SVS COSMEDLAB

COSMETIC PRODUCT SAFETY REPORT
for cosmetic product – LIQUID SOAP WITH ALOE VERA (TRADE MARK: GALAX)

PART A – Cosmetic product safety information

1. COSMETIC PRODUCT INFORMATION

Trade Mark: **GALAX**
Product name: **LIQUID SOAP WITH ALOE VERA**
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	10 - 25
ROKamina K30 / *(Aqua (and) Cocamidopropyl Betaine (and) Sodium Chloride)*	PCC Exol SA, Poland	1 - 5
ROKamid KAD / *(Cocamide DEA)*	PCC Exol SA, Poland	1 - 5
Galaxy PEG 7 Glyceryl Cocoate / *(PEG-7 Glyceryl Cocoate)*	Galaxy Surfactants Limited, India	1 - 5
Glycamed 99,7% / *(Glycerin)*	Glaconchemie GmbH, Germany	1 - 5
Sodium Chloride / (*Sodium Chloride*)	Central Drug House (P) Ltd., India	0.1 - 1.0
Euperlan PCO / *(Styrene/Acrylates Copolymer (and) Caprylyl/Capric Glucoside (and) Coco-Glucoside (and) Benzoic Acid)*	BASF SE, Germany	0.1 - 1.0
Citric Acid Monohydrate / *(Citric Acid)*	RZBC（JUXIAN） CO., LTD., China	0.1 - 1.0
Disodium dihydrogen ethylenediaminetetraacetate / *(Disodium EDTA)*	Suppl. "Shijiazhuang Jackchem Co.", Ltd., China	0.1 - 1.0
Salimix MCI / *(Aqua (and) Methylchloroisothiazolinone (and) Methylisothiazolinone)*	Suppl. "ROSCOSMETICA" Ltd., Ukraine	<0.0015 %
Fragrance: Aloe Vera CFB 33882 / *(Parfum)*	ROSCOSMETICA Ltd., Ukraine	0.1 - 1.0
Барвник харчовий синтетичний FOODCO G Фісташковый U 123 01 / *(CI 19140 (and) CI 14720 (and) CI 42090)*	ТОВ "ЕКО РЕСУРС УКРАЇНА", Ukraine	<0.01
Amount:		**100.00**

2. QUANTITATIVE AND QUALITATIVE COMPOSITION OF THE COSMETIC PRODUCT

INCI	CAS No.	EC No.	FUNCTION	Amount, %
Aqua	7732-18-5	231-791-2	Solvent	75 - 100 (87.5)
Sodium Laureth Sulfate	68891-38-3	500-234-8	Surfactant-Cleansing, Foaming, Emulsifying	10 – 25 (17.5)

Cocamide DEA	68155-07-7	931-329-6	Surfactant-Cleansing, Emulsion Stabilizing, FoamBoosting, Emulsifying, Viscosity Controlling	1 – 5 (3.0)
Cocamidopropyl Betaine	61789-40-0	263-058-8/ 931-296-8	Surfactant-Cleansing, Antistatic, Hair Conditioning, Foam Boosting, Viscosity Controlling	1 – 5 (3.0)
PEG-7 Glyceryl Cocoate	68201-46-7	-	Surfactant-Cleansing, Surfactant-Emulsifying	1 – 5 (3.0)
Glycerin	56-81-5	200-289-5	Humectant, Skin Conditioning, Skin Protecting, Solvent, Viscosity Controlling	1 – 5 (3.0)
Sodium Chloride	7647-14-5	231-598-3	Viscosity Controlling	0.1 – 1.0 (0.5)
Parfum	-	-	Perfuming	0.1 – 1.0 (0.5)
Caprylyl/Capryl Glucoside	68515-73-1	500-220-1	Surfactant-Cleansing, Foaming	0.1 – 1.0 (0.5)
Coco-Glucoside	110615-47-9	-	Cleansing, Foaming, Surfactant	0.1 – 1.0 (0.5)
Styrene/Acrylates Copolymer	27306-39-4; 25034-86-0; 25085-34-1; 9010-92-8	-	Opacifying, Film Forming	0.1 – 1.0 (0.5)
Citric Acid	77-92-9/ 5949-29-2	201-069-1	Buffering, Chelating	0.1 – 1.0 (0.5)
Disodium EDTA	139-33-3	205-358-3	Chelating, Viscosity Controlling	0.1 – 1.0 (0.5)
Methylchloroisothiazolinone	26172-55-4	247-500-7	Preservative	<0.0015 % (CMI:MI=3:1) (0.014)
Methylisothiazolinone	2682-20-4	220-239-6		
Benzoic Acid	65-85-0	200-618-2	Preservative	0.001 – 0.01 (0.005)
Hexyl Cinnamal	*101-86-0*	*202-983-3/ 639-566-4*	*Perfuming*	*<0.01*
CI 19140	1934-21-0	217-699-5	Colorant	0.001-0.01 (0.01)
CI 14720	3567-69-9	222-657-4	Colorant	0.001-0.01 (0.01)
CI 42090	3844-45-9	223-339-8	Colorant	0.001-0.01 (0.01)

Fragrance allergens:
Cosmetic product contains one allergen Hexyl Cinnamal ≥ 0.01 % (for Rinse-Off cosmetic products) which 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 mass without impurities
Colour	Visual. Complies with the reference model.	Pale green
Smell	Organoleptic. Complies with the reference model.	Characteristic
pH value	pH meter	3.5 – 8.5 (tests result: 4.69)

The manufacturer (**LLC "UKRAINIAN-GERMAN COMPANY "2K", Ukraine**) confirms that the product is stable for 30 months from the manufacture date.
Samples of the **LIQUID SOAP WITH ALOE VERA (TRADE MARK: GALAX)** were tested to assess the product's stability (reference: Declaration of cosmetic products stability test No. 188, date of issue: 04.05.2021, "LLC "UKRAINIAN-GERMAN COMPANY "2K", Ukraine). Samples of the product were tested in at recommended temperature from +5 °C to +25 °C 30 months. Observations of the samples' appearance, colour, odour, pH were made and recorded (according ТУ У 20.4-37915506-002:2019 «Засоби косметичні для очищення шкіры та волосся. Технічні умови».)
The product is stable under reasonably foreseeable conditions of use during its shelf-life – 30 moths 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 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 **LIQUID SOAP WITH ALOE VERA (TRADE MARK: GALAX)** are belong to Category 2.

Microbiological properties of the **LIQUID SOAP WITH ALOE VERA (TRADE MARK: GALAX)** were tested by Laboratorija AUCTORITAS, Ltd, Latvia, Test report No. 4521/21 (Sample delivered to laboratory in original packaging (DUOPACK), 500 g) from 28.05.2021. 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	$<1 \cdot 10^1$
Candida albicans (in per 1 g/ 1ml)	Absent	LVS EN ISO 18416:2016	Absent
Staphylococcus aureus (in per 1 g/ 1 ml)	Absent	LVS EN ISO 22718:2016	Absent
Pseudomonas aeruginosa (in per 1 g/ 1ml)	Absent	LVS EN ISO 22717:2016	Absent
Escherichia coli (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 liquid soap was tested by Laboratorija AUCTORITAS, Ltd, Latvia, Test report No. 4521/21 (Sample delivered to laboratory in original packaging) from 28.05.2021. with satisfactory results. The product conforms to specification LVS EN ISO 11930:2012, criterion A.

5. IMPURITIES, TRACES, INFORMATION ABOUT THE PACKAGING MATERIAL

Cosmetic product **LIQUID SOAP WITH ALOE VERA (TRADE MARK: GALAX)** contains raw material Cocamide DEA (ROKamid KAD) with max. 3 % inevitable impurity **Diethanolamine** and in finished product Diethanolamine content is 0.09%. The REGULATION (EC) No 1223/2009 ANNEX III, Reference No. 60 states that no more than 5% free amine in a raw material and less than 0.5% in a finished product can be used. Not to be used with nitrosating systems too. Raw material ROKamid KAD (Cocamide DEA) contains max. 3% free amine and in finished product contains 0.09 % free amine-Diethanolamine. ROKamid KAD does not use with nitrosating systems. Therefore, the quality of the ROKamide KAD and the compatibility of ingredients in the formulation corresponds to REGULATION (EC) No 1223/2009 ANNEX III, Reference No. 60.

Cosmetic product **LIQUID SOAP WITH ALOE VERA (TRADE MARK: GALAX)** contains preservatives Methylchloroisothiazolinone (and) Methylisothiazolinone (Salimix MCI) with two impurities (stabilizers): **Magnesium Chloride** (max 0.8 %) – 0.00011 % (1.1 ppm) and **Magnesium Nitrate** (max 1.4 %) - 0.0002 % (2 ppm).
These ingredient 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 (1.1 and 2 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 шкіры 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 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. 1534 from 06.05.2021, conducted by the company ПП НЦЛД « Еталон», Ukraine.
LLC UKRAINIAN-GERMAN COMPANY "2K" confirms that packaging complies with the requirement&regulations which state that packaging may be safely used for cosmetic product packaging.
Packaging materials:

Product packaging - primary	Documentation
White PET Bottle (500 ml)	Material for bottles: PET (Polyethylene Terephthalate, NEOPET), NEO Group, Lithuania MSDS from 11.09.2017. Declaration about the type of material Nr. 189 from 06.05.2021. (СУНП **"**2K**"** Ltd, Ukraine) Quality certificate Nr. 000237089/3 from 22.10.2020. for PET (Polyethylene Terephthalate) (Material: CR-8816) Preforms from manufacturer: Retal Dnipro Ltd (Ukraine); The bottles conforms to ТУ У 22.2-34657144-001:2013 and correspond to the quality of the packaging for the food industry (Certificate of Expertise Nr. 602-123-20-1/1818 from 31.01.2019. (State Inspectorate of Ukraine on Labour Issues (Derzhpratsi).
Polypropylen (PP) bottle pump white dispenser	Pump dispenser material: PPH-T03, Manufacturer: Sinopec Zhenhai Refining & Chemical Company (China), Machinery & Electrical Products Testing Center SMEC (China) Quality Test Report 201602202751-1-1 from 4/5/2016.; Company "UKR-TARA_OPT", Ukraine Quality Certificate Nr. 19-02/2019-1 from 19.-02.2019.,"ITAK", Ukraine; the bottle pump dispenser conforms to ДСТУ 2437-94.
Flexible plastic packaging white Doypack (for Liquid soap 500 g or 1500 g) material, manufactured by company "ITAK", Ukraine for СУНП **"**2K**"** Ltd, Ukraine	**Doypack for 500 g Soap**; (stand-up pouch) materials: PET (transparent)+ PET (metal.)12+ PE LD (transparent) 120; The doypack conforms to ТУ У 22.1-16476839-001:2004; Quality Certificate for Batch Nr. 2951 from 03.08.2021.,"ITAK", Ukraine. **Doypack for 1500 g Soap**; (stand-up pouch)

	materials: PET (transparent)+ PET (metal.)12+ PE LD (transparent) 140; The doypack conforms to ТУ У 22.1-16476839-001:2004; Quality Certificate for Batch Nr. 2251 from 19.07.20201.,"ITAK", Ukraine.
Screw white dispenser with screw cap for doypack	Material for screw caps: **PE TIPELIN 1100J**+ **PE Homopolymer Purell PE3020D** (**PE TIPELIN 1100J**: MOL Petrochemicals Co. Ltd, Slovakia, Food Contact Declaration Data Sheet from 30.06.2021., version Nr. 2021-v2; **PE Homopolymer Purell PE3020D:** Basell Sales & Marketing Company B.V. , Netherlands, MSDS from 26.05.2020., version Nr. 1.5)

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

GALAX
LIQUID SOAP WITH ALOE VERA (TRADE MARK: GALAX)
500 g (or 500 g, 1500 g in Doypack)
Method of use: apply a small amount on a wet skin, spit, rinse with water.
Safety precautions: keep out of the reach of children.
IF IN EYES: rinse immediately with water.
IF SWALLOWED: cause vomiting, seek medical attention.
Caution: increased individual sensitivity to specific components.
Shelf life: 30 months. Use before: (month,day) and Batch number to be specified on the package.
Keep at temperature from +5ºC to +25ºC away from light and heaters.
INGREDIENTS: Aqua, Sodium Laureth Sulfate, Cocamide DEA, Cocamidopropyl Betaine, PEG-7 Glyceryl Cocoate, Glycerin, Sodium Chloride, Parfum, Caprylyl/Capryl Glucoside, Coco-Glucoside, Styrene/Acrylates Copolymer, Citric Acid, Disodium EDTA, Methylchloroisothiazolinone, Methylisothiazolinone, Hexyl Cinnamal, CI 19140, CI 14720, CI 42090.

Normal (hand wash soap, 10 times a day) use 20 g/day and reasonably foreseeable (as shower gel, 1.43 times a day) use 18.67 g/day.
Normal application area: area hands
Reasonably foreseeable application area: total body area

7. EXPOSURE TO THE COSMETIC PRODUCT

Cosmetic product application areas: hands area and total body area
Normal area of skin contact: 860 cm^2 (SCCS 11th Revision*)
Reasonably foreseeable area of skin contact: 17500 cm^2 (SCCS 11th Revision*)
Duration of contact: Rinse-off product.
Quantity of product used at application: 20 g normal use; 18.67 g – reasonably foreseeable use. (SCCS 11th Revision*)

Frequency of application: for normal use 10 times a day, for reasonably foreseeable application use 1.43 times a day. (SCCS 11th Revision*)
Normal and reasonably foreseeable use way: hands and body 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 (60 for Diethanolamine)
Retention Factor	F_{ret} (-)	0.01 (don't have unit)
Frequency of application of the finished product	F (1/day) or (day $^{-1}$)	10 (hands soap) 1.43 (as shower gel)
Skin Surface Area expected to be treated with the finished cosmetic product	SSA (cm^2)	860 (hands soap) 17500 (as shower gel)
Body weight (adults)	kg	60 kg – default human body weight

Mode of application	Specific exposure
Normal use	As hands soap – 10 times a day
Reasonable use	As shower gel – 1.43 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 quidance document at its plenary meeting on 30-31 March 2021.

8. EXPOSURE TO THE SUBSTANCES

EXPOSURES OF RAW MATERIALS CALCULATION:

SED = $E_{prod.}$ x C/100 x 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.

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	87.500	100	3.33	2.913750	2.79	2.441250
Sodium Laureth Sulfate	17.500	100	3.33	0.582750	2.79	0.488250
Cocamide DEA	3.000	100	3.33	0.099900	2.79	0.083700
Impurity of Cocamide DEA:						
Diethanolamine (max. 3 %)	*0.090*	*60*	*3.33*	*0.001798*	*2.79*	*0.001507*
Cocamidopropyl Betaine	3.000	100	3.33	0.099900	2.79	0.083700
PEG-7 Glyceryl Cocoate	3.000	100	3.33	0.099900	2.79	0.083700
Glycerin	3.000	100	3.33	0.099900	2.79	0.083700
Sodium Chloride	0.500	100	3.33	0.016650	2.79	0.013950
Parfum	0.500	100	3.33	0.016650	2.79	0.013950
Hexyl Cinnamal	*0.010*	*100*	*3.33*	*0.000333*	*2.79*	*0.000279*
Caprylyl/Capryl Glucoside	0.500	100	3.33	0.016650	2.79	0.013950
Coco-Glucoside	0.500	100	3.33	0.016650	2.79	0.013950
Styrene/Acrylates Copolymer	0.500	100	3.33	0.016650	2.79	0.013950
Citric Acid	0.500	100	3.33	0.016650	2.79	0.013950

Disodium EDTA	0.500	100	3.33	0.016650	2.79	0.013950
Methylchloroisothiazolinone Methylisothiazolinone	0.0014	100	3.33	0.000047	2.79	0.000039
Stabilizers of Methylchloroisothiazolinone & Methylisothiazolinone:						
Magnesium Chloride (0.8 %)	*0.00011*	*100*	*3.33*	*0.000004*	*2.79*	*0.000003*
Magnesium Nitrate (1.4 %)	*0.00020*	*100*	*3.33*	*0.000007*	*2.79*	*0.000006*
Benzoic Acid	0.010	100	3.33	0.000333	2.79	0.000279
CI 19140	0.010	100	3.33	0.000333	2.79	0.000279
CI 14720	0.010	100	3.33	0.000333	2.79	0.000279
CI 42090	0.010	100	3.33	0.000333	2.79	0.000279

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, PODsys 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	2.913750	2.441250	Not toxic	Not toxic
Sodium Laureth Sulfate	225	0.582750	0.488250	386	461
Cocamide DEA	125	0.099900	0.083700	1251	1493
Impurity of Cocamide DEA:					
Diethanolamine	*14*	*0.001798*	*0.001507*	*7786*	*9292*
Cocamidopropyl Betaine	750	0.099900	0.083700	7508	8961
PEG-7 Glyceryl Cocoate	3000	0.099900	0.083700	30030	35842
Glycerin	1280	0.099900	0.083700	12813	15293
Sodium Chloride	2533	0.016650	0.013950	152132	181577
Parfum	not applicable	0.016650	0.013950	not applicable	not applicable
Hexyl Cinnamal	*29.9*	*0.000333*	*0.000279*	*89790*	*107168*
Caprylyl/Capryl Glucoside	1000	0.016650	0.013950	60060	71685
Coco-Glucoside	1000	0.016650	0.013950	60060	71685
Styrene/Acrylates Copolymer	200	0.016650	0.013950	12012	14337
Citric Acid	4000	0.016650	0.013950	240240	286738
Disodium EDTA	500	0.016650	0.013950	30030	35842
Methylchloroisothiazolinone Methylisothiazolinone	2.8	0.000047	0.000039	60060	71685
Stabilizers of Methylchloroisothiazolinone & Methylisothiazolinone:					
Magnesium Chloride	*140*	*0.000004*	*0.000003*	*38220038*	*45617465*
Magnesium Nitrate	*1500*	*0.000007*	*0.000006*	*225225225*	*268817204*

Benzoic Acid	500	0.000333	0.000279	1501502	1792115
CI 19140	2640	0.000333	0.000279	7927928	9462366
CI 14720	400	0.000333	0.000279	1201201	1433692
CI 42090	630	0.000333	0.000279	1891892	2258065

9. TOXICOLOGICAL PROFILE OF THE SUBSTANCES

INGREDIENTS (INCI Name)	CAS No.	Introduction,% by quantity (in average)	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	87.500	Not toxic	Not toxic	Not skin irritant and not sensitising	Not toxic	-
Sodium Laureth Sulfate	68891-38-3	17.500	4100	>225	>2000 Causes skin irritation. Not sensitising.	No evidence of CMR toxicity	Causes serious eye damage.
Cocamide DEA	68155-07-7	3.000	>2000 (rat)	125*	>2000 (rabbit) Causes skin irritation. Not sensitising.	No evidence of CMR toxicity	Causes serious eye damage.
Impurity of Cocamide DEA:							
Diethanolamine	*111-42-2*	*0.09000*	*>1100 (calc.)*	*14*	*>2000 Causes skin irritation. Not sensitising.*	*No evidence of CMR toxicity*	*Causes serious eye damage.*
Cocamidopropyl Betaine	61789-40-0	3.000	>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	3.000	>2000	3000**	>2000 Not skin irritant and not sensitising	No evidence of CMR toxicity	-
Glycerin	56-81-5	3.000	>11500	1280 (rat)	56750 (guinea pig) Not skin irritant and not sensitising	No evidence of CMR toxicity	-
Sodium Chloride	7647-14-5	0.500	3550	2533*	>10000 (rabbit) Not skin irritant and not sensitising	No evidence of CMR toxicity	-
Parfum	-	0.500	>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.
Hexyl Cinnamal	*101-86-0*	*0.010*	*> 2000 (rat)*	*29.9 (rat)*	*>2000 (rabbit) Not skin irritant. May cause an allergic skin reaction.*	*No evidence of CMR toxicity*	*Skin Sens. 1, H317*
Caprylyl/Capryl Glucoside	68515-73-1	0.500	>2000 (rat) practically non toxic	1000 (rat)	>2000 (rabbit) Not skin irritant and not sensitising	No evidence of CMR toxicity	Causes serious eye damage.
Coco-Glucoside	110615-47-9	0.500	>5000 (rat)	1000	>2000 (rabbit) Causes skin irritation. Not sensitising	No evidence of CMR toxicity	Causes serious eye damage.
Styrene/Acrylates Copolymer	27306-39-4/ 25034-86-0/ 25085-34-1/ 9010-92-8	0.500	>2000	200	>2000 Not skin irritant and not sensitising	No evidence of CMR toxicity	-
Citric Acid	77-92-9/ 5949-29-2	0.500	>3000	4000	>2000 Not skin irritant and not sensitising	No evidence of CMR toxicity	Causes serious eye irritation
Disodium EDTA	139-33-3	0.500	2800 (rat)	>500 (rat)	>2000 (rat) Not skin irritant and not sensitising	No evidence of CMR toxicity	-

Methylchloroiso-thiazolinone	26172-55-4	0.0014	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
Methylisothiazo-linone	2682-20-4						
Stabilizers of Methylchloroisothiazolinone & Methylisothiazolinone:							
Magnesium Chloride	*7786-30-3*	*0.00011*	*5000 (rat)*	*140 (rat)*	*2000 (rat)*	No evidence of CMR toxicity	Acute Tox. 4:H302
Magnesium Nitrate	*10377-60-3*	*0.00020*	*2000 (rat)*	*1500 (rat)*	*5000 (rat)*	No evidence of CMR toxicity	Acute Tox. 4:H302
Benzoic Acid	65-85-0	0.010	>2000	500 (rat)	>2000 (rat) Causes skin irritation. Not sensitising.	No evidence of CMR toxicity	Causes serious eye damage.
CI 19140	1934-21-0	0.010	>2000	2640	>2000 Not skin irritant and not sensitising	No evidence of CMR toxicity	Food additive
CI 14720	3567-69-9	0.010	>2000	400	>2000 Not skin irritant and not sensitising	No evidence of CMR toxicity	Food additive
CI 42090	3844-45-9	0.010	>2000	630	Not skin irritant and not sensitising	No evidence of CMR toxicity	Food additive

*** As LOEL**
**** As PEG-8 caprylic/capric glycerides**

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. 1534 from 06.05.2021. Test report from ПП НЦЛД « Еталон», Ukraine.
2. **SULFOROKAnol L270/1** / *(Sodium Laureth Sulfate (and) Aqua)* - MSDS (PCC Exol SA, Poland) from 01.08.2018., version No. 6.
3. **ROKamina K30** / *(Aqua (and) Cocamidopropyl Betaine (and) Sodium Chloride)* - MSDS (PCC Exol SA, Poland) from 09.09.2019., version No. 8.
4. **ROKamid KAD** / *(Cocamide DEA)* - MSDS (PCC Exol SA, Poland) from 02.09.2019., version No. 6. and Certificate of analysis No.: 890000240958 from 14.12.2019.
5. **Galaxy PEG 7 Glyceryl Cocoate** / *(PEG-7 Clyceryl Cocoate*) - MSDS (Galaxy Surfactants Limited, India) from 25.02.2014 (version No. 1.), Technical Data from 25.07.2014.
6. **Glucamed 99,7 %** / *(Glycerin)* - MSDS (Glaconchemie GmbH, Germany) from 01.04.2018., version No. 1.
7. **Sodium Chloride** / (*Sodium Chloride*) - MSDS (Central Drug House (P) Ltd., India).
8. **Euperlan PCO** / *(Styrene/Acrylates Copolymer (and) Caprylyl/Capric Glucoside (and) Coco-Glucoside (and) Benzoic Acid)* - MSDS (BASF SE, Germany) from 06.02.2017, version No. 3.0.
9. **Citric Acid Monohydrate** / *(Citric Acid)* - MSDS (RZBC (JUXIAN) CO., LTD., China) from 08.11.2017.
10. **Disodium dihydrogen ethylenediaminetetraacetate** / *(Disodium EDTA)* - MSDS (Suppl. "Shijiazhuang Jackchem Co.", Ltd., China) from 31.03.2014, Version No. 1.
11. **Salimix MCI** / *(Aqua (and) Methylchloroisothiazolinone (and) Methylisothiazolinone)* - MSDS (Suppl. "ROSCOSMETICA" Ltd., Ukraine), Version No. EN 4.1. from 10.04.2019.
12. **Fragrance: Aloe Vera CFB 33882** / *(Parfum)* - MSDS (ROSCOSMETICA Ltd., Ukraine) from 12.04.2019., Version No. 4.3.

13. **Барвник харчовий синтетичний FOODCO G Фісташковый U 123 01** / *(CI 19140 (and) CI 14720 (and) CI 42090)* – Specification (ТОВ "ЕКО РЕСУРС УКРАЇНА", Ukraine) from 07.08.2020.

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 they 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):
https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15887

Cocamide DEA:
Cocamide DEA is the most common of amides used in the cosmetics industry and has long been a go-to when formulating surfactant based products. The amides used in the cosmetics industry are 1:1 amides, produced by reacting 1 mole of coconut fatty acids or their esters with 1 mole of dithanolamine (DEA) and are classed as non-ionic surfactants.
Amides and betaines are the two most commonly used secondary surfactants that are used for their excellent foam building and foam stabilising properties alongside their ability to build viscosity. When used in conjunction with each other, they provide an excellent surfactant profile.
Ingredient 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.
Alkanolamines, the family of chemicals cocamide DEA is part of, already have restrictive use in cosmetics across several global regions as they can form nitrosamine, a known carcinogen. Methods of analysis have been available since the 1970s to ensure use is restricted to conform to recommended levels set in the different global regions. The REGULATION (EC) No 1223/2009 ANNEX III 60 states that no more than 5% free amine in a raw material and less than 0.5% in a finished product can be used. Raw material ROKamid KAD (Cocamide DEA) contains max. 3% free amine.
Cocamide DEA is currently permitted for use in cosmetics as it do not have the same nitrosamine-forming potential as DEA on its own. However, to mitigate the risk associated with the potential presence of DEA impurities, their use in combination with nitrosamine-forming agents is unacceptable for cosmetics.

- Safety Assessment of Diethanolamides as Used in Cosmetics. CIR International Journal of Toxicology 32(Supplement 1) 36S-58S, 2013.
- Information from the ECHA website (Diethanolamine):
https://echa.europa.eu/lv/registration-dossier/-/registered-dossier/15770/1

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 hight 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.

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

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

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 Parfum):

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. Hair conditioner 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: 0.01 % 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.

Caprylyl/Capryl Glucoside:

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.

Ingredient function primarily is surfactants. But it is used as a skin conditioning agents, hair conditioning agents, or emulsion stabilizer.

- Information from the ECHA website:
https://echa.europa.eu/lv/registration-dossier/-/registered-dossier/14947

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: Decyl Glucoside and Other Alkyl Glucosides: http://www.cir-safety.org/sites/default/files/119_draft_decylg.pdf

- Safety Assessment of Decyl Glucoside and Other Alkyl Glucosides as Used in Cosmetics, CIR International Journal of Toxicology 32 (Supplement 3) 22S-48S, 2013.

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.

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 International Journal of Toxicology 32 (Supplement 3) 22S-48S, 2013.

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.

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 acidm has been well substantiated in that this ingredients is food additives.

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

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.

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(2H)-one (CMIT) and 2-methylisothiazol-3(2H)-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(2H)-One/2-Methylisothiazol-3(2H)-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(2H)-one and 2-methylisothiazolin-3(2H)-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*

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

Colour CI 19140:
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. Colour CI 19140 is included REGULATION (EC) No 1223/2009 ANNEX IV List of Colorant Allowed in Cosmetic Products, Reference number: 44.
Skin penetration of Color CI 19140 is low. A skin penetration rate of 5.4 µg CI 19140/cm² (about 0.11 % of the applied amount) and 13.2 µg CI 19140/cm² (0.26 % of the applied dose) within 24 hours has been calculated for the pure substance and a commercial formulation, respectively, including the amounts present in the stratum corneum and thus assuming worst case conditions. A penetration rate of 13.2 µg/cm² (0.26 %) representing the highest value derived from the above described test will be used as a worst case scenario for the final risk assessment.
- Information from the ECHA website (CI 19140):
https://echa.europa.eu/lv/registration-dossier/-/registered-dossier/17292
- Scientific Opinion on the re-evaluation Tartrazine (E 102), EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), EFSA Journal 2009; 7(11):1331.
- Opinion of the Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers, ACID YELLOW 23, COLIPA n° C29. SCCNFP/0786/04.

Colour CI 14720:
Ingredient 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. Colour CI 14720 is included REGULATION (EC) No 1223/2009 ANNEX IV List of Colorant Allowed in Cosmetic Products, Reference number: 19.

- Information from the ECHA website (CI 14720):
https://echa.europa.eu/registration-dossier/-/registered-dossier/17281
- Scientific Opinion on the re-evaluation of Azorubine/Carmoisine (E 122) as a food additive, EFSA Journal 2009; 7(11):1332.

Colour CI 42090:

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. Colour CI 42090 is included REGULATION (EC) No 1223/2009 ANNEX IV List of Colorant Allowed in Cosmetic Products, Reference number: 63.
Any measurable permeation through skin was not detected (Limit of detection: 5.5 - 5.7 µg/cm2 in the two experiments, equivalent to 0.09-0.12% of the applied total amount).
- Information from the ECHA website (CI 42090):
https://echa.europa.eu/lv/registration-dossier/-/registered-dossier/20547/1
- Opinion of the Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers Concerning, ACID BLUE 9, COLIPA No C40. SCCNFP/0787/04.
- Scientific Opinion on the re-evaluation of Brilliant Blue FCF (E 133) as a food additive, EFSA Journal 2010;8(11):1853.

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 **LIQUID SOAP WITH ALOE VERA (TRADE MARK: GALAX)** 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 **LIQUID SOAP WITH ALOE VERA (TRADE MARK: GALAX)** 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

LIQUID SOAP WITH ALOE VERA (TRADE MARK: GALAX)
500 g (or 500 g, 1500 g in Doypack)
Method of use: apply a small amount on a wet skin, spit, rinse with water.
Safety precautions: keep out of the reach of children.
IF IN EYES: rinse immediately with water.
IF SWALLOWED: cause vomiting, seek medical attention.
Caution: increased individual sensitivity to specific components.
Shelf life: 30 months. Use before: (month,day) and Batch number to be specified on the package. Keep at temperature from +5ºC to +25ºC away from light and heaters.

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 **LIQUID SOAP WITH ALOE VERA (TRADE MARK: GALAX)** 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.
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&regulations which state that packaging may be safely used for cosmetic product packaging.

Microbiological properties of the **LIQUID SOAP WITH ALOE VERA (TRADE MARK: GALAX)** were tested by Laboratorija AUCTORITAS, Ltd, Latvia, Test report No. 4521/21 (Sample delivered to laboratory in original packaging) from 28.05.2021. 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 **LIQUID SOAP WITH ALOE VERA (TRADE MARK: GALAX)** was tested by Laboratorija AUCTORITAS, Ltd, Latvia, Test report No. 4521/21 (Sample delivered to laboratory in original packaging) from 28.05.2021. with satisfactory results. The product conforms to specification LVS EN ISO 11930:2012, criterion A.

Cosmetic product **LIQUID SOAP WITH ALOE VERA (TRADE MARK: GALAX)** is safe.

Cosmetic product **LIQUID SOAP WITH ALOE VERA (TRADE MARK: GALAX)** 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. The SCCS adopted this quidance document at its plenary meeting on 30-31 March 2021.

4. ASSESSOR'S CREDENTIALS AND APPROVAL OF PART B

ASSESSOR: "SVS CosMedLab" Ltd chemist Valentina Scerbinina,
Riga, University of Latvia (LU), Expert, Master's degree in chemical sciences.

Diploma: Series ЖБ Nr. 261472, issued in Riga on 26th June 1981 (in the Annex) and Academic Information Centre Solution (5th level of professional qualification in chemistry) Nr. 142/28257 from 15th December 2014 (in the Annex).

Work experience in chemistry: 43 years.
Work experience in cosmetic sciences (cosmetics and technologies developer, documents preparation): 34 years (of which – 21 years - in JSC "Dzintars" (Latvia); 5 years – "Cita Lieta" Ltd (Latvia) and 8 years in "SVS CosMedLab" Ltd).

_____ (V. Sherbinina)
(signature)

Date: 05st November 2021

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.