Cosmetic Product Safety Report

Client : MUMUSO (SHANGHAI) CO., LTD.

Address : ROOM 201,209, BUILDING 4, NO.1065, WUZHONG ROAD, MINHANG DISTRICT.SHANGHAI, CHINA.

Description of the submitted sample(s):

Sample Name	:	FRUIT SERIES LIP BALM (STRAWBERRY)
Sample Quantity	:	1 Document
Style / Item No.	:	/
Product Reference	:	/
Type of Product	:	Leave-on product
Labeled Age Grading	:	Adult
Physical Form	:	Paste
Mass or Volume	:	11.6 g/pc
Buyer	:	Not Provided
Vendor	:	Not Provided
Manufacturer	:	Zhejiang Cheerflor Cosmetics Co., Ltd.
Destination	:	EU
Country of Origin	:	China
Sample Received Date	:	2025-08-13
Sample Reported Date	:	2025-09-26
Test Requested	:	EU Cosmetic Product Safety Report (EU CPSR)
Test Result(s)	:	Please refer to the following page(s).

EXECUTIVE SUMMARY

Cosmetic Product Safety Report

The sample(s) COMPLY with the following requirement(s):

- The product safety requirements of the EU Cosmetic Regulation (EC) No 1223/2009 and its amendments. The product must be manufactured according to Good Manufacturing Practice.

Note: The Cosmetic Product Safety Report was performed at a Centre Testing International Group Co., Ltd. approved subcontract lab.

TEST RESULTS:

Cosmetic Product Safety Report

PART A – COSMETIC PRODUCT SAFETY INFORMATION

INTRODUCTION

CTI has conducted a safety assessment of the Fruit Series Lip Balm (Strawberry) product formulation to ensure consumer safety during product use. This product is intended for the EU market and adult users. Intended use: To color and beautify the lips (may also provide gloss and conditioning). The assessment exclusively focused on the product formulation itself and did not involve the evaluation or verification of product efficacy. As a cosmetic product, the safety evaluation complies with EU Cosmetic Regulation (EC) No 1223/2009 and its amendments. Detailed assessment information is provided below.

1. Quantitative and qualitative composition of the cosmetic product

This formulation below refer to the raw materials is an overview of the composition, listing only the chemical name and quantities.

Chemical Name/INCI Name	CAS No.	Conc. %	Intended Function
HYDROGENATED POLYISOBUTENE	68937-10-0	44.125	EMOLLIENT
SYNTHETIC WAX	8002-74-2	19.611	BINDING
POLYISOBUTENE	9003-27-4	15.444	VISCOSITY CONTROLLING
ETHYLHEXYL PALMITATE	29806-73-3	11.767	EMOLLIENT
OZOKERITE	12198-93-5	3.922	BINDING
MICROCRYSTALLINE WAX	63231-60-7	2.451	BINDING
TRIDECYL TRIMELLITATE	94109-09-8	0.808	EMOLLIENT
BUTYROSPERMUM PARKII BUTTER	194043-92-0	0.500	EMOLLIENT
PARFUM(STRAWBERRY LP HK433466)	/	0.500	PERFUME
DICHLOROBENZYL ALCOHOL	1777-82-8	0.150	PRESERVATIVE

Chemical Name/INCI Name	CAS No.	Conc. %	Intended Function
TOCOPHERYL ACETATE	7695-91-2	0.100	ANTIOXIDANT
BARIUM SULFATE	7727-43-7	0.082	FILLER
WATER	7732-18-5	0.074	SOLVENT
CAPRYLYL GLYCOL	1117-86-8	0.070	HUMECTANT
ROSIN	8050-09-7	0.041	FILLER
ETHYLHEXYLGLYCERIN	70445-33-9	0.030	EMOLLIENT
BUTYLENE GLYCOL	107-88-0	0.020	SKIN CONDITIONING
SORBITAN SESQUIISOSTEARATE	71812-38-9	0.012	SURFACTANT -EMULSIFYING
FRAGARIA ANANASSA FRUIT EXTRACT	/	0.005	SKIN CONDITIONING
1,2-HEXANEDIOL	6920-22-5	0.001	SKIN CONDITIONING
Colorant (may contain)			
CI 15850	5858-81-1	0.287	COLORANT

INGREDIENTS ALLERGENS

This series of products contains fragrance. The fragrance allergens CITRUS LIMON PEEL OIL, LIMONENE must be listed on the label.

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

Form: Paste Odor: Strawberry

Color: Red

To evaluate the Stability and Packaging Compatibility of the product formulation, ZHEJIANG CHEERFLOR COSMETICS CO.,LTD. conducted a 3-month stability test on the product.

Test conditions: 50 ℃, room temperature (RT) and 0 ℃ .

Test parameters: Appearance, Compatibility.

Conclusion: The Stability and Packaging Compatibility of the formulation are acceptable for this application.

3. Microbiological quality

3.1 The microbiological test result on formulation, with reference to British Pharmacopoeia 2014, appendix XVI C, efficacy of antimicrobial preservation and the European Pharmacopoeia, 11.0 edition, Chapter 5.1.3 Efficacy of antimicrobial preservation. By third party laboratory (Center Testing International Pinbiao(Shanghai) Co., Ltd. report no. A2250529217101001), with a testing period of 2025/07/24~2025/08/01, was submitted and reviewed based on the following criteria as required by the SCCS Notes of Guidance.

Types of microorganism	Category 1	Category 2
Total Aerobic Mesophilic Microorganisms (Bacteria plus yeast and mould)	≤ 100 CFU per g or ml	≤ 1000 CFU per g or ml
Escherichia coli, Pseudomonas aeruginosa, Staphyloccocus aureus and Candida albicans	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
Category 1: Products specifically intended for children under three years of age, the eye area or mucous membranes. Category 2: Other cosmetics.		

Conclusion: The microbiological quality of the formulation is acceptable for this application.

3.2 Preservation efficacy test.

The product was tested for water activity by Center Testing International Pinbiao (Shanghai) Co., Ltd. (Report No. A2250557626101002). The result showed that the product has a water activity (aw) ≤ 0.75, which classifies it as a low microbial risk product, and therefore it can be exempted from preservative efficacy (challenge) testing.

4. Impurities, traces, information about the packaging material

4.1 Heavy metals in products

Based on the test results from Center Testing International Pinbiao(Shanghai) Co., Ltd. (Report No.: A2250529217101002), the testing period spanned from 2025/07/24~2025/07/30, with an evaluation conducted in accordance with the test findings.

	The heavy metal test results on the part of formulation were reviewed according to

	German Journal of Consumer Protection and Food Safety, Technically Avoidable Heavy Metal Contents in Cosmetic Products, October 2016 as following criteria:					
Test items	Lead	Arsenic	Cadmium	Mercury	Antimony	Soluble Nickel
Limit(mg/kg)	2	0.5	0.1	0.1	0.5	10

Conclusion: The heavy metal content of the formulation is acceptable for this application.

4.2 Heavy metals in packaging materials

Packaging Material: Plastic

The heavy metal test results on the packaging material of the product were reviewed according to the requirements of regulation 5 of the Packaging (Essential Requirements) Regulations 2015. The sum of the concentration residual heavy metal levels of lead, cadmium, mercury and hexavalent chromium of that packaging or of its packaging components does not exceed 14 ppm. According to the test results by Center Testing International Pinbiao(Shanghai) Co., Ltd.(Report No.: A2250529266101001), the samples met the criteria above, and can be considered to be acceptable for this application.

5. Normal and reasonably foreseeable use

The intended purpose of this product is as a Fruit Series Lip Balm (Strawberry) for individuals aged 16 and above. Although accidental ingestion might pose a potential health risk, it is not considered a foreseeable use of this product. Inhalation exposure is highly unlikely for this product.

6. Exposure to the cosmetic product

Body site of application: Lip

Surface area of application: 4.8 square centimeters

The duration of exposure: Leave-on

The frequency of use: 730 uses per year

The amount per application: 0.05 g

The targeted population: 16 years old and above

Minimum weight: 60 kg

Retention Factor: 1

Calculated relative daily exposure: 0.416667 mg/kg/day

7. Exposure to the substances

HYDROGENATED POLYISOBUTENE

CAS No.: 68937-10-0

EINECS/ELINCS: N/A

CLP Classification: N/A

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: Safe to be used up to 96%

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 1000 mg/kg bw/day (with reference to Polyisobutene)

SED: 0.183854 mg/kg bw/day

MOS: 5,439

Hydrogenated Polyisobutene is homopolymers of isobutene. It is used as emollient, skin conditioning and viscosity controlling in cosmetic. The most reported use of Hydrogenated Polyisobutene was lipstick. The highest reported maximum concentration of use is up to 95% in lipsticks. Hydrogenated polyisobutene at 100% did not irritate rabbit skin and eyes, and not irritate and sensitize to human skin. In rabbit studies, the dermal LD50 values for hydrogenated polyisobutene was >2000 mg/kg. The LC50 for 100% hydrogenated polyisobutene was > 5 mg/L. The available data indicated hydrogenated polyisobutene has low systemic toxicity at high doses in single-dose and repeated-dose animal studies, no teratogenic effects in animal studies, and no genotoxicity in in vitro and in vivo studies. Although molecular weights are in the range that could be dermally absorbed, the lack of heteroatom functional groups dramatically limits solubility and would prevent significant absorption. The lack of functional groups also limits interactions with other biomolecules and probably accounts for the apparent

biological inertness of these ingredients. The CIR Expert Panel concluded that Hydrogenated Polyisobutene is safe in cosmetics in the present practices of use and concentrations.

SYNTHETIC WAX

CAS No.: 8002-74-2

EINECS/ELINCS: 232-315-6

CLP Classification: N/A

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: Safe as used in rinse off product up to 5% and safe at concentration up to 29% in leave on products

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 1500 mg/kg bw/day (oral, rats, 90-day)

SED: 0.081712 mg/kg bw/day

MOS: 18,357

Synthetic Wax is a blend of low molecular weight homopolymers of ethylene, which has a molecular weight of 500 – 700. It is sometimes referred to as Fisher-Tropch hydrocarbon was or synthetic paraffin. It is produced by the catalytic reaction of hydrogen and carbon monoxide at high pressures (300 – 450 psi) and temperature (230 – 250 ℃). Homopolymerization of ethylene also produces Synthetic Wax. Synthetic Wax imparts gloss and structure to cosmetics, and hardens soft waxes. It showed no acute oral toxicity in rats, no irritation in ocular irritation test, but caused mild to moderate irritation when applied to intact and abraded skin of rabbits. Human Patch test showed that it is a non-irritant and a non-sensitizer. The CIR Expert Panel concluded this ingredient is safe as cosmetic ingredient in the present practices of use and concentration.

POLYISOBUTENE

CAS No.: 9003-27-4

EINECS/ELINCS: N/A

CLP Classification: N/A

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: Safe to be used up to 76%

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 1000 mg/kg bw/day

SED: 0.064350 mg/kg bw/day

MOS: 15,540

Polyisobutene is the homopolymer of 2-methyl-1 propene which is used for binding, film forming and viscosity controlling in cosmetic. Polyisobutene is an approved direct food additive for chewing gum bases. The LD50 of undiluted polyisobutene was > 15,400 mg/kg in an oral rat study. In rabbit studies, the dermal LD50 values for polyisobutene was >25,000 mg/kg. No treatment-related gross microscopic changes were observed following exposure to 100% polyisobutene in a 90-day dietary study of rats and 2-year dietary studies in rats or dogs. Polyisobutene at 100% was not carcinogenic in rats (dosed up to 20,000 ppm) or dogs (dosed up to 1000 mg/kg) in oral studies, and was not irritating to rabbit skin and eyes in respective irritation studies. The available data indicated polyisobutene has low systemic toxicity at high doses in single-dose and repeated-dose animal studies, no teratogenic effects in animal studies, and no genotoxicity in in vitro and in vivo studies. Although molecular weights are in the range that could be dermally absorbed, the lack of heteroatom functional groups dramatically limits solubility and would prevent significant absorption. The lack of functional groups also limits interactions with other biomolecules and probably accounts for the apparent biological inertness of these ingredients. The CIR Expert Panel concluded that Polyisobutene is safe in cosmetics in the present practices of use and concentrations.

ETHYLHEXYL PALMITATE

CAS No.: 29806-73-3

EINECS/ELINCS: 249-862-1

CLP Classification: N/A

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: Safe to be used up to 78%

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 1000 mg/kg bw/day (Read across to 2-ethylhexyl stearate)

SED: 0.049029 mg/kg bw/day

MOS: 20,396

Ethylhexyl Palmitate is the ester of 2-ethylhexyl alcohol and palmitic acid. It is used as emollient and perfuming in cosmetics. The acute oral LD50 in rats is estimated to be greater than 64.0 ml/kg. It was also shown to be nontoxic in sub-chronic dermal studies. Rabbit skin tests with the Palmitates showed that they were non-irritating and non-sensitizing. Also, Draize rabbit eye irritation tests produced either no or only very slight ocular irritation. A body lotion containing 77.9% of Ethylhexyl Palmitate is not an irritant or a sensitizer when applied neat on 104 subjects in a HRIPT test (24-h semi-occlusive). Up to 45% of ethylhexyl palmitate is reported to be used in indoor tanning preparation which could be inhaled. There were no repeated-dose inhalation toxicity data available for the alkyl esters, but the actual exposure in the breathing zone is small and given the concentrations at which the ingredients are used, the available information indicates that incidental inhalation would not be a significant route of exposure that might lead to local respiratory or systemic effects. Also, this ingredient is large molecule and insoluble in water, which supports the view that it is unlikely to be absorbed or cause local effects in the respiratory tract. The CIR states concluded that alkyl esters tend not to produce systemic toxicity at high does in single-dose oral, dermal, or inhalation studies and not to produce significant system toxicity in oral repeated-dose studies. The CIR Expert Panel concluded that Ethylhexyl Palmitate is safe in the present practices of use and concentration when formulated to be non-irritating.

OZOKERITE

CAS No.: 64742-33-2

EINECS/ELINCS: 265-134-6

CLP Classification: N/A

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: Safe to be used up to 22%

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: --

SED: 0.016341 mg/kg bw/day

MOS: --

Ozokerite is a naturally occurring fossil wax which consists of aliphatic series of straight-chain, cyclic hydrocarbons, and some oxygenated resinous bodies. It has a delicate needle or short plate microcrystalline structure. Ozokerite is found near soft shale, which acts as a molecular filter and condenser. It has been suggested that the wax was produced into large ones. Wax from different deposits has somewhat different chemical compositions and physical properties. No toxic effects were reported after gastric administration to mice of up to 200 mg/kg of a 0.2% solution of Ozokerite, or to rabbits of up to 200 mg/kg of a 2.0% solution of the wax. Rabbit skin test and ocular irritation test showed that Ozokerite was mild/non-irritating. The available human clinical data indicated mild to minimal reactions. The CIR Expert Panel concluded this ingredient is safe as cosmetic ingredient in the present practices of use and concentration.

MICROCRYSTALLINE WAX

CAS No.: 63231-60-7

EINECS/ELINCS: 264-038-1

CLP Classification: N/A

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: Safe to be used up to 50%

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 1100 mg/kg bw/day

SED: 0.010212 mg/kg bw/day

MOS: 107,716

Microcrystalline Wax is a wax derived from petroleum and characterized by the fineness of its crystals in contrast to the larger crystals of paraffin wax. It consists of high molecular weight saturated aliphatic hydrocarbons. It is used as emulsion stabilizers, viscosity controlling, binding and bulking agents in cosmetics. Based on the available documented animal and clinical test data, the CIR concluded that it is safe for use as cosmetic ingredients in the present practices of concentration and use.

TRIDECYL TRIMELLITATE

CAS No.: 94109-09-8

EINECS/ELINCS: 302-446-4

CLP Classification: N/A

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: Safe to be used up to 57.1% when formulated to be non-irritating

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 100 mg/kg bw/day (Read across to Triethylhexyl Trimellitate)

SED: 0.003366 mg/kg bw/day

MOS: 29,708

Tridecyl Trimellitate is the triester of Tridecyl Alcohol and trimellitic acid. It is used as emollient and skin conditioning in cosmetics. Tridecyl trimellitate has a molecular weight of 757 Da, low water solubility, and high log P value, it is expected that there is limited absorption capacity through skin and the GI tract, therefore, systemic availability is limited. The acute oral toxicity of Tridecyl Trimellitate was found to be low in a gavage rat study, where an LD50 of 5000 mg/kg bw/day was found in a limit test. 10% tridecyl trimellitate was slightly irritating to rabbit skin following a single occlusive application, but undiluted tridecyl trimellitate was non-irritating to mouse skin. Up to 100% tridecyl trimellitate was negative in a local lymph node assay. In human repeated insult patch tests, tridecyl trimellitate (57.1% in a lipstick formulation and undiluted) was not a sensitizer. A NOAEL of 100 mg/kg bw/day was established for repeated dose toxicity from a reproductive/developmental screening study on the analogue chemical, Triethylhexyl Trimellitate. The CIR Expert Panel concluded that

tridecyl trimellitate is safe in cosmetics in the present practices of use and concentration when formulated to be non-irritating. The NICNAS has concluded that the risk to the public from use of the Tridecyl Trimellitate at ≤40% in foundation, lipstick, eye shadow and eyeliner, and ≤9% in hand and face cream, is not considered to be unreasonable.

BUTYROSPERMUM PARKII BUTTER

CAS No.: 91080-23-8

EINECS/ELINCS: 293-515-7

CLP Classification: N/A

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: Safe to be used up to 100% in leave-on cosmetics, 10% in rinse-off cosmetics.

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 7500 mg/kg bw/day

SED: 0.002083 mg/kg bw/day

MOS: 3,600,576

Butyrospermum Parkii (Shea) Butter is the fat from the kernels of Vitellaria paradoxa. Human data and in vitro tests indicate low irritation and sensitization potential (e.g., EpiSkin™ non-irritant when undiluted; HRIPTs negative up to 60%; in-use studies up to 45% with no irritation; ocular tests of undiluted material “not irritating”; phototoxicity negative). Oral repeated-dose studies in rats reported no adverse effects at ~7.5 g/kg bw/day, supporting a high NOAEL. The CIR Panel concluded this ingredient is safe in present practices of use; industry survey data indicate use up to 100% in leave-on moisturizers and up to 10% in rinse-off products, which are reflected above as specific CIR recommendations.

PARFUM(STRAWBERRY LP HK433466)

CAS No.: N/A (Mixture)

EINECS/ELINCS: N/A (Mixture)

CLP Classification: N/A

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: None

Food additive recommendation: None

Toxicological profile by chemical supplier: May cause sensitization by skin contact.

NOAEL: --

SED: 0.002083 mg/kg bw/day

MOS: --

Parfum STRAWBERRY LP HK433466, supplied by CPL Aromas (Far East) Ltd. together with the corresponding IFRA Certificate (51st Amendment), allergen declaration, and SDS/MSDS, was used at 0.5% in the formulation. According to applicable industry standards, the submitted IFRA certificate indicates that this fragrance ingredient has no restriction for use in lip products (IFRA Category 1).

DICHLOROBENZYL ALCOHOL

CAS No.: 1777-82-8

EINECS/ELINCS: 217-210-5

CLP Classification: Acute Tox. 4 (H302); Skin Irrit. 2 (H315); Eye Dam. 1 (H318); STOT SE 3 (H336).

EU Cosmetic Regulation: Annex V/22 — preservative, maximum 0.15% (all cosmetic products).

SCCS opinion: Same as EU Cosmetic Regulation

CIR recommendation: None

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 400 mg/kg bw/day (90-day oral, rat).

SED: 0.000625 mg/kg bw/day

MOS: 640,000

Dichlorobenzyl Alcohol (specifically the 2,4-isomer) is an antimicrobial preservative permitted in the EU at up to 0.15% in all cosmetic product types. Available regulatory and supplier data indicate irritation hazards (skin/eye) and harmful if swallowed; the historical SCCNFP review also reported forestomach irritation in rats at high oral doses but affirmed the 0.15% preservative limit. Overall, when used at or below 0.15% as a preservative and with standard cosmetic use patterns, DICHLOROBENZYL ALCOHOL is considered safe with adequate margin, while label/handling should avoid eye contact and ingestion.

TOCOPHERYL ACETATE

CAS No.: 7695-91-2

EINECS/ELINCS: 231-710-0

CLP Classification: N/A

EU Cosmetic Regulation: None

SCCS opinion: alpha-tocopheryl acetate does not pose a threat to the health of the consumer and therefore no restrictions or conditions on the use of alpha-tocopherol acetate in cosmetic products were proposed

CIR recommendation: Safe to be used up to 36% (100% in vitamin E oil)

Food additive recommendation: Yes, but no given ADI

Toxicological profile by chemical supplier: None

NOAEL: 500 mg/kg bw/day

SED: 0.000416 mg/kg bw/day

MOS: 1,201,923

Tocopheryl Acetate functions as antioxidant or skin-conditioning agent in cosmetic formulations. Tocopheryl Acetate can be hydrolyzed to Tocopherol which is a natural component of cell membranes protecting against oxidative damage. It has been reported that Tocopheryl Acetate and Tocopherol protected against ultraviolet radiation induced skin damage. Tocopheryl Acetate is generally not toxic in animal feeding studies, although very high doses (2 g/kg/day) have hemorrhagic activity. It is generally not irritating or sensitizing to skin or irritating to eyes, but it was shown in one animal test that Tocopheryl Acetate produced sensitization. Reproductive and developmental toxicity tests in animals were all negative or showed some effects of reducing toxicity. It was almost uniformly negative in genotoxicity, exhibited anti-mutagenic activity and was not carcinogenic. Based on current

knowledge, the Scientific Committee on Cosmetic Products and Non-Food Products Intended For Consumers (SCCNFP) concluded that alpha tocopheryl acetate does not pose a threat to the health of the consumer and therefore no restrictions or conditions on the use of alpha-tocopherol acetate in cosmetic products were proposed. The CIR Expert Panel also concluded that Tocopheryl Acetate is safe as used in cosmetic formulations, but the purity of the Tocopherol should be of similar grade to that used in food.

BARIUM SULFATE

CAS No.: 7727-43-7

EINECS/ELINCS: 231-784-4

CLP Classification: N/A

EU Cosmetic Regulation: Annex IV/122 — CI 77120 (colorant), allowed for use as a colorant.

SCCS opinion: None

CIR recommendation: Safe to be used up to 37% in leave-on cosmetics, 0.99% in rinse-off cosmetics.

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 371 mg/kg bw/day

SED: 0.000341 mg/kg bw/day

MOS: 1,087,976

Barium Sulfate (CI 77120) is an insoluble inorganic salt used as a colorant/opacifying agent. The European Union lists it in Annex IV (entry IV/122) as an allowed colorant; there are no specific concentration limits in the annex beyond general safety requirements. The CIR Expert Panel concluded it is safe in cosmetics as currently used; industry data reported maximum use levels up to 37% in leave-on products (e.g., lipsticks) and up to 0.99% in rinse-off products (skin cleansers). It is not harmonised-classified under CLP, and registrant dossiers do not typically assign hazard classes. Additional exposure considerations noted by CIR include uses in sprays (up to ~15%) and powders (up to ~15.8%); as with any particulate, formulations should be designed to minimise respirable particle generation and avoid direct inhalation.

WATER(AQUA）

CAS No.: 7732-18-5

EINECS/ELINCS: 231-791-2

CLP Classification: N/A

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: None

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: --

SED: 0.000308 mg/kg bw/day

MOS: --

Aqua (water) is a clear, odorless, tasteless liquid that is essential for most animal and plant life, and is normally used as solvent in cosmetic products and is not expected to result in any acute or chronic toxicity following typical exposures. The source of water should be known, monitored to GMP and either a deionised or high purity grade free from toxins, pollutants and bacteriological contamination should be used in cosmetic products.

CAPRYLYL GLYCOL

CAS No.: 1117-86-8

EINECS/ELINCS: 214-254-7

CLP Classification: N/A

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: Safe to be used from 0.00003 to 5%

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 300 mg/kg bw/day

SED: 0.000291 mg/kg bw/day

MOS: 1,030,927

Caprylyl Glycol is the diol that is used as emollient, hair conditioning and skin conditioning in cosmetics. The available safety test data indicate it is not significantly acute toxic, dermal irritating, sensitizing or photosensitizing. It is also not genotoxic and non-carcinogenic. The CIR Expert Panel concluded the ingredient is safe in the present practices of use and concentration.

ROSIN

CAS No.: 8050-09-7

EINECS/ELINCS: 232-475-7

CLP Classification: Skin Sens. 1 H317

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: None

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 368 mg/kg bw/day

SED: 0.000170 mg/kg bw/day

MOS: 2,164,705

Rosin (Colophonium) is the residue left after distilling off the volatile oil from the oleoresin obtained from Pinus palustris and other species of Pinaceae. It is composed primarily of resin acids and modified resin acids such as dimers and decarboxylated resin acids. It also includes rosin stabilized by catalytic disproportionation. Rosin is generally used in cosmetics for binding, depilatory, film forming, viscosity controlling. Rosin is not acutely toxic in rats following oral or dermal exposure (LD50 >2000 mg/kg bw in both instances). Low vapour pressure of Rosin precludes inhalation exposure. The physico-chemical properties of sin indicate no requirement for classification with regard of aspiration hazard (kinematic viscosity exceeds 20.5 mm2/s at 40° C). Rosin is not irritating to skin or eye. The sensitisation potential of Rosin is well understood and comprises results from tests conducted using local lymph node, Guinea Pig Maximisation and Buehler methods. The results consistently show no evidence of a potential to induce skin sensitisation using methods equivalent or similar to current

regulatory guidelines. However, Rosin is currently classified as “Skin Sensitizer Category 1” and assigns the hazard statement H317: May cause an allergic skin reaction by EU CLP Regulation (EC) No. 1272/2008. Rosin is not mutagenic or clastogenic in bacterial and/or mammalian cells in vitro. The systemic toxicity NOAEL of Rosin was determined to be 5000 ppm (equivalent to a mean achieved dosage of 335.2 mg/kg bw/day for males and 401.2 mg/kg bw/day for females) based on reduced body weight gains in animals of either sex exposed to 7500 ppm in a repeated dose 90-day oral toxicity study. The systemic toxicity NOAEL of Rosin was determined to be 2500 ppm (equivalent to a mean achieved dosage of 199.3 mg/kg bw/day) based on lower maternal body weight gain during gestation and an initial effect on food consumption at 7500 ppm and lower maternal body weight gain at 5000 ppm in a prenatal developmental toxicity study. The systemic toxicity NOAEL of Rosin was determined to be 1000 ppm in males (equivalent to 84 mg/kg bw/d) and 3000 ppm in females (equivalent to 309 mg/kg bw/d) based upon reduced feed consumption and lower weight gain in animals consuming higher dietary concentrations of the test material in a reproduction/developmental toxicity screening test. In a key combined repeated dose, reproductive/developmental toxicity screening study (Harlan Laboratories Ltd, 2015a), the sytemic toxicity NOAEL for Tall oil rosin was determined to be 5000 ppm. In another key combined repeated dose, reproductive/developmental toxicity study (Harlan Laboratories Ltd., 2014a), the systemic toxicity NOAEL for Gum Rosin was determined to be 2500 ppm. A NOEL (No Observed Effect Level) for general toxicity could not be established due to effects on body weights at all dose levels in females during the lactation period. Rosin is one of the food additives permitted for direct addition to food for human consumption by US FDA (21CFR172.510).

ETHYLHEXYLGLYCERIN

CAS No.: 70445-33-9

EINECS/ELINCS: 408-080-2

CLP Classification: Eye Dam. 1, H318; Aquatic Chronic 3, H412

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: Safe to be used up to 8% (Maximum in rinse-off products)

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 50 mg/kg bw/day

SED: 0.000125 mg/kg bw/day

MOS: 400,000

Ethylhexylglycerin is the organic compound that is used for skin conditioning in cosmetic up to 8% in rinse off product according to the FDA. It was indicated to be highly soluble in organic solvents and with an estimated Log Pow of 2.4. The oral LD50 and dermal LD50 in rats were reported to be greater than 2000 mg/kg. Both of the NOAEL and LOAEL were indicated to be 50 mg/kg/day by different studies. It was not a sensitizer in a LLNA up to 50%. There was absence of reproductive and developmental toxicity in oral studies, and was negative in skin irritation, sensitization, phototoxicity and photoallergenicity. Taking into account the available animal toxicity and clinical data, including the low dermal absorption, the CIR Expert Panel concluded that the ingredient is safe in the present practices of use and concentration.

BUTYLENE GLYCOL

CAS No.: 107-88-0

EINECS/ELINCS: 203-529-7

CLP Classification: N/A

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: Safe to be used from 0.00007 to 89%

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 5000 mg/kg bw/day

SED: 0.000083 mg/kg bw/day

MOS: 60,240,963

Butylene Glycol is the aliphatic diol which is used as fragrance ingredients/skin-conditioning agents/solvents generally in products such as, baby lotions, bath oils, eye shadows, lipsticks. The results of acute, subchronic, and chronic oral toxicity studies using a variety of animal species indicate a low order of toxicity for Glycols. Results of parenteral injection, inhalation, and acute and subchronic cutaneous toxicity studies likewise support a low order of toxicity. Butylene Glycol caused minimal to mild irritation of rabbit skin, and produced mild to severe ocular irritation when tested in rabbits.

Undiluted Butylene Glycol was not an eye irritant to rabbits, but was to humans. Human skin patch tests on undiluted Butylene Glycol produced a very low order of primary skin irritation. A repeated insult patch test on Butylene Glycol produced no evidence of skin sensitization. Based on the available data CIR panel concluded that Butylene Glycol is safe as presently used in cosmetics.

SORBITAN SESQUIISOSTEARATE

CAS No.: 71812-38-9

EINECS/ELINCS: -

CLP Classification: N/A

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: Safe to be used up to 3% in leave-on cosmetics, 3% in rinse-off cosmetics.

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 7500 mg/kg bw/day

SED: 0.000050 mg/kg bw/day

MOS: 150,000,000

Sorbitan Sesquiisostearate is a mixture of mono- and di-esters of isostearic acid and sorbitan used mainly as a non-ionic emulsifier. The CIR Panel has concluded the sorbitan esters group (including Sorbitan Sesquiisostearate) is safe in cosmetics under present practices of use and concentration;

FRAGARIA ANANASSA FRUIT EXTRACT

CAS No.: N/A

EINECS/ELINCS: N/A

CLP Classification: None

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: None

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: --

SED: 0.000021 mg/kg bw/day

MOS: --

FRAGARIA ANANASSA (STRAWBERRY) FRUIT EXTRACT is the extract of the fruit of Fragaria ×ananassa (Rosaceae). In cosmetics it's most often used as a skin-conditioning/antioxidant ingredient. No standardized NOAEL values or systemic toxicity studies are available for the whole extract, and no Ames or micronucleus assays specific to Fragaria × ananassa fruit extract were found; however, available data on similar fruit extracts indicate low acute toxicity (oral LD50 > 2000 mg/kg in rats for supplier-tested strawberry fruit powder). Regulatory databases (e.g., CosIng) list this extract as a skin-conditioning agent without restrictions, and CIR has concluded that the related strawberry seed oil is "safe as used," which provides supportive but not conclusive evidence. Typical cosmetic use concentrations are 0.5–5% (up to 10% depending on the extract form and solvent system). The derived SED is below the threshold limit for a Class I compound according to the TTC approach (i.e. 30μg/kg bw/day). Therefore, this ingredient is not expected to be systemically toxic to the consumers under reasonably foreseeable condition of use.

1,2-HEXANEDIOL

CAS No.: 6920-22-5

EINECS/ELINCS: 230-029-6

CLP Classification: None

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: Safe to use from 0.00005 to 10%

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 700 mg/kg bw/day (dermal, rat, 93-day)

SED: 0.000004 mg/kg bw/day

MOS: 175,000,000

1,2-Hexanediol belongs to the short chain 1,2-glocol group as used as organic solvent in cosmetic products. The available safety test data for 1,2-glycols indicate that they are not significant acute toxicants, are not significantly genotoxic, are non-carcinogenic, and are not significant dermal irritants or photosensitizers. Mouse local lymph node assay test result for 1,2-Hexanediol up to 100% was negative. It is not skin sensitizer. A 50:50(w/w) mixture of 1,2-Hexanediol and caprylyl glycol, with tested concentration of 1% aqueous (effective concentration per ingredient is 0.5%), was classified as a severe ocular irritant in a Draize test result. The CIR determined that evaluation of reproductive/developmental toxicity data would be the key to determining toxicity studies on this ingredient. The result of oral reproductive/developmental toxicity study on 1,2-Hexanediol was negative, and there was no evidence of systemic toxicity in other oral repeated does toxicity studies involving other glycols. The NOEL for developmental toxicity was considered to be 300 mg/kg bw/day. The dermal absorption is not of a concern because the 1,2-glycol has a low blood level following oral exposure and systemic toxicity is absent in the oral studies, while 1,2-glycol in blood level following dermal exposure is known to be much lower. The CIR Expert Panel concluded that 1,2- hexanediol is safe in the present practices of used and concentration.

CI 15850

CAS No.: 72432-82-7

EINECS/ELINCS: -

CLP Classification: N/A

EU Cosmetic Regulation: Annex IV

SCCS opinion: None

CIR recommendation: None

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 150 mg/kg bw/day

SED: 0.001195 mg/kg bw/day

MOS: 125,523

CI 15850 (Disodium 3-hydroxy-4-[(4-methyl-2-sulphonatophenyl)azo]-2-naphthoate and its insoluble barium, strontium and zirconium lakes, salts and pigments) is generally used as red colorant and allowed in cosmetic products according to EU Cosmetic Regulation. However, it should fulfill the purity requirement as set out in Commission Directive 95/45/EC (E 180).

8. Toxicological profile of the substances

There are no nanoparticles included in this formulation.

All of the ingredients were found to be present at levels that were permitted by the Cosmetic Regulation (EC) No 1223/2009.

The Responsible Person must ensure that all ingredients are of cosmetic or any appropriate grade.

MOS values for all toxicologically significant components (other than those whose presence is governed / prescribed specifically by the Annexes of Regulation (EC) No 1223/2009) have been calculated and are satisfactory (MOS >100).

9. Undesirable effects and serious undesirable effects

No undesirable effects were reported according to the statement from the client. Manufacturer / responsible person must ensure that details of any concerns or complaints relating to consumer safety and adverse health effects are submitted so that the safety assessment can be updated accordingly.

10. Information on the cosmetic product

According to the declaration provided by the client, it is confirmed that the product was manufactured in compliance with GMP requirements. The client has provided Intertek-certified U.S. GMPC (Good Manufacturing Practice for Cosmetics) certificates, Certificate Numbers: SZ2504E5, valid until 13 May, 2028. In addition, the customer should ensure that the product is manufactured in compliance with the GMP standard of ISO 22716.

PART B – COSMETIC PRODUCT SAFETY ASSESSMENT

1. Assessment conclusion

The data review indicates no significant risk under normal and foreseeable conditions of use provided the labeling practices below are followed, and the product fulfills the required criteria of Regulation (EC) No 1223/2009 to be marketed in the EU.

2. Labelled warnings and instructions of use

This product contains rosin. It should not be used by persons with a known hypersensitivity or allergy to rosin.

3. Reasoning

CMRs – not included in this formulation

Nano materials – not included in this formulation

Local toxicity – Phototoxic materials are not included in this formulation at levels of concern.

Dermal irritants – not expected to be irritating to the skin and respiratory tract under normal condition of use.

Dermal sensitizers - unlikely to produce sensitization by skin contact in the majority of the consumers under normal and reasonably foreseeable conditions of use.

Eye irritants – Under normal and reasonably anticipated conditions of use, this product does not pose an eye irritation hazard.

Interaction of substances – No significant interactions expected, based on a review of the chemical properties of the species included in this formulation.

The stability and packaging compatibility, microbiological quality and heavy metal content of the formulation and packaging have been assessed for this product.

MOS values for all toxicologically significant components (other than those whose presence is governed / prescribed specifically by the Annexes of Regulation (EC) No 1223/2009) have been calculated and are satisfactory (MOS >100).

4. Assessor's credentials and approval of Part B

Dr. Jikuai Chen,DABT, ERT

Diplomate of the American Board of Toxicology

European Registered Toxicologist

Regulatory Toxicologist & Counselor

Date: September 26, 2025

General Notes

The Responsible Person must ensure that the safety report is kept up to date (Reg. 1223/2009, Art. 10(1)(c)) , the safety of the finished product should be reassessed regularly. When changes in the legal requirements occur (e.g. restrictions of one of the substances included in the formulation), it should be checked, amongst others (e.g. labelling), whether the formulation still complies with the law, and the safety assessment should be reviewed and, if necessary, updated.

The safety assessment should also be reviewed and, if necessary, updated, where one or more of the following circumstances apply:

(a) new scientific findings and toxicological data on the substances are available which could modify the result of the existing safety assessment;

(b) changes occurring in the formulation or specifications of raw materials;

(c) changes occurring in the conditions of use;

(d) a rising trend in terms of the nature, severity and frequency of undesirable effects, both under reasonably foreseeable conditions of use and in the case of misuse.

Statement:

1. This report is considered invalidated in one or more of the following conditions: no testing seal of CTI; altered; a copy without the red testing seal of CTI.

2. Without written approval of CTI, this report shall not be reproduced partly.

3. The sample Information is provided by the customer, and the results shown in this test report refer only to the sample(s) tested.

4. Unauthorized use of the test results for improper publicity is impermissible.

5. Objection to the test results should be raised within 7 working days from the date of receiving the report, otherwise it will not be accepted.

*** End of report ***