



Test Report

No. HKHC2208006137HC

Date :Aug 30, 2022

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MID OCEAN BRANDS B.V.

ADDRESS 7/F., KINGS TOWER, 111 KING LAM STREET, CHEUNG SHA WAN, KOWLOON, HONG KONG

The following sample was submitted and identified by the client as SUNSCREEN LOTION (1 formulation).

Net Weight : 30ml or 45ml per consumer product
Item no. : MO6115/ MO8512
SGS Report No. : HKHC2208006137HC
SGS Case No. : HKHC220500001715 -101 (XMCPCH220500936)
Buyer : Mid Ocean Brands B.V.
Manufacturer : 113285
Region of Origin : China
Region of Destination : EU
Sample Receiving Date : May 30, 2022 – Aug 19, 2022
Test Period : May 30, 2022 – Aug 30, 2022

Test Requested

This Cosmetic Product Safety Report (CPSR) is carried out according to Regulation (EC) No. 1223/2009 and its amendments.

Test Results

Please refer to the following pages.

Summary

It is my opinion that this cosmetic formulation is safe to use under normal or reasonably foreseeable conditions of use.

This assessment takes account of:

- a) The general toxicological profile of each ingredient used.
- b) The chemical structure of each ingredient.
- c) The level of exposure of each ingredient.
- d) The specific exposure characteristics of each ingredient on the areas on which the cosmetic product will be applied.
- e) The specific exposure characteristics of the class of individuals for which the cosmetic product is intended.

If there is an adverse reaction from using this formulation then the undersigned should be informed so that the formulation can be further reviewed.

Signed for and on behalf of
SGS Hong Kong Ltd.

Mei-Yin CHIU, Sonly
MSc, FRSB, CBiol, ERT, DABT
Cosmetic Safety Assessor

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PART A - COSMETIC PRODUCT SAFETY INFORMATION
INTRODUCTION

SGS is requested to review the safety of the product formula SUNSCREEN LOTION for consumer health and no other part of the product. The product is for EU market and intended for application on body skin for protecting it by children of 3 years old or above.

The net weight of this product (The formula under assessment) is 30ml or 45ml per consumer product. Detailed formulation is submitted by the client as in Section 1.

LITERATURE SOURCES

This review was compiled by using information gathered from raw material suppliers and various online databases including the EU Scientific Committee on Consumer Safety (SCCS) opinions, Cosmetic Ingredients Review (CIR); detailed references are not reported here but are recorded in the SGS Scientific Archives.

1. Quantitative and qualitative composition of cosmetic product under assessment

INCI or Chemical Name	CAS No.	EINECS/ELINCS	Conc. %	Intended Function
Aqua	7732-18-5	231-791-2	53.1000000000	Solvent
Ethylhexyl Methoxycinnamate	5466-77-3	226-775-7	7.0000000000	Uv absorber
Isopropyl Myristate	110-27-0	203-751-4	5.0000000000	Binding / emollient / masking / perfuming
Caprylic/Capric Triglyceride	73398-61-5	277-452-2	5.0000000000	Skin conditioning
Cetearyl Alcohol	8005-44-5	267-008-6 / -	5.0000000000	Emulsion Stabilising / Emulsifying
Glycerin	56-81-5	200-289-5	5.0000000000	Humectant
Ethylhexyl Salicylate	118-60-5	204-263-4	5.0000000000	UV absorber / UV filter
C12-15 Alkyl Benzoate	68411-27-8	270-112-4	4.0000000000	Emollient / skin conditioning
Ceteth-25	9004-95-9	N/A	3.0000000000	Emulsifying
Glyceryl Stearate	31566-31-1	250-705-4	3.0000000000	Emollient / emulsifying
Benzophenone-3	131-57-7	205-031-5	2.0000000000	UV absorber / UV filter
Titanium Dioxide	13463-67-7	236-675-5	2.0000000000	UV absorber / UV filter
Parfum (VANILLA MY11-S089)	N/A (Mixture)	N/A (Mixture)	0.3000000000	Perfuming
DMDM Hydantoin	6440-58-0	229-222-8	0.3000000000	Preservative
Methylparaben	99-76-3	202-785-7	0.2000000000	Preservative
Propylparaben	94-13-3	202-307-7	0.1000000000	Preservative

FRAGRANCE ALLERGENS

Fragrance allergens **COUMARIN** must be declared on the product label in the ingredients section according to EU Cosmetic Regulation.

2. Physical/chemical characteristics and stability of the formulation

2.1 The product is a white colored cream with the parfum (VANILLA MY11-S089) with pH value of 7.25.

2.2 The stability test result on formulation, by in house method of _____ on product name Sunscreen Lotion, with a testing period of Apr 09 – Jul 09, 2022, was submitted and reviewed. It is the responsibility of manufacturer or responsible person to determine the product's minimum durability and period-after-opening (PAO), if applicable, using the available data.

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Testing conditions : -5°C, -15°C, 25°C, 40°C and light exposure for 12 weeks; cycle test (40°C/8h, 4°C/8h, 40°C/8h, 4°C/8h, room temperature/4h) for 3 cycles
 Testing parameters : Appearance, Colour, Odor, pH value and TVC bacteria (cfu/g)
 Conclusion: The stability of the formulation is acceptable for this application.

3. Microbiological quality

3.1 The microbiological test results on formulation, with reference to European Pharmacopoeia 9.0 2.6.12 and 2.6.13, by in house method of _____ on product name SUNSCREEN LOTION, with a testing date of Jul 10, 2022, was submitted and reviewed based on following criteria as required by SCCS Notes of Guidance.

Product Category of this product: 2

Micro-organisms	Total viable count and Total yeast and mold	<i>E. Coli</i> , <i>P.aeruginosa</i> , <i>S.aureus</i> and <i>C.albicans</i>
Category 1: Products specifically intended for children under 3 years, to be used in the eye area and on mucous membranes	≤ 100 cfu/g or 100 cfu/ml	not detectable in 1g or 1 ml
Category 2: Other products	≤ 1000 cfu/g or 1000 cfu/ml	not detectable in 1g or 1 ml

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

3.2 The preservation efficacy test result on formulation, with reference to European Pharmacopoeia 10.0, 5.1.3, by in house method of _____, on the trade name Sunscreen Lotion, with a testing period of May 10 – Jun 10, 2022, was submitted and reviewed based on following criteria.

		Day 2	Day 7	Day 14	Day 28
		Log reduction			
Criteria A	<i>E.coli</i> , <i>P.aeruginosa</i> , <i>S.aureus</i>	2	3	/	NI
	<i>C. albicans</i>	/	/	2	NI
	<i>A. brasiliensis (niger)</i>	/	/	2	NI
Criteria B	<i>E.coli</i> , <i>P.aeruginosa</i> , <i>S.aureus</i>	/	/	3	NI
	<i>C. albicans</i>	/	/	1	NI
	<i>A. brasiliensis (niger)</i>	/	/	1	NI

NI: No increase

Conclusion: The preservative efficacy of the formulation achieved criteria B and is acceptable for this application.

4. Impurities, traces and information about the formulation and the packaging material

4.1 The heavy metal test results on formulation, by in house method of _____, on product name SUNSCREEN LOTION, with a testing period of Jul 10 – 17, 2022, was submitted and reviewed based on following criteria.

	German Health Authority BgA (Recommendation from German Health Journal No. 28, July 1985) and The German Health Journal No. 7/1992, Session 45 from November 14, 1991					
Test items	As	Hg	Pb	Sb	Cd	Ni (soluble)
Limit (mg/kg)	≤5	≤1	≤20	≤10	≤5	≤10

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

4.2 The client has supplied the following list of packaging parts for this product as the immediate container.

Style 1

No.	Immediate Container	Material
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1.	Tube	PE
2.	Cap	PP
3.	Foil Seal	Aluminum Foil

Style 2

No.	Immediate Container	Material
1.	Cap	PP
2.	Bottle	PE

4.3 For the packaging materials, the test results of total Lead (Pb), Cadmium (Cd), Mercury (Hg), Chromium VI (Cr (VI)), by third party laboratory (GIG report no. GNBC22062411EN), with testing period of Jun 29 – Jul 01, 2022, indicate the total amount of lead, cadmium, mercury and chromium (VI) is less than 100ppm.

Conclusion: The heavy metal content of the packaging material is acceptable.

4.4 Packaging compatibility test results on packaging material, tested together with the formulation, by in house method of _____ on product name Sunscreen Lotion, with a testing period of Apr 09 – Jul 09, 2022, was submitted and reviewed.

Testing conditions : -5°C, -15°C, 25°C, 40°C and light exposure for 12 weeks; cycle test (40°C/8h, 4°C/8h, 40°C/8h, 4°C/8h, room temperature/4h) for 3 cycles

Testing parameters : Appearance and appearance of package

Conclusion: The stability of the packaging material is acceptable.

5. Normal and reasonably foreseeable use

The normal use of this product is for application on body skin by children of age 3 years or above. Application of this product to face is possible. Ingestion of this product would be a misuse.

6. Exposure to cosmetic product

Product type: Suncare products

Use category: Sunscreen lotion

Physical form: Liquid

The site(s) of application: Body skin

The surface area(s) of application: 17500 cm²

The amount per application: 9 g

The duration of exposure: 150 minutes

The frequency of use: 730 times per year

The normal and reasonably foreseeable exposure route(s): Primarily via dermal contact

The targeted (or exposed) population(s): Children of age 3 years or above

The body weight: 15.1 kg

Estimated daily amount applied: 18000 mg/day

7. Exposure and toxicological profile of the substances

There are no nanoparticles indicated to be used in this formulation.

For toxicological profile of ingredients, refer to Annex 1.

Systemic Exposure Dose(SED) is derived for each substance, taking into account of 50 % bioavailability as a default value for oral and dermal absorption, and 100 % bioavailability for inhalation, unless otherwise specified. Margins of safety(MoS) is calculated by dividing systemic NO(A)ELs by the SED, when NO(A)EL or relevant Point of Departure(POD) is available in the present stage of knowledge.

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8. Undesirable effects and serious undesirable effects

No data on any undesirable effects associated with this product has been supplied.

9. Information on the cosmetic product

The product is indicated to be manufactured by _____, in a manufacturing setting according to GMPC (2008) issued by US FDA, with scope of compliance on production of wax-based unit (wax-based), general liquid unit (hair care cleansing) and cream lotion unit (skin care cleansing) products (within the scope of production license), by third party laboratory (TOTAL QUALITY CERTIFICATION SERVICES INTERNATIONAL (CHINA) CO., LTD Certificate SHZH-2-0164 which is valid until Dec 07, 2022).

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PART B - COSMETIC PRODUCT SAFETY ASSESSMENT**1. Assessment conclusion**

The product complies with the Regulation (EC) No. 1223/2009 and its subsequent amendments. Provided the manufacturer's instructions are followed, it is considered that, in the present state of knowledge, the submitted formulation put on the market is unlikely to pose a significant risk to the health of intended consumer under normal and reasonably foreseeable conditions of use.

2. Recommended labelled warnings and instructions of use**Contains Benzophenone-3 (Mandatory)**

Avoid contact with eyes. Rinse eyes immediately should the product comes into contact with them.

Stop using the product if it disagrees with you.

Keep out of reach of children except use under adult supervision.

Do not stay too long in the sun, even while using a sunscreen product.

Keep babies and young children out of direct sunlight.

Over-exposure to the sun is a serious health threat.

Apply the sunscreen product before exposure.

Re-apply frequently to maintain protection, especially after perspiring, swimming or toweling.

Do not stay too long in the sun, even while using a sunscreen product.

3. Reasoning

All the ingredients in the formulation are either reported to be used in cosmetic or within the recommended limit as suggested by SCCS and Cosmetic Ingredient Review (CIR). No CMR substance is indicated to be intentionally added to the formulation.

Margin of Safety (MoS) was derived for all ingredients except those which No Observed (Adverse) Effect Levels (NO(A)ELs) or other Point of Departure (POD) were not available. For ingredients that MoS cannot be derived, their safety is substantiated by history of safe use at similar levels in related cosmetic products, reference doses, TTC approach, etc. Detailed explanation is given in the individual ingredient toxicological summary in annex 1.

The formulation is not expected to be irritating to the skin and respiratory tract, phototoxic, and is unlikely to cause damage to internal organs through skin in the majority of consumers under normal and reasonably foreseeable conditions of use. Accidental exposure to eyes may cause slight irritation but is expected to be minimal after rinsing. 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.

The potential interactions between ingredients have been considered. 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 GMPC (2008) issued by US FDA.

Although the concentration used for the formaldehyde releaser, DMDM Hydantoin, is below the EU regulatory limits, the client is highly recommended to determine the formaldehyde content in the final product and label the product accordingly if the product contains more than 0.001% (10ppm) formaldehyde, irrespective of whether the finished product contains one or more substances releasing formaldehyde

4. Assessor's credentials and approval of Part B

Date: Aug 30, 2022

Mei-Yin CHIU, SONDY MSc, FRSB, CBIOL, DABT, EUROTOX Registered Toxicologist

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The validity of this review depends on the validity of disclosure by both the manufacturer of the components and that of the finished products. Best professional capabilities are used in performing this review and if the client wishes to use this opinion with any alternations to the submitted formula, SGS (HK) Ltd. or any of its employees will not be held liable for any injury or damage resulting from this product. This review will need to be updated upon reformulation or upon change of the new significant safety information.

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ANNEX 1 TOXICOLOGICAL PROFILE OF INDIVIDUAL INGREDIENT
1. 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: 79.6500000000 mg/kg bw/day

MOS: --

Aqua is a ubiquitous liquid that is normally used as solvent in cosmetic products and is not expected to result in any acute or chronic toxicity following typical exposures.

2. Ethylhexyl Methoxycinnamate

CAS No.: 5466-77-3

EINECS/ELINCS: 226-775-7

CLP Classification: N/A

EU Cosmetic Regulation: Annex VI: Maximum authorized concentration in ready for use preparation is 10% as UV Filters

SCCS opinion: Same as EU Cosmetic Regulation

CIR recommendation: None

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 522 mg/kg bw/day

SED: 0.42000000 mg/kg bw/day (Percutaneous absorption: 2%)

MOS: 621

Ethylhexyl Methoxycinnamate (or octyl-methoxycinnamate (OMC)) is the ester of 2-ethylhexyl alcohol and methoxycinnamic acid. It is used as UV absorber and UV filter in cosmetic. It is the approved cosmetic UV filter under the EU Cosmetic Regulation and it is restricted at a maximum concentration 10% in ready for use preparation. The safety of OMC has been reviewed by the SCCC (SPC/1037/93, S28) in 1993. It was concluded that the compound has a low acute toxicity. OMC is not irritating or sensitising in animals, but can be very rarely responsible for allergic contact dermatitis in man. Mutagenicity, photomutagenicity and photoclastogenicity tests were negative. Industry has provided data on uterotrophic assays in rats for OMC (not according to OECD guidelines, but under GLP conditions), in which no positive uterotrophic effect could be detected.

3. Isopropyl Myristate

CAS No.: 110-27-0

EINECS/ELINCS: 203-751-4

CLP Classification: N/A

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: Safe to be used up to 77.3% for leave-on products; 67% for rinse-off products; 22% for diluted use products

Food additive recommendation: None

Toxicological profile by chemical supplier: None

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NOAEL: 5500 mg/kg bw/day (read across to Ethyl Oleate)

SED: 7.5000000000 mg/kg bw/day

MOS: 366

Isopropyl Myristate is the ester of isopropyl alcohol and myristic acid. It is used for binding, emollient, perfuming, skin conditioning and as solvent. The oral LD50 was indicated to be greater than 16ml/kg in rats and 49.7ml/kg in mice. Isopropyl Myristate is also considered not acute and chronic dermal toxic to animals. No toxic effects were observed in subchronic inhalation toxicity studies in guinea pigs and in cynomolgus monkeys. Isopropyl myristate at concentrations up to 100% produced minimum eye irritation in rabbits. Undiluted isopropyl myristate produced no more than mild irritation in 24 hour in primary skin irritation studies with rabbits. Subchronic skin irritation studies for 28 days with mice and 14 days with rabbits showed moderate irritation. It was reported to be minimally irritating to the rabbit eye and was not a skin sensitizer in studies with guinea pigs. Human studies with isopropyl myristate indicated that it was not a human skin irritant or sensitizer when applied in a product formulation containing 15% to 58% of the ingredient. A product containing 43% of isopropyl myristate produced no phototoxicity and no photocontact allergenicity in human studies. Isopropyl Myristate is not genotoxic and carcinogenic. The CIR Expert Panel concluded that it is safe in the present practices of use and concentration when formulated to be nonirritating.

4. Caprylic/Capric Triglyceride

CAS No.: 73398-61-5 / 65381-09-1

EINECS/ELINCS: 277-452-2 / 265-724-3

CLP Classification: N/A

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: Safe to be used up to 95.6% for leave-on products; 89.2% for rinse-off products; 0.099% for diluted use products

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 5000 mg/kg bw/day

SED: 7.5000000000 mg/kg bw/day

MOS: 333

Caprylic/Capric Triglyceride is the mixed triester of glycerin and caprylic and capric acids, and is used as masking, perfuming and skin conditioning in cosmetic products. Acute oral LD50 values for Caprylic/Capric Triglyceride were >25 ml/kg in mice and >5 g/kg in rats. In human testing, a facial oil containing 95.51% Caprylic/Capric Triglyceride was not an irritant in a 24-h single insult occlusive patch test in 17 subjects, was not a sensitizer in a human modified maximization patch test with 26 subjects, and was not a photosensitizer. Undiluted Caprylic/Capric Triglyceride was not irritating in rabbit eyes. Short-term and subchronic feeding studies were conducted with Caprylic/Capric Triglyceride. The CIR Expert Panel concluded that the Caprylic/Capric Triglyceride is safe in cosmetics in the present practices of use and concentration.

5. Cetearyl Alcohol

CAS No.: 67762-27-0 / 8005-44-5

EINECS/ELINCS: 267-008-6 / -

CLP Classification: N/A

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: Safe as used in rinse off product up to 15% and safe at concentration up to 13% in leave on products

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 1000 mg/kg bw/day (Read across to Stearyl Alcohol)

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SED: 0.1500000000 mg/kg bw/day (Dermal absorption 1%)

MOS: 3333

Cetearyl Alcohol is a mixture of fatty alcohols consisting predominantly of cetyl and stearyl alcohols. It is a white, waxy solid, usually in flake form, and is insoluble in water and soluble in alcohol and oil. It is widely used in skin lotions and creams as emollient, emulsion stabilizer, viscosity control agent, coupling agent and foam stabilizer. Cetearyl alcohol was not mutagenic in *Salmonella typhimurium* LT2 mutant strains in the spot test. The oral LD50 of cetearyl alcohol in fasted rats was more than 8.2 g/kg. It induced minimal ocular and skin irritation but no sensitization or comedogenicity in rabbits; and clinical studies indicated a low order of skin irritation and sensitization. Furthermore, results were negative in clinical phototoxicity and photosensitization studies. The CIR Expert Panel concluded that Cetearyl alcohol is safe as cosmetic ingredient in the present practices of use. Repeated exposure to aliphatic alcohols is generally without significant systemic toxicological findings and this category is therefore regarded to be of a low order of toxicity upon repeated exposure.

According to the ECHA Registered substance database, the QSAR model predicts the permeability of this ingredient to human skin is quite low. The permeability coefficient was determined to be 0.001 mg/cm², which is around 1% of the skin penetration rate. Predicted dermally absorbed coefficient was determined to be K_p (est)=2.04 cm/hr.

6. 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: 7.5000000000 mg/kg bw/day

MOS: 146

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 carcinogenic to rats in a long-term feeding study. There

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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 \geq 2200 mg/kg/d.

7. Ethylhexyl Salicylate

CAS No.: 118-60-5

EINECS/ELINCS: 204-263-4

CLP Classification: N/A

EU Cosmetic Regulation: Annex VI: Maximum concentration in ready for use preparation is 5% as UV filter
SCCS opinion: None

CIR recommendation: Safe to be used up to 5.1% for leave on products and 0.21% for rinse off products when formulated to avoid irritation and to avoid increasing sun sensitivity, or when increased sun sensitivity would be expected, directions for use include the daily use of sun protection.

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: --

SED: 7.50000000 mg/kg bw/day

MOS: --

Ethylhexyl Salicylate is the ester of 2-ethylhexyl alcohol and salicylic acid. Ethylhexyl Salicylate is used as sunscreen agent, and UV light absorber. The SCCS has reviewed this ingredient (SCCS/1860/95) and indicated that this ingredient has low oral acute toxicity, low dermal and oral sub-chronic toxicity with a high no effect level, as well as negative result to irritation and corrosively. Repeated exposure to the compound in man, in the course of two separate experiments, showed no adverse effects. Test for photo-toxicity, photo-contact allergy in man; mutagenicity, clastogenicity, photo-mutagenicity and photo-clastogenicity, using bacterial and tissue culture test systems were negative. Tests for percutaneous absorption in the course of 6 experiments using human skin ex vitro showed very low absorption. The margin of safety was accordingly judged to be very high. The compound had been the subject of provisional authorisation for a substantial period of time, and no adverse effects in use had been reported. The dermal LD50 in rabbits exceeded 5.0 g/kg. For the developmental toxicity, based on observations of increased post-implantation loss, reduction in the gestation index, and lower litter size, the no-observe-adverse-effect-level (NOAEL) for developmental toxicity was determined to be 25 mg/kg/day. Clinical tests for cumulative irritation are available for the Ethylhexyl Salicylate at 4% indicates there is no irritation. In a 48-h closed patch test involving 23 male subjects, 4% Ethylhexyl Salicylate in petrolatum did not cause skin irritation. Maximization test data on Ethylhexyl Salicylate indicate that skin sensitization was not observed in guinea pigs (number not stated) induced with 2.5% Ethylhexyl Salicylate (intradermally) and 50% Ethylhexyl Salicylate (topically) and challenged with a 25% solution of Ethylhexyl Salicylate in ethanol/diethyl phthalate (DEP) (1:1).

8. C12-15 Alkyl Benzoate

CAS No.: 68411-27-8

EINECS/ELINCS: 270-112-4

CLP Classification: None

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: Safe as used in rinse off product up to 50% and safe at concentration up to 59% in leave on products

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: --

SED: 6.0000000000 mg/kg bw/day

MOS: --

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C12-15 Alkyl Benzoate is the ester of benzoic acid and C12-15 alcohols. Orally administered C12-15 Alkyl Benzoate was not toxic to rats at 5000 g/kg. C12-15 Alkyl Benzoate at 100% was not dermally toxic, mildly dermal irritating to rabbits, and not irritating dermally to humans; but it was a mild ocular irritant in in vivo tests. In guinea pigs, up to 10% of C12-15 Alkyl Benzoate was nonsensitizing. It was not genotoxic and phototoxic. Data on reproductively toxicity is not available, but structurally similar isononyl benzoate demonstrated an absence of reproductively/developmental toxicity. Due to the lack of irritation at use concentrations when used in cosmetic formulation, alkyl benzoates are not expected to result in any cytotoxicity. The particle sizes produced by cosmetic aerosols containing alkyl benzoates are not respirable. C12-15 Alkyl Benzoate is expected to be poorly absorbed through the skin and therefore would not likely cause systemic toxicity. However, if it penetrated the skin, it may be cleaved and results in systemic exposure to the component alcohol and benzoic acid, which are not carcinogenic, genotoxic, reproductive toxic, and dermal sensitizers. In acute inhalation toxicity study on 10 Wistar-derived rats, the LC50 of the test material was determined as being >200 mg/l. There was a 10 % (1 out of 10 rats) mortality observed in the exposed rats. Under the conditions of this study, C12-15 Alkyl Benzoate is considered to be not toxic by inhalation to rats. The CIR Expert Panel concluded that C12-15 Alkyl Benzoate is safe in present practice of use and concentration.

9. Ceteth-25

CAS No.: 9004-95-9

EINECS/ELINCS: N/A

CLP Classification: None

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: None

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: --

SED: 4.5000000000 mg/kg bw/day

MOS: --

Ceteth-25 is the polyethylene glycol ether of Cetyl Alcohol, it is manufactured by the ethoxylation of cetyl alcohol with 25 moles of ethylene oxide. Ceteths are surfactants used as emulsifying, cleansing, and solubilizing agents in cosmetic formulations. Limited safety test data are available on ingredients in the Ceteth family, all consistent with surfactant properties. Irritation effect of ceteth is seen on abraded skin but not intact skin. Although metabolites of ethylene glycol monoalkyl ethers are reproductive and developmental toxins, it was considered unlikely that the relevant metabolites would be found in or produced from the use of Ceteths in cosmetic formulations.

The submitted certificate of analysis (Batch No. 21031802), as supplied by Hangzhou Electrochemical Group Auxiliary Chemical Co., Ltd., on the trade name CETETH-25, indicates that dioxane is not detected, with detection limit of 0.01%. It is the manufacturer's responsibility to ensure each batch of the ingredient used in the formulations are of acceptable grade to substantiate the safety of the product and to comply with the EU Cosmetic Regulation. If it is not the case, it will void this assessment.

10. Glyceryl Stearate

CAS No.: 31566-31-1 / 11099-07-3 / 123-94-4 / 85666-92-8 / 85251-77-0

EINECS/ELINCS: 250-705-4 / 234-325-6 / 204-664-4 / - / -

CLP Classification: N/A

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: Safe as used in rinse off product up to 18.9% and safe at concentration up to 17% in leave on products

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Food additive recommendation: None
 Toxicological profile by chemical supplier: None
 NOAEL: 2500 mg/kg bw/day (Read across)
 SED: 4.5000000000 mg/kg bw/day
 MOS: 277

Glyceryl Stearate is the monoester of glycerin and stearic acid. 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 non-toxic 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).

11. Benzophenone-3

CAS No.: 131-57-7

EINECS/ELINCS: 205-031-5

CLP Classification: N/A

EU Cosmetic Regulation: Annex VI/4: Maximum concentration is 6% in face products, hand products, and lip products, excluding propellant and pump spray products; 2.2% in body products, including propellant and pump spray products; and 0.5% in other products

SCCS opinion: SCCS/1625/20

CIR recommendation: Safe to be used up to 7%

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 200 mg/kg bw/day

SED: 0.6000000000 mg/kg bw/day (take 10% dermal absorption)

MOS: 166

Benzophenone-3 is a benzophenone derivative. The safety of Benzophenone-3 for its usage in sunscreen products for over the counter (OTC) products was first peer reviewed by the US FDA in 1978. Based on the data available at that time the FDA expert panel classified Benzophenone-3 as safe and effective. Benzophenone-3 displays a low acute toxicity profile with oral and dermal LD50-values exceeding the classification limit of 2000 mg/kg. Benzophenone-3 is not considered as being irritating to the skin and the eyes, nor sensitizing to skin. However, it is a photoallergen. Benzophenone-3 can be used as UV filters as 6% in face products, hand products, and lip products, excluding propellant and pump spray products, but not more than 0.5% to protect product formulation; 2.2% in body products, including propellant and pump spray products, but not more than 0.5% to protect product formulation, according to the EU Cosmetic Regulation with warning "Contains Benzophenone-3"; 0.5% in other products, not more than 0.5%. The warning can be exempted if the concentration is 0.5% or less and when it is used only for product protection purpose.

12. Titanium Dioxide

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

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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: N/A

CIR recommendation: None

Food additive recommendation: None

Toxicological profile by chemical supplier:

NOAEL: --

SED: 3.0000000000 mg/kg bw/day

MOS: --

Titanium dioxide is the inorganic oxide with an empirical formula O_2Ti . 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 2008/128/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's specifications 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. On Jun 9, 2017, the ECHA's Committee for Risk Assessment (RAC) assessed the carcinogenic potential of titanium dioxide against the criteria in the Classification, Labelling and Packaging (CLP) Regulation and, having considered the available scientific data, concluded that it meets the criteria to be classified as suspected of causing cancer (category 2, through the inhalation route) (ECHA/PR/17/10). The committee also concluded that there was insufficient evidence to classify titanium dioxide in the more severe category for carcinogenicity (category 1B) as was originally proposed by the French Agency for Food, Environmental and Occupational Health and Safety (Anses). The proposed opinion will be formally adopted later by written procedure. For titanium dioxide (nano), commission regulation (EU) 2019/1857 of 6 November 2019 indicated the following conditions has to be fulfilled: Not to be used in applications that may lead to exposure of the enduser's lungs by inhalation. Only nanomaterials having the following characteristics are allowed: — purity $\geq 99\%$, — rutile form, or rutile with up to 5 % anatase, with crystalline structure and physical appearance as clusters of spherical, needle, or lanceolate shapes, — median particle size based on number size distribution ≤ 30 nm, — aspect ratio from 1 to 4,5, and volume specific surface are ≤ 460 m²/cm³, — coated with Silica, Hydrated Silica, Alumina, Aluminium Hydroxide, Aluminium Stearate, Stearic Acid, Trimethoxycaprylylsilane, Glycerin, Dimethicone, Hydrogen Dimethicone, Simethicone, or coated with one of the following combinations: — Silica at a maximum concentration of 16 % and Cetyl Phosphate at a maximum concentration of 6 %, — Alumina at a maximum concentration of 7 % and Manganese Dioxide at a maximum concentration of 0,7 % (not to be used in lip products), — Alumina at a maximum concentration of 3 % and Triethoxycaprylylsilane at a maximum concentration of 9 %, — photocatalytic activity $\leq 10\%$ compared to corresponding non-coated or non-doped reference, — nanoparticles are photostable in the final formulation. Wording of conditions of use and warnings For face products containing Titanium Dioxide (nano) coated with the combination Alumina and Manganese Dioxide: Not to be used on the lips.

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13. Parfum (VANILLA MY11-S089)

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, H317, H319 and H411

NOAEL: --

SED: 0.4500000000 mg/kg bw/day

MOS: --

Parfum (VANILLA MY11-S089) as supplied by MEIYI Flavor Fragrance CO., LTD and the corresponding IFRA certificate of 50th amendment was provided, was used at 0.3% in the formulation. The industry recommendations are applicable and the submitted IFRA Certificate indicates up to 4.75% of this parfum can be used in leave on sunscreen lotion product (Class 5A product).

14. DMDM Hydantoin

CAS No.: 6440-58-0

EINECS/ELINCS: 229-222-8

CLP Classification: N/A

EU Cosmetic Regulation: Annex V: Maximum authorized concentration is 0.6%

SCCS opinion: Same as EU Cosmetic Regulation

CIR recommendation: Safe to be used up to 1%

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 440 mg/kg bw/day

SED: 0.4500000000 mg/kg bw/day

MOS: 488

DMDM Hydantoin is a preservative, which is used in cosmetic products at concentrations up to 1%. It is a formaldehyde donor containing up to 2% of the free aldehyde in equilibrium with the hydantoin. The LD50 dermal and oral toxicity of DMDM hydantoin was greater than 2 g/kg. No significant toxic effects were noted in a subchronic oral toxicity study. In skin irritation studies using product formulations, results ranged from non-irritating to moderate skin irritation. At most, transient minimal irritation was noted in albino rabbits treated with DMDM hydantoin formulations. In clinical studies, skin irritation ranged from none to observations of intense erythema and edema when various formulations containing DMDM hydantoin were applied. DMDM hydantoin formulations did not induce sensitization in some clinical studies. DMDM hydantoin formulations were neither phototoxic nor photoallergenic. Use of DMDM hydantoin at its current concentration of use in cosmetic products would not expose the consumer to levels of formaldehyde above the limit previously considered as acceptable in cosmetic products. Based on the available data, it is concluded that DMDM hydantoin is safe as a cosmetic ingredient in the present practices of use. However, all finished products containing formaldehyde releaser which release formaldehyde must be labelled with the warning 'contains formaldehyde' where the concentration of formaldehyde in the finished product exceeds 0.05 % according to the EU Cosmetic Regulation.

15. Methylparaben

CAS No.: 99-76-3

EINECS/ELINCS: 202-785-7

CLP Classification: None

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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: 0.3000000000 mg/kg bw/day

MOS: 1666

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 17 β -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 17 β -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 17 β -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.

16. 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 concen

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: 1000 mg/kg bw/day (NOEL)

SED: 0.1500000000 mg/kg bw/day

MOS: 3333

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, non-carcinogenic, non-

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Test Report

No. HKHC2208006137HC

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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 17 β - 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 17 β -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 17 β -estradiol level. The EU Cosmetic regulation limits propylparaben at 0.14% (as 4-hydroxybenzoic acid) for single ester; 0.8% (as 4-hydroxybenzoic acid) for mixtures of esters, and it is not to be used in leave-on products designed for application on the nappy area of children under three years of age.

***** End of Annex *****

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