

**COSMETIC PRODUCT SAFETY REPORT**for cosmetic product – SHOWER CREAM-GEL “SHEA BUTTER AND SPICY VANILLA”
(TRADE MARK: DALAS)**PART A – Cosmetic product safety information****1. COSMETIC PRODUCT INFORMATION**

Trade Mark: DALAS
Product name: SHOWER CREAM-GEL “SHEA BUTTER AND SPICY VANILLA”
Safety report version: 1.00
Class of cosmetic product: Personal skin care product. Rinse-off product.
The manufacturer: LLC “UKRAINIAN-GERMAN COMPANY “2K”,
 Address: Passage by Yuri Kozlovsky, 7/1, 29016, Khmelnytskyi, Ukraine
Assessors: SIA “SVS CosMedLab”, Address: Kartupelu street 45-3, Riga, Latvia,
 LV-1058

Raw materials:

Raw material trade name / (INCI Name)	Manufacturer/supplier	%
Вода питна (водопровідна) / (Aqua)	LLC “UKRAINIAN-GERMAN COMPANY “2K”	75.0 – 85.0
SULFOROKAnol L270/1 / (Sodium Laureth Sulfate (and) Aqua)	PCC Exol SA, Poland	12.5 – 13.9
ROKamina K30 / (Aqua (and) Cocamidopropyl Betaine (and) Sodium Chloride)	PCC Exol SA, Poland	8.0 – 10.5
Glycerin / (Glycerin)	Prisma Comercial Exportadora de Oleoquimicos Ltda., Brazil	2 - 5
ROKAcet KO300G / (PEG-7 Glyceryl Cocoate)	PCC Exol SA, Poland	1 - 4
Fragrance: Grapefruit Vanilla Vitabath CFB 21638 / (Parfum)	“Aroma Ukraine” Ltd., Ukraine	0.1 - 1.0
Sodium chloride dry / (Sodium Chloride)	CIECH Soda Polska S.A., Poland	0.1 - 1.0
Shea butter / (Butyrospermum Parkii Butter)	GUSTAV HEESS GmbH, Germany	0.1 - 1.0
Amides, coco, N-(hydroxyethyl) / (Cocamide MEA)	Spak Orgochem (India) Pvt., Ltd., India	0.1 - 1.0
Tinci (R) POLYQUATA 550 / (Polyquaternium-7)	Guangzhou Tinci Materials Technology Co., Ltd., China	0.1 - 1.0
Euperlan® PK 3000 AM / (Aqua (and) Glycol Distearate (and) Laureth-4 (and) Cocamidopropyl Betaine (and) Sodium Chloride (and) Glycerin (and) Formic Acid)	BASF T.O.V. LLC, Ukraine	0.5 – 2.0
Citric Acid Monohydrate / (Citric Acid)	Weifang Ensign Industry Co., Ltd., China	0.1 - 1.0
Euperlan® PCO / (Styrene/Acrylates Copolymer (and) Coco-Glucoside (and) Citric Acid (and) Benzoic Acid)	BASF T.O.V. LLC, Ukraine	0.1 – 0.5
EDTA 4Na / (Tetrasodium EDTA)	Shijiazhuang Jackchem Co., Ltd., China	0.1 - 0.4
Salimix MCI / (Aqua (and) Methylchloroisothiazolinone (and) Methylisothiazolinone)	Suppl. “ROSCOSMETICA” Ltd., Ukraine	<0.1
Amount:		100.00

2. QUANTITATIVE AND QUALITATIVE COMPOSITION OF THE COSMETIC PRODUCT

INCI	CAS No.	EC No.	FUNCTION	Amount, % (max.)
Aqua	7732-18-5	231-791-2	Solvent	75 - 100 (97.8628)
Sodium Laureth Sulfate	68891-38-3	500-234-8	Surfactant-Cleansing, Foaming, Emulsifying	9 – 10 (10.0000)



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Glycerin	56-81-5	200-289-5	Humectant, Skin Conditioning, Skin Protecting, Solvent, Viscosity Controlling	2 – 5 (5.0000)
Cocamidopropyl Betaine	61789-40-0	263-058-8/ 931-296-8	Surfactant-Cleansing, Antistatic, Hair Conditioning, Foam Boosting, Viscosity Controlling	3 – 4 (4.0000)
PEG-7 Glyceryl Cocoate	68201-46-7	-	Surfactant-Cleansing, Surfactant-Emulsifying	1 – 4 (4.0000)
Parfum	-	-	Perfuming	0.1 – 1.0 (1.0000)
Sodium Chloride	7647-14-5	231-598-3	Viscosity Controlling	0.1 – 1.0 (1.0000)
Butyrospermum Parkii Butter	194043-92-0	293-515-7	Skin conditions	0.1 – 1.0 (1.0000)
Cocamide MEA	68140-00-1	268-770-2	Surfactant – Foaming Boosting, Viscosity Controlling	0.1 – 1.0 (1.0000)
Polyquaternium-7	26590-05-6	-	Antistatic, Film Forming, Viscosity Controlling	0.1 – 1.0 (1.0000)
Glycol Distearate	627-83-8	211-014-3	Opacifying, Skin Conditioning – Emollient, Surfactant – Emulsifying, Viscosity controlling	0.1 – 1.0 (0.8000)
Citric Acid	77-92-9/ 5949-29-2	201-069-1	Buffering, Chelating	0.1 – 1.0 (1.0000)
Styrene/Acrylates Copolymer	27306-39-4/ 25034-86-0/ 25085-34-1/ 9010-92-8	-	Opacifying, Film Forming	0.1 – 1.0 (0.2500)
Laureth-4	5274-68-0 9002-92-0 68439-50-9	226-097-1 500-002-6 500-213-3	Antistatic, Surfactant – Cleansing, Surfactant - Emulsifying	0.1 – 1.0 (0.4000)
Disodium EDTA	139-33-3	205-358-3	Chelating, Viscosity Controlling	0.1 – 1.0 (0.4000)
Coco-Glucoside	110615-47-9	-	Cleansing, Foaming, Surfactant	≤0.1 (0.1000)
Benzoic Acid	65-85-0	200-618-2	Preservative	<0.1 (0.0025)
Formic Acid	64-18-6	200-579-1	Preservative	<0.1 (0.0060)
Methylchloroisothiazolinone	26172-55-4	247-500-7	Preservative	<0.0015 (CMI:MI=3:1) (0.0015)
Methylisothiazolinone	2682-20-4	220-239-6		
Hexyl Cinnamal*	101-86-0	202-983-3	Perfuming	0.0200

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*The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)g when its concentration exceeds:

- 0.001% in leave-on products
- 0.01% in rinse-off products

Cosmetic product contains the allergen (Hexyl Cinnamal) that must be declared on the product label in the ingredients section according to EU Cosmetic Regulation.

3. PHYSICAL/CHEMICAL CHARACTERISTICS AND STABILITY OF THE COSMETIC PRODUCT

Purity and analytical specifications of raw materials are contained on the relevant Certificates of Analysis / Sales Specifications, which are held by the manufacturer.

Raw material physical characteristics and suppliers' hazard classifications are given in the safety data sheets, which are held by the manufacturer.

The physical/chemical specification of the ingredients are well known and commonly used in similar products. Their inclusions in the finished product at the specified concentrations do not give rise to any concerns.

Physical/Chemical characteristics of the finished cosmetic product:

Parameter	Method	Specification (ТУ У 20.4-37915506-002:2019)
Appearance	Visual. Complies with the reference model.	Homogeneous viscous gel mass. Pearlizing agent is allowed.
Colour	Visual. Complies with the reference model.	White
Smell	Organoleptic. Complies with the reference model.	Characteristic
pH value	pH meter	3.5 – 8.5 (tests result: 5.65)

The manufacturer (LLC “UKRAINIAN-GERMAN COMPANY “2K”, Ukraine) confirms that the product is stable for 30 months from the manufacture date.

Samples of the **SHOWER CREAM-GEL “SHEA BUTTER AND SPICY VANILLA” (TRADE MARK: DALAS)** were tested to assess the product's stability. Samples of the product were tested in at recommended temperature from +5 °C to +25 °C. Observations of the samples' appearance, colour, odour, pH were made and recorded. The manufacturer confirms the stability of the product within 30 months according to the technical specification (ТУ У 20.4-37915506-002:2019 «Засоби косметичні для очищення шкіри та волосся. Технічні умови» dated 07.10.2021).

The product is stable under reasonably foreseeable conditions of use during its shelf-life – 30 months from the manufacture data.

It was concluded that the product is stable under reasonably foreseeable conditions of use during its shelf-life. The quality of goods is warranted under condition of their proper storage at recommended temperature from +5 °C to +25 °C.

4. MICROBIOLOGICAL QUALITY

The objective of Hygiene Norm is to define microbiological qualitative and quantitative limits for finished cosmetic products in order to ensure their microbiological safety.

Skin and mucous membranes are protected from microbial attack by a natural mechanical barrier and various defence mechanisms. However, these may be damaged and slight trauma may be caused by the action of some cosmetics that may enhance microbial infection. This may become of particular concern when cosmetics are used around the eyes, on mucous membranes in



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general, on damaged skin, on children under 3 years, on elderly people and persons with compromised immune system. Consequently, two separate categories of cosmetic products are defined in the microbiological quality control limits:

Category 1: Products specifically intended for children under 3 years, to be used in the eye area and on mucous membranes.

Category 2: Other products.

Microbiological limits for SHOWER CREAM-GEL “SHEA BUTTER AND SPICY VANILLA” (TRADE MARK: DALAS) are belong to Category 2.

Microbiological properties of the SHOWER CREAM-GEL “SHEA BUTTER AND SPICY VANILLA” (TRADE MARK: DALAS) were tested by Laboratorija AUCTORITAS, Ltd, Latvia, Test report No. 11819/22 (Sample delivered to laboratory in original packaging) dated 25.11.2022 with satisfactory results.

Microbiological test results:

Types of microorganism	Regulatory limit	Method	Test Result
Total Aerobic Mesophilic Microorganisms (Bacteria plus yeast and mould) (CFU per 1 g)	$<1 \cdot 10^3$	LVS EN ISO 21149:2017	$<1 \cdot 10^1$
<i>Candida albicans</i> (in per 1 g/ 1ml)	Absent	LVS EN ISO 18416:2016	Absent
<i>Staphylococcus aureus</i> (in per 1 g/ 1 ml)	Absent	LVS EN ISO 22718:2016	Absent
<i>Pseudomonas aeruginosa</i> (in per 1 g/ 1ml)	Absent	LVS EN ISO 22717:2016	Absent
<i>Escherichia coli</i> (in per 1 g/ 1ml)	Absent	ISO 21150:2015	Absent

A challenge test has been performed to test the efficacy of the preservation system of this product. Evaluation of the antimicrobial protection of the product was tested by Laboratorija AUCTORITAS, Ltd, Latvia, Test report No. 11819/22 (Sample delivered to laboratory in original packaging) dated 25.11.2022 with satisfactory results. The product conforms to specification LVS EN ISO 11930:2020, criterion A.

5. IMPURITIES, TRACES, INFORMATION ABOUT THE PACKAGING MATERIAL

Cosmetic product SHOWER CREAM-GEL “SHEA BUTTER AND SPICY VANILLA” (TRADE MARK: DALAS) contains preservatives Methylchloroisothiazolinone (and) Methylisothiazolinone (Salimix MCI) with two impurities (stabilizers): **Magnesium Chloride** (max 0.8 %) – 0.0008 % (8 ppm) and **Magnesium Nitrate** (max 1.4 %) - 0.0014 % (14 ppm).

These ingredients are not prohibited and does not have restrictions in cosmetic products according to the REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products. These two ingredients are not prohibited, but as impurities in very small concentrations (8 and 14 ppm) are not declared on the label.

Heavy metals:

The cosmetic regulation 1223/2009 prohibits the use of heavy metals such as lead, arsenic and mercury unless they are present at trace levels and their presence is inevitable from correct manufacturing processes. No heavy metals are listed in the product (ТУ У 20.4-37915506-002:2019 «Засоби косметичні для очищення шкіри та волосся. Технічні умови» and ТУ У 20.4-42281913-002:2020 «Засоби косметичні для догляду за шкірою та волоссям. Технічні умови»). The highest percentage of input in the product is allocated to water (more than

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75%). Water contains < 0.01 ppm Lead (Pb), < 0.01 ppm Arsenic (As), < 0.01 ppm Zinc (Zn), < 0.03 ppm Copper (Cu) - Вода питна (водопровідна), LLC “UKRAINIAN-GERMAN COMPANY “2K”, Test report No. 2077 from 07.11.2022, conducted by the company ПП НЦІД «Еталон», Ukraine.

LLC UKRAINIAN-GERMAN COMPANY “2K” confirms that packaging complies with the requirements & regulations which state that packaging may be safely used for cosmetic product packaging.

Packaging materials:

Product packaging - primary	Documentation
Colored HDPE Bottle (500 ml or 1000 ml)	Material for bottles: HDPE (High Density Polyethylene), Manufacturer: JV “Uz-Kor Gas Chemical” LLC Republic of Uzbekistan, MSDS dated 28.04.2021.
Colored prefabricated polymer bottle pump white dispenser	Manufacturer: Multipack Ltd., Ukraine. Pump dispenser material: PP (Polypropylene) resin, MSDS dated 04.08.2021, Applicant: Fujian Refining & Petrochemical Company Limited, China.
Dyes:	Dyes: Pearlizing agent, Article PE 1113 F, Manufacturer: Private enterprise “Taycoon”, Ukraine, MSDS and Quality Certificate No. 935 from 16.11.2022.

The product is packaged in suitable for the cosmetic hermetic package. Packaging material is stable under normal conditions of use.

6. NORMAL AND REASONABLY FORESEEABLE USE**SHOWER CREAM-GEL “SHEA BUTTER AND SPICY VANILLA” (TRADE MARK: DALAS)
500 g (or 1000 g)**

Incredibly gentle shower cream-gel “Shea butter and spicy vanilla” gives unforgettable emotions, fill you with energy and vigor for the whole day! The cream-gel gently cleanses and refreshes your skin. Gentle components of its formula provide nutrition and necessary level of skin hydration, protect it, give silkiness and smoothness.

Method of use: apply cream-gel on a washcloth or palm, lightly foam and spread it over body, then rinse foam with water.

Warning: Keep out of reach of children. For external use only. Avoid contact with eyes. In case of contact with eyes, rinse immediately with plenty of water. In case of any adverse reactions, stop using and seek for medical advice.

Storage conditions: Store in the packaging of the manufacturer at a temperature of +5°C to +25°C away from direct sunlight and air humidity 50-80%, as well as not less than 1 meter away from heating devices.

Shelf life: 30 months. Use before: (month, day) and Batch number to be specified on the package.

INGREDIENTS: Aqua, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Glycerin, PEG-7 Glyceryl Cocoate, Coco-Glucoside, Parfum, Sodium Chloride, Butyrospermum Parkii Butter, Cocamide MEA, Styren/Acrylates Copolymer, Polyquaternium-7, Glycol Distearate, Citric Acid, Benzoic Acid, Formic Acid, Tetrasodium EDTA, Laureth-4, Methylchloroisothiazolinone, Methylisothiazolinone, Hexyl Cinnamal.

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Normal (as shower gel, 1.43 times a day) use 18.67 g/day and reasonably foreseeable (hand wash soap, 10 times a day) use 20 g/day.

Normal application area: total body area

Reasonably foreseeable application area: area hands

7. EXPOSURE TO THE COSMETIC PRODUCT**Cosmetic product application areas:** total body area and hands area**Normal area of skin contact:** 17500 cm² (SCCS 11th Revision*)**Reasonably foreseeable area of skin contact:** 860 cm² (SCCS 11th Revision*)**Duration of contact:** Rinse-off product.**Quantity of product used at application:** 18.67 g normal use; 20 g – reasonably foreseeable use. (SCCS 11th Revision*)**Frequency of application:** for normal use 1.43 times a day, for reasonably foreseeable application use 10 times a day. (SCCS 11th Revision*)**Normal use way:** body skin cleansing**Reasonably foreseeable use way:** hand skin cleansing**Consumer target group:** adults

Name	Short name, unit	Explanation
Systemic Exposure Dose (d. Dermis)	SED (mg/kg bw/day)	Per 1 kg body weight to day 1
Dermal Absorption	DA _p (%)	Accepted as 100
Retention Factor	F _{ret} (-)	0.01 (don't have unit)
Frequency of application of the finished product	F (1/day) or (day ⁻¹)	1.43 (as shower gel) 10 (hands soap)
Skin Surface Area expected to be treated with the finished cosmetic product	SSA (cm ²)	17500 (as shower gel) 860 (hands soap)
Body weight (adults)	kg	60 kg – default human body weight
Mode of application	Specific exposure	
Normal use	As shower gel – 1.43 times a day	
Reasonable use	As hands soap – 10 times a day	

*The Scientific Committee on Consumer Safety Notes of Guidance for The Testing of Cosmetic Ingredients and Their Safety Evaluation 11th Revision SCCS/1628/21. The SCCS adopted this guidance document at its plenary meeting on 30-31 March 2021.

8. EXPOSURE TO THE SUBSTANCES**EXPOSURES OF RAW MATERIALS CALCULATION:**

$$SED = E_{prod.} \times C/100 \times DA_p/100$$

SED (mg/kg bw/day) – Systemic Exposure Dosage**E_{prod.} (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**C (%)** - concentration of the substance under study in the finished cosmetic product on the application site**DA_p (%)** - Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions.

In the case of no dermal absorption data available, 100% dermal absorption is used.



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INCI name	C, %	DA _p , %	Normal use		Reasonably foreseeable use	
			E _{prod.} (mg/kg bw/day)	SED (mg/kg*d)	E _{prod.} (mg/kg bw/day)	SED (mg/kg*d)
Aqua	97.8628	100	2.79	2.730372	3.33	3.258831
Sodium Laureth Sulfate	10.0000	100	2.79	0.279000	3.33	0.333000
Glycerin	5.0000	100	2.79	0.139500	3.33	0.166500
Cocamidopropyl Betaine	4.0000	100	2.79	0.111600	3.33	0.133200
PEG-7 Glyceryl Cocoate	4.0000	100	2.79	0.111600	3.33	0.133200
Parfum	1.0000	100	2.79	0.027900	3.33	0.033300
<i>Parfum contains:</i>						
<i>Hexyl Cinnamal</i>	<i>0.0200</i>	<i>100</i>	<i>2.79</i>	<i>0.000558</i>	<i>3.33</i>	<i>0.000666</i>
Sodium Chloride	1.0000	100	2.79	0.027900	3.33	0.033300
Butyrospermum Parkii Butter	1.0000	100	2.79	0.027900	3.33	0.033300
Cocamide MEA	1.0000	100	2.79	0.027900	3.33	0.033300
Polyquaternium-7	1.0000	100	2.79	0.027900	3.33	0.033300
Glycol Distearate	0.8000	100	2.79	0.022320	3.33	0.026640
Citric Acid	1.0000	100	2.79	0.027900	3.33	0.033300
Styrene/Acrylates Copolymer	0.2500	100	2.79	0.006975	3.33	0.008325
Laureth-4	0.4000	100	2.79	0.011160	3.33	0.013320
Disodium EDTA	0.4000	100	2.79	0.011160	3.33	0.013320
Coco-Glucoside	0.1000	100	2.79	0.002790	3.33	0.003330
Benzoic Acid	0.0025	100	2.79	0.000070	3.33	0.000083
Formic Acid	0.0060	100	2.79	0.000167	3.33	0.000200
Methylchloroisothiazolinone	0.0015	100	2.79	0.000042	3.33	0.000050
Methylisothiazolinone						
<i>Stabilizers of Methylchloroisothiazolinone & Methylisothiazolinone:</i>						
<i>Magnesium Chloride (0.8 %)</i>	<i>0.0008</i>	<i>100</i>	<i>2.79</i>	<i>0.000022</i>	<i>3.33</i>	<i>0.000027</i>
<i>Magnesium Nitrate (1.4 %)</i>	<i>0.0014</i>	<i>100</i>	<i>2.79</i>	<i>0.000039</i>	<i>3.33</i>	<i>0.000047</i>

MARGIN OF SAFETY (MoS) CALCULATION:

MoS = POD_{sys}/SED of raw materials

(If MoS>100 indicates that a cosmetic ingredient is considered safe for use)

POD_{sys} - is a dose descriptor for the systemic exposure to a substance and is calculated from the oral POD by use of the proportion of the substance systemically absorbed. In this equation, POD_{sys} is NOAEL or LOAEL.

INCI nosaukums	NOAEL, mg/kg/day	SED of raw materials (Normal use)	SED of raw materials (Reasonably foreseeable use)	MoS (Normal use)	MoS (Reasonably foreseeable use)
Aqua	Not toxic	2.730372	3.258831	Not toxic	Not toxic
Sodium Laureth Sulfate	225	0.279000	0.333000	806	676
Glycerin	1280	0.139500	0.166500	9176	7688
Cocamidopropyl Betaine	750	0.111600	0.133200	6720	5631
PEG-7 Glyceryl Cocoate	3000	0.111600	0.133200	26882	22523
Parfum	Not applicable	0.027900	0.033300	Not applicable	Not applicable
<i>Parfum contains::</i>					
<i>Hexyl Cinnamal</i>	<i>29.9</i>	<i>0.000558</i>	<i>0.000666</i>	<i>53584</i>	<i>44895</i>



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Sodium Chloride	2533	0.027900	0.033300	90789	76066
Butyrospermum Parkii Butter	Not toxic	0.027900	0.033300	Not toxic	Not toxic
Cocamide MEA	750	0.027900	0.033300	26882	22523
Polyquaternium-7	2000	0.027900	0.033300	71685	60060
Glycol Distearate	1000	0.022320	0.026640	44803	37538
Citric Acid	4000	0.027900	0.033300	143369	120120
Styrene/Acrylates Copolymer	200	0.006975	0.008325	28674	24024
Laureth-4	500	0.011160	0.013320	44803	37538
Disodium EDTA	500	0.011160	0.013320	44803	37538
Coco-Glucoside	1000	0.002790	0.003330	358423	300300
Benzoic Acid	500	0.000070	0.000083	7168459	6006006
Formic Acid	400	0.000167	0.000200	2389489	2002002
Methylchloroisothiazolinone	2.8	0.000042	0.000050	66906	56056
Methylisothiazolinone					
Stabilizers of Methylchloroisothiazolinone & Methylisothiazolinone:					
Magnesium Chloride	140	0.000022	0.000027	6272401	5255255
Magnesium Nitrate	1500	0.000039	0.000047	38402458	32175032

9. TOXICOLOGICAL PROFILE OF THE SUBSTANCES

INGREDIENTS (INCI Name)	CAS No.	Introduction,% by quantity (maximum)	Acute oral toxicity, LD ₅₀ mg/kg	Subchronic toxicity, NOAEL, mg/kg/day	Dermal irritation, sensitisation, Acute dermal toxicity - LD ₅₀ mg/kg	CMR toxicity (Carcinogenic, mutagenic, reprotoxic)	Remarks
Aqua	7732-18-5	97.8628	Not toxic	Not toxic	Not skin irritant and not sensitising	Not toxic	-
Sodium Laureth Sulfate	68891-38-3	10.0000	4100	>225	>2000 Causes skin irritation. Not sensitising.	No evidence of CMR toxicity	Causes serious eye damage.
Glycerin	56-81-5	5.0000	>11500	1280 (rat)	56750 (guinea pig) Not skin irritant and not sensitising	No evidence of CMR toxicity	-
Cocamidopropyl Betaine	61789-40-0	4.0000	>2000	750	>2000 (rabbit) Not skin irritant and not sensitising	No evidence of CMR toxicity	Causes serious eye damage.
PEG-7 Glyceryl Cocoate	66105-29-1/ 68201-46-7	4.0000	>2000	3000*	>2000 Not skin irritant and not sensitising	No evidence of CMR toxicity	-
Parfum	-	1.0000	>2000 (not classified)	not applicable	>2000 (not classified) Causes skin irritation. May cause an allergic skin reaction.	No evidence of CMR toxicity	Causes serious eye irritation.
Parfum contains:							
Hexyl Cinnamal	101-86-0	0.0200	> 2000 (rat)	29.9 (rat)	>2000 (rabbit) Not skin irritant. May cause an allergic skin reaction.	No evidence of CMR toxicity	Allergen
Sodium Chloride	7647-14-5	1.0000	3550	2533**	>10000 (rabbit) Not skin irritant and not sensitising	No evidence of CMR toxicity	-



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Butyrospermum Parkii Butter	194043-92-0	1.0000	>2000 (not classified)	Not toxic	>2000 (not classified) Not skin irritant and not sensitising	No evidence of CMR toxicity	-
Cocamide MEA	68140-00-1	1.0000	>5000 (rat)	>750	>2000 Causes skin irritation. Not sensitising.	No evidence of CMR toxicity	Causes serious eye damage.
Polyquaternium-7	26590-05-6	1.0000	>5000 (rat)	2000 (rat)	>2000 (rat) Not skin irritant and not sensitising	No evidence of CMR toxicity	-
Glycol Distearate	627-83-8	0.8000	>2000 (rat)	1000 (rat)	>2000 (rat) Not skin irritant and not sensitising	No evidence of CMR toxicity	-
Citric Acid	77-92-9/ 5949-29-2	1.0000	>3000	4000	>2000 Not skin irritant and not sensitising	No evidence of CMR toxicity	Causes serious eye irritation
Styrene/Acrylates Copolymer	27306-39-4/ 25034-86-0/ 25085-34-1/ 9010-92-8	0.2500	>2000	200	>2000 Not skin irritant and not sensitising	No evidence of CMR toxicity	-
Laureth-4	68439-50-9	0.4000	>2000 (rat)	500 (rat)	>3000 (rabbit) Not skin irritant and not sensitising	No evidence of CMR toxicity	-
Disodium EDTA	139-33-3	0.4000	2800 (rat)	>500 (rat)	>2000 (rat) Not skin irritant and not sensitising	No evidence of CMR toxicity	-
Coco-Glucoside	110615-47-9	0.1000	>5000 (rat)	1000	>2000 (rabbit) Causes skin irritation. Not sensitising	No evidence of CMR toxicity	Causes serious eye damage.
Benzoic Acid	65-85-0	0.0025	>2000	500 (rat)	>2000 (rat) Causes skin irritation. Not sensitising.	No evidence of CMR toxicity	Causes serious eye damage.
Formic Acid	64-18-6	0.0060	730 (rat)	400 (rat)	>2000 (rat) Causes severe skin burns and eye damage. Not sensitising.	No evidence of CMR toxicity	-
Methylchloroisothiazolinone	26172-55-4	0.0015	50 – 78.5	2.8	Calc. 117,82 Causes severe skin burns and eye damage. May cause an allergic skin reaction.	No evidence of CMR toxicity	Maximum allowed concentration 0.0015%, rinse-off products only. Causes serious eye irritation
Methylisothiazolinone	2682-20-4						
Stabilizers of Methylchloroisothiazolinone & Methylisothiazolinone:							
Magnesium Chloride	7786-30-3	0.0008	5000 (rat)	140 (rat)	2000 (rat) Not skin irritant and not sensitising	No evidence of CMR toxicity	-
Magnesium Nitrate	10377-60-3	0.0014	2000 (rat)	1500 (rat)	5000 (rat) Not skin irritant and not sensitising	No evidence of CMR toxicity	-

* As PEG-8 caprylic/capric glycerides

** As LOEL

Comments: The calculation was made taking into account the information provided by the manufacturer and authoritative literature sources.

Documents from manufacturer LLC “UKRAINIAN-GERMAN COMPANY “2K”:

1. **Aqua:** Вода питна (водопровідна), LLC “UKRAINIAN-GERMAN COMPANY “2K”, Test report No. 2077 dated 07.11.2022. Test report from ППІ НЦІД «Еталон», Ukraine.
2. **SULFOROKAnol L270/1 / (Sodium Laureth Sulfate (and) Aqua) - MSDS (PCC Exol SA, Poland) dated 01.10.2019, version No. 4.**

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3. **ROKamina K30** / (*Aqua (and) Cocamidopropyl Betaine (and) Sodium Chloride*) - MSDS (PCC Exol SA, Poland) dated 22.11.2019., version No. 2.
4. **Glycerin** / (*Glycerin*) - MSDS (Prisma Comercial Exportadora de Oleoquimicos Ltda., Brazil) dated 28.04.2014, version No. 0.1.
5. **ROKAcet KO300G** / (*PEG-7 Glyceryl Cocoate*) - MSDS (PCC Exol SA, Poland) dated 04.09.2020, version No. 3.
6. **Fragrance: Grapefruit Vanilla Vitabath CFB 21638** / (*Parfum*) - MSDS (“Aroma Ukraine” Ltd., Ukraine) dated 06.05.2021, Version No. EN 4.6 and List of Allergen, Version En4.6 dated 18.10.2022.
7. **Sodium chloride dry** / (*Sodium Chloride*) – Product Specification (CIECH Soda Polska S.A., Poland) No SP/ZLJ/05 dated 22.12.2016.
8. **Shea butter** / (*Butyrospermum Parkii Butter*) - MSDS (GUSTAV HEESS GmbH, Germany), Version: j dated 04.12.2019.
9. **Amides, coco, N-(hydroxyethyl)** / (*Cocamide MEA*) - MSDS (Spak Orgochem (India) Pvt., Ltd., India) dated 14.12.2017.
10. **Tinci (R) POLYQUATA 550** / (*Polyquaternium-7*) - MSDS (Guangzhou Tinci Materials Technology Co., Ltd., China), Version: A/2 dated 19.03.2013.
11. **Euperlan® PK 3000 AM** / (*Glycol Distearate (and) Laureth-4 (and) Cocamidopropyl Betaine*) - MSDS (BASF T.O.V. LLC, Ukraine), Version: 1.0 dated 11.04.2017 and Technical Information, Revision 8.0 dated 30.01.2020.
12. **Citric Acid Monohydrate** / (*Citric Acid*) - MSDS (Weifang Ensign Industry Co., Ltd., China) dated 08.11.2017.
13. **Euperlan® PCO** / (*Styrene/Acrylates Copolymer (and) Coco-Glucoside (and) Citric Acid (and) Benzoic Acid*) – Technical Information (BASF T.O.V. LLC, Ukraine), Revision 8.1 and Composition Sheet, Revision 1.0.
14. **EDTA 4Na** / (*Disodium EDTA*) - MSDS (Suppl. “Shijiazhuang Jackchem Co.”, Ltd., China) dated 16.07.2019, Version No. 1.0.
15. **Salimix MCI** / (*Aqua (and) Methylchloroisothiazolinone (and) Methylisothiazolinone*) - MSDS (Suppl. “ROSCOSMETICA” Ltd., Ukraine), Version No. EN 4.1. from 10.04.2019.

REFERENCE LIST (authoritative literature sources):**(Descriptions, Acute toxicity, NOAEL values, Dermal irritation, other toxicity)****Sodium Laureth Sulfate:**

Ingredient is not prohibited and does not have restrictions in cosmetic products according to the REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products.

In the test substance was not rinsed off for 48 h. Here 0.9% of the applied test substance was absorbed through the rat skin. Thus, under these stringent conditions, absorption is considered to be very low.

Sodium laureth sulfate was demonstrated to be a dermal and ocular irritant but not a sensitizer. Sodium laureth sulfate is used as shampoo, bath, and skin-cleansing ingredients, primarily because of both their high degree of foaming and detergency and their “softness” to the skin.

The CIR (Cosmetic Ingredient Review) Expert Panel concluded that ingredient is safe as cosmetic ingredient in the practices of use and concentrations as described in CIR safety assessment (Personal hygiene products: Bath soaps and detergent to 47%).

- Final Report of the Amended Safety Assessment of Sodium Laureth Sulfate and Related Salts of Sulfated Ethoxylated Alcohol. CIR International Journal of Toxicology 29(Supplement 3) 151S-161S, 2010.

- Information from the ECHA website (Sodium Laureth Sulfate):



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<https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15887>

Glycerin:

Ingredient is not prohibited and does not have restrictions in cosmetic products according to the REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products.

The CIR (Cosmetic Ingredient Review) Expert Panel concluded that ingredient is safe as cosmetic ingredient in the practices of use and concentrations as described in CIR safety assessment (Rinse-off products up to 99.4 %).

- Safety Assessment of Glycerin as Used in Cosmetics. CIR Final Report, January 14, 2015.

- Information from the ECHA website (Glycerin):

<https://echa.europa.eu/lv/registration-dossier/-/registered-dossier/14481>

Cocamidopropyl Betaine:

Ingredient is not prohibited and does not have restrictions in cosmetic products according to the REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products.

Cocamidopropyl betaine (CAPB) is a zwitterion used primarily as a surfactant in cosmetic products.

The CIR Expert Panel (the Panel) concluded that Cocamidopropyl Betaine is safe for use in rinse off cosmetic products at the current levels of use.

- Final Report of the Cosmetic Ingredient Review Expert Panel on the Safety Assessment of Cocamidopropyl Betaine (CAPB). CIR, Ingredient Journal of Toxicology 31(Supplement 1) 77S-111S, 2012.

- Information from the ECHA website (Cocamidopropyl Betaine):

<https://echa.europa.eu/de/registration-dossier/-/registered-dossier/25362>

PEG-7 Glyceryl Cocoate:

Ingredient is not prohibited and does not have restrictions in cosmetic products according to the REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products.

Groups of 10 male rats were fed a diet containing 0, 2.5, 5.0, or 7.5% of a formulation containing 0.8% PEG-7 glyceryl cocoate for 28 days. All animals survived until study termination. For all groups, select tissues were weighed at necropsy. Select tissues of animals in the control and high-dose group were examined microscopically. Spleen weights were significantly decreased in high-dose animals; although there were no associated microscopic changes, the researchers stated the change could be associated with dosing. Soft feces, a distended cecum, and enlarged mesenteric lymph nodes were observed at necropsy in the mid- and high-dose animals. The no-observable effect level (NOEL) was 2.5% of the formulation containing 0.8% PEG-7 glyceryl cocoate.

The CIR (Cosmetic Ingredient Review) Expert Panel concluded that ingredient is safe as cosmetic ingredient in the practices of use and concentrations as described in CIR safety assessment (PEG-7 glyceryl cocoate has the high rinse-off concentration of use reported, i.e., 10% in skin cleansing products).

- Information from the ECHA website (PEG-7 Glyceryl Cocoate):

<https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/125990>

- Safety Assessment of PEGylated Alkyl Glycerides As Used in Cosmetics. Cosmetic Ingredient Review, Final Report, Release Date January 13, 2015.



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Parfum (Fragrance):

The perfume composition is a mixtures of natural and/or synthetic origin for which it is not possible to determine an exact NOAEL value.

Hexyl Cinnamal (from Fragrance):

Hexyl Cinnamal is fragrance component, very low concentration.

The Expert Panel for Fragrance Safety (IFRA standard amendment 49) reviewed all the available data for Hexyl Cinnamal and recommends the limits for the 12 different product categories, which are the acceptable use levels of Hexyl Cinnamal in the various product categories. Shower Gel is a 9 categorie and restricted limit in the finished product is 19%

Ingredient is not prohibited in cosmetic products according to the REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products. Hexyl Cinnamal has restriction in REGULATION (EC) No 1223/2009 ANNEX III List of Substances Which Cosmetic Products Must not Contain except subject to the Restrictions Laid Down, Reference number: 87. The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: - 0.001% in leave-on products or 0.01% in rinse-off products.

- Amyl and hexyl cinnamaldehyde: Human health tier II assessment. Australian Government Department of Health, IMAP Group Assessment Report, 20.04.2020.

- RIFM fragrance ingredient safety assessment, α -butylcinnamaldehyde, CAS Registry Number 7492-44-6, Food and Chemical Toxicology, 84 (2015) S100-S109.

- IFRA stadndart, Amendment 49.

Sodium Chloride:

Ingredient not prohibited and does not have restrictions in cosmetic products accordance REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products.

Sodium chloride is a naturally occurring material, and is a normal part of the human body. At low concentrations as used in bathing, or at higher amounts in salt scrub products, there is no skin irritation. It is considered that sodium chloride is safe as used in the current application.

Sodium chloride has been used to flavor and preserve foods for thousands of years.

- Information from the ECHA website (Sodium Chloride):

<https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15467>

Butyrospermum Parkii Butter:

Ingredient not prohibited and don't have restrictions in cosmetic products accordance REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products.

The CIR Expert Panel concluded that ingredient is safe as cosmetic ingredient in the practices of use and concentrations as described in CIR safety assessment (Leave-on products up to 100%).

No relevant published acute toxicity or case reports on Butyrospermum parkii (shea) butter was identified in a literature search for this ingredient and no unpublished data were submitted.

- MSDS of Lipex Shea (Aarhus Karlshamn Sweden AB, Sweden) revised 02.01.2017 and Analytical Certificate (Batch 0002025584).

- Safety Assessment of Plant-Derived Fatty Acid Oils, CIR, International Journal of Toxicology 2017, Vol. 36(Supplement 3) 51S-129S

- Safety Assessment of Butyrospermum parkii (Shea)- Derived Ingredients as Used in Cosmetics, CIR, Final Report, October 5, 2017.



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Cocamide MEA:

Ingredient is not prohibited and does not have restrictions in cosmetic products according to the REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products.

Most of the ethanolamides are reported (the CIR (Cosmetic Ingredient Review) Expert Panel) to function in cosmetics as hair-conditioning agents, skin-conditioning agents, and surfactant—foam boosters. Cocamide MEA has the highest frequency of use. Cocamide MEA is reported to be used at up to 18% in rinse-off formulations and at up to 5% in leave-on formulations.

- Safety Assessment of Ethanolamides as Used in Cosmetics. CIR, International Journal of Toxicology 2015, Vol. 34(Supplement 1) 18S-34S.

- Information from the ECHA website (Cocamide MEA):

<https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/114617>

Polyquaternium-7:

Ingredient is not prohibited in cosmetic products according to the REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products. Polyquaternium-7 have restriction in REGULATION (EC) No 1223/2009 ANNEX III List of Substances Which Cosmetic Products Must not Contain except subject to the Restrictions Laid Down, Reference number: 66. Maximum residual acrylamide content 0.5 mg/kg. Dermal exposure of rats to 2.25 ml/kg per day for 14 weeks was nonirritating to both intact and abraded skin. Dermal exposure of rabbits to an 8% solution produced no irritation, and ocular exposure showed mild irritation that cleared after 24 h. Polyquaternium-7 was not mutagenic in an Ames test. Repeated insult patch test data suggest that 8% Polyquaternium-7 is at best a mild cumulative irritant, but not a sensitizer. Clinical tests with an 8% solution indicated that Polyquaternium-7 is not a photosensitizer. Given its structure, this material is considered not likely to be significantly absorbed in the skin and therefore is unlikely to produce general toxicity, developmental toxicity, or mutagenic/carcinogenic effects under use conditions. The presence of unreacted acrylamide monomer is considered sufficiently low so as to have no toxicologic significance. Based on the available data, it is concluded that Polyquaternium-7 is safe for use in cosmetic formulations. The CIR (Cosmetic Ingredient Review) Expert Panel concluded that ingredient is safe as cosmetic ingredient (Shampoo from 0.04 % to 1 %).

- Information from the ECHA website (Polyquaternium-7):

<https://echa.europa.eu/lv/substance-information/-/substanceinfo/100.113.772>

- Information from the Journal of the American College of Toxicology (Polyquaternium-7):

<https://journals.sagepub.com/doi/pdf/10.3109/10915819509010307>

Glycol Distearate:

Ingredient is not prohibited and does not have restrictions in cosmetic products according to the REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products.

- Information from the ECHA website:

<https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15184>

Citric Acid:

Ingredient is not prohibited and does not have restrictions in cosmetic products according to the REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products.

The CIR Expert Panel considered that the oral safety of citric acid has been well substantiated in that this ingredients is food additives.



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Available repeated insult patch testing at the highest leave-on concentration of 4% citric acid demonstrated an absence of both dermal irritation and sensitization, suggesting that these ingredients would not be irritants in formulation.

- Safety Assessment of Citric Acid, Inorganic Citrate Salts, and Alkyl Citrate Esters as Used in Cosmetics. CIR, International Journal of Toxicology 2014, Vol. 33(Supplement 2) 16S-46S.

- Information from the ECHA website (Citric Acid):

<https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15451/1>

Styrene/Acrylates Copolymer:

Ingredient is not prohibited and does not have restrictions in cosmetic products according to the REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products.

The CIR (Cosmetic Ingredient Review) Expert Panel concluded that ingredient is safe as cosmetic ingredient in the practices of use and concentrations as described in CIR safety assessment (Total up to 8.2%).

- Safety Assessment of Styrene and Vinyl-type Styrene Copolymers as Used in Cosmetics. CIR, Final Report, October 2, 2014.

Laureth-4:

Ingredient is not prohibited and does not have restrictions in cosmetic products according to the REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products.

- Information from the ECHA website:

<https://echa.europa.eu/de/registration-dossier/-/registered-dossier/16040/7/3/1>

Disodium EDTA:

Ingredient is not prohibited and does not have restrictions in cosmetic products according to the REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products.

Dermal absorption was investigated for human volunteers indicating only 0.001 % absorption for CaNa₂EDTA. It is concluded that systemic exposure via dermal route is negligible. This conclusion is supported by the independent evaluation of the MAK Commission for the Investigation of Health Hazards of Chemical Compounds in the work area.

The CIR (Cosmetic Ingredient Review) Expert Panel concluded that ingredient is safe as cosmetic ingredient in the practices of use and concentrations as described in CIR safety assessment (Total concentration ranges to 0.3%).

- Final Report on the Safety Assessment of EDTA, Calcium Disodium EDTA, Diammonium EDTA, Dipotassium EDTA, Disodium EDTA, TEA-EDTA, Tetrasodium EDTA, Tripotassium EDTA, Trisodium EDTA, HEDTA, and Trisodium HEDTA. CIR, International Journal of Toxicology, 21(Suppl. 2):95-142, 2002.

Coco-Glucoside:

Ingredient is not prohibited and does not have restrictions in cosmetic products according to the REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products.

In clinical testing, the sensitization potential of 0.5%, 0.75%, and 1.8% ai decyl glucoside (in formulation), 5% ai aq decyl and lauryl glucoside, and 1% ai aq coco-glucoside was evaluated in a human repeated insult patch test (HRIPT). These ingredients were not irritating or sensitizing.



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The CIR (Cosmetic Ingredient Review) Expert Panel concluded that ingredient is safe as cosmetic ingredient in the practices of use and concentrations as described in CIR safety assessment (Rinse-off products from 0.2 % to 15 %).

- Information from the ECHA website (Coco-Glucoside):

<https://echa.europa.eu/es/registration-dossier/-/registered-dossier/14407>

- Safety Assessment of Decyl Glucoside and Other Alkyl Glucosides as Used in Cosmetics, CIR

Benzoic Acid:

Benzoic Acid is included in the REGULATION (EC) No. 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products, Annex V (List of preservatives allowed in cosmetic products), reference number 1 - Maximum concentration in ready for use preparation (Rinse-off products, except oral products) is 2.5%.

The results, presented only in scientific papers, are from studies both on volunteers and patients from dermatological clinics. 2% benzoic acid in petrolatum over 46h did not irritate intact skin of healthy volunteers. 24h application of 30% benzoic acid in ethanol was found to be the lowest irritating concentration.

Chamber test (20 min/occlusive), open test (30 min): 15 µl of 5 % benzoic acid in petrolatum, 15 atopic and 16 non-atopic patients. The atopics showed redness in both the chamber test, (73 %) and the open test, (80 %). Non-atopics showed 80% redness in both the chamber test and in the open test. There was no statistical difference between atopics and non-atopics.

8 out of 627 patients (1.3%) from dermatological clinics showed positive reactions to 5 % benzoic acid, in petrolatum under an occlusive dressing for 24 or 48 h. At this concentration, the authors suggest that these results could be interpreted as marginally irritating, rather than allergic.

In the United States, benzoic acid and sodium benzoate are on the FDA list of substances that are generally recognized as safe (GRAS). Both may be used as antimicrobial agents, flavouring agents and as adjuvants with a current maximum level of 0.1% in food. The FDA has not determined whether significantly different conditions of use would be GRAS. The FDA has sought fully up-to-date toxicology information.

- Information from the ECHA website (Benzoic Acid):

<https://echa.europa.eu/lv/registration-dossier/-/registered-dossier/13124>

- Safety Assessment of Benzyl Alcohol, Benzoic Acid and its Salts, and Benzyl Benzoate, CIR, International Journal of Toxicology 2017, Vol. 36(Supplement 3) 5S-30S

- Opinion of The Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers, Benzoic Acid and Sodium Benzoate, SCCNFP/0531/01

- Scientific Committee on Consumer Products SCCP, Opinion on Benzoic Acid and Sodium Benzoate, SCCP/0891/05

Formic Acid:

Formic Acid and its sodium salt are included in the REGULATION (EC) No. 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products, Annex V (List of preservatives allowed in cosmetic products), reference number 14 - Maximum concentration in ready for use preparation is 0.5 % (as acid).

- Safety Assessment of Formic Acid and Sodium Formate as Used in Cosmetics. International Journal of Toxicology 2016. Vol. 35(Supplement 2) 41S-54S.

- Information from the ECHA website (Formic Acid):

<https://echa.europa.eu/lv/registration-dossier/-/registered-dossier/15127>



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Methylchloroisothiazolinone and Methylisothiazolinone:

Reaction mass of 5-chloro-2-methyl-2*H*-isothiazol-3-one and 2-methyl-2*H*-isothiazol-3-one (3:1) (CAS No. 55965-84-9, Index Number: 613-167-00-5).

Methylchloroisothiazolinone and Methylisothiazolinone mixture in the ratio 3:1 not prohibited in cosmetic products accordance REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products. Methylchloroisothiazolinone and Methylisothiazolinone mixture in the ratio 3:1 have restriction in REGULATION (EC) No 1223/2009 ANNEX V List of Preservatives Allowed in Cosmetic Products, Reference number: 39. Maximum concentration in ready for use preparation 0.0015%, use rinse-off products only.

The mixture of 5-chloro-2-methylisothiazol-3(2*H*)-one (CMIT) and 2-methylisothiazol-3(2*H*)-one (MIT), CMIT/MIT, is a preservative in cosmetics. CMIT/MIT is a highly effective preservative; however, it is also a commonly known skin sensitizer. The concentration 0.0015% of CMIT/MIT is the maximum MIT level allowed in current products. The no observed adverse effect level (NOAEL) for CMIT/MIT was 2.8 mg/kg bw/day obtained from a two-generation reproductive toxicity test, and the skin sensitization toxicity standard value for CMIT/MIT.

The SCCS concluded that the mixture of Methylchloroisothiazolinone and Methylisothiazolinone in a ratio of 3:1 does not pose a risk to the health of the consumer when used as a preservative up to a maximum authorised concentration of 0,0015 % in rinse-off cosmetic products, apart from its skin sensitising potential. The SCCS indicated that induction and elicitation would be less likely in a rinse-off product than when the same concentration is present in a leave-on product.

- Risk Assessment of 5-Chloro-2-Methylisothiazol-3(2*H*)-One/2-Methylisothiazol-3(2*H*)-One (CMIT/MIT) Used as a Preservative in Cosmetics. Toxicological Research 2019;35:103-117.

- OPINION ON the mixture of 5-chloro-2-methylisothiazolin-3(2*H*)-one and 2-methylisothiazolin-3(2*H*)-one, COLIPA n° P56. The SCCS adopted this opinion at its 5th plenary meeting of 8 December 2009.

Stabilizers:

1. **Magnesium Chloride** - Information from ECHA website:<https://echa.europa.eu/registration-dossier/-/registered-dossier/15140>

2. **Magnesium Nitrate** - Information from ECHA website:<https://echa.europa.eu/registration-dossier/-/registered-dossier/16076/6/2/2>

Information provided are from publicly available sources: CosIng (European Commission database with information on cosmetic substances and ingredients), SCCS (Scientific Committee on Consumer Safety), CIR (Cosmetic Ingredient Review), ECHA (European Chemicals Agency) and other relevant scientific literature.

10. UNDESIRABLE EFFECTS AND SERIOUS UNDESIRABLE EFFECTS

Undesirable effects are not expected during normal and reasonably foreseeable use of cosmetic product.

11. INFORMATION ON THE COSMETIC PRODUCT

No additional information is provided.

**PART B – Cosmetic product safety assessment****1. ASSESSMENT CONCLUSION**

The safety assessment has been prepared for a cosmetic product that is meant for adults. All calculated **MoS** values higher than **100**. The calculation was made on Rinse-off product. Through research and calculations, it was shown that the product **SHOWER CREAM-GEL “SHEA BUTTER AND SPICY VANILLA” (TRADE MARK: DALAS)** is safe.

Product components in the given concentrations and product meet generally recognized as safe in accordance with Regulation (EC) No 1223/2009.

Cosmetic product **SHOWER CREAM-GEL “SHEA BUTTER AND SPICY VANILLA” (TRADE MARK: DALAS)** is safe for human health when used under normal or reasonably foreseeable conditions of use.

This assessment is based on information that has been published in recognizing authoritative literature, however, taking into account the accuracy of the information, the undersigned person can not be held responsible for the submitted erroneous information that could be used in the preparation of this assessment.

The safety assessment is based on information currently available and may be revised as soon as new information becomes available.

2. LABELLED WARNINGS AND INSTRUCTIONS OF USE**SHOWER CREAM-GEL “SHEA BUTTER AND SPICY VANILLA” (TRADE MARK: DALAS)****500 g (or 1000 g)**

Incredibly gentle shower cream-gel “Shea butter and spicy vanilla” gives unforgettable emotions, fill you with energy and vigor for the whole day! The cream-gel gently cleanses and refreshes your skin. Gentle components of its formula provide nutrition and necessary level of skin hydration, protect it, give silkiness and smoothness.

Method of use: apply cream-gel on a washcloth or palm, lightly foam and spread it over body, then rinse foam with water.

Warning: Keep out of reach of children. For external use only. Avoid contact with eyes. In case of contact with eyes, rinse immediately with plenty of water. In case of any adverse reactions, stop using and seek for medical advice.

Storage conditions: Store in the packaging of the manufacturer at a temperature of +5°C to +25°C away from direct sunlight and air humidity 50-80%, as well as not less than 1 meter away from heating devices.

Shelf life: 30 months. Use before: (month,day) and Batch number to be specified on the package.

INGREDIENTS: Aqua, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Glycerin, PEG-7 Glyceryl Cocoate, Coco-Glucoside, Parfum, Sodium Chloride, Butyrospermum Parkii Butter, Cocamide MEA, Styren/Acrylates Copolymer, Polyquaternium-7, Glycol Distearate, Citric Acid, Benzoic Acid, Formic Acid, Tetrasodium EDTA, Laureth-4, Methylchloroisothiazolinone, Methylisothiazolinone, Hexyl Cinnamal.

There are no extra labelling requirements for this product.

In accordance with Regulation (EC) No. 1223/2009, article 19, there must be warnings stated on the label: None.

The evaluation of the functional properties of the product declared by the manufacturer is not part of this assessment.

**3. REASONING**

The safety report for the product **SHOWER CREAM-GEL “SHEA BUTTER AND SPICY VANILLA” (TRADE MARK: DALAS)** was done based on information from the suppliers and other information publicly available. The available data do not suggest for the product hazard.

This assessment is based on toxicological profile of the ingredients, toxicological/dermatological documentations of the raw materials, level of exposure based on the conditions of applications, material safety data sheets, legal regulations. The safety of the cosmetic product is based on the safety of its ingredients and results of the clinical study, the product stability data. This cosmetic product contains only the allowed ingredients in allowed concentrations.

The ingredients are not prohibited as per Cosmetic Regulation (EC) No. 1223/2009 and its amendments and the safety assessment has been carried out in accordance with this regulation, Annex I.

The calculation of the exposure to the product and to each of the ingredients in the cosmetic product was carried out according to the “SCCS’s Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation, 11th revision SCCS/1628/21”. A retention factor of 0.01 is used, as this is a Rinse-off product.

In the case of raw materials which the results of chronic toxicity were available (NOAEL) margin of safety (MoS) was calculated. Values are > 100, recommended as safe. All calculated The Margins of Safety (MoS) of ingredients above 100, which supports the safety of the cosmetic product.

NOAEL values are not applied to some components of this cosmetic product.

NOAEL value is not applied to fragrance composition. The manufacturer's recommendations are followed. Fragrance is used in low concentration and is not expected to pose a risk to human health.

NOAEL value is not applied to Butyrospermum Parkii Butter of this cosmetic product. Butyrospermum Parkii Butter is not toxic and is not classified according to the CLP Regulation. Butyrospermum Parkii Butter has a long history of use in cosmetic industry and is well-known in cosmetics, the good researched ingredient, and this component is widely used today in the manufacture of cosmetics. The manufacturer of the raw material guarantees that this ingredient is safe in the given concentration.

Butyrospermum Parkii Butter is not prohibited and does not have restrictions in cosmetic products according to the REGULATION (EC) No. 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products. Butyrospermum Parkii Butter is listed Cosmetic ingredients database (CosIng).

It is not expected that any of the raw materials would pose a risk to human health at the intended use frequency.

There were no incompatibility in the recipe.

Undesirable effects are not expected during normal and reasonably foreseeable use of cosmetic product.

The manufacturer (LLC “UKRAINIAN-GERMAN COMPANY “2K”) confirms that the product is stable for 30 months from the manufacture date.

It was concluded that the product is stable under reasonably foreseeable conditions of use during its shelf-life. The quality of goods is warranted under condition of their proper storage at recommended temperature from +5 °C to +25 °C.

The manufacturer (LLC “UKRAINIAN-GERMAN COMPANY “2K”) confirms that packaging complies with the requirement®ulations which state that packaging may be safely used for cosmetic product packaging.

Microbiological properties of the **SHOWER CREAM-GEL “SHEA BUTTER AND SPICY VANILLA” (TRADE MARK: DALAS)** were tested by Laboratorija AUCTORITAS, Ltd,



SVS COSMEDLAB

COSMETIC PRODUCT SAFETY REPORT

for cosmetic product – SHOWER CREAM-GEL “SHEA BUTTER AND SPICY VANILLA”
(TRADE MARK: DALAS)

Latvia, Test report No. 11819/22 (Sample delivered to laboratory in original packaging) dated 25.11.2022 with satisfactory results.

A challenge test has been performed to test the efficacy of the preservation system of this product. Evaluation of the antimicrobial protection of the **SHOWER CREAM-GEL “SHEA BUTTER AND SPICY VANILLA” (TRADE MARK: DALAS)** was tested by Laboratorija AUCTORITAS, Ltd, Latvia, Test report No. 11819/22 (Sample delivered to laboratory in original packaging) dated 25.11.2022 with satisfactory results. The product conforms to specification LVS EN ISO 11930:2020, criterion A.

Cosmetic product **SHOWER CREAM-GEL “SHEA BUTTER AND SPICY VANILLA” (TRADE MARK: DALAS)** is safe.

Cosmetic product **SHOWER CREAM-GEL “SHEA BUTTER AND SPICY VANILLA” (TRADE MARK: DALAS)** complies with Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products and The SCCS's Notes Of Guidance For The Testing Of Cosmetic Ingredients And Their Safety Evaluation 11th Revision SCCS/1628/21.

4. ASSESSOR'S CREDENTIALS AND APPROVAL OF PART B

ASSESSOR: SIA “SVS CosMedLab” chemist J. Visnevskā,

Riga Technical University, Engineering Master's degree in chemical technology

Diploma: Series PD E No. 0906, issued in Riga on 1 July 2011 (in the Annex No 1)

Work experience in chemistry: 16 years.

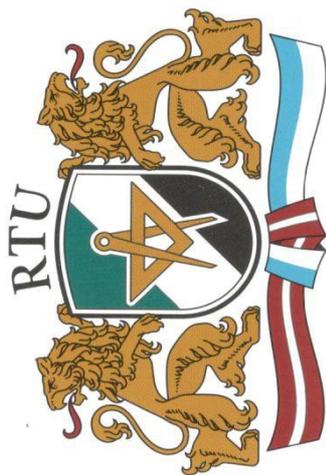
(J. Visnevskā)

(signature)

Date: 10st February 2023

This safety report is based upon information available at this date. The safety of the product should be reviewed on a regular basis. Reviews of this assessment should be conducted when new information becomes available.

RĪGAS TEHNISKĀ UNIVERSITĀTE



MAGISTRA DIPLOMS

AR IZCĪLĪBU

Sērija MD E

Nr. 0906 *

Ar Materiālzinātnes un lietišķās
ķīmijas fakultātes domes
2011. gada 22. jūnija lēmumu Nr. 9

Jūlija Višņevska
personas kods 170286-12414

ieguvusi
**inženierzinātņu
MAGISTRA GRĀDU**
ķīmijas tehnoloģijā

Rektors

Materiālzinātnes un lietišķās ķīmijas
fakultātes domes priekšsēdētājs


Leonīds Ribickis

Z.v.

Rīgā
2011. gada 1. jūlijā
Reģistrācijas Nr. 140-022

