

Cosmetic Product Safety Report

Report No.: A2250555434101001

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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 (WHITE PEACH)

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 : 10 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

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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 (White Peach) 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	44.207	EMOLLIENT
SYNTHETIC WAX	8002-74-2	19.647	BINDING
POLYISOBUTENE	9003-27-4	15.472	VISCOSITY CONTROLLING
ETHYLHEXYL PALMITATE	29806-73-3	11.788	EMOLLIENT
OZOKERITE	12198-93-5	3.93	BINDING
MICROCRYSTALLINE WAX	63231-60-7	2.456	BINDING
TRIDECYL TRIMELLITATE	94109-09-8	0.733	EMOLLIENT
BUTYROSPERMUM PARKII BUTTER	194043-92-0	0.5	EMOLLIENT
PARFUM(White Peach MY24-G051-6)	/	0.5	PERFUME
DICHLOROBENZYL ALCOHOL	1777-82-8	0.15	PRESERVATIVE

Chemical Name/INCI Name	CAS No.	Conc. %	Intended Function
TOCOPHERYL ACETATE	7695-91-2	0.1	ANTIOXIDANT
SORBITAN SESQUIISOSTEARATE	71812-38-9	0.012	SURFACTANT -EMULSIFYING
3-O-ETHYL ASCORBIC ACID	86404-04-8	0.01	ANTIOXIDANT
BARIUM SULFATE	7727-43-7	0.0014	FILLER
ROSIN	8050-09-7	0.0007	FILLER
Colorant (may contain)			
CI 77891	13463-67-7	0.488	COLORANT
CI 15850	5858-81-1	0.0049	COLORANT

INGREDIENTS ALLERGENS

This series of products contains fragrance. The fragrance allergens HEXYL CINNAMAL, LINALOOL, ROSE KETONES, BENZALDEHYDE must be listed on the label.

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

Form: Paste Odor: White Peach
Color: Pink

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 °C, room temperature (RT) and 0 °C .

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. A2250529217101004), 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, Staphylococcus 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. A2250557626101001). 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.: A2250529217101005), 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 (White Peach) 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: 0.184195 mg/kg bw/day

MOS: 5,429

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

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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: 0.081862 mg/kg bw/day

MOS: 18,323

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 wax 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 °C). 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: 0.064466 mg/kg bw/day

MOS: 15,512

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: 0.049116 mg/kg bw/day

MOS: 20,359

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 doses 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: 0.016375 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: 0.010233 mg/kg bw/day

MOS: 107,495

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: 0.003054 mg/kg bw/day

MOS: 32,743

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 $\leq 40\%$ in foundation, lipstick, eye shadow and eyeliner, and $\leq 9\%$ in hand and face cream, is not considered to be unreasonable.

BUTYROSPERMUM PARKII BUTTER

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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(White Peach MY24-G051-6)

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 White Peach MY24-G051-6, supplied by MEIYI Flavor Fragrance Co., Ltd. together with the corresponding IFRA Certificate (51st Amendment), allergen declaration, and SDS/MSDS, was used at 0.5% in the formulation. Industry recommendations apply, and the submitted IFRA Certificate indicates that up to 38.30% of this fragrance may be used in lip-applied 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: 6,400,000

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.

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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 Sesquiosostearate 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 Sesquiosostearate) is safe in cosmetics under present practices of use and concentration.

3-O-ETHYL ASCORBIC ACID

CAS No.: 86404-04-8

EINECS/ELINCS: 617-849-3

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: 0.000041 mg/kg bw/day

MOS: --

3-O-Ethyl Ascorbic Acid is the 3-O-ethyl ether of L-ascorbic acid used mainly as an antioxidant/skin-conditioning agent. Regulatory dossiers indicate no harmonized EU CLP classification; an Australian public assessment (NICNAS/AICIS) concluded the substance was not recommended for classification and, when used in cosmetics at $\leq 10\%$, does not pose an unreasonable risk to public health. In vitro and human data support a low irritation/sensitization profile: reconstructed-epidermis skin tests were non-irritant; a human patch test at 2% was non-irritating; a RIPT conducted with neat (100%) material found no evidence of sensitization; a bacterial reverse-mutation (Ames) assay was negative. Eye-irritation screening gave mixed outcomes (NRR at 10% non-cytotoxic; HET-CAM at 3% "moderately irritating"), consistent with supplier SDS that often self-classify as Eye Irrit. 2—so avoiding eye contact is prudent. Dermal penetration appears limited ($\approx 2.13\%$ over 8 h at 32 °C when tested at 2.06%), aligning with its hydrophilicity (reported log Pow ≈ -0.7). The Australian report also notes potential depigmenting effects and recommends labeling to warn consumers about possible unintended skin lightening and to formulate to minimize pro-oxidant activity.

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: 0.000005 mg/kg bw/day

MOS: 74,200,000

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.

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: 0.000003 mg/kg bw/day

MOS: 122,666,666

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 systemic 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).

CI 77891

CAS No.: 13463-67-7 / 1317-70-0 / 1317-80-2

EINECS/ELINCS: 236-675-5 / 215-280-1 / 215-282-2

CLP Classification: N/A

EU Cosmetic Regulation: Annex IV; Annex VI: Maximum concentration in ready for use preparation is 25% as UV filter (sum of Titanium Dioxide and Titanium Dioxide (nano))

SCCS opinion: No

CIR recommendation: None

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 2250 mg/kg bw/day

SED: 0.002033 mg/kg bw/day

MOS: 1,106,738

Titanium dioxide is the inorganic oxide with an empirical formula TiO_2 . It functions as opacifier, UV absorber, UV filter and colorant in cosmetics. INCI name CI 77891 should be used when it functions as colorant. CI 77891 is generally used as white colorant and allowed in cosmetic products according to EU Cosmetic Regulation and should fulfill the purity criteria as set out in Commission Directive 95/45/EC(E171). IARC concluded that there is inadequate evidence in humans for the carcinogenicity of titanium dioxide but sufficient evidence in experimental animals for the carcinogenicity of titanium dioxide. Both nano and non nano size Titanium dioxide was classified as a Group 2B carcinogen (Possibly carcinogenic to humans). Titanium dioxide particles have shown to lead to carcinogenic effects after inhalation. Therefore the SCCS does not recommend the use of nano titanium dioxide in applications that might lead to inhalation exposure to the nanoparticles (such as powders or sprayable products). However, due to the lack of penetration of titanium dioxide nanoparticles through human skin, systemic exposure of the titanium dioxide to reach viable cells of the epidermis, dermis, or other organs is unlikely. Therefore, the SCCS considers that the use of nano titanium dioxide in dermally applied cosmetic products should not pose any significant risk to the consumer. The EU Cosmetic Regulation currently allows the safe use of titanium dioxide as a UV-filter at a maximum concentration of 25% in cosmetic products. In light of the SCCS opinions mentioned above, titanium dioxide (nano), according to the SCCS's specifications, should be authorised for use as a UV-filter in cosmetic products at a maximum concentration of 25 % w/w, except in applications that may lead to exposure of the end-user's lungs by inhalation.

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: 0.000020 mg/kg bw/day

MOS: 7,500,000

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.
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*** End of report ***