. Conventional impellers such as propellers or turbines are recommended.

Wetting Time, Dispersion Viscosity, and Others

The total wetting time is dependent upon the amount of Carbopol® Ultrez 21 polymer added, vessel geometry, and most importantly, water temperature. When the Carbopol® Ultrez 21 polymer dispersion is first neutralized, the surface texture may have a grainy "applesauce" appearance. Over the next 30-60 minutes, the neutralized gel clusters continue to relax and expand. Light mixing will yield a smooth gel.

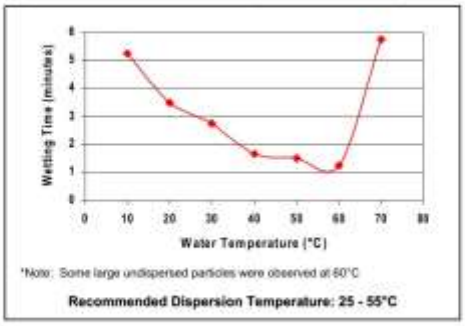
Some users choose to predisperse Carbopol® Ultrez 21 polymer in water and then add this dispersion to their formulation mix tank. Unlike the traditional Carbopol® polymers, Carbopol® Ultrez 21 polymer can be dispersed at concentrations up to 6% and still remain pumpable. See Figure 3.

Figure 3 – Dispersion Viscosity



Under high shear agitation, dispersions of Carbopol® Ultrez 21 polymer can stabilize entrapped air. Antifoam, at use levels of 0.02 - 0.05%, can be added to the water prior to the Carbopol® Ultrez 21 polymer in order to minimize or eliminate foaming.

Figure 4 – Effect of Water Temperature on Wetting Time



Water temperature can help speed the dispersion and swelling process. With traditional carbomers, warm water is avoided because of lumping problems it incurs. With Carbopol® Ultrez 21 polymer, however, any heating needed for formulation can begin before or during the dispersion process. As figure 4 shows, the wetting time of the polymer decreases with warmer temperatures to about 55°C. Once above this temperature, the effect is reversed and lumping may result.

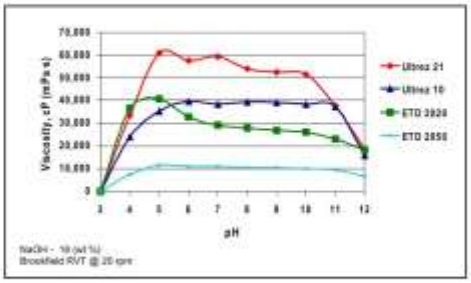
Formulating Guidelines

In most situations, Carbopol® Ultrez 21 polymer should be added to the water at the start of the batch cycle. This will allow it time to thoroughly wet out and disperse. At this point, the pH will be about 3 with a very low viscosity.

Neutralization

Upon neutralization, the Carbopol® Ultrez 21 polymer instantly thickens as shown in Figure 5.

Figure 5 – Effect of pH on Viscosity



Because of the high viscosity, the addition of the neutralizing agent is often best added towards the end of the batch cycle. For formulations with high levels of electrolytes or surfactants, the addition of a small amount of the neutralizer to the Carbopol® Ultrez 21 polymer dispersion is beneficial (partial neutralization).

Different neutralizers can be used, and different amounts are needed for the dispersion to reach a pH value of 7.0. Table 2 provides the weight ratios of commonly used neutralizers vs. Carbopol® Ultrez 21 polymer to achieve pH 7.

For a complete list of neutralizers that can be used with Carbopol® polymers, see TDS-237 - Neutralizing Carbopol® and Pemulen® Polymers in Aqueous and Hydroalcoholic Systems.

Table 2

Weight ratios of commonly used neutralizers vs. Carbopol® Ultrez 21 polymer to achieve pH 7

Neutralizer Trade Name/Supplier	Neutralizer INCI Name	Weight Ratio – Neutralizer / Carbopol® Ultrez 21
TEA (99%)	Triethanolamine	1.5 / 1.0
AMP-95® / Angus	Aminomethyl Propanol	0.9 / 1.0
Neutrol® TE / BASF	Tetrahydroxypropyl Ethylenediamine	2.3 / 1.0
NaOH (18%)	Sodium Hydroxide	2.3 / 1.0
Diisopropanolamine / Dow	Diisopropanolamine	1.2 / 1.0

Preservation

Carbopol® Ultrez 21 polymer does not support bacteria or fungal growth, but neither does it prevent such growth on nutrients found in normal water systems. The addition of a preservative is recommended for applications inclined to these issues.

Carbopol® Ultrez 21 polymer is compatible with most preservatives, such as Germaben® II, DMDM Hydantoin, Dowicil® 200, Parabens and Phenonip®. Phenonip® has limited solubility in clear gel formulations, which may result in reduced clarity.

Compatibility

The viscosity of products with Carbopol® Ultrez 21 polymer is moderately sensitive to ions. Increased levels of monovalent ions (like sodium) will result in a decrease in application viscosity. The effect can be minimized by the use of potassium salts or amine neutralizing agents. Di-and multi-valent ions (like calcium and magnesium) will precipitate Carbopol® polymers. Therefore, formulating with deionized (or at least soft) water is highly recommended.

Due to its anionic nature, Carbopol® Ultrez 21 polymer has limited compatibility with cationic formulating materials.

Handling and Storage

Carbopol® Ultrez 21 polymer is supplied in 20-kilogram cardboard boxes.

In the dry form, Carbopol® Ultrez 21 polymer is stable for a long period of time. It is important, however, to keep the containers tightly closed to prevent moisture pick-up.

See the Material Safety Data Sheet for Carbopol® Ultrez 21 polymer for further information on the proper handling and safety aspects of this product.

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REGULATORY SUMMARY

CARBOPOL®* Ultrez 21 Polymer

Product name: CARBOPOL® Ultrez 21 Polymer
Manufacturer's name and address: Lubrizol Advanced Materials, Inc.
9911 Brecksville Road
Cleveland, Ohio 44141
General information: 216-447-5000
Manufacturing sites for this product: United States of America, Belgium
Manufacturing process: Proprietary polymerization process

COMPOSITION

Ingredient/INCI Name	CAS #	Function	%
Acrylates/C10-30 alkyl Acrylate Crosspolymer[1]	Proprietary	Key Ingredient	~100

[1] Japan INCI name available upon request

Antioxidants, Preservatives: No antioxidants or preservatives added

REGULATORY STATUS

USA (TSCA)	Compliant
Canada (DSL)	Listed
EU (EINECS)	Exempt polymer, monomers listed
Japan (ENCS)	Listed
Australia (AICS)	Listed
China (SEPA)	Listed
Philippines (PICCS)	Listed
Korea (KICS)	Listed
EU Cosmetic Directive Compliant (including. 7th amendment)?	Yes
US Food, Drug and Cosmetic Act Compliant?	Yes

ORIGIN AND SAFETY DATA

Raw Material Origin: Synthetic
GMO Content: Does not contain GMO content
Toxicology Data: See Toxicology Summary
Molecular Weight: Greater than 500,000 Daltons
Animal testing: No animal testing conducted by or on behalf of Lubrizol
MSDS: Available upon request

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REGULATORY SUMMARY

CARBOPOL®* Ultrez 21 Polymer

RESIDUALS, BY-PRODUCTS OR IMPURITIES

Chemical	Listed on Proposition 65?[2]	CMR Designation[2]	Typical Expected Level	Category
Ethyl Acetate and Cyclohexane	No	-----	<0.45% Total	Residual Solvents
Acrylic Acid	No	-----	<500 ppm	Residual Monomer
Benzene	Yes	C1, M2	<1 ppm	Potential Impurity

[2]No other chemicals are known to be present in reportable quantities.

Are any of the 26 allergens present as defined by the 7th amendment to the EU Cosmetic Directive? None expected or tested

Microbiological content: Not conducive to microbial growth

Heavy metals: No heavy metals are utilized as catalysts or as part of the manufacturing process. See product specification for heavy metal content.

1,4-Dioxane: None expected or tested

Ethylene Oxide: None expected or tested

Acrylamides: None expected or tested

Solvent content: Contains less than 0.45% Ethyl Acetate and Cyclohexane

VOC content: Contains less than 0.45% Ethyl Acetate and Cyclohexane

For more information see product specification or visit www.personalcare.noveon.com

Last update:	FINAL: 7 October 2010

Lubrizol Advanced Materials, Inc. / 9911 Brecksville Road, Cleveland, Ohio 44141-3247 / TEL: 800.379.5389 or 216.447.5000

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MSDS (Material Safety Data Sheet)

Prepared in accordance with GB/T 16483-2008 "Chemical Safety Data Sheet Content and Item Sequence" and GB/T 17519-2013 "Chemical Safety Data Sheet Compilation Guide".

Version 1.0
Date of preparation 2020.05.10

8D Hyaluronic Acid

1、CHEMICAL AND CORPORATE IDENTIFICATION	
1.1 PRODUCT NAME	8D Hyaluronic Acid
1.2 INCI NAME	Sodium hyaluronate crosspolymer (105524-32-1), sodium hyaluronate-medium molecular weight(9067-32-7), acetylated sodium hyaluronate (287390-12- 9), hydrolyzed sodium hyaluronate (/), phenoxyethanol (122-99-6), ethylhexylglycerin (70445-33-9), Aqua (7732-18-5), hyaluronic acid-Medium molecular weight(9004-61-9), Hydroxypropyltrimonium Hyaluronate (1714127-68-0), hydrolyzed hyaluronic acid (/), Hyaluronic acid-Low molecular weight (9004-61-9)
1.3 MANUFACTURER	AMHWA BIOPHARM CO.,LTD
1.4 ADDRESS	NO.488 HUANGHE 12 ROAD, BINZHOU CITY, CHINA
1.5 TEL	0543-3080088
1.6 WEBSITE	www.amhwa.com
2、HAZARD OVERVIEW	
2.1 GHS HAZARD CATEGORY	Not a hazardous substance or mixture according to the Globally Harmonized System (GHS).
2.2 DESCRIPTION OF GHS LABEL ELEMENTS	Not a hazardous substance or mixture according to the Globally Harmonized System (GHS).
2.3 PHYSICS AND CHEMICAL	Currently available information, no physical or chemical hazards.
2.4 HEALTH DANGER	Currently available information, no health hazards.
2.5 ENVIRONMENTAL HAZARDS	Currently available information, no environmental hazards.
2.6 OTHER HAZARDS	NO

3、COMPOSITION

Number	INCI name	Cas NO.	EINECS/ELINC No.	Assay
1	Sodium hyaluronate-MMW	9067-32-7	618-620-0	0.3% ~ 1.0%
2	Hyaluronic acid-MMW	9004-61-9	232-678-0	0.2% ~ 1.0%
3	Hydroxypropyltrimonium Hyaluronate	1714127-68-0	--	0.1% ~ 0.3%
4	Sodium hyaluronate crosspolymer	105524-32-1	232-678-0	0.2% ~ 0.5%
5	Sodium acetylated hyaluronate	287390-12-9	690-986-4	0.5% ~ 1.2%
6	Hydrolyzed sodium hyaluronate	/	/	0.1% ~ 0.2%
7	Hydrolyzed hyaluronic acid	/	/	0.05% ~ 0.2%

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Tel: 0543-3080088
Address: No.488 Huanghe12 Road,Binzhou,Shandong 256600,China
www.amhwa.com; Email: christine@amhwa.com

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8	Hyaluronic acid（LMW）	9004-61-9	618-620-0	0.2%～0.5%
9	phenoxyethanol	122-99-6	212-985-6	0.1%～0.8%
10	ethylhexylglycerin	70445-33-9	408-008-2	0.05%～0.2%
11	Aqua	7732-18-5	231-791-2	Add to100%

4、FIRST-AID METHOD	
4.1 EYES CONTACT	Non-irritating.
4.2 SKIN CONTACT	No need special protection
4.3 INHALE	No need special protection
4.4 SWALLOW	No need special protection
5、FIRE-FIGHTING MEASURES	
5.1 FIRE FIGHTING METHOD	Fight fire with water mist, alcohol-resistant foam, dry chemical or carbon dioxide.
5.2 Special fire fighting operations	NO
5.3 EXPLODE DANGER	NO
6、CLEANING MEASURES	
6.1 Cleaning measures after scattering	Clean
6.2 Waste treatment measures	No danger
6.3 NOTICE	If the sample is scattered on the ground, the ground will be slippery.
7、HANDLING AND STORAGE	
7.1 OPERATION PROCEDURE	No need special protection
7.2 STORAGE	Protect from light, seal and store at room temperature.
8、CONTACT PROTECTION	
8.1 CONTACT CONTROL	No need protection
8.2 PERSONAL PROTECTION	
BREATH PROTECTION	No need protection
EYE PROTECTION	No need protection
BODY PROTECTION	No need protection
HAND PROTECTION	No need protection
9、PHYSICAL AND CHEMICAL PROPERTIES	
9.1 APPEARANCE	Clear and transparent viscous liquid
9.2 ODOR	Slight characteristic odor
9.3 pH VALUE	5.0～7.0
9.4 SOLUBILITY	Soluble in water
9.5 MELTING POINT/FREEZING POINT	No data
9.6 INITIAL BOILING POINT AND BOILING RANGE	No data.
9.7 FLASH POINT	No data.

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9.8 EVAPORATION RATE	No data.
9.9 FLAMMABILITY	No data.
9.10 HIGH AND LOW FLAMMABILITY LIMITS	No data.
9.11 VAPOR PRESSURE	No data.
9.12 VAPOUR DENSITY	No data.
9.13 DENSITY/RELATIVE DENSITY	No data.
9.14 N-OCTANOL/WATER PARTITION COEFFICIENT	No data.
9.15 AUTO-IGNITION TEMPERATURE	No data.
9.16 DECOMPOSITION TEMPERATURE	No data.
9.17 VISCOSITY	No data.
9.18 EXPLOSIVE PROPERTIES	No data.
9.19 OXIDATIVE	No data.
10、STABILITY AND REACTION	
10.1ENVIRONMENT TO AVOID	High temperature and high humidity.
10.2 SUBSTANCES TO AVOID	oxidizing agent.
10.3 HAZARDOUS POLYMERIZATION	no
11、TOXICOLOGICAL INFORMATION	
11.1 Oral toxicity test in mice	LD_{50} >5000mg/kg。
12、ECOLOGICAL INFORMATION	
12.1 ECOTOXICITY	No data
12.2 PERSISTENCE AND DEGRADABILITY	biodegradable.
12.3 BIOACCUMULATION POTENTIAL	No data
12.4 MOBILITY IN SOIL	No data
13、DISPOSAL	
	Disposal of waste must comply with the relevant legal requirements of the local country or region.
14、TRANSPORTATION	
14.1 TRANSPORTATION DANGER	No danger
14.2 INCOMPATIBLE SUBSTANCES	Strong acid, strong base.
15、RELATIVE REGULATORY INFORMATION	
	This document provides safety information related to this product

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	only.
16、OTHER INFORMATION	
	The above information statement is based on the essential properties of the substance and is intended for guidance only. This information does not represent a guarantee of the nature of this product. Buyers are subject to regulatory requirements in their region.

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TDS（TECHNICAL DATA SHEET）

1、Manufacturer information	
COMPANY NAME	AMHWA BIOPHARM CO.,LTD.
ADDRESS	NO.488 HUANGHE 12 ROAD, BINZHOU CITY, CHINA
POST CODE	256600
TEL	0531-88813687
WEBSITE	www.amhwa.com
2、Product information	
Product Chinese name	8D 透明质酸
Product English name	8D Hyaluronic Acid
INCI NAME	Sodium hyaluronate crosspolymer, sodium hyaluronate, Sodium acetylated hyaluronate, hydrolyzed sodium hyaluronate, phenoxyethanol, ethylhexylglycerin, Aqua, hyaluronic acid low molecular weight, Hydroxypropyltrimonium Hyaluronate, hydrolyzed hyaluronic acid, medium molecular weight hyaluronic acid
Grade	Cosmetic grade

3、Quality specification

ITEM	Standard
Physical test	
Appearance	Clear and transparent viscous liquid
color	Colorless to light yellow
odor	Slight characteristic odor
uronic acid reaction	Positive reaction
transparency	≥97.0%
pH VALUE	5.0 ~ 7.0
Dynamic viscosity	≥500mPa.S
Purity test	
Heavy metal	≤10ppm
Arsenic	≤2ppm
Microbiological test	
Bacteria count	≤100CFU/g
Yeast and Mold	≤10CFU/g
Escherichia coli	Negative
Staphylococcus aureus	Negative
Pseudomonas aeruginosa	Negative
4、Application	

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Main functions	Cosmetics
Functions and Mechanism	1. Three-dimensional sponge layer structure 2. Precisely locate different levels of the skin 3. Three-dimensional moisturizing effect
5、Package and storage	
Storage	Light proof, ordinary temperature and seal container.
Package	50g/bottle, 1kg/bottle based on customer's requirements
Validity	Two years

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8D composition statement

INCI name	CAS No.	EINECS/ELINC NO.	ASSAY
Sodium Hyaluronate (MMW: 0.75-1.5million)	9067-32-7	618-620-0	0.3%~1.0%
Hyaluronic Acid (MMW: 0.75-1.5million)	9004-61-9	232-678-0	0.2%~1.0%
Hydroxypropyltrimonium Hyaluronate	1714127-68-0	/	0.1%~0.3%
Sodium hyaluronate crosspolymer	105524-32-1	232-678-0	0.2%~0.5%
Sodium acetylated hyaluronate	287390-12-9	690-986-4	0.5%~1.2%
Hydrolyzed sodium hyaluronate （Oligo MW: less 10K）	9067-32-7	618-620-0	0.1%~0.2%
Hydrolyzed hyaluronic acid （Oligo MW: less 10K）	9004-61-9	232-678-0	0.05%~0.2%
Hyaluronic acid （LMW: 0.1-0.5million）	9004-61-9	232-678-0	0.2%~0.5%
Phenoxyethanol	122-99-6	212-985-6	0.1%~0.8%
Ethylhexylglycerin	70445-33-9	408-008-2	0.05%~0.2%
Aqua	7732-18-5	231-791-2	Add to100%

山东安华生物医药股份有限公司 | AMHWA BIOPHARM CO., LTD.
No.488 Huanghe12 Rd, BinZhou City, Shandong 256600, China
+86 543 3080087 | amy@amhwa.com | www.amhwa.com

TECHNICAL DATA SHEET

GENENCARE® OSMS MI

The Energizing Osmolyte

Product description

GENENCARE® OSMS MI, is a highly purified myo-inositol, natural osmolyte extracted from upcycled sugar production side stream. Inositol is a natural source of energy for cells and skin. It helps to stimulate fibroblast metabolism by increasing energy content, oxygen consumption and protein production to reinforce the dermis matrix. At a clinical level, GENENCARE® OSMS MI helps fight the effects of aging by improving skin elasticity and oxygenation for healthier looking skin.

Benefits

Elasticity

A precursor molecule for biological processes *(in vitro)*[1]

- Inositol is a building block of membrane phospholipids and secondary messengers IP3 and IP6.
- Inositol increases the production of PDGF-BB, a platelet derived growth factor for dermal stem cells

Improves the metabolism of dermal fibroblast *(In-vitro – Fig. 1)*[1]

- Inositol (0,1%) improves energy stock (+62%), and protein synthesis (+84%) of dermal fibroblasts. Fibroblasts synthetize important structural proteins such as elastin and collagen, responsible for the dermis structure, integrity and its biomechanical properties.

Improves skin elasticity *(5-week clinical study on 40 volunteers – Fig. 2)*

- 3% GENENCARE® OSMS MI significantly improves the elastic recovery rate Ur/Uf (+10 %*) and the rate of elastic deformation Ur/Ue (+11 %**) of the skin.

Oxygenation

Improves cells oxygenation *(in-vitro – Fig.1)*[1]

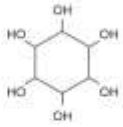
- Inositol (0,1%) improves mitochondrial respiration (+22%) of dermal fibroblasts.

Improves skin oxygenation *(1-week clinical study, 10 volunteers)*[1]

- Inositol (0.4%) helps increase the skin partial pressure of oxygen by 10%.

Product identification

INCI name Inositol
Chemical name Myo-inositol
CAS number 87-89-8



Typical characteristics	
Appearance	free-flowing white crystals
Bulk density	0.7–0.9 g/ml
Melting point	224–226°C
Molar weight	180.16 g/mol
pH (5% solution in DiH_2O)	6.0–9.0
Solubility in water	14 g/100 ml (25°C)
Purity	min 97% d.s. inositol
Moisture	max 0.5% (when packed)

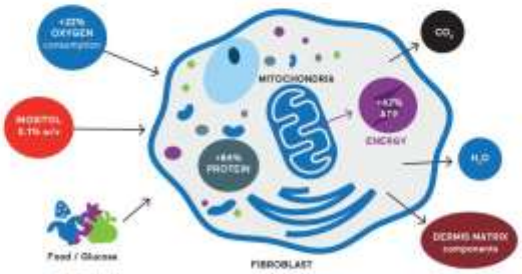


Figure 1: Effect of 0.1% inositol on dermal fibroblast metabolism

[1] Literature references available upon request

Benefits cont.

Osmoprotection / Moisturization

Increases filaggrin expression *(in-vitro)*[1]

- Inositol increases filaggrin expression in normal human epidermal keratinocytes by 65%. Filaggrin is a key differentiation marker in keratinocytes and a precursor protein of the N.M.F. for water retention in the stratum corneum.

Manages water balance in living cells *(in-vitro)*[1]

- Myo-inositol is an osmoprotectant that allows the keratinocytes to maintain their cell size/volume and water homeostasis under hyperosmotic stress.

Applications

Category: Skin care

Recommended use: 0.5–3%

Formulation

GENENCARE® OSMS MI is soluble in water and therefore easy to formulate. It gives colorless solutions and is compatible with most ingredients allowing a wide range of applications and formulation possibilities. In hot process, can be added in the main water tank before emulsification, or, preferably, at the end at T°<40°C, as such or premixed in water.
Starting point formulations are available for download on **ULProspector.com**

Regulatory information

- Listed on all relevant global chemical inventories.
- Complies with European, United States, Canada, Australia/ New Zealand, Korea, China, Japan, Brazil and Taiwan cosmetic regulations for use in general cosmetics.

Certifications and statements

- Natural certifications: Ecocert/Cosmos, Natrue
- Kosher and Halal: certified
- Natural Index (ISO 16128): NI=1, NOI = 1
- Upcycled™ certified ingredient by UFA
- Source: Non-GMO sugar beet
- Origin: produced in Finland
- For other statements, please refer to the Quality & Regulatory summary or contact your sales representative.

Shelf life

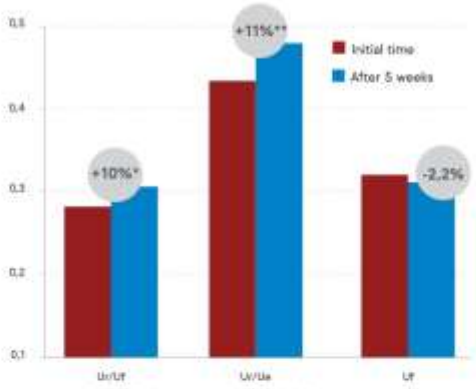
36 months from date of manufacture when stored in original packaging.

Storage conditions

Product is hygroscopic (attracting water). It must be stored in unopened cartons and protected from humidity to maintain shelf life.

Packaging

Available in 20kg cartons with polyethylene inner bag in one way 1000kg pallet.



Ur/Uf: rate of elastic recovery to total deformation
Ur/Ue: rate of elastic deformation = net elasticity
Uf: Total deformation

Control cream effect as baseline
* significant effect versus To and versus control cream (Student T test, p<0.01)
** significant effect versus To and versus control cream (Student T test, p<0.05)

Figure 2: Effect of 3% inositol on the evolution of 3 biomechanical parameters of the skin over a 5 weeks in-use test

Contact information

North America
Rochester, New York (USA)
Tel.: +1 800 847 5311
Fax.: +1 585 256 5295

Latin America
Barueri, Brazil
Tel.: +55 (11) 94361-6592

Europe, Middle East & Africa
Oegstgeest, The Netherlands
Tel.: +31 71 5686 168
Fax.: +31 71 5686 169

Asia/Pacific
Singapore
Tel: +65 6586 3688
Fax: +65 6272 7494

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www.genencor.com

Valid from: June 24, 2021

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PRODUCT SPECIFICATION - PS A56003-4.0EN

Material no. A56003

GENENCARE® OSMS MI

Description

Myo-Inositol For Personal Care

Physical/chemical specifications

Myo-Inositol Content (dry substance)	97 - 100 %
Colour (ICUMSA method)	Max. 150
pH, 5% Solution in DiH2O	6.0 - 9.0
Moisture	Max. 0.5 % (when packed)
Chloride	Max. 50 mg/kg
Sulphate	Max. 100 mg/kg
Melting Range	224 - 227 °C
Residue on Ignition	0 - 0.2 %

Microbiological specifications

Total Viable Count	Max. 100 CFU/g
Yeasts	Max. 100 CFU/g
Molds	Max. 100 CFU/g
Total Coliforms	NEG /g
E. coli	NEG /g
Salmonella	NEG /25g

Heavy metal specifications

Heavy metals	Max. 10 mg/kg
Arsenic	Max. 0.5 mg/kg
Lead	Max. 0.5 mg/kg
Iron	Max. 5.0 mg/kg

Storage

Stability data is available upon request

Product and manufacturing certifications

- ISO 9001
- Kosher
- ISO 22716

Additional information

Regional contact information:

Asia / Pacific: +65.838.7410
Europe / Africa: +31.71.5686.168
Latin America: +54.11.5199.9550
United States & Canada: 800.847.5311

CHAMOMILE GERMAN EXTRACT 20 GLY-LG

Safety Data Sheet

FORM NO: 300.GLY.1158 Date prepared : 30.09.2015 Arranged : - Revised : 00

according to (R.G. 13.12.2014 – 29204)

1. Identification of the product and the company

1.1. Product Details

Product Name	CHAMOMILE GERMAN EXTRACT 20 GLY-LG
Product Code	300.GLY.1158

1.2.Application of the Substance / the Preparation

Field of use of the product	Additives for the cosmetics industry

1.3. Manufacturer/Supplier

Company Name	Surya Kimya San.Tic.Ltd.Sti.
Address	Ferhatpasa Mah. Maresal Fevzi Cakmak Cd. G-22.Sk. No:52 Atasehir / Istanbul / Turkey
Phone	+90 216 417 88 02
Contact Person	Chemist Aslı SALAR (TSE GBF Certificate number:1990) info@surya.com.tr

1.4.Emergency Information

Phone	+90 216 417 88 02

2.Hazards Identification

2.1 Classification of the Substance or Mixture

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008 [CLP]

This substance is not classified as dangerous according to Directive 67/548/EEC

2.2 Label Elements

The product does not need to be labelled according to Regulation (EC) No 1272/2008 [CLP] and respective national laws

2.3 Other Hazards

None

3.Composition/Information on Ingredients

This product does not known to contain any harmful materials.

Active Ingredients INCI Name	CAS No	EC No	REACH Registration Numbers	*Content
Chamomilla Recutita Flower Extract	84082-60-0	282-006-5	-	C
Auxilary Ingredients INCI Name	**CAS No**	**EC No**	**REACH Registration Numbers**	***Content**
Aqua (Water)	7732-18-5	231-791-2	-	A
Glycerine	56-81-5	200-289-5	01-2119471987-18	C
2-phenoxyethanol	122-99-6	204-589-7	01-2119488943-21	F
Benzoic acid	65-85-0	200-618-2	01-2119455536-33	G
Dehydroacetic Acid	520-45-6	208-293-9	-	G

*FDA – Code: A: >50% - B: 25-50% - C: 10-25% - D: 5-10% - E:1-5% - F: 0,1-1% - G: <0,1%

4. First Aid Measures

4.1 Description of First Aid Measures

General Information	Consult a physician. Show this safety data sheet to the doctor in attendance.
Following Inhalation	Remove casualty to fresh air and keep warm and at rest. Consult a physician.
Following Skin Contact	Wash immediately with soap and plenty of water. Consult a physician.
Following Eye Contact	After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately
Following Ingestion	If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention
Self Protection of the First Aider	Pay attention to self-protection!
Most Important Symptoms and Effects, both Acute and Delayed	No data available
Indication of any Immediate Medical Attention and Special Treatment Needed	Specific treatment: First aid, decontamination, treatment of symptoms Notes for the doctor: Treat symptomatically

5.Fire Fighting Measures

5.1 Extinguishing Media

Suitable extinguishing media	Foam, Carbon dioxide (CO_2), Dry extinguishing powder
Unsuitable extinguishing media	Water
Unusual fire/explosion hazards	None

5.2 Special Hazards Arising From the Substance or Mixture

No data available

5.3 Advice For Firefighters

Wear a self-contained breathing apparatus and chemical protective clothing for fire fighting if necessary

5.4 Additional Information

No data available

6.Accidental Release Measures

6.1 Personal Precautions, Protective Equipment and Emergency Procedures

Use personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation.(See Section 8)

6.2 Environmental Precautions

No special measures required

6.3 Methods and Materials For Containment and Cleaning Up

Clean contaminated objects and areas thoroughly observing environmental regulations. Packaging may be reused or recycled after cleaning.

6.4 Reference to Other Sections

Personal protection equipment: see Section 8.

7.Handling and Storage

7.1 Precautions For Safe Handling

Protective measures	Use only well-ventilated areas. Handle and open container with care. Always close containers tightly after the removal product. Wear personal protective clothing (see section 8)
Measures to prevent fire	This product is not flammable. No special fire protection measures are necessary.
Measures to prevent aerosol and dust generation	During filling, metering and sampling should be used if possible: splashproof grounded devices.
Measures to protect the environment	Shafts and sewers must be protected from entry of the product
Advice on general occupational hygiene	Work in well-ventilated zones or use proper respiratory protection. Avoid contact to skin, eyes and clothes. provide eye shower and label its location conspicuously. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat, drink, smoke, sniff. Remove contaminated, saturated clothing immediately. Wash contaminated clothing prior to re-use.

7.2 Conditions For Safe Storage, Including Any Incompatibilities

Technical measures and storage conditions	Store at room temperature
Requirements for storage rooms and vessels	Keep/store only in original container. Provide for retaining containers, e.g. floor pan without outflow. The floor should be leak tight, jointless and not absorbent. Ensure adequate ventilation of the storage area.
Further information on storage conditions	Protect containers against damage.

7.3 Specific End Uses

No data available

8.Exposure Controls and Personal Protection

8.1 Control Parameters

No data available

8.2 Exposure Controls

Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas.

Substance/mixture related measures to prevent exposure during identified uses	No specific measures
Structural measures to prevent exposure	No specific measures
Organisational measures to prevent exposure	Handle in accordance with good industrial hygiene and safety practice. When using, do not eat, drink or smoke. Avoid contact with skin, eyes and clothing. Keep away from food, drink and animal feeding stuffs. Wash hands before breaks and at the end of workday. Take off all contaminated clothing immediately. Do not breathe vapours or spray mist.
Technical measures to prevent exposure	No specific measures

Personal protective equipment

Eye and face protection	Goggles
Skin protections	
Hand protection	Gloves
Other skin protection	No specific measures
Respiratory protection	If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn.
Thermal hazards	No specific measures

Environmental exposure controls

Emission from ventilation or work process equipment should be checked to ensure they comply with the requirements environmental protection legislation.

Substance/mixture related measures to prevent exposure	No specific measures
Introduction measures to prevent exposure	No specific measures
Organisational measures to prevent exposure	No specific measures
Technical measures to prevent exposure	No specific measures

9.Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Appearance	Transparent liquid to slightly turbid
Colour	Between light yellow to yellow
Odour	Characteristic
Specific gravity (20 ℃)	1.000-1.100
Solubility	Soluble in aqueous solutions
pH	3.0-5.5
Flash Point	No data available
Boiling Point	>100 °C
Evaporation Rate	No data available
Flammability (solid, gas)	Does not apply, substance is a liquid
Auto-ignition Temperature	Product is not self-igniting
Explosive Properties	Does not apply, substance is not explosive. There are no chemical groups associated with explosive properties.
Oxidising Properties	Does not apply, substance is not oxidising. There are no chemical groups associated with oxidising properties.

9.2. Other information

No additional information relevant to safe use of the substance

10.Stability and Reactivity

10.1 Reactivity

No specific data related to reactivity available for this product or its ingredients

10.2 Chemical stability

The substance is chemically stable under recommended conditions of storage, use and temperature

10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions

10.4 Conditions to avoid

Direct sunlight, extreme heat exposure

10.5 Incompatible materials

Very strong oxidizing agents

10.6 Hazardous decomposition products

Does not decompose when used for intended uses

11. Toxicological Information

11.1. Information on toxicological effects

Product

Acute Toxicity	By appropriate use of the product no health damage is known
Acute oral toxicity	Not classified based on available information. Repeated or prolonged skin contact may lead to irritation
Acute dermal toxicity	Not classified based on available information. May be an eye irritant
Acute inhalation toxicity	Not classified based on available information. Breathing in vapour, mists or aerosols may produce respiratory irritation
Skin corrosion / irritation	Not classified based on available information
Serious eye damage / irritation	Not classified based on available information
Respiratory or skin sensitisation	Not classified based on available information
Germ cell mutagenicity	Not classified based on available information
Carcinogenicity	Not classified based on available information
Reproductive toxicity	Not classified based on available information
Specific target organ toxicity (single exposure)	Not classified based on available information
Specific target organ toxicity (repeated exposure)	Not classified based on available information
Aspiration hazard	Not classified based on available information

Components	The product referred contains lesser amount of components than the maximum
2-phenoxyethanol	H302: Harmful if swallowed, H319: Causes serious eye irritation
Maximum concentration in ready for use preparation	1.0%
Benzoic acid	H315: Causes skin irritation, H318: Causes serious eye damage, H372: Causes damage to organs through prolonged or repeated exposure . Lungs, Inhalation
Maximum concentration in ready for use preparation	Rinse-off products, except oral care products: 2.5% (acid) Oral care products: 1.7% (acid) Leave-on products: 0.5% (acid)
Dehydroacetic Acid	H302: Harmful if swallowed
Maximum concentration in ready for use preparation	0.6% (as acid)
12. Ecological Information	
Toxicity	Not classified based on available information
Persistence and degradability	Not classified based on available information
Bioaccumulative potential	Not classified based on available information
Mobility in soil	Not classified based on available information
Results of PBT and vPvB assessment	This substance does not meet the PBT / vPvB criteria of REACH, annex XIII
Other adverse effect	None
13.Disposal Considerations	
13.1 Waste treatment methods	
Product / packaging disposal	Waste disposal according to directive 2008/98/EC, covering waste and dangerous waste Waste must be disposed of in line with local regulations. Waste code should be assigned by the users, preferable in discussion with the waste disposal authorities.
Waste treatment-relevant information	Can be incinerated together with household waste in compliance with applicable technical regulations following consultation with approved waste disposal management companies and authorities in charge.
Sewage disposal-relevant information	Smaller quantities can be disposed of with household waste.
Other disposal recommendation	Contaminated packaging should be emptied as far as possible and after appropriate cleaning may be taken for re-use
14. Transport Information	
UN-No.	Not applicable
UN proper shipping name	Not applicable
Transport hazard class(es)	Not applicable
Packing group	Not applicable
Environmental hazards	Not applicable
Special precaution for user	Not applicable
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code	Not applicable
Road and rail transport (SDR/RID)	Not applicable
Air transport (ICAO/IATA-DGR)	Not applicable
Sea transport (IMO/IMDG)	Not applicable
Inland navigation (ADN/ADRN)	Not applicable
	Not dangerous according to the above specifications. The product does not constitute a hazardous substance in national / international road, rail, sea and air transport.
15. Regulatory Information	
	This safety data sheet complies with the requirements of 29204 TC and European Regulations
Safety, health and environmental regulations/legislation specific for the substance or mixture	No data available
Chemical Safety Assessment	No data available
16. Other information	

Arranged or revised according to regulation (EU) No: 453/2010 amending regulation (EC) No: 1907/2006 (REACH). It should not be construed as guaranteeing specific properties of the products described or their suitability for a particular application. All information and instructions provided in this Safety Data Sheet (SDS) are based on regulations, databases, literature and our current knowledge. However, it does not constitute a guarantee for any specific product features and does not establish a legally valid contractual relationship. Existing acts and regulations must be observed by the recipient of our products under their own responsibility.

SURYA

Chamomile German Extract 20 GLY-LG

Technical Data Sheet

Product Number 300.GLY.1158

Plant of Material Flower

Description

German chamomile (Matricaria recutita)is an annual plant of the family Asteraceae.It has a branched, erect and smooth stem, which can reach up to a height of 15–90 cm.The small daisy-like flowers have white collars circling raised, cone-shaped, yellow centers and grow on long, thin, light green stems. The white ray florets are furnished with a ligule, while the disc florets are yellow. The hollow receptacle is swollen and lacks scales. They can grow wild and close to the ground but also can be found bordering herb gardens. It is native to Europe, north Africa, and some parts of Asia. The strong, aromatic smelling flowers bloom in early to midsummer.

Application For use in every cosmetic formulations

Recommended level of use 1 - 10 %

Surya Kimya - Maresal Fevzi Cakmak Cad. G-22 Sk. No.52 Ferhatpasa - Atasehir / Istanbul **T**: +90 216 417 88 02 - 04 **F**: +90 216 593 90 69
info@surya.com.tr
www.surya.com.tr

FR-KK005-02-V0 Arranged : 04.06.2015 Revised : 1

SURYA

Chamomile German Extract 20 GLY-LG

Technical Data Sheet

Specifications

Assay	Minimum Value	Maximum Value
Aspect	transparent liquid	slightly turbid
Colour	light yellow	yellow
Odour	characteristic	
Specific Gravity (20°C)	1.000	1.100
pH	3.0	5.5
Solubility	soluble in aqueous solutions	
Total Microbial Count		
Bacteria		*1000 cfu/ml*
Moulds and Yeasts		*100 cfu/ml*

Storage

Temp. between 15-22°C,dark place in closed containers

Shelf Life

When stored accordingly, stable for 12 months

INCI Name	CAS - No.	EINECS No.	Function (CTFA)	Function (EU)
Water	7732-18-5	231-791-2	-	Solvent
Glycerine	56-81-5	200-289-5	Hair conditioning agent, Skin conditioning agent	Denaturant, Hair condetioning, Humectant, Masking, Oral care, Perfuming, Skin protecting, Viscosity controlling
Chamomilla Recutita Flower Extract	84082-60-0	282-006-5	Fragrance ingredients; skin conditioning agents miscellaneous; skin conditioning agents occlusive	Masking, Skin conditioning
Phenoxyethanol	122-99-6	204-589-7	Preservative	Preservative
Benzoic acid	65-85-0	200-618-2	Preservative, Solvent, Viscosity decreasing agent	Bulking, Masking, Preservative
Dehydroacetic acid	520-45-6	208-293-9	Preservative	Preservative

Special Note:

The information above is to the best of our knowledge, reliable. Users should, however, conduct their own tests to determine the suitability of our products for their own specific purposes. Statements contained herein should not be considered as warranty of any kind, expressed or implied, and no liability is accepted for the infringements of any patents.

Surya Kimya - Maresal Fevzi Cakmak Cad. G-22 Sk. No.52 Ferhatpasa - Atasehir / Istanbul **T**: +90 216 417 88 02 - 04 **F**: +90 216 593 90 69
info@surya.com.tr
www.surya.com.tr

FR-KK005-02-V0 Arranged : 04.06.2015 Revised : 1

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : PENTAVITIN®

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Ingredient for personal care products

1.3 Details of the supplier of the safety data sheet

Company : DSM Nutritional Products Ltd.
PO Box 2676
4002 Basel

Telephone : +41618158888
E-mail address of person responsible for the SDS : sds.nutritionalproducts@dsm.com

1.4 Emergency telephone number

+41 848 00 11 77 (Carechem 24 International)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3: Composition/information on ingredients

Brief description of the product : Mixture (preparation) containing active ingredients and auxiliary substances

3.1 Substances

Not applicable

3.2 Mixtures

Hazardous components

Remarks : No hazardous ingredients

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : No hazards which require special first aid measures.

If inhaled : Move to fresh air.

If symptoms persist, call a physician.

In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off with soap and plenty of water.

In case of eye contact : Flush eyes with water as a precaution.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.

If swallowed : Clean mouth with water and drink afterwards plenty of water.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No specific symptoms known.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Alcohol-resistant foam
Dry chemical
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : None known.

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Further information : Standard procedure for chemical fires.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment.

6.2 Environmental precautions

Try to prevent the material from entering drains or water courses.

6.3 Methods and material for containment and cleaning up

Wipe up with absorbent material (e.g. cloth, fleece).
Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For personal protection see section 8.
For disposal considerations see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling	:	For personal protection see section 8.
Advice on protection against fire and explosion	:	Take necessary action to avoid static electricity discharge. Product will burn under fire conditions.
Hygiene measures	:	General industrial hygiene practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	:	Protect against light. Keep container tightly closed and dry.
Advice on common storage	:	No special restrictions on storage with other products.
Recommended storage temperature	:	15 - 25 °C

7.3 Specific end use(s)

Specific use(s)	:	Not applicable

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Personal protective equipment

Eye protection	:	Safety glasses
Hand protection	:	Glove material: for example nitrile rubber
Skin and body protection	:	Lightweight protective clothing
Respiratory protection	:	No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	:	viscous liquid
Colour	:	pale yellow - amber
Odour	:	sweet
Odour Threshold	:	No information available.
pH	:	4.0 - 5.0
Melting point/range	:	not determined
Boiling point/boiling range	:	not determined
Flash point	:	> 100 °C

Evaporation rate	:	not determined
Lower explosion limit	:	not determined
Upper explosion limit	:	not determined
Vapour pressure	:	not determined
Relative vapour density	:	Not applicable
Relative density	:	1.240 - 1.255 (at 20 °C)
Density	:	not determined
Water solubility	:	soluble
Solubility in other solvents	:	Oils and fats: insoluble
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Ignition temperature	:	not determined
Thermal decomposition	:	No data available
Viscosity, dynamic	:	not determined
Explosive properties	:	No data available
Oxidizing properties	:	No data available

9.2 Other information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No hazards to be specially mentioned.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Possible incompatibility with materials listed under section 10.5.

10.4 Conditions to avoid

Heat

10.5 Incompatible materials

Strong acids and strong bases
Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if used as directed.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg

Skin irritation	:	No skin irritation (human, Patch Test 48 Hrs.)
	:	no phototoxic skin reaction (Guinea pig)
Eye irritation	:	No eye irritation (Rabbit, OECD Test Guideline 405)
Sensitisation	:	Did not cause sensitization. (Guinea pig, OECD Test Guideline 406)
	:	no photoallergenic skin reaction (Guinea pig)
Carcinogenicity	:	This information is not available.
Genotoxicity in vitro	:	not mutagenic (Ames test, OECD Test Guideline 471)
	:	not genotoxic (Chromosome aberration test in vitro, OECD Test Guideline 487)
Reproductive toxicity	:	This information is not available.
STOT - single exposure (Acute exposure)	:	The substance or mixture is not classified as specific target organ toxicant, single exposure.
STOT - repeated exposure	:	This information is not available.
Aspiration toxicity	:	No aspiration toxicity classification

SECTION 12: Ecological information

12.1 Toxicity

No data is available on the product itself.

12.2 Persistence and degradability

Biodegradability	:	Taking into consideration the properties of several components, the product is estimated to be biodegradable according to OECD classification.

12.3 Bioaccumulative potential

Bioaccumulation	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable

12.4 Mobility in soil

Distribution among environmental compartments	:	No data available

12.5 Results of PBT and vPvB assessment

Assessment	:	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Additional ecological information	:	There is no data available for this product.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	:	Offer surplus and non-recyclable solutions to a licensed disposal company.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Remarks	:	Not classified as dangerous in the meaning of transport regulations.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

NFPA Classification : Health hazard: 0
Fire Hazard: 1
Reactivity Hazard: 0

15.2 Chemical safety assessment

Not applicable

SECTION 16: Other information

Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

GB / EN

Product Information

Product Data Sheet

PENTAVITIN®

Description

PENTAVITIN® is 100% natural and plant-derived. The Saccharide Isomerate is formed by isomerisation of plant-derived D-glucose and is similar to that of the carbohydrate complex found in human skin. It is suitable for both skin- and hair care applications.
PENTAVITIN® is ECOCERT- and COSMOS approved, as well as NATRUE certified.

Product identification

Product code: 50 3315 2

Composition

INCI name	Content	CAS No.	EINECS/ELINCS
Saccharide Isomerate	> 50%	100843-69-4	none
Aqua	25-50%	7732-18-5	231-791-2
Citric Acid	0.1-1%	77-92-9	201-069-1
Sodium Citrate	0.1-1%	68-04-2	200-675-3

The two main components of the Saccharide Isomerate are glucose (CAS No. 50-99-7, EINECS No. 200-075-1) and fructose (CAS No. 57-48-7, EINECS No. 200-333-3).

Specifications

Appearance:	clear, yellowish to slightly amber coloured, slightly viscous liquid
pH:	4.0 - 5.0
Residue on drying:	52.0 - 55.0 % m/m
Relative density d20/20:	1.240 - 1.255
Refractive index n25:	1.422 - 1.430
Identity by Infrared spectrum:	corresponds to reference spectrum
Total aerobic mesophile plate count:	< 100 CFU / ml
Specified microorganisms:	not detectable in one milliliter

Solubility

PENTAVITIN® is soluble in water.

Product Information

Product Data Sheet

PENTAVITIN®

Stability and storage

PENTAVITIN® may be stored for at least 36 months from the date of manufacture in the unopened original container protected from light in a clean place and at a temperature between 15 and 25°C. The 'Best use before' date is printed on the label. Keep package tightly closed. Once opened, use contents quickly. In order to avoid secondary microbial contamination, following opening, containers should be handled with special care.

Uses

PENTAVITIN® is an ingredient for personal care products. PENTAVITIN® can be processed either warm (< 60°C) or cold, and should be incorporated into the aqueous phase of a cosmetic formulation. For skin care preparations, the addition of 1 to 5% PENTAVITIN® is recommended and for hair applications we recommend 0.2% in shampoo and 0.5% in conditioner/treatments.

Certifications

ECOCERT

PENTAVITIN® is approved by Ecocert Greenlife according to the Ecocert Standard for Natural and Organic Cosmetics available at http://cosmetics.ecocert.com.
100% Natural origin, 0% Synthetic origin

COSMOS

PENTAVITIN® is approved by Ecocert Greenlife according to the Cosmos Standard available at http://cosmos.ecocert.com.
100% Natural origin, 67.1% CPAI (Chemically Processed Agro-Ingredient)

NATRUE

PENTAVITIN® complies with the NATRUE criteria
2% Natural (0% Organic), 48% Water, 50% Derived Natural, 0% Nature-identical

Safety

This product is safe for the intended use. Avoid ingestion or direct contact by applying suitable protective measures and personal hygiene.

For full safety information and necessary precautions, please refer to the respective DSM Material Safety Data Sheet.

Legal notice

The information given in this publication is based on our current knowledge and experience, and may be used at your discretion and risk. It does not relieve you from carrying out your own precautions and tests. We do not assume any liability in connection with your product or its use. You must comply with all applicable laws and regulations, and observe all third party rights.

Product Information

Product Data Sheet

PENTAVITIN®

Additional information

To find out more about our ingredients, please contact your nearest DSM Nutritional Products office.

DSM Nutritional Products Ltd Product Management Building 241 PO Box 2676 CH-4002 Basel Switzerland	Tel.: +41 (0) 61 815 8899 Internet www.dsmnutritionalproducts.com

DSM Nutritional Products LLC 45 Waterview Boulevard Parsippany, NJ 07054-1298	Tel.: +1 (800) 526 0189 (Human Nutrition, Personal Care) Tel.: +1 (800) 451-8325 (Animal Nutrition) Internet www.unlimitednutrition-na.dsm.com
DSM Nutritional Products Europe Ltd. PO Box 2676 CH-4002 Basel Switzerland	Tel.: +41 (0) 61 815 7777 Internet www.unlimitednutrition-eu.dsm.com
DSM Singapore Industrial Pte Ltd. trading as DSM Nutritional Products Asia Pacific 30 Pasir Panjang Road #13-31 Mapletree Business City Singapore 117440	Tel.: + (65) 66326500 Internet www.dsmnutritionalproducts.com
DSM Nutritional Products China No. 476, Li Bing Road Zhangjiang High-Tech Park Pudong Area, Shanghai 201203 P.R. of China	Tel.: + 86 (0)21 6141 8188 Internet www.dsmnutritionalproducts.cn
DSM Produtos Nutricionais Brasil S.A. Avenida Engenheiro Billings, nº 1729 - Prédio 31 Sala A CEP:05321-010 São Paulo - SP Brasil	Tel.: + 55 (11) 3760-6300 Internet www.dsmnutritionalproducts.com

Material Safety Data Sheet

According to EU Regulation 1907/2006

Aloe Vera 10:1, Concentrate

Date Created: 18.10.2016

Date Revised: N/A

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier

Product Name	Aloe Vera 10:1, Concentrate				
Biological Definition	The juice expressed from the centre fillet of the plant Aloe barbadensis and preserved by the addition of Citric acid, Sodium benzoate and Potassium sorbate.				
INCI Name	Aloe barbadensis Leaf Juice, Citric acid, Sodium benzoate, Potassium sorbate				
Synonyms & Trade Names	N/A				
Internal Product Code	R00048				
CAS-No	85507-69-3 / 77-92-9 / 532-32-1/ 590-00-1	EC No.	287-390-8 / 201-069-1 / 208-534-8 / 246-376-1	EINECS No.	287-390-8 / 201-069-1 / 208-534-8 / 246-376-1

1.2 Details of the supplier of the safety data sheet

Company Identification	**The Kerfoot Group Ltd**, Olive House, Standard Way Industrial Estate, Darlington Road, Northallerton, North Yorkshire, England DL6 2XA E-mail: speciality@kerfootgroup.co.uk

1.3 Details of the supplier of the safety data sheet

Emergency Contact	☎ Mr Tom Kerfoot – Tel: 01609 766790

Material Safety Data Sheet

According to EU Regulation 1907/2006

Aloe Vera 10:1, Concentrate

Date Created: 18.10.2016

Date Revised: N/A

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (67/548/EEC)	Not classed as a hazardous substance.
Classification (EU 1272/2008)	Not classed as a hazardous substance.

2.2 Label elements

Label in accordance with Regulation (EC) No 1272/2008

GHS Label:	None
Signal word:	None
Contains	No hazardous substances
Hazard Statements:	None
Precautionary Statements:	None
Supplementary Precautionary Statements:	None

Risk phrases and Safety phrases in full refer to *Section 16 – Other Information*

2.3 Other hazards

Adverse physio-chemical properties	None
Adverse effects on human health	None

SECTION 3: Composition/information on ingredients

3.1 Substances

EU INCI		Cas No:	Hazards
Aloe barbadensis Leaf Juice	Cas No:	85507-69-3	Not classed as a hazardous substance
Citric acid	Cas No:	77-92-9	Not classed as a hazardous substance
Sodium benzoate	Cas No:	532-32-1	Not classed as a hazardous substance
Potassium sorbate	Cas No:	590-00-1	Not classed as a hazardous substance

3.2 Mixtures

EU INCI	Cas No:	hazards
N/A	N/A	N/A

The Kerfoot Group, Olive House, Standard Way Industrial Estate, Darlington Way, Northallerton, DL6 2XA
Tel: 01609 766790
E-mail: speciality@kerfootgroup.co.uk

SECTION 4: First aid measures

4.1 Description of first aid measures

General Information	See below.
Inhalation	Remove affected person to fresh air. Seek medical attention if any discomfort continues.
Ingestion	Rinse mouth with water. Seek medical attention if discomfort occurs.
Skin Contact	Remove contaminated clothing. Wash skin with soap and water. Seek medical attention if any discomfort continues.
Eye Contact	Immediately flush with plenty of water for up to 15 minutes. Remove any contact lenses and open eyes wide apart. Seek medical attention if irritation continues.

4.2 Most important symptoms and effects, both acute and delayed

None.

4.3 Indication of any immediate medical attention and special treatment needed

No specific recommendations.

SECTION 5: Fire fighting measures

5.1 Extinguishing Media

Extinguishing media: Carbon dioxide (CO_2). Dry Chemical Powder. Foam.
Unsuitable extinguishing media: Water

5.2 Special hazards arising from the substance or mixture.

Oxides of carbon formed on combustion.

5.3 Advice for fire-fighters

Remove containers close to fire or cool with water. Wear positive pressure self-contained breathing apparatus (SCBA) and appropriate protective clothing.

SECTION 6: Accidental release measures

6.1 Personal precautions

Wear suitable protective equipment, including gloves, goggles/face shield, respirator, boots, clothing or apron, as appropriate. In case of spills, beware of slippery floors and surfaces.

6.2 Environmental precautions

No known negative effects on aquatic environment.

6.3 Methods and material for containment and cleaning up

Contain and absorb spillage with sand, earth or other non-combustible material. Collect and place in suitable waste disposal containers and seal securely. Label the containers containing waste and contaminated materials and remove from the area as soon as possible. Wash thoroughly after dealing with a spillage.

6.4 References to other sections.

Please refer to *Section 8 - Exposure controls/personal protection* for further information on personal precautions
Please refer to *Section 13 - Disposal Considerations* for further information on waste treatment.

The Kerfoot Group, Olive House, Standard Way Industrial Estate, Darlington Way, Northallerton, DL6 2XA
Tel: 01609 766790
E-mail: speciality@kerfootgroup.co.uk

SECTION 7: Handling and Storage

7.1 Precautions for safe handling

Handle all packages and containers carefully to minimise spills.

7.2 Conditions for safe storage, including any incompatibilities

Store in tightly closed, original container in a cool, dry and well ventilates area. Keep away from heat, sparks and open flame. Protect from freezing and direct sunlight.

7.3 Specific end use(s)

No additional data available.

SECTION 8: Exposure controls/personal protection

8.1 Control Parameters

None

8.2 Exposure Controls

Eye protection		Eyewear complying with an approved standard should be worn if a risk assessment indicates eye contact is possible. The following protection should be worn: Chemical splash goggles or face shield.
Hand protection		Chemical-resistant, impervious gloves complying with an approved standard should be worn if a risk assessment indicates skin contact is possible.
Respiratory Equipment	No specific recommendations. Respiratory protection may be required if excessive airborne contamination occurs. Ensure area is well ventilated	
Skin protection	Wear appropriate clothing to prevent any possibility of skin contact. Wear apron or protective clothing.	
Hygiene Measures	Good personal hygiene practices are always advisable, especially when working with chemicals / oils.	
Engineering Measures	No special measure required	

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	Mobile Liquid
Colour	Clear yellow to brown
Odour	Characteristic - vegetable like
Relative Density	1.011 - 1.025 @20°C
Flash Point (°C)	N/A
Refractive Index	N/A
Melting Point (°C)	N/A
Boiling Point (°C)	N/A
Vapour Pressure	N/A
Solubility in Water @20°C	N/A
Auto-ignition temperature (°C)	N/A

9.2 Other information

The Kerfoot Group, Olive House, Standard Way Industrial Estate, Darlington Way, Northallerton, DL6 2XA
Tel: 01609 766790
E-mail: speciality@kerfootgroup.co.uk

N/A

SECTION 10: Stability and reactivity

10.1 Reactivity

Stable under normal handling conditions.

10.2 Chemical stability

Stable under the recommended handling and storage conditions.

10.3 Possibility of hazardous reactions

Will not polymerise

10.4 Conditions to avoid

Avoid heat, flames and other sources of ignition.

10.5 Incompatible materials

Strong oxidising agents. Strong acids. Strong alkalis.

10.6 Hazardous decomposition products

Thermal decomposition or combustion products may include the following substances: Oxides of carbon. Oxides of nitrogen.

SECTION 11: Toxicological information

11.1 Information on toxicological effects.

Acute toxicity:	No specific health hazards known
Skin corrosion / irritation:	No specific health hazards known. May cause allergic contact eczema. Prolonged or repeated exposure may cause the following adverse effects: Allergic rash. Seek medical attention.
Serious eye damage/irritation:	Vapour or spray in the eyes may cause irritation and smarting.
Respiratory or skin sensitisation:	No specific health hazards known.
Germ cell mutagenicity:	No additional data available
Carcinogenicity:	No additional data available
Reproductive toxicity:	No additional data available
STOT-single exposure:	No additional data available
STOT-repeated exposure:	No additional data available
Aspiration hazard:	No additional data available
Other information:	No additional data available

SECTION 12: Ecological information

12.1 Toxicity

No negative effects on the aquatic environment are known.

12.2 Persistence and degradability

The product is expected to be biodegradable.

12.3 Bio-accumulative potential

The product does not contain any substances expected to be bio-accumulating.

12.4 Mobility in soil

The product is soluble in water.

12.5 Results of PBT and VPVB assessment

This product does not contain any substances classified as PBT or vPvB.

12.6 Other adverse effects

None.

SECTION 13: Disposal considerations

13.1 Waste Treatment Methods

When possible recover spilled product. When product must be discarded, do so into an authorised dump or recycling service station. Act in accordance with local and national regulations.

SECTION 14: Transport information

Warning Icon	No data available.
Proper Shipping Name	Not bound under transport regulations.
UN No. Road	Not bound under transport regulations.
ADR Class	None
Hazard No (ADR)	None
Hazchem Code	None
UN No. SEA	Not bound under transport regulations.
IMDG Class	None
IMDG Pack Gr.	None
EMS	None
UN No. AIR	Not bound under transport regulations.
Air Class	None
Air Pack Gr.	None

The Kerfoot Group, Olive House, Standard Way Industrial Estate, Darlington Way, Northallerton, DL6 2XA
Tel: 01609 766790
E-mail: speciality@kerfootgroup.co.uk

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU Directives	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18th Dec 2006 Concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 199/45/EC and repealing Council Regulation Council Regulation (EEC) No793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, and 93/105/EEC and 2000/21/EC including amendments.
Statutory Instruments	The Chemicals (Hazard Information and Packaging for Supply Regulations 2009 (S.I. 2009 No 716).
Approved Code of Practice	Classification and Labelling of Substances and Preparations Dangerous for Supply. Safety Data Sheets for Substances and Preparations
Guidance Notes	Workplace Exposure Limits EH40. CHIP for everyone HSG 108.

15.2 Chemical safety assessment

An assessment has not been executed.

SECTION 16: Other information

Training instructions: Refer to possible hazard before use of this product.

Abbreviations and acronyms:

MSDS	Material Safety Data Sheet
INCI	International Nomenclature of Cosmetic Ingredients
CAS	Chemical Abstract Service
IMDG	International Maritime Code for Dangerous Goods
ADR	Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
RID	International Carriage of Dangerous Goods by Rail
ICAO	International Civil Aviation Organization
ADN	International Carriage of Dangerous Goods by Inland Waterways
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
Trem Card	Transport Emergency Card
STOT	Specific Target Organ Toxicity
N/A	Not Available
Risk Phrases in full:	N/A
Safety Phrases in full:	N/A

Complies with REACH guidance for SDS as circulated by ECHA 2011.

The Kerfoot Group, Olive House, Standard Way Industrial Estate, Darlington Way, Northallerton, DL6 2XA
Tel: 01609 766790
E-mail: speciality@kerfootgroup.co.uk

Material Safety Data Sheet

According to EU Regulation 1907/2006

Aloe Vera 10:1, Concentrate

Date Created: 18.10.2016

Date Revised: N/A

Revisions in this document

Date (DD-MM-YYYY)	Change	Revision Number
18/10/2016	New Issue	0

The Kerfoot Group, Olive House, Standard Way Industrial Estate, Darlington Way, Northallerton, DL6 2XA
Tel: 01609 766790
E-mail: speciality@kerfootgroup.co.uk

KERFOOT
Avril GROUP

Date: 05/03/2020

To Whom It May Concern

Re: INCI Breakdown - Aloe Vera 10:1 Concentrate – R00048

We can confirm that the Aloe Vera 10:1 Concentrate supplied on R00048 is produced from:

INCI Name	EINECS	INCI Breakdown (%)
Aloe Barbadensis Leaf Juice	287-390-8	> 98.0 to ≤ 100.0
Citric Acid	201-069-1	≤ 1.0
Sodium Benzoate	208-534-8	≤ 0.1
Potassium Sorbate	246-376-1	≤ 0.2

The Kerfoot/Avril Group can also confirm that the Aloe Vera 10:1 Concentrate is a mixture composition.

Yours Faithfully,

The Kerfoot Technical Team

t: +44 (0) 1609 766 790
e: info@kerfootgroup.co.uk
w: www.kerfootgroup.co.uk

VAT number 329311570
Registered Number 1501275

Kerfoot/Avril Group
The Olive House
Standard Way Industrial Park
Darlington Road, Northallerton

North Yorkshire DL6 2XA UK

V.Finished Product
Certificate of Analysis

bioniks

BRAND NAME: BIONIKS
PRODUCT NAME: INTENSIVE MOISTURIZING CREAM

CERTIFICATE OF ANALYSIS

General Characteristic

ANALYSIS	SPECIFICATION	METHOD
Appearance	Cream	INHOUSE
Color	White	INHOUSE
Odor	Characteristic	INHOUSE

Chemical Specifications

ANALYSIS	SPECIFICATION	METHOD
Viscosity (at 25°C)	N/A	INHOUSE
Refractometric Index	N/A	INHOUSE
pH	5,6	INHOUSE
Flash Point	N/A	INHOUSE

Other Specifications

ANALYSIS	SPECIFICATION	METHOD
Type of Bottle	Jar	-

Microbiological Specifications

DECLERATION OF MICROBIAL IN COSMETIC PRODUCTS				
ANALYSIS	METHODS	RESULT	VALUE	LIMITS
Total Microorganism Count	European Pharmacopoeia Chapter 2.6.12 ve 2.6.13	<10	kob/ml	$\leq 2x10^3$
Mold and Yeast Count	European Pharmacopoeia Chapter 2.6.12 ve 2.6.13	<10	kob/ml	$\leq 2x10^3$
Pseudomonas aeruginosa	European Pharmacopoeia Chapter 2.6.12 ve 2.6.13	Absence	g/ml	Absence
Staphylococcus aureus	European Pharmacopoeia Chapter 2.6.12 ve 2.6.13	Absence	g/ml	Absence
Escherichia coli	European Pharmacopoeia Chapter 2.6.12 ve 2.6.13	Absence	g/ml	Absence
Candida albicans	European Pharmacopoeia Chapter 2.6.12 ve 2.6.13	Absence	g/ml	Absence

Approved By:
Dr. Pharm. Neslihan ŞAHİN

BİONİKS MEDİKAL KOZMETİK LİMİTED ŞİRKETİ
Cevizli Mah. Mustafa Kemal Cad. Hukukçular İş Merkezi No: 34 İç Kapı No: 15
Kartal/ İstanbul

VI. Statement Of Animal Testing

DECLARATION ON ANIMAL TESTING

PRODUCER: RK KOZMETİK HİJYEN ÜRÜNLERİ SAN. DIŞ. TİC. A.Ş.

SUPPLIER ADDRESS: RK KOZMETİK HİJYEN ÜRÜNLERİ SAN. DIŞ. TİC. A.Ş.
İstanbul Deri Organize Sanayi Bölgesi Nokra Caddesi.
No:2/A No:2 3495 TUZLA / İSTANBUL

We (BİONİKS MEDİKAL KOZMETİK LİMİTED ŞİRKETİ) as being producing company of Manufacturer (BIONIKS INTENSIVE MOISTURIZING CREAM), hereby declare that no animal testing was conducted on any BIONIKS INTENSIVE MOISTURIZING CREAM / Skin Care Cosmetic Product after March 11th 2013 or any ingredients/raw materials after March 11th 2013 (Art. 4a, 76 /768/EEC; Art.18, 1223/2009 EC) for the purpose of compliance with the European Legislation on cosmetic products.

RK KOZMETİK HİJYEN ÜRÜNLERİ SAN. DIŞ. TİC. A.Ş.
İstanbul Deri Organize Sanayi Bölgesi Nokra Caddesi. No:2/A 4No:2 3495
TUZLA / İSTANBUL

VII. Adverse and Serious Adverse Effect Declaration

bioniks

DECLARATION

Dear Sir/Madam;

Any adverse reactions and serious adverse effects have not been reported for;

- BIONIKS INTENSIVE MOISTURIZING CREAM - 50 ml

REGARDS,
BİONİKS MEDİKAL KOZMETİK LİMİTED ŞİRKETİ

BİONİKS MEDİKAL KOZMETİK LİMİTED ŞİRKETİ
CEVİZLİ MAH. MUSTAFA KEMAL CAD. HUKUKÇULAR İŞ MERKEZI NO: 34 İÇ KAPI NO: 15 KARTAL/ İSTANBUL

VIII. Statement Regarding To Nano Materials

bioniks

DECLARATION OF NANO MATERIALS IN COSMETIC PRODUCT

Company: RK KOZMETİK HİJYEN ÜRÜNLERİ SAN. DIŞ. TİC. A.Ş.

Adress: İstanbul Deri Organize Sanayi Bölgesi Nokra Caddesi. No:2/A No:2 3495
TUZLA / İSTANBUL

We declare to that we don't use nanomaterial ingredients in the manufacture of cosmetic products which is listed below.

- BIONIKS INTENSIVE MOISTURIZING CREAM - 50 ml

We commit to inform to that as per our contractual obligation,of any changes to our declaration with respect to animal testing of substances in or final our cosmetic products.

REGARDS

RK KOZMETİK HİJYEN ÜRÜNLERİ SAN. DIŞ. TİC. A.Ş.

RK KOZMETİK HİJYEN ÜRÜNLERİ SAN. DIŞ. TİC. A.Ş.
İstanbul Deri Organize Sanayi Bölgesi Nokra Caddesi. No:2/A No:2 3495
TUZLA / İSTANBUL

IX. Statement Regarding To Claims

bioniks

SAFETY-RELATED CLAIM

Brand Name : **BIONIKS**
Product Name : **INTENSIVE CARE CREAM**

There are no safety related claims on this product.

REGARDS
Maruderm Güzellik ve Kozmetik Ürünleri San. ve Tic. A.Ş.

BİONİKS MEDİKAL KOZMETİK LİMİTED ŞİRKETİ
CEVİZLİ MAH. MUSTAFA KEMAL CAD. HUKUKÇULAR İŞ MERKEZI NO: 34 İÇ KAPI NO: 15 KARTAL/ İSTANBUL

Claims of Proof

There are also the following phrases on the label: Enriched with Hyaluronic Acid Complex, Niacinamide, Chamomile Extract, Aloe Barbadensis Leaf Water, Panthenol, and Betaine, this intense moisturizer deeply hydrates and soothes the skin. It helps maintain the skin's optimal moisture balance, keeping it soft and supple, all day long.

Niacinamide:

Nicotinic acid/niacinamide and the skin

Nicotinic acid (also generally known as niacin) and niacinamide (also known as nicotinamide) are similarly effective as a vitamin because they can be converted into each other within the organism. The blanket term vitamin B(3) is used for both. Niacinamide is a component of important coenzymes involved in hydrogen transfer. Here, the two codehydrogenases, nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP) are of central importance. Topical application of niacinamide has a stabilizing effect on epidermal barrier function, seen as a reduction in transepidermal water loss and an improvement in the moisture content of the horny layer. Niacinamide leads to an increase in protein synthesis (e.g. keratin), has a stimulating effect on ceramide synthesis, speeds up the differentiation of keratinocytes, and raises intracellular NADP levels. In ageing skin, topical application of niacinamide improves the surface structure, smoothes out wrinkles and inhibits photocarcinogenesis, it is possible to demonstrate anti-inflammatory effects in acne, rosace and nitrogen mustard-induced irritation. Because of its verifiable beneficial effects, niacinamide would be a suitable component in cosmetic products for use in disorders of epidermal barrier function, for ageing skin, for improving pigmentary disorders and for use on skin prone to acne.

[Ref: Gehring W. Nicotinic acid/niacinamide and the skin. J Cosmet Dermatol. 2004 Apr;3(2):88-93. doi: 10.1111/j.1473-2130.2004.00115.x. PMID: 17147561.]

Niacinamide is vitamin B3, an essential nutrient. In the body, it is converted to the co-factors NADH and NADPH that are involved in many biochemical reactions. Dietary deficiency of this water-soluble member of the vitamin B family causes pellagra, a disease which includes dermatitis and red lesions. Pellagra caused thousands of deaths in the United States in the first half of the twentieth century, until simple dietary supplementation with this absorbable vitamin was found to cure the disorder. NAD+ and NADPH levels in skin cells decline with age. Thus, supplementing skin with the precursor to these vital co-factors has the potential to provide appearance benefits to aging skin. Since niacinamide penetrates the skin's surface readily, it is bioavailable from topical application for targeted delivery to specific skin sites. Clinical evaluations of topical

formulations containing this vitamin have identified a wide range of skin care benefits. Among the many cosmetic effects for skin are reductions in the appearance of hyperpigmented spots, redness, yellowing (sallowness), surface sebum, pore size, surface texture, and fine lines and wrinkles. Additionally, there are improvements in moisturization, stratum corneum barrier integrity and elastieity. Further clinical evaluations have found that specific combinations of niacianamide with other cosmetic skin care ingredients can provide an even greater magnitude of appearance benefits.benefits.

Niacinamide effect (ex vivo, in vitro)	Postulated skin appearance benefits
Inhibition of sebum production, specifically reducing the content of diglycerides, triglycerides, and fatty acids	Reduced acne Reduced pore size Improved texture
Stimulation of epidermal skin barrier lipids (ceramides) and proteins (keratin, involucrin, filaggrin)	Improved skin barrier and moisturization Reduced skin redness Rosacea appearance benefits
Anti-inflammatory (inhibition of inflammatory cytokines)	Anti-aging Reduced skin redness Rosacea appearance benefits
Increased production of collagen	Anti-wrinkle
Inhibition of production of excess dermal GAGS (glycosaminoglycans)	Anti-wrinkle
Inhibition of melanosome transfer from melanocytes to keratinocytes	Reduced hyperpigmentation
Inhibition of protein glycation via anti-oxidant effects (niacinamide, as precursor, increases levels of the redox co-factors NADH and NADPH)	Inhibit skin yellowing Sun protection

[Ref: CHAPTER 10 Niacinamide : A Topical Vitamin with Wide-Ranging Skin Appearance Benefits, D. Berson, R. Osborne, J. Oblong, T. Hakozaki, M. B. Johnson, D. Bissett, 2013]

Niacinamide is the biologically active form of vitamin B3. It is likely to act via an inhibition of the transfer of melanosomes from melanocytes into keratinocytes. In fact, it inhibits both in vitro and in vivo melanogenesis, most hikely through the abolition of melano-some transfer [53]. In addition, vitamin B3 has no effect on purified tyrosinase, therefore, skin darkening is decreased in the co-culture system or in reconstructed epidermis and not in melanocyte monocultures [21].

[Ref:https://rudiapt.files.wordpress.com/2017/11/cosmeceuticals-and-active-cosmetics-3rd-ed-2016.pdf]

Aloe Barbadensis Leaf Juice:

COSMETOLOGICAL IMPORTANCE

Cosmetology is the study of cosmetics and their uses and cosmetics are the preparations externally applied to change or enhance the beauty of skin, hair, nails, lips, and eyes. Aloe vera has been used since ancient times for healing infection and burns. However with the improvement in cosmetology, it has been proved that Aloe vera is a very important component of cosmetics. It contains almost 20 amino acids, minerals like calcium, magnesium and sodium in sufficient quantities, enzymes, vitamins, polysaccharides, nitrogen and other components that make it a miracle beauty herb. Some of the most important applications of Aloe vera for purpose of Cosmetology are being explained here briefly.

Pigmentation

Melanin is a pigment which is responsible for the color of the human skin. Hyper pigmentation is a situation in which large amount of melanin is synthesized. This generally happens due to excess exposure of the skin to the sun. In reaction to UV rays in sunbeams, the skin cells called melanocytes initiate to synthesize melanin. This increased synthesis of melanin is responsible for the emergence of darkened patches on the skin. Aloe vera has the property of diminishing the pigmentation and dark spots on the face [28,29].

Skin Eruption

Aloe vera containing creams are beneficial for skin eruptions. Aloe vera gels have been proved to be the best remedy for burns and wounds. Actually, cellular regeneration, anti-bacterial and anti-fungal activities of Aloe vera make it useful for skin eruption [30,31].

Sclap and other Skin Problems

Aloe vera is very valuable for skin disorders. It may also be used for the treatment of scalp, stings, sprains, sunburns, eczema, sore muscles, arthritis, scrapes, cold sores, scalds, abrasions, psoriasis, bruises, etc [32,33].

Itching and Blisters

Aloe vera also provides relief from itching and also helps to treat blisters. Aloe contains vitamin B1, B2, B6, B12 and vitamin C that provide soothing and pleasing sensation to skin [34,35].

Skin Aging

Aloe vera initiates the synthesis of elastin as well as collagen. These proteins are essential for preventing the aging of the skin [36,37]. Acne Aloe vera helps to eradicate acne scars by performing as an immune booster and an anti-inflammatory agent. Beauty products composed of Aloe vera may diminish the rigorousness of acne. It is also composed of the chemical ingredients which have the property to save the skin to initiate the acne [38,39].

Freshness

Aloe vera impart the sensation freshness. It helps in increasing distribution of blood therefore providing easier oxygen exchange among the cells, hence giving them nourishment [40]. Sun-burns Aloe Vera has an outstanding possession in diminishing the hurting of sunburn. For this purpose, it is rubbed directly on skin. The fresh fluid from the plant or Aloe vera containing after-sun creams may be used for sun-burns [41].

Moisturizing Agent

Aloe vera may also be used for softening and moisturizing the skin. There are so many products available in the market containing Aloe vera which may be used post-showering to obtain the skin in super soft shape. Aloe vera gel, cream or lotion applied on the face forms a delicious cover that helps to shield the skin from dust and other natural elements which may be injurious to the skin [42,43].

[Ref: https://www.researchgate.net/publication/233818204_Medicinal_and_cosmetological_importance_of_Aloe_vera]

Aloe vera deeply moisturizes the scalp, reduces dandruff, and enhances the natural shine of hair. Its proteolytic enzymes repair dead skin cells on the scalp, promoting healthy hair growth. Additionally, it improves hair elasticity, prevents breakage, and makes hair easier to style.

[Ref: https://www.medicoverhospitals.in/tr/articles/aloe-vera-gel-for-hair?utm_]

Chamomilla Recutita Flower Extract:

Enriched with Chamomile Extract to help soothe and protect the skin from sun-induced irritation and oxidative stress."

(Supports skin comfort and reduces visible signs of photo-induced inflammation.)

[Ref: Srivastava, J.K., Shankar, E., & Gupta, S. (2010). Chamomile: A herbal medicine of the past with bright future. Molecular Medicine Reports, 3(6), 895–901.
https://doi.org/10.3892/mmr.2010.377]

Chamomilla recutita (Matricaria) flower extract is renowned for its soothing and anti-inflammatory properties, making it particularly beneficial for sensitive skin. Rich in bioactive compounds such as apigenin, chamazulene, and α-bisabolol, this extract helps to calm irritated skin, reduce redness, and support the skin's natural barrier function.

Clinical studies have demonstrated that formulations containing Chamomilla recutita extract are generally non-irritating and well-tolerated. For instance, human repeat insult patch tests (HRIPT) on products with concentrations ranging from 0.01% to 0.4% showed no adverse skin reactions, underscoring its suitability for daily use in intimate care products.

[Ref: https://journals.sagepub.com/doi/10.1177/1091581818801814?utm_]

Sodium Hyaluronate:

Sodium Hyaluronate is a derivative of hyaluronic acid, known for its moisturizing, anti-wrinkle, and plumping effects in skincare. With its high water retention capacity, it helps maintain the skin’s moisture balance, enhances elasticity, and reduces the appearance of fine lines. Additionally, it nourishes and repairs the skin barrier, improving the overall appearance and feel of the skin. Due to its plumping effect, it is frequently used in anti-aging products.

As an acidic polysaccharide, the formation of Hyaluronic acid (HA) is typically Sodium Hyaluronate (SH) for knee repair, oral treatment, skincare and as a food additive. Nevertheless, little information is available on the anti-ageing activity of SH as a food additive. Therefore, we treated C. elegans with SH, then inferred the anti-aging activity of SH by examining the lifespan physiological indicators and senescence-associated gene expression. Compared with the control group, SH (800 μg/mL) prolonged the C. elegans' lifespans in regular, 35 °C and H2O2 environment by 0.27-fold, 0.25-fold and 1.17-fold. Simultaneously, glutathione peroxidase (GSH-Px), antioxidant enzyme superoxide dismutase (SOD) and catalase (CAT) were increased by 8.6%, 0.36% and 167%. However, lipofuscin accumulation, reactive oxygen species (ROS) and malondialdehyde

(MDA) were decreased by 36%, 47.8-65.7% and 9.5-13.1%. After SH treatment, athletic ability was improved and no impairment of reproductive capacity was seen. In addition, SH inhibited the blocking effect of age-1 and up-regulated gene levels involving daf-16, sod-3, gst-4 and skn-1. In conclusion, SH provides potential applications in anti-ageing and anti-oxidation and regulates physiological function.

[Ref: https://pubmed.ncbi.nlm.nih.gov/37048222/]

Due to the unique hydration, viscoelastic, and biocompatibility properties of HA and in view of a range of molecular-weight materials' ability to penetrate skin, HA is being extensively used in cosmetic products as moisturizer, thickener, and stabilizer. Since HA is a water-soluble product, it can be easily incorporated in the water phase of cosmetic formulas.

In hair-care and hair-treatment formulations, HA restructures the keratin fibers "inside" the fibers, improves elasticity of hair, and increases the washing resistance of colored hair

[Ref: https://www.researchgate.net/publication/272175669_Hyaluronan_Hyaluronic_Acid_a_natural_moisturizer_for_skin_care]

The product is claimed to be dermatologically tested. Dermatological testing has been initiated, and the file will be updated once the test report becomes available.

X. Finished Product MSDS

MATERIAL SAFETY DATA SHEET

Prepared in accordance with Annex II of the REACH Regulation EC 1907/2006
In compliance with regulation (EC) no. 1272/2008
According to Regulation (EU) No 2020/878

Printing Date: 25.05.2026 **Revision Date:** 25.05.2026
Revision No: 1 **Form No:** B-012

BIONIKS INSENTIVE CARE CREAM - 50 ml

1. IDENTIFICATION OF THE SUBSTANCE /MIXTURE AND OF THE COMPANY /UNDERTAKING

1.1 SUBSTANCE / IDENTIFICATION OF THE MIXTURE

PRODUCT NAME	BIONIKS INSENTIVE CARE CREAM - 50 ml
CHEMICAL FAMILY	COSMETIC-SKIN CARE PRODUCT
CAS No	N/A
EINECS No	N/A

1.2 DETERMINED USES AND RECOMMENDED USAGE OF THE SUBSTANCE / MIXTURE

USAGE	COSMETIC- SKIN CARE PRODUCT

1.3 SAFETY DATA SHEET SUPPLIER INFORMATION

PRODUCT OWNER:	BİONİKS MEDİKAL KOZMETİK LİMİTED ŞİRKETİ CEVİZLİ MAH. MUSTAFA KEMAL CAD. HUKUKÇULAR İŞ MERKEZI NO: 34 İÇ KAPI NO: 15 KARTAL/ İSTANBUL

1.4 EMERGENCY TELEPHONE NUMBER

EMERGENCY TELEPHONE NUMBER	National Poison Information Center (UZEM) 114 Emergency First Aid Center 112 Fire Department 112
MSDS RESPONSIBLE PERSON	Dr.Ecz.Neslihan Şahin

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008:

Not classified as Hazardous.

2.2 Label Informations

It is not included in the classification according to the provisions of le Regulation on the Safety Data Sheets for Hazardous Substances and Mixtures if dated 1272/2008. Therefore, there is no pigtogram, warning or hazard word.

Precautionary Statements

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove the contact lenses if they are installed and easy to do. Continue rinsing.

Additional Hazard Statements

No Relationship

MATERIAL SAFETY DATA SHEET

Prepared in accordance with Annex II of the REACH Regulation EC 1907/2006
In compliance with regulation (EC) no. 1272/2008
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Printing Date: 25.05.2026 **Revision Date:** 25.05.2026
Revision No: 1 **Form No:** B-012

BIONIKS INSENTIVE CARE CREAM - 50 ml

3. COMPOSITION / INFORMATION ON INGREDIENTS

INGREDIENTS (INCI): Aqua, Glycerin, Niacinamide, Caprylic/Capric Triglyceride, Bis-Diglyceryl Polyacyladipate-2, Glyceryl Stearate, Panthenol, Cetearyl Alcohol, 1,2-Hexanediol, Betaine, Aloe Barbadensis Leaf Juice, Phenoxyethanol, Dimethicone, Polyacrylamide, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Saccharide Isomerate, Laureth-7, Sodium Stearoyl Lactylate, C13-14 Isoparaffin, Sodium Lauroyl Glutamate, Dimethicone Crosspolymer, Chamomilla Recutita Flower Extract, Ethylhexylglycerin, Squalane, Hyaluronic Acid, Citric Acid, Sodium Acetylated Hyaluronate, Sodium Hyaluronate, Sodium Citrate, Sodium Hyaluronate Crosspolymer, Hydroxypropyltrimonium Hyaluronate, Hydrolyzed Hyaluronic Acid, Hydrolyzed Sodium Hyaluronate, Potassium Sorbate, Sodium Benzoate, Benzoic Acid, Dehydroacetic Acid.

4. FIRST AID MEASURES

4.1 Description of first aid measures

Eye : Rinse with lukewarm water for at least 30 minutes , keeping eyelids open. If there is a contact lens, it is removed and washed in running water for 5 minutes. Then go to the ophthalmologist for medicated treatment.

Skin : In case of skin contact , remove contaminated clothing and shoes and wash your skin under running water for at least 15 minutes. Do not wear clothes and shoes again without washing.

Ingestion : Do not induce vomiting. Rinse mouth with water. Never give anything by mouth to an unconscious patient. Get immediate medical attention.

Inhalation : Remove patient to fresh air immediately. If breathing has stopped, apply artificial respiration. If breathing is difficult, give oxygen. Get immediate medical attention.

4.2 Most important symptoms and effects

Significant symptoms: headache, nausea, difficulty breathing, sore throat, redness of the skin. Sensitivity to the product may occur on repeated or continuous contact. Asthmatic disease may occur as a result of repeated or permanent inhalation of the product.

4.3 First signs for medical intervention and special treatment

Depending on the extent of exposure to the product, it is recommended that people who use it should undergo a medical examination at certain times.

5. FIRE-FIGHTING MEASURES

5.1 Fire Extinguishers

Suitable extinguishing media: Foam, carbon dioxide or extinguishing powder. Water spray can be used if there is no fire extinguishing agent.

Unsuitable fire Extinguishers: High volume water jet.

5.2 Special hazards arising from the substance or mixture

Carbon oxide (CO), Sodium Oxide.

5.3.Recommendations for fire-fighting teams

Fire tank tanks must be cooled by water spraying.

Special protective equipment: Firefighters are required to wear protective clothing with compressed air and compressed, compressed air, and all-face masking, protective footwear, protective gloves, protective helmet and protective clothing.

MATERIAL SAFETY DATA SHEET

Prepared in accordance with Annex II of the REACH Regulation EC 1907/2006
In compliance with regulation (EC) no. 1272/2008
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Printing Date: 25.05.2026 **Revision Date:** 25.05.2026
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5.4.Other Information

Do not breathe fumes in the event of fire or explosion. Fire in the vicinity of the product may cause pressure build-up and cracking hazard in the container of the product. Storage tanks exposed to fire risks must be cooled with water and, if possible, taken out of the hazardous area.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Contact emergency safety personnel immediately. Empty the space in question. To avoid breathing vapors, leave the space in question and move in a direction perpendicular to the direction of the breeze. Impurities must be carried out by qualified personnel. Unauthorized persons without work must be removed from the scene.

6.2.Environmental measures

Prevent contaminated water from being used in fire fighting, ground or surface water. Also prevent the material from spreading into the environment and spread to the sewage network.

6.3. Methods and materials for containment and cleaning

It is necessary to impregnate the exposed materials with sand, soil or other absorbent materials and leave them with the absorbent materials for 30 minutes in order to achieve the required effect. Care must be taken not to use sawdust or similar flammable substances in the impregnation process. Wastes must be collected in a barrel or tank that can be opened and closed from the top, due to subsequent waste disposal. The contaminated area should then be cleaned with water.

7. HANDLING AND STORAGE

7.1 Use

Do not breathe vapor, avoid eye and skin contact. Avoid prolonged use. It should be kept away from any igniter. Precautions should be taken against electrostatic charge.

7.2 Storage

It should be stored tightly closed in dry and well ventilated areas. Keep away from combustible materials, heat and igniters

7.3 Fire and Explosion Protection Information

Keep away from sources of ignition. No smoking. Protect against electrostatic charges.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Technical Measures
Adequate ventilation, emergency body and eye shower should be available.

Respiratory Device

MATERIAL SAFETY DATA SHEET

Prepared in accordance with Annex II of the REACH Regulation EC 1907/2006
In compliance with regulation (EC) no. 1272/2008
According to Regulation (EU) No 2020/878

Printing Date: 25.05.2026 **Revision Date:** 25.05.2026
Revision No: 1 **Form No:** B-012

It was not found to have a specific temper, but in extreme cases it may be necessary to use respiratory protection in extreme cases.

Eyes protection
If there is a risk of splashing, wear safety goggles or face shield.

Health Measures
Wash each shift and before eating, before smoking, and before going to the toilet. Wash immediately if the skin gets wet or dirty. Remove all contaminated clothing immediately. Use a suitable skin cream to prevent the skin from drying out. Do not eat or drink anything during use and do not smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Cream
Color	Transparent
Odor	Characteristic
Ph Value	N/A
Density 20 ° C	N/A
Viscosity 60 ° C	N/A
Flash Point	N/A
Resolution	Soluble in water.

10. STABILITY AND REACTIVITY

10.1 Reaction
No relationship

10.2 Chemical stability
It is stable at temperature and pressure under normal ambient conditions and the prescribed storage and handling condition

10.3 Possibility of Hazardous Reactivity
No relationship.

10.4 Conditions to Avoid
Keep away from heat and sun.

10.5 Incompatible materials
No relationship

11. TOXICOLOGICAL INFORMATION

This is a personal care or cosmetic product that is safe for consumers and other users under intended and reasonably foreseeable use. Additional information on toxicological endpoints is available from the supplier upon request.

Chronic Effects: Finished product is not expected to have chronic health effects.

MATERIAL SAFETY DATA SHEET

Prepared in accordance with Annex II of the REACH Regulation EC 1907/2006
In compliance with regulation (EC) no. 1272/2008
According to Regulation (EU) No 2020/878

Printing Date: 25.05.2026 **Revision Date:** 25.05.2026
Revision No: 1 **Form No:** B-012

BIONIKS INSENTIVE CARE CREAM - 50 ml

Target Organs: No adverse health effects on target organs expected for finished product.

Carcinogenicity: Finished product is not expected to be carcinogenic.

NTP: No **IARC:** No **OSHA:** No

12. ECOLOGICAL INFORMATION

Contact with the environment sould be avoied. Spills and leaks must be cleaned immediately. All precautions should be taken to prevent contact with the environment.

13. DISPOSAL INFORMATION

General Information
Packaging must be collected for re-use.

Disposal Methods
Dispose of Waste and Disposal in accordance with local authority regulations.

14. TRANSPORT INFORMATION

Land transport (ADR/RID/GGVSE):
No dangerous good in terms of the regulations.

Sea transport (IMDG/GGVSee):
No dangerous good in terms of the regulations.

Air transport (ICAO-TI/IATA-DGR):
No dangerous good in terms of the regulations

15. REGULATORY INFORMATION

15.1. Legal Information

By-Law on the Classification, Labeling and Storage of Substances [R.G. 11/12 / 2013-28848 - Repeating]
Regulation on Safety Data Sheets for Hazardous Substances and Mixtures [13/12/2014 - 29204 - official newspaper.]
According to Commission Regulation (EU) 2020/878, Amending regulation (EC) No 1907 / 2006

16. OTHER INFORMATIONS

Full text of H (Harm) Phrases
H319 : Causes serious eye irritation

Full text of P (Precaution) Statements

P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove the contact lenses if they are installed and easy to do. Continue rinsing

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BIONIKS INSENTIVE CARE CREAM - 50 ml

Information on the product in this Safety Data Sheet has been compiled from knowledge of the individual components. The data here are based on current knowledge and experience. This safety data sheet reviews the product in terms of safety requirements and does not give any warranty as to the specifications of the product. The data herein is only valid when the product is used for the appropriate application (s). The product is not sold in accordance with other applications - its use may lead to risks not mentioned in this list. Do not use for other applications without consulting the manufacturer

MSDS Preparer Neslihan Şahin
EXPERT ACCREDITATION NO: LONCA KDU 255 / 2023. 70
Date of Certification: 25.05.2023
Date of Expiration: 25.05.2028

LONCA

TÜRKAK

AB-0222-P

LONCA BELGELENDİRME A.Ş.

Kimyasal Değerlendirme Uzmanı (KDU) Sertifikası

NESLİHAN ŞAHİN

TC KİMLİK NO : 21217601088

Kimyasal Değerlendirme Uzmanı (KDU)

T.C. Çevre ve Şehircilik Bakanlığı Tarafından 23/06/2017 tarihli ve 30105 mükerrer sayılı Resmi Gazete'de yayımlanan "Kimyasalların Kaydı, Değerlendirilmesi, İzni ve Kısıtlanması Hakkında Yönetmelik (KKDİK)" çerçevesinde yapılan "Kimyasal Değerlendirme Uzmanı (KDU) Sınavında" başarılı olarak bu sertifikayı almaya hak kazanmıştır.

Belge Düzenleme Tarihi : 25.05.2023

Belge Geçerlilik Tarihi : 25.05.2028

Belge No : LONCA KDU 255/ 2023. 70

Cengizhan KUTLU
Genel Müdür

Karaman Mah. İzmiryolu Cad. No:90 Kat:4 Nilpark AVM NİLÜFER—BURSA
T: +90 532 155 62 12 / +90 224 909 06 30
bilgi@loncabelgelendirme.com.tr
Www.loncabelgelendirme.com.tr

FRM 106/ 12.12.2019/ REV:01

En/CAE Training Certificate No: Kutlu/08-15-56

KUTLU

KUTLU

KDU EĞİTİM KURULUŞU

CERTIFICATE OF COMPLETION

CHEMICAL ASSESSMENT EXPERT (CAE)

TRAINING

"NESLİHAN ŞAHİN"
(T.R. I.D. No: 21217601088)

This is to certify that 'Neslihan ŞAHİN (TR ID NO: 21217601088)' successfully completed the 64 Hours/8 Days Chemical Assessment Expert (CAE) Training Course of which the program is defined by the Annex-18 of Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) by-law, dated 23/06/2017 and numbered 30105, by Turkish Republic (TR) Ministry of Environment, Urbanization and Climate Change.

Training dates : 15, 16, 17, 18, 19, 22, 23, 24 May 2023
Course duration : 64 hours / 8 days

Trainer:
Sibel TAHİROĞLU
Chemical Engineer

Chemical Safety Assessor
Trainer

Training Center:
Tuğba KUTLU SAĞLAM
Company Director

Kutluhan Sürücü Kursu ve Özel Egt. Hiz. Servis Taşımacılığı Turizm, Gıda San. Tic. Ltd. Şti.

Issue Date: 25/05/2023

This certificate is the English translation version of the original one in Turkish with the same date and certificate number for the person who is awarded. A certificate without signatures and a seal is not valid.

KUTLUHAN SÜRÜCÜ KURSU VE ÖZEL EĞİTİM HİZMETLERİ, SERVİS TAŞIMACILIĞI, TURİZM, GIDA SAN. TİC. LTD. ŞTİ.
Cevizdibi Mah. Ankara Bulvarı No:110 Yıldırım/BURSA/TÜRKİYE
+90 (555) 028 20 43 / +90 (224) 240 86 43

TÜRKİYE CUMHURİYETİ ÇEVRE, ŞEHİRCİLİK VE İKLİM DEĞİŞİKLİĞİ BAKANLIĞI