CPSR Report No.: 70.431.25.40231.01
Date: 2025-05-20

Applicant:	GUANGZHOU MUJIN COSMETICS CO., LTD.
Address:	NO. B AREA, 3RD FLOOR AND NO. B AREA, 1ST FLOOR, BUILDING NO. 2, NO. 23, HUAGANG ROAD, XIUQUAN STREET, HUADU DISTRICT, GUANGZHOU CITY, GUANGDONG PROVINCE, CHINA.
Product Name:	HAND CREAM
Net Content:	50 g/pc/style
Model No:	White Peach & Oolong, Milk, Strawberry, Rose, Lavender
Country of origin:	CHINA
Country of Destination:	EU
Receipt Date of Sample:	2025-05-07
Date of Testing:	2025-05-07 ~ 2025-05-15
Test Result:	Refer to the data listed in following pages

Test Item

1. Cosmetic Product Safety Report as cosmetics for the said product

Result Summary

Please refer to the assessment based on the EU Cosmetic Regulation (EC) No 1223/2009 issued by Toxicological & Regulatory Assessor.

Remark: This report was finished by TÜV SÜD and Subcontractor.

TÜV SÜD Certification and Testing (China) Co., Ltd. Shanghai Branch
Testing Center

Prepared by:

Jenny Yao
Technical Engineer

Authorized by:

Sawyer Tang
Technical Manager

Note:

(1) The TÜV SÜD Certification and Testing (China) Co., Ltd. "General Terms & Conditions" applied.
Any use for advertising purposes must be granted in writing. This technical report may only be quoted in full. This report is the result of a single examination of the object in question. It does not imply a general statement regarding the quality of products from regular production. For further details please see "Testing, Certification, Validation and Verification Regulations", chapter A-3.3.
For full version, please visit: EN : https://www.tuvsud.cn/zh-cn/resource/terms-and-conditions---en ; SCN: https://www.tuvsud.cn/zh-cn/terms-and-conditions ; TCN: https://www.tuvsud.com/zh-tw/terms-and-conditions

(2) Sample and (or) material information is provided by the client. TÜV SÜD assumes no responsibility for verifying the accuracy, appropriateness and (or) completeness of the information provided by the client.

(3) The testing results are only valid for the sample tested.

(4) The test report shall not be reproduced except in full, without the written approval of the laboratory.

(5) Disclaimer Measurement Uncertainty:
Unless otherwise agreed upon, Pass or Fail verdicts are given based on the measured values without any considerations of measurement uncertainties. Please note, every test method has a measurement uncertainty which has been evaluated by the laboratory according to ISO/IEC 17025 requirements. By taking measurement uncertainties into account it might happen that measured values can neither be assessed as Pass nor as Fail.

PART A – COSMETIC PRODUCT SAFETY INFORMATION

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 RN	Conc.% (w/w)	Function
Aqua	7732-18-5	73.2450	Solvent
Glycerin	56-81-5	5.0000	Moisturizer
Mineral Oil	8012-95-1	5.0000	Emollient
Butyrospermum Parkii (Shea) Butter	91080-23-8	3.0000	Skin Conditioner
Palmitic Acid	57-10-3	2.4000	Emulsifier
Dimethicone	9006-65-9	2.0000	Emollient
Stearyl Alcohol	112-92-5	1.8000	Emollient
Stearic Acid	57-11-4	1.6000	Emulsifier
Polysorbate 60	9005-67-8	1.5000	Emulsifier
Cetyl Alcohol	36653-82-4	1.2000	Emulsifier
Sorbitan Stearate	1338-41-6	1.0000	Emulsifier
Glyceryl Stearate	123-94-4	0.5000	Emulsifier
Peg-100 Stearate	9004-99-3	0.5000	Emulsifier
Phenoxyethanol	122-99-6	0.5000	Preservative
Triethanolamine	102-71-6	0.4000	pH Regulator
Methylparaben	99-76-3	0.1500	Preservative
Propylparaben	94-13-3	0.1000	Preservative
Fragaria Ananassa (Strawberry) Fruit Extract	1175540-74-5	0.1000	Skin Conditioner
Rosa Rugosa Flower Extract	92347-25-6	0.1000	Skin Conditioner
Lavandula Angustifolia (Lavender) Extract	90063-37-9	0.1000	Skin Conditioner
Milk Extract	NA	0.1000	Skin Conditioner
Prunus Persica (Peach) Fruit Extract	84012-34-0	0.0500	Skin Conditioner
Uuron-Cha Ekisu	NA	0.0500	Skin Conditioner
Parfum (3105)	NA	0.0050	Aromatic
Parfum (3154)	NA	0.0050	Aromatic
Parfum (8117)	NA	0.0050	Aromatic
Parfum (86029)	NA	0.0050	Aromatic
Parfum (PR-300133)	NA	0.0050	Aromatic

INGREDIENTS ALLERGENS
Fragrance allergens are present but none of them are required to be declared on the product label in the ingredients section according to EU Cosmetic Regulation.

2. Physical/chemical characteristics of the formulation

Form: Cream
Odor: Lavender, Milk, Rose, Strawberry, White Peach & Oolong
Color: White

3. Stability of the formulation

Samples of the product were tested to assess the product's stability. Samples of the product were tested at -2±1°C, Room condition, 40± 2°C& 60± 5% humidity for a 3-month period by NINGBO PRODUCT TEST CENTER CO., LTD. Determination of the samples' appearance, odour, colour and pH were carried out and recorded.
Packaging material was tested to assess the package's compatibility. Samples of the product were tested at -2±1°C, Room condition, 40± 2°C& 60± 5% humidity for a 3-month period by NINGBO PRODUCT TEST CENTER CO., LTD. Determination of the samples' breakage, leakage and the words on the package were carried out and recorded.

At the end of the 3-month test period, the stability data of the formula and packaging material after storage meet the specified characteristics of the product specifications. The data confirm a sufficient stability of the tested formula and packaging material.

4. Microbiological quality

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 the mucous membranes. Category 2: Other products		

This product is classified as Category 2 according to the criteria as required by SCCS Note of Guidance 11th (SCCS/1628/21). According to the test results of the product by NINGBO PRODUCT TEST CENTER CO., LTD., samples of the product were compared with the manufacturer's microbiological specification with the results above. The results from the microbiological test are considered to be acceptable.
The product also underwent a 28-day Preservative Efficacy Challenge Test in accordance with European Pharmacopoeia 10.0, 10.1.3 to determine the efficacy of its preservative system. According to the test results by NINGBO PRODUCT TEST CENTER CO., LTD., the samples met the Criteria A, and can be considered to be adequately preserved.

5. Impurities, traces, information about the packaging material

The heavy metal test results on 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: Lead 5 ppm, Arsenic 0.5 ppm, Cadmium 0.1 ppm, Mercury 0.1 ppm, Antimony 0.5 ppm and Soluble Nickel 10 ppm. According to the test results by NINGBO PRODUCT TEST CENTER CO., LTD., the samples met the criteria above, and can be considered to be acceptable for this application.

Packaging Material: Aluminum Plastic Pipe
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 20 ppm. According to the test results by NINGBO PRODUCT TEST CENTER CO., LTD., the samples met the criteria above, and can be considered to be acceptable for this application.

6. Normal and reasonably foreseeable use

The normal use of this product is application on hands for keeping it in good conditions by the population of 16 years old and above. Ingestion of this product would be considered as misuse and is not considered in this report. Inhalation of the product is not expected due to the product format.

7. Exposure to the cosmetic product

Body site of application: hands
Surface area of application: 860 square centimeters
The duration of exposure: 720 minutes
The frequency of use: 2/day
Estimated daily amount applied: 1.08 g / time
The targeted population: 16 years old and above
Minimum weight: 60 kg

8. Exposure and toxicological profile of the substances

There are no nanoparticles included in this formulation.
All 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).

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: 13.1841000 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.

Glycerin
CAS No.: 56-81-5
EINECS/ELINCS: 200-289-5
CLP Classification: None
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used at up to 79.2% in leave-on products and 99.4% in rinse-off products
Food additive recommendation: Yes, but no given ADI
Toxicological profile by chemical supplier: None
NOAEL: ≥2200 mg/kg bw/day
SED: 0.9000000 mg/kg bw/day
MOS: 1,222
Glycerin is the polyhydric alcohol that is naturally occurring and abundant in animal and human tissues, including the skin and blood. Glycerin is reported to function in cosmetics as a denaturant, fragrance ingredient, hair conditioning agent, humectants, oral care agent, oral health care drug, skin protectant, skin conditioning agent and viscosity decreasing agent. Glycerin is absorbed following ingestion and metabolised by glycerokinase in the liver to carbon dioxide and water or incorporated in the standard metabolic pathways to form glucose and glycogen. The weight of evidence indicates that glycerin is of low toxicity when ingested, inhaled or in contact with the skin. Glycerin is of a low order of acute oral and dermal toxicity with LD50 values in excess of 4000 mg/kg bw. At very high dose levels, the signs of toxicity include tremor and hyperaemia of the gastro-intestinal -tract. Skin and eye irritation studies indicate that glycerin has low potential to irritate the skin and the eye. The available human and animal data, together with the very widespread potential for exposure and the absence of case reports of sensitisation, indicate that glycerin is not a skin sensitiser. Repeated oral exposure to glycerin does not induce adverse effects other than local irritation of the gastro-intestinal tract. The 2-year study of Hine (1953) was chosen to establish the overall NOEL after prolonged treatment with glycerin of 10,000 mg/kg bw/day (20% in diet), which is in agreement with the findings in other studies. At this dose level, no systemic or local effects were observed. For inhalation exposure to aerosols, the NOAEC for local irritant effects to the upper respiratory tract is 165 mg/m3 and 662 mg/m3 for systemic effects. Glycerin is not considered to possess genotoxic potential. There were no reproductive or developmental effects observed in oral studies using rats, mice, and rabbits. Glycerin was not genotoxic in multiple in vitro tests and was not carcinogenetic to rats in a long-term

feeding study. There were no signs of toxicity or effects on blood or on urine production when human subjects were orally administered approximately 1300-2200 g/kg/d glycerin for 50 days. The NOAEL was ≥2200 mg/kg/d.

Mineral Oil
CAS No.: 8012-95-1
EINECS/ELINCS: 232-384-2
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: None
Food additive recommendation: 12 mg/kg bw/day by EFSA, 2013
Toxicological profile by chemical supplier: None
NOAEL: 1200 mg/kg bw/day
SED: 0.9000000 mg/kg bw/day
MOS: 667
Mineral Oil is a highly refined petroleum mineral oil consisting of a complex combination of hydrocarbons obtained from the intensive treatment of a petroleum fraction with sulfuric acid and oleum, or by hydrogenation, or by a combination of hydrogenation and acid treatment. Additional washing and treating steps may be included in the processing operation. It consists of saturated hydrocarbons having carbon numbers predominantly in the range of C15 through C50. In the United States, Mineral Oil may be used as an active ingredient in OTC drug products. The EFSA Panel established an acceptable daily intake (ADI) of 12 mg/kg bw/day for high viscosity white mineral oils based on the NOAEL of 1200 mg/kg bw/day.
The submitted statement of Mineral Oil indicates that Mineral Oil is of cosmetic grade, and not classified as carcinogenic substance.

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 as used in rinse off product up to 30% and safe at concentration up to 60% in leave on products
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 7200 mg/kg bw/day
SED: 0.5400000 mg/kg bw/day
MOS: 6,667
Butyrospermum Parkii (Shea) Butter is a fat obtained from the fruit of Butyrospermum parkii. It is used as skin conditioning agent ranges from 0.0005 to 60%. The major composition is the stearic and oleic acid. Since it is edible, the systemic toxicity potential is regarded as low. It is not a dermal irritant or sensitizer in HRIPT. As supplied, it is not irritating and only produces mild conjunctival reactions in rabbit. The CIR Expert Panel concluded that the plant-derived fatty acid oil is safe in the present practices of use and concentration.

Palmitic Acid
CAS No.: 57-10-3
EINECS/ELINCS: 200-312-9
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 21%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 1000 mg/kg bw/day (Read across to Behenic Acid)

SED: 0.4320000 mg/kg bw/day
MOS: 1,157
Palmitic Acid is the fatty acid that is used as fragrance ingredient, surfactant - cleansing/ emulsifying agent in products such as baby oils, tablet, and salts. It is non-irritating to skin and eyes. The LD50 was > 5000 mg/kg bw. Little acute toxicity was observed when Palmitic Acid or cosmetic formulations containing this fatty acid were given to rats orally at doses of 15-19 g/kg body weight. Results from topical application of Palmitic Acid to the skin of mice, rabbits, and guinea pigs produced little or no apparent toxicity. Animal studies also indicate that this fatty acid is not eye irritant. Laurie Acid was non-carcinogenic in separate animal tests. Cosmetic product formulations containing Palmitic Acids at concentrations ranging up to 13% were not primary or cumulative irritants, nor sensitizers. On the basis of available data from studies using animals and humans, CIR concluded that Palmitic Acid is safe in present practices of use and concentration in cosmetics.

Dimethicone
CAS No.: 9006-65-9
EINECS/ELINCS: N/A
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 85% in leave-on products; up to 23.4% in rinse-off products
Food additive recommendation: Yes, the ADI is 0-1.5 mg/kg bw (applied only to compounds with a relative molecular mass in the range of 200-300
Toxicological profile by chemical supplier: None
NOAEL: 1500 mg/kg bw/day
SED: 0.3600000 mg/kg bw/day
MOS: 2,083
Dimethicone is a fluid mixture of fully methylated linear siloxane polymers end-blocked with trimethylsiloxy units. It is used as conditioning agents in cosmetic formulations at concentrations of use of 80% in hair preparation and up to 24% in make-up products, Clinical and animal absorption studies reported that dimethicone was not absorbed following oral or dermal exposure due to their large molecular weight. No adverse reactions were found in rabbits following short-term dermal dosing with 6 to 79% Dimethicone. Mice and rats were dosed for 90 days with up to 10% dimethicone without adverse effect. It also did not produce adverse effects in acute and short-term inhalation-route studies. The dermal LD50 for dimethicone was greater than 2 g/kg in rats and rabbits. Most dermal irritation studies using rabbits classified dimethicone as a minimal irritant. Dimethicone was not a sensitizer in four assays using mice and guinea pigs. It was not a sensitizer at 5% in a clinical repeated insult patch test using 83 panelists. Most ocular irritation studies using rabbits classified dimethicone as a mild to minimal irritant. Dimethicone was negative in all mutagenicity assays. It was negative in both an oral and dermal dose carcinogenicity assay using mice. Dimethicone was found to cause no treatment-related adverse effects in numerous oral-dose (using rats) and dermal-dose (using rats, rabbits and monkeys) reproductive and developmental toxicity studies. Adverse effects were noted in one inhalation study with small aerosol particles. Although there were only limited inhalation toxicity findings, dimethicone is only used in aerosol formulations at a very low concentration. The CIR Panel indicated that particles from cosmetic formulation containing dimethicone would not likely be inhaled. In particular, it was stated that expected particle sizes would primarily be in the range of 60-80 µm, and less than 1% would be under 10 µm, which is an upper limit for respirable particles. The CIR Panel expects that the manufacture process for cosmetic formulations in which dimethicone is found and which may be inhaled would continue to produce particle size distribution that are not significantly respirable. The CIR Expert Panel concluded that Dimethicone is safe as used in cosmetic formulations at concentrated known to be used.

Stearyl Alcohol
CAS No.: 112-92-5
EINECS/ELINCS: 204-017-6
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used at up to 56% in leave-on products
Food additive recommendation: None

Toxicological profile by chemical supplier: None
NOAEL: 4400 mg/kg bw/day (read across to hexadecan-1-ol)
SED: 0.3240000 mg/kg bw/day
MOS: 6,790
Stearyl Alcohol is a mixture of solid fatty alcohols that consists predominantly of n-octadecanol (90 percent minimum assay) with varying amounts of n-hexadecanol, n-tetradecanol, n-eriosanol, and n-dodecanol along with unspecified uneven and branched-chain alcohols. The predominant component conforms to the formula: CH3 (CH2)16CH2OH. Stearyl Alcohol is a white, waxy, practically inert solid with a faint odor. It is reported to be used as skin conditioning - emollient, surfactant - emulsifying, foam boosting and cleansing, emulsion stabilising, fragrance, opacifying, refatting, viscosity controlling in cosmetics. The acute dermal median lethal dose (LD50) of Stearyl Alcohol in the rabbit is 8000 mg/kg body weight by read-across from structurally analogous substance tetradecan-1-ol (CAS 112-72-1). The acute oral median lethal dose (LD50) of Stearyl Alcohol in the rat was found to be greater than 2000 mg/kg body weight. Stearyl Alcohol is classified as non-irritant to the skin or eyes. Stearyl Alcohol is classified as a non-sensitiser to the skin. No genotoxic effects of Stearyl Alcohol were observed in the in-vitro Ames test, the mutagenicity in mammalian cells and the cytogenicity test in mammalian cells. Octadecan-1-ol, the analogue of Stearyl Alcohol, is not classified as carcinogenic according to Regulation (EC) No 1272/2008. In a key reliable study conducted according to draft OECD guideline 422, parental NOAEL was 2000 mg/kg bw/day and the NOAEL for reproductive effects for octadecan-1-ol can be considered as 2000 mg/kg bw/day (highest dose level) (Hansen, 1992b). Data from a reliable one-generation reproduction study using docosan-1-ol in rats reported a NOAEL of 1000 mg/kg (Iglesias 2002a; rel 2). Data from a reliable study using dodecan-1-ol reported a parental NOAEL of 2000 mg/kg bw/day and a NOAEL for reproductive effects of 2000 mg/kg bw/day (highest dose level) (Hansen 1992a). A feeding studies reported a lack of effects on the reproductive organs of rats receiving hexan-1-ol (NOAEL 1127 mg/kg) (Scientific Associates Inc., 1966, rel; 2). No adverse effects were noted at any of the dose levels administered during the study. No effects in reproductive organs have been observed in repeated dose studies with any category member. In the key study, no adverse effects were seen after dietary administration of a reliable 13 week oral feeding study in rats using hexadecan-1-ol reported a NOAEL value of >4400 mg/kg bw. (Scientific Assoc, 1966a; rel. 2) In addition read across from a reliable 28 day oral gavage study in rats using octadecan-1-ol reported a NOAEL value of >1000 mg/kg bw (Henkel, 1985a; rel. 2). A four week reliable oral study in rats using octadecan-1-ol reported a NOAEL value of 1000 mg/kg bw, the highest dose tested (Henkel, 1986a; rel. 1). A reliable 26 week oral gavage study in rats using docosan-1-ol reported no adverse effects at the highest dose tested, 1000 mg/kg bw (Iglesias et al., 2002a). Further supporting data come from a 90 day feeding study in rats with of Alcohols, C14-15-branched and linear (Ito et al., 1978) which reported a NOAEL value of >3548 mg/kg bw/day. A read across from a reliable 13 week dietary study in rats using hexan-1-ol reported a NOAEL of 1127 mg/kg (Scientific Associates Inc., 1966). No adverse effects were noted at any of the dose levels administered during the study. The CIR Panel concluded that Stearyl Alcohol is safe in cosmetics in the practices of use and concentration.

Stearic Acid
CAS No.: 57-11-4
EINECS/ELINCS: 200-313-4
CLP Classification: None
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used at more than 50%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: >1000 mg/kg bw/day
SED: 0.2880000 mg/kg bw/day
MOS: 1,736
Stearic Acid is the fatty acid that occurs as hard, white or faintly yellow, somewhat glossy crystals or leaflets or as an amorphous white or yellow-white powder. It has a slight odor and its taste resembles that of tallow. It is primarily used as an intermediate in the manufacture of corresponding alkali salts, which are, in turn, used as emulsifiers, emollients, and lubricants in a variety of creams, cakes, soaps and pastes. It may also be used as base component of the oil phase of many cosmetic formulations. A topically applied dose of 5 g/kg commercial grade of stearic acid was not toxic to rabbits. Intra-dermal administration of 10 - 100 mM Stearic Acid to guinea pigs and rabbits resulted in mild erythema. Slight local edema and no deaths were observed among NZW rabbits after 4 weeks of topical administration of product

formulations containing 2.0% Stearic Acid. In carcinogenicity studies, feeding of up to 50 g/kg/day dietary stearic acid to mice was non-carcinogenic. In clinical primary and cumulative irritation studies, Stearic Acid at concentration of 100% or 40 - 50% in mineral oil was non-irritating. In clinical repeated insult patch tests (open, occlusive, and semi-occlusive), maximization tests, and prophetic patch tests with cosmetic product formulations containing Stearic Acid at concentrations ranging from 1 to 13%, no primary or cumulative irritation or sensitization was reported. Cosmetic product formulations containing 1 - 13% of Stearic Acid produced no photosensitization in human subjects. On the basis of available data from studies using animals and humans, it is concluded that Stearic Acid is safe in present practices of use and concentration in cosmetics.

Polysorbate 60
CAS No.: 9005-67-8
EINECS/ELINCS: N/A
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 25%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 1000 mg/kg bw/day
SED: 0.2700000 mg/kg bw/day
MOS: 1,852
Polysorbate 60 (Sorbitan, monooctadecanoate, poly(oxy-1,2-ethanediyl) derivs.) is a mixture of stearate esters of sorbitol and sorbitol anhydrides, consisting predominantly of the monoester, condensed with approximately 20 moles of ethylene oxide. It is used as fragrance ingredients and surfactant in cosmetic range from 0.1% to 25%. The oral LD50 in rats was reported to be greater than 60ml/kg. It causes minimum irritation to eyes in studies using rabbits. Clinical skin patch test indicated no irritation and sensitization in in tested subjects. The FDA has approved Polysorbate 60 at up to 4.5% in foods. The CIR Panel concludes it is safe as a cosmetic ingredient in the concentration of present use.

Cetyl Alcohol
CAS No.: 36653-82-4
EINECS/ELINCS: 253-149-0
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: >1000 mg/kg bw/day
SED: 0.2160000 mg/kg bw/day
MOS: 2,315
Cetyl Alcohol (Hexadecan-1-ol) is a white, waxy solid in flake or powder form and is used as emollient, emulsifying, emulsion stabilising, foam boosting, masking, opacifying, surfactant and viscosity controlling. The LD50 was determined to be greater than 2.6g/kg in albino rabbits. 100% of cetyl alcohol was determined to cause minimum to slight irritation in rabbits under 24-h occlusive dressing and no irritation in 24-48 h occlusive patch test in human. It is also either minimally irritating or nonirritating in New Zealand albino rabbits by Draize Test.

Sorbitan Stearate
CAS No.: 1338-41-6
EINECS/ELINCS: 215-664-9
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used at up to 5% in leave-on products.
Food additive recommendation: None

Toxicological profile by chemical supplier: None
NOAEL: 5000 mg/kg bw/day (based a diet study for 2 years in 30 male rats)
SED: 0.1800000 mg/kg bw/day
MOS: 13,889
Sorbitan Stearate is the monoester of stearic acid and hexitol rnonoanhydride and dianhydride derived from sorbitol. It is reported to be used as surfactant - emulsifying in cosmetics. The acute inhalation median lethal dose (LC50) of Sorbitan Stearate in the rat is > 5.27 mg/L air. The acute oral median lethal dose (LD50) of Sorbitan Stearate in the rat was found to be greater than 2000 mg/kg body weight. Sorbitan Stearate is classified as non-irritant to the skin or eyes. Sorbitan Stearate is classified as a non-sensitiser to the skin. No genotoxic effects of Sorbitan Stearate were observed. Based on expert judgment, there is no evidence that Sorbitan Stearate cause carcinogenicity. Based on the group concept, all available data on reproductive and developmental toxicity do not meet the classification criteria according to Regulation (EC) 1272/2008 or Directive 67/548/EEC, and are therefore conclusive but not sufficient for classification. In clinical testing published since the original assessments, 30% sorbitan stearate, was not an irritant or sensitizer when applied for up to 5 days, followed by a challenge application after 7 to 10 days. Sorbitan palmitate, 50%, also was not an irritant after a 72-hour occlusive application. The greatest maximum potency concentration used in topically administered drugs is 8% Sorbitan Stearate and in orally administered drugs is 15% sorbitan oleate. Additionally, Sorbitan Stearate is one of the diluents in color additive mixtures for drug use exempt from certification (ingested drugs) (21CFR73.1001). The CIR Panel concluded that Stearyl Alcohol is safe in cosmetics in the practices of use and concentration.

Glyceryl Stearate
CAS No.: 123-94-4
EINECS/ELINCS: 204-664-4
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: 2500 mg/kg bw/day (read across)
SED: 0.0900000 mg/kg bw/day
MOS: 13,889
Glyceryl Stearate is the monoester of glycerin and stearic acid. It conforms generally to the formula C21H42O4. It is a white or cream-coloured wax-like solid with a faint odor and an agreeable fatty taste. It is soluble in alcohol, petroleum ether, benzene, acetone, and mineral oil but insoluble in water. It is widely used in cosmetics. When applied to skin, it may produce a waxy, occlusive, water-soluble film, which makes it useful for hand lotions and creams. Glyceryl stearate is used as a surfactant, emulsifier, flavor, dispersant, anti-sticking, and thickening agent. In acute oral toxicity studies in rats, glyceryl stearate is nontoxic or mildly toxic. In chronic studies, application of 15 – 20% glyceryl stearate in the diet of rats for three consecutive generations had no adverse effects. Rats fed with a diet containing 25% glyceryl stearate for two years developed renal calcifications. Glyceryl stearate was mildly irritating or non-irritating to the skin of rabbits; and mildly irritating or non-irritating when instilled in the eyes of rabbits. It was not a sensitizer to guinea pig. According to clinical studies, it was non-sensitizing and non-irritating to human skin. Products containing 2% glyceryl stearate were non-phototoxic and non-photoallergic. The CIR Expert Panel concluded that Glyceryl Stearate is safe for topical application to humans in the present practices of use and concentration. It is also a Generally Recognized as Safe (GRAS) substance regulated by the US Food and Drug Administration (FDA).

PEG-100 Stearate
CAS No.: 9004-99-3
EINECS/ELINCS: N/A
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 25%
Food additive recommendation: None

Toxicological profile by chemical supplier: None
NOAEL: 2000 mg/kg bw/day
SED: 0.0900000 mg/kg bw/day
MOS: 11,111
PEG-100 Stearate is the polyethylene glycol (PEG) ester of stearic acid. It is used mainly in cosmetic products as surfactant and emollient at concentration up to 25%. It was non-lethal to test animals up to 10 g/kg. Only low-level skin irritation and minimal eye irritation was observed when tested at 100% concentration in test animals. It produced no significant changes in mortality rates, histopathologic observations or hematologic values in long-term feeding studies. Clinical studies on the PEG Stearates indicated that these ingredients are neither irritants nor sensitizers at concentrations of ≤25%. The CIR Expert Panel concluded that PEG-100 Stearate is safe as cosmetic ingredient in the present practices of concentration and use.

Phenoxyethanol
CAS No.: 122-99-6
EINECS/ELINCS: 204-589-7
CLP Classification: Acute Tox. 4 H302; Eye Irrit. 1 H318; STOT SE. 3 H335
EU Cosmetic Regulation: Annex V/29: Maximum authorized concentration is 1.0%
SCCS opinion: Same as EU Cosmetic Regulation
CIR recommendation: up to 1%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 357 mg/kg bw/day (dermal, rabbit, 90-day)
SED: 0.0900000 mg/kg bw/day
MOS: 1,983
Phenoxyethanol is generally used as a preservative in cosmetic formulations at a maximum concentration of 1.0% and also used as a fixative for perfumes and soaps. Undiluted 2-phenoxyethanol is considered as a mild irritant to the rabbit skin, and an irritant to the rabbit eye. Contact sensitisation in humans has been documented, but from the available studies it can be concluded that this is rare. The risk of becoming sensitised is very low. Phenoxyacetic acid is the main metabolite of phenoxyethanol in humans, data on background levels of 2-phenoxyacetic acid in human urine samples suggest that cosmetic products are a major source of phenoxyethanol exposure to consumers. Haematotoxicity is a predominant toxicological feature of phenoxyethanol in vivo and in vitro. Systemic availability of phenoxyethanol after oral exposure of rats is very low due to a strong first pass effect in rat liver and the rapid formation of the main metabolite 2-phenoxyacetic acid, which may accumulate in the kidney and may be responsible for kidney toxicity in rats after oral exposure. In contrast, dermal exposure of rats to phenoxyethanol revealed much higher concentrations of the parent compound in blood than after oral exposure. This may also be true for other species such as humans. In dermal treatment studies, Phenoxyethanol was neither teratogenic, embryotoxic, nor fetotoxic at doses which were maternally toxic. Phenoxyethanol was non-mutagenic in the Ames test, with and without metabolic activation, and in the mouse micronucleus test. The SCCS concludes that phenoxyethanol is safe for use as a preservative with a maximum concentration of 1.0%, even for infants and children.

Triethanolamine
CAS No.: 102-71-6
EINECS/ELINCS: 203-049-8
CLP Classification: None
EU Cosmetic Regulation: Annex III: Maximum authorized concentration is 2.5% for non-rinse-off products; do not use with nitrosating systems; minimum purity of 99%; maximum secondary amine content of 0.5% (applies to raw materials); maximum nitrosamine content of 50 µg/kg; keep in nitrite-free containers
SCCS opinion: Same as EU Cosmetic Regulation
CIR recommendation: Safe to be used for rinse-off products but up to 5% for leave-on products; safe for use in cosmetic formulations designed for discontinuous, brief use followed by thorough rinsing from the surface of the skin; should not be used with products containing N-nitrosating agents
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 1000 mg/kg bw/day

SED: 0.0720000 mg/kg bw/day
MOS: 6,944
Triethanolamine (TEA) is clear, colourless, viscous liquid with ammoniacal odor. It is widely used in cosmetic formulations as emulsifier, thickener, wetting agent, detergent and alkalizing agent. The LD50 value for rats of TEA is 4.19 g/kg. Long-term oral ingestion of TEA by rats and guinea pigs produced lesions limited mainly to the liver and kidney. Long-term cutaneous applications to animals of the ethanolamines also produced evidence of hepatic and renal damage. TEA showed little potential for rabbit skin irritation in acute and subchronic skin irritation tests. A lotion containing 1% TEA was not phototoxic to guinea pigs, and TEA was not a guinea pig skin sensitizer. TEA did not cause DNA-damage inducible repair in an unscheduled DNA synthesis test. TEA had no carcinogenic or cocarcinogenic activity when dermally applied to mice for 18 months. Clinical skin testing of TEA and cosmetic products containing TEA showed mild skin irritation in concentration above 5%. There was very little skin sensitization. TEA does not react with N-nitrosating agents to directly from nitrosamines. However, it can act as precursors in nitrosamine formation by undergoing nitrosative cleavage. The resultant secondary amine, diethanolamine, can then be N-nitrosated to products that may be carcinogenic. Therefore, TEA or TEA-containing ingredients should not be used in cosmetic products in which N-nitroso compounds can be formed.
No supporting document of Triethanolamine has been provided. The purity, content of secondary amine and nitrosamine should be complicant with EU Cosmetic Regulation in order to be a cosmetic ingredient. If this is not the case, it will void this assessment.

Methylparaben
CAS No.: 99-76-3
EINECS/ELINCS: 202-785-7
CLP Classification: None
EU Cosmetic Regulation: Annex V: Maximum authorized concentration is 0.4% (as 4-hydroxybenzoic acid) for single ester (equivalent to 0.44% methylparaben), 0.8% (as 4-hydroxybenzoic acid) for mixtures of esters
SCCS opinion: Same as EU Cosmetic Regulation
CIR recommendation: Safe to be used up to 0.4% if used alone; parabens mixture up to 0.8%
Food additive recommendation: Yes, the ADI is 0 to 10 mg/kg bw
Toxicological profile by chemical supplier: None
NOAEL: 1000 mg/kg bw/day
SED: 0.0270000 mg/kg bw/day
MOS: 18,519
Methylparaben is the ester of Methyl Alcohol and p-Hydroxybenzoic acid that is used as preservative in cosmetics. Parabens are rarely irritating or sensitizing to normal human skin at concentration used in cosmetics. With regard to their general toxicological profile, acute, sub-acute and chronic toxicity studies in rats, dogs and mice, have proven parabens to be practically non-toxic, non-carcinogenic, non- genotoxic or co-carcinogenic, and non-teratogenic. Parabens are not expected to accumulate in tissues and the ester linkage of the parabens is expected to be readily hydrolyzed. Until a properly conducted dermal absorption and toxicokinetic study in humans will allow the assignment of a more scientifically solid value, the SCCS uses a dermal absorption value of 3.7% in its MOS safety calculations.
The major concern on parabens is the endocrine disrupting property. In a number of in vitro studies, such as the recombinant yeast estrogen screen, parabens have proven to be able to bind to the estrogen receptor, to activate genes controlled by these receptors, and to stimulate cell growth and increase the level of immune reactive estrogen receptor protein. The estrogenic potency increases with increasing length and branching of the alkyl side chains (methyl < ethyl < propyl < butyl < isobutyl). The potency, however, remained at all times 1,000 to 1,000,000 times below the potency of 17β- estradiol. p-Hydroxybenzoic acid, the common metabolite of all parabens, was inactive in the in vitro assays. The in vivo estrogenic activities of parabens have been tested in uterotrophic assays employing female rodents. Butylparaben appeared to be more potent than propyl-, ethyl- and methylparaben, and again the values remained several magnitudes of order below the potency of 17β-estradiol. Conflicting results, however, were reported for p-Hydroxybenzoic acid tested in vivo. One study claimed that it had no estrogenic effect, whereas another study gave potency values 1000-fold below the 17β-estradiol level. Taking into account all the available data, the EU Cosmetic regulation continue to limit Methylparaben at 0.4% (as 4-hydroxybenzoic acid) for single ester; 0.8% (as 4-hydroxybenzoic acid) for mixtures of esters.

Propylparaben
CAS No.: 94-13-3
EINECS/ELINCS: 202-307-7
CLP Classification: N/A
EU Cosmetic Regulation: Annex V: Maximum authorized concentration in ready for use preparation is 0.14% (as 4-hydroxybenzoic acid) for single ester (equivalent to 0.18% propylparaben), 0.8% (as 4-hydroxybenzoic acid) for mixtures of esters, where the sum of the individual concentrations of butyl- and propylparaben and their salts does not exceed 0.14%
SCCS opinion: Same as EU Cosmetic Regulation
CIR recommendation: Safe to be used up to 0.4% if used alone; parabens mixture up to 0.8%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 2 mg/kg/day (NOEL)
SED: 0.0180000 mg/kg bw/day
MOS: 56
Propylparaben is the ester of n-propyl alcohol and p-hydroxybenzoic acid that is used as masking and preservative in cosmetics. Parabens are rarely irritating or sensitizing to normal human skin at concentration used in cosmetics. With regard to their general toxicological profile, acute, sub-acute and chronic toxicity studies in rats, dogs and mice, have proven parabens to be practically non-toxic, noncarcinogenic, non- genotoxic or co-carcinogenic, and non-teratogenic. Parabens are not expected to accumulate in tissues and the ester linkage of the parabens is expected to be readily hydrolyzed. Until a properly conducted dermal absorption and toxicokinetic study in humans will allow the assignment of a more scientifically solid value, the SCCS uses a dermal absorption value of 3.7% in its MOS safety calculations.
The major concern on parabens is the endocrine disrupting property. In a number of in vitro studies, such as the recombinant yeast estrogen screen, parabens have proven to be able to bind to the estrogen receptor, to activate genes controlled by these receptors, and to stimulate cell growth and increase the level of immune reactive estrogen receptor protein. The estrogenic potency increases with increasing length and branching of the alkyl side chains (methyl < ethyl < propyl < butyl < isobutyl). The potency,however, remained at all times 1,000 to 1,000,000 times below the potency of 17β- estradiol. p-Hydroxybenzoic acid, the common metabolite of all parabens, was inactive in the in vitro assays. The in vivo estrogenic activities of parabens have been tested in uterotrophic assays employing female rodents. Butylparaben appeared to be more potent than propyl-, ethyl- and methylparaben, and again the values remained several magnitudes of order below the potency of 17β-estradiol. Conflicting results, however, were reported for p-Hydroxybenzoic acid tested in vivo. One study claimed that it had no estrogenic effect, whereas another study gave potency values 1000-fold below the 17β-estradiol level.

Fragaria Ananassa (Strawberry) Fruit Extract
CAS No.: 1175540-74-5
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: 720 mg/kg bw/day
SED: 0.0180000 mg/kg bw/day
MOS: 20,000
Fragaria Ananassa (Strawberry) Fruit Extract is the extract of the Strawberry, Fragaria ananassa, Rosaceae. It is reported to be used as skin conditioning agent in cosmetics. To obtain strawberry extract, a process called supercritical CO2 extraction is used. This sounds very technical, but it means that carbon dioxide (which usually behaves as a gas at standard temperature and pressure) is heated beyond its critical point of temperature and pressure. At this point it adopts properties midway between a gas and a liquid, making it fantastic as an extraction solvent. When the CO2 is evaporated or recycled by condensation from the starting material (in this case strawberries) only the extract remains which takes on the delicious flavour of strawberries. Another important benefit is that the CO2 process is non-toxic, non-

flammable and has a low environmental impact. The sweet, juicy taste of fresh strawberries is captured in strawberry extract. When the extract is added to products for the teeth and mouth, taste buds will enjoy a tempting fruity taste and breath will be refreshed. Fragaria Ananassa (Strawberry) Fruit Extract has a high content of fiber, vitamin C, antioxidants, potassium, folic acid and minerals. Strawberry extract has important moisturising and conditioning properties.

Rosa Rugosa (Rugose Rose) Flower Extract
CAS No.: 92347-25-6
EINECS/ELINCS: 296-213-3
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: 0.0180000 mg/kg bw/day
MOS: --
Rosa Rugosa Flower Extract is an extract obtained from the flowers of the Rose, Rosa rubiginosa L., Rosaceae. It is reported to be used as skin conditioning agent in cosmetics. Rosa rugosa extract is rich in bioflavonoids, polyphenols, and peptides. Its antioxidant, antibacterial, anti-retroviral, and anti-inflammation properties provide immune support to help combat colds and flu and the frequency and onset of urinary tract infections. Study shows that Rose (Rosa rugosa)-flower extract administered endogastrically at 80mg/kg/day increases the activities of antioxidant enzymes and their gene expression and reduces lipid peroxidation senescence-accelerated mice (SAM mice) treated for 30 or 60 days.

Lavandula Angustifolia Extract
CAS No.: 90063-37-9
EINECS/ELINCS: 289-995-2
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: 160 mg/kg bw/day
SED: 0.0180000 mg/kg bw/day
MOS: 4,444
Lavandula Angustifolia (Lavender) Extract is the extract of the whole plant of the Lavender, Lavandula angustifolia, Labiatae. Lavandula Angustifolia (Lavender) is listed as direct food substances generally recognized as safe (GRAS) by the US Food and Drug Administration. Lavandula Angustifolia (Lavender) is enlisted as Class 1 in the botanical safety handbook as herbs that can be safely consumed when used appropriately.

Milk Extract
CAS No.: N/A
EINECS/ELINCS: N/A
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: 0.0180000 mg/kg bw/day
MOS: --

Milk Extract is the extract of Milk (q.v.). It is reported to be used as skin conditioning agent in cosmetic products. According to the U.S. FDA, bovine milk is considered generally recognized as safe (GRAS) as it is a substance used in food prior to January 1, 1958, through experience based on common use in food (21 CFR§170.30). daily exposures from food use of bovine milk would result in much greater systemic exposures than those resulting from use in cosmetic products. Hydrolyzed Milk Protein and Hydrolyzed Casein were not mutagenic at concentration up to 5000 µg/plate in Ames assays. Hydrolyzed Milk Protein (concentration not reported) was negative in an in vitro dermal irritation assay. Hydrolyzed Milk Protein was not irritating to rabbits or humans when tested at up to 25% and 5%, respectively. No dermal sensitization was observed in a guinea pig maximization study of Hydrolyzed Milk Protein at up to 100%. No sensitization was observed in a study of Hydrolyzed Milk Protein in sensitized patients (concentration not reported). Hydrolyzed Milk Protein was not a photoirritant or a photosensitizer in human subjects when tested at 5%. No ocular irritation was predicted to Hydrolyzed Milk Protein (concentration not reported) in vitro assays. Hydrolyzed Milk Protein was not irritating to rabbit eyes when tested at up to 25%. No adverse effects from cosmetic use of milk protein or protein-derived ingredients were discovered in the published literature. The CIR Expert Panel concluded that Milk Protein is safe as cosmetic ingredient in the present practices of use.
The client should assure that Milk Extract is not free from BSE.

Prunus Persica (Peach) Fruit Extract
CAS No.: 84012-34-0
EINECS/ELINCS: 281-678-7
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: 0.0090000 mg/kg bw/day
MOS: --
Prunus Persica (Peach) Fruit Extract is an extract of the fruit of the Peach, Prunus persica, Rosaceae. Peach fruit extract is made by first peeling and drying the fruit, then mixing it with a solvent and separating the solid particles using filtration or other methods. Vitamin C and E are Anti-oxidants present in peach that helps wound recover faster and prevent aging of the skin by reducing oxygen-free radicals. The peach liquid extract has a variety of minerals that are beneficial to the skin like Calcium, Potassium, Copper, Iron, Magnesium, Phosphorous, etc. It makes skin soft, smooth and hydrated. It is reported to be used as abrasive, bulking, moisturising, skin conditioning agent in cosmetics. Vitamins in peaches reduces the formation of proper lines or wrinkles around the skin. Peaches can cure many diseases and more importantly the cancer and heart problems as you may know that it contains beta carotene that gives colour to peaches and it contains lycopene and lutein that can prevent from loss of sharp vision. Peaches have numerous antioxidants but the most striking benefits of chlorogenic acid (an antioxidant) makes is a healthy fruit. Peaches are a rich source of beta carotene that increases blood floe in all parts of the body thus, protecting your eyes from weakening. The Cosmetics Ingredients Review has deemed that plant-derived fatty acid oils, including peach kernel oil, are generally safe for use in cosmetics. Whole Foods has deemed the ingredient acceptable in its body care and cleaning product quality standards.
Uuron-Cha Ekisu
CAS No.: 84650-60-2
EINECS/ELINCS: 283-519-7
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: up to 2% in leave-on products, 1% in rinse-off products, and up to 0.1% in bath products.
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 4000 mg/kg bw/day
SED: 0.0090000 mg/kg bw/day
MOS: 222,222

Camellia Sinensis Leaf Extract, also know as Uuron-Cha Ekisu and Green Tea Extract, is an extract of the leaves of the Tea, Camellia sinensis, Theaceae. The functions of this ingredient include antimicrobial agent, antioxidant, cosmetic astringent, oral care agent, skin protectant, emollient and humectant. The Botanical Safety Handbook classified the leaf of Camellia sinensis (L.) Kuntze as Class 1. Herbs that can be safely consumed when used appropriately. The FDA considers C. sinensis to be GRAS for use as a food additive. The oral LD50 for rats was >2 g/kg for camellia sinensis leaf extract as both green and black tea. Camellia sinensis leaf extract was not irritating or sensitizing in 2 HIRPTs conducted on 2 cosmetic products that contain this ingredient at 0.86%. Quercetin and several compounds containing quercetin have been reported in the leaf, plant, and shoot. A positive genotoxic effect in an Ames assay has been reported, and genotoxicity was observed in in-vitro tests and in some in-vivo studies of ip exposures, but results were consistently nongenotoxic in oral exposure studies using mice and rats. The CIR Expert Panel noted that the quercetin found in C. sinensis leaves and essential oil, depending on growing conditions and methods of manufacture, may or may not be found in cosmetic ingredients. Therefore, when formulating products, manufacturers should avoid reaching levels of these plant constituents, and any other constituent, that may cause sensitization or other adverse health effects. The CIR Expert Panel concluded that C. sinensis leaf-derived ingredients are safe as used in cosmetic products when formulated to be non-sensitizing. However, IFRA has proposed a restriction on Tea leaf absolute (Camellia sinensis leaf extract). The RIFM Expert Panel reviewed the critical effect data for tea leaf absolute and based on the weight of evidence established the No Expected Sensitization Induction Level (NESIL) as 480 µg/cm². Please refer to IFRA Standards Booklet for the restriction in each category of products.

Parfum (3105)
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: Causes serious eye irritation; Causes skin and eye irritation.
NOAEL: --
SED: 0.0009000 mg/kg bw/day
MOS: --
Parfum 3105 as supplied by Guangzhou BaiXin Flavors & Fragrances Co., Ltd. and the corresponding IFRA certificate of 51st amendment, allergen declaration and MSDS, was used at 0.005% in the formulation. The industry recommendations are applicable and the submitted IFRA Certificate indicates up to 13.3% of this parfum can be used in hand cream product (Class 5C product).

Parfum (3154)
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 an allergic skin reaction; Toxic to aquatic life; Harmful to aquatic life with long lasting effects.
NOAEL: --
SED: 0.0009000 mg/kg bw/day
MOS: --
Parfum 3154 as supplied by Guangzhou BaiXin Flavors & Fragrances Co., Ltd. and the corresponding IFRA certificate of 51st amendment, allergen declaration and MSDS, was used at 0.005% in the formulation. The industry recommendations are applicable and the submitted IFRA Certificate indicates up to 40% of this parfum can be used in hand cream product (Class 5C product).

Parfum (8117)
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 an allergic skin reaction; Toxic to aquatic life; Harmful to aquatic life with long lasting effects.
NOAEL: --
SED: 0.0009000 mg/kg bw/day
MOS: --
Parfum 8117 as supplied by Guangzhou Baiyi Fragrance Co., Ltd. and the corresponding IFRA certificate of 51st amendment, allergen declaration and MSDS, was used at 0.005% in the formulation. The industry recommendations are applicable and the submitted IFRA Certificate indicates up to 8.5% of this parfum can be used in hand cream product (Class 5C product).

Parfum (86029)
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 an allergic skin reaction; Toxic to aquatic life; Harmful to aquatic life with long lasting effects.
NOAEL: --
SED: 0.0009000 mg/kg bw/day
MOS: --
Parfum 86029 as supplied by Guangzhou BaiXin Fragrance Co., Ltd. and the corresponding IFRA certificate of 51st amendment, allergen declaration and MSDS, was used at 0.005% in the formulation. The industry recommendations are applicable and the submitted IFRA Certificate indicates up to 11% of this parfum can be used in hand cream product (Class 5C product)
Parfum (PR-300133)
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: H315 Causes skin irritation, H317 May cause an allergic skin reaction, H318 Causes serious eye damage,H304 May be fatal if swallowed and enters airways, H411 Toxic to aquatic life with long lasting effects
NOAEL: --
SED: 0.0009000 mg/kg bw/day
MOS: --
Parfum PR-300133 as supplied by Guangzhou ZhuoZhiYue Flavors & Fragrances Co., Ltd.. and the corresponding IFRA certificate of 51st amendment, allergen declaration and MSDS, was used at 0.005% in the formulation. The industry recommendations are applicable and the submitted IFRA Certificate indicates up to 2.0% of this parfum can be used in hand cream product (Class 5C product).

9. Undesirable effects and serious undesirable effects

No previous complaints data is available for review. 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

The product is indicated to be manufactured by Guangzhou Mujin Cosmetics Co., Ltd in a manufacturing setting according to ISO 22716: 2007 Cosmetics - Good Manufacturing Practices (GMP) and Cosmetic Good Manufacturing Practice Guidelines (2020) Published by U.S. Food and Drug Administration with scope of compliance on design and manufacture of cosmetics, including General Liquid Units (Hair Care Cleaning Category, Skin Care Category, Gel Category); Cream Emulsion Unit (Skincare Cleaning Class Category, Hair Conditioner Category) by third party laboratory (Bureau Veritas Certificate CNSH21695605-ISO22716 and CNSH21695605-USFDA which is valid until May 14, 2027).

PART B – COSMETIC PRODUCT SAFETY ASSESSMENT

1. **Assessment conclusion**

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

2. Recommended Labelled warnings and instructions of use

No specific warnings required other than standard usage instructions.
Stop use if the product disagrees with you. Consult a physician and seek medical treatment if necessary.

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 - There are substances of allergenic potential but at low level that is not expected to induce an allergenic reaction in most of the users under normal and reasonably foreseeable conditions of use. However, sensitized people can react to allergen present at extremely low concentrations.
Eye irritants – Accidental exposure to eyes may cause irritation, but is expected to be minimal after rinsing.
Interaction of substances – No significant interactions expected, based on a review of the chemical properties of the species included in this formulation.
Stability, microbiological quality and heavy metal in the formulation and packaging material have been assessed for this product. No supporting document of ingredient has been provided to indicate impurities. The materials must be free from, or contain technically unavoidable trace amount of residual solvent and monomer in order to be a cosmetic ingredient. If this is not the case, it will void this assessment.
The submitted test results indicate the product will be safe for intended use concerning the impurity, stability, microbiological quality, and preservative efficacy while the product was manufactured in accordance with ISO 22716: 2007 Cosmetics - Good Manufacturing Practices (GMP) and Cosmetic Good Manufacturing Practice Guidelines (2020) Published by U.S. Food and Drug Administration .
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 if possible.

4. Assessor's credentials and approval of Part B

General Notes

The product must be in order to ensure that the cosmetic product safety report is kept up to date as required by Article 10(1)(c) of Regulation (EC) No 1223/2009, 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.

Date: 2025-05-20

Quanren He, Ph. D., DABT
Diplomate of the American Board of Toxicology
Regulatory Toxicologist & Counselor

-End of Test Report-