MID OCEAN BRANDS B.V.
WELLENSIEKSTRAAT 2，6718 XZ EDE，THE NETHERLANDS

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

Net Weight	:	45 mL per consumer product
Style/Item No.	:	MO6115
SGS Report No.	:	HKHC1911009195HC
SGS Case No.	:	HKHC191100003688-101 (XMCPCH191101374)
Manufacturer	:	113285
Region of Origin	:	China
Region of Destination	:	EU
Sample Receiving Date	:	Nov 19, 2019 – Nov 21, 2019
Test Period	:	Nov 19, 2019 – Nov 27, 2019

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.

Cc

Shuping Yu, Cecilia
MSc (Food safety and Toxicology), MSc (Bioscience), MRSB
Cosmetic Safety Assessor

PART A - COSMETIC PRODUCT SAFETY INFORMATION

INTRODUCTION

SGS is requested to review the safety of the product 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 protection by children above 3 years old. Neither the efficacy nor the claim of the product has been verified or assessed in this report. This product is assessed based on cosmetic product.
The net weight of the product (The formulation under assessment) is 45 mL 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	51.2500	Solvent
Ethylhexyl Methoxycinnamate	5466-77-3	226-775-7	7.0000	Uv absorber / uv filter
Caprylic/Capric Triglyceride	65381-09-1	265-724-3	5.0000	Masking / perfuming / skin conditioning
Cetearyl Alcohol	67762-27-0	267-008-6	5.0000	Emollient / emulsifying / emulsion stabilising / foam boosting / opacifying / surfactant / viscosity controlling
Isopropyl Myristate	110-27-0	203-751-4	5.0000	Binding / emollient / masking / perfuming
Glycerin	56-81-5	200-289-5	5.0000	Denaturant / hair conditioning / humectant / masking / oral care / perfuming / skin protecting / viscosity controlling
Ethylhexyl Salicylate	118-60-5	204-263-4	4.0000	Uv absorber / uv filter
Titanium Dioxide	13463-67-7	236-675-5	4.0000	Cosmetic colorant / opacifying / uv absorber / uv filter
C12-15 Alkyl Benzoate	68411-27-8	270-112-4	4.0000	Antimicrobial / emollient / skin conditioning
Benzophenone-3	131-57-7	205-031-5	3.0000	Uv absorber / uv filter
Ceteth-25	9004-95-9	N/A	3.0000	Cleansing / emulsifying / surfactant
Glyceryl Stearate	123-94-4	204-664-4	3.0000	Emollient / emulsifying
Parfum (MY11-S089 Vanilla)	N/A (Mixture)	N/A (Mixture)	0.3000	Deodorant / masking / perfuming
DMDM Hydantoin	6440-58-0	229-222-8	0.2500	Preservative
Propylparaben	94-13-3	202-307-7	0.1000	Perfuming / preservative
Methylparaben	99-76-3	202-785-7	0.1000	Preservative

FRAGRANCE ALLERGENS

Fragrance allergens **BENZYL BENZOATE** 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 coloured lotion, with pH 5.9 and fragrance MY11-S089 Vanilla.

2.2 The stability test results on formulation, by in house method of manufacturer, on product name SUNSCREEN LOTION with item no. JS-03004, with a testing period Mar 04 – Jun 04, 2018, were 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.

Testing conditions : -15℃, -5℃, 25℃, 40℃ light exposure and cycle test

Testing parameters : Appearance, colour, odour, pH, and TVC bacteria

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 third party laboratory (SGS report no. XMCPCH180901037.1), with testing period Sep 13 – Sep 21, 2018, were submitted and reviewed based on following criteria as required by the SCCS Note of Guidance. Test results of Salmonella, Bile- Tolerant Gram-Negative Bacteria, and Clostridia were also reviewed.

Product Category of this product: 2

Micro-organisms	Total viable count and Total yeast and mold	*E. Coli, P.aeruginosa*, *S.aureus* and *C.albicans*
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 Pharmacopeia 9.0 5.1.3, by in third party laboratory (SGS report no. XMCPCH180901037.3), with testing period Sep 13 – Oct 24, 2018, was submitted and reviewed based on following criteria.

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

NI: No increase

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

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

4.1 The heavy metal test result on formulation, by third party laboratory (SGS report no. XMCPCH180901037.2), with testing period Sep 14 – Sep 19, 2018, 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.

No.	Immediate Container	Material
1.	Bottle	PE
2.	Cover	PP
3.	Aluminum mountaineering buckle	Aluminum

4.3 For packaging material, test results of lead, cadmium, mercury and chromium (VI) of immediate container by third party laboratory (SGS report no. XMCPCH191001235), with testing period Oct 21 – Oct 24, 2019, was submitted and reviewed based on following criteria, indicate the total amount is less than 100ppm.

For the packaging material Aluminum mountaineering buckle, no supporting material on the chemical purity has been provided by the time of assessment. It is recommended to provide the relevant information to demonstrate its chemical purity.

Conclusion: The heavy metal content of the packaging material PE bottle and PP cover is acceptable.

4.4 Packaging compatibility test result on packaging material, indicated to be tested together with the product, by in house method of manufacturer, on product name SUNSCREEN LOTION with item no. JS-03004, with a testing period Mar 04 – Jun 04, 2018, were submitted and reviewed.

Testing conditions : -15℃, -5℃, 25℃, 40℃ light exposure and cycle test

Testing parameters : 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 3 years old or above. Application of this product to face is possible. Ingestion of this product would be a misuse.

6 Exposure to the cosmetic product

Product type: Skin care cosmetics
Use category: Sunscreen lotion
Physical form: Liquid
The site(s) of application: Body skin
The surface area(s) of application: 6100 square centimeter
The amount per application: 3.43 g
The duration of exposure: 720 minutes
The frequency of use: 832 times per year
The normal and reasonably foreseeable exposure route(s): Primarily via dermal contact
The targeted (or exposed) population(s): Children above 3 years old
The body weight: 15.1 kg
Estimated daily amount applied: 7819 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)ELsys by the SED, when NO(A)EL or relevant Point of Departure (POD) is available in the present stage of knowledge.

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 in a manufacturing setting in compliance with the requirement of GMP with reference to ISO22716:2007(E) COSMETICS – GUIDELINES ON GOOD MANUFACTURING PRACTICES, with scope of registration on Manufacturing of General Liquid Unit, Including Hair Care & Cleansing Products, Manufacturing of Cream & Lotion Unit, Including Skin Care & Cleansing Products, and Manufacturing of Wax Base Unit, Including Lipstick and Lip Balm (Intertek Certificate No. SZ1705B1 which is valid until May 11, 2020).

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

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.
Contains Benzophenone-3

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, be sensitizing, 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 of eye may cause 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. In addition, it should be drawn to the attention that all finished products containing formaldehyde releaser which release formaldehyde must be labelled with the warning 'contains formaldehyde' when the concentration of formaldehyde in the finished product exceeds 0.05% according to the EU Cosmetic Regulation. 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 0.05% formaldehyde.
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 ISO 22716:2007 Cosmetic GMP. No test result or supporting material on the chemical purity of the packaging material aluminum mountaineering buckle has been provided by the time of assessment. It is recommended to provide the relevant information to demonstrate its chemical purity.
This product is a sunscreen product, appropriate warning statements and usage instructions must be labelled according to the sunscreens recommendation 2006/647/EC, to ensure its safe use and its compliance with the regulation.

4. Assessor's credentials and approval of Part B

Date: Nov 27, 2019

Shuping Yu, Cecilia MSc (Food safety and Toxicology), MSc (Bioscience), MRSB

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.

******** End of Report ********

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: 33.3915982 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: 0.182432148 mg/kg bw/day (The percutaneous absorption was estimated to be 2%)
MOS: 1431
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. 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%

Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 5000 mg/kg bw/ day
SED: 3.2577169 mg/kg bw/day
MOS: 767
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 is 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.

4. 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 to be used up to 25%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 1000 mg/kg bw/day (Read across to Stearyl Alcohol)
SED: 3.2577169 mg/kg bw/day
MOS: 153
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 photoxicity 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.

5. 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 82%
Food additive recommendation: None

Toxicological profile by chemical supplier: None
NOAEL: 5500 mg/kg bw/day (read across to Ethyl Oleate)
SED: 3.2577169 mg/kg bw/day
MOS: 844
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.

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: 3.2577169 mg/kg bw/day
MOS: 338
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.

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 from 0.001 - 5% 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: 2.6061735 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.

8. 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
EU Cosmetic Regulation: Annex IV; Annex VI: Maximum concentration in ready for use preparation is 25% as UV filter (sum of Titanium Dioxide and Titanium Dioxide (nano))
SCCS opinion: No
CIR recommendation: None
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 2.6061735 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 95/45/EC (E171). IARC concluded that there is inadequate evidence in humans for the carcinogenicity of titanium

dioxide but sufficient evidence in experimental animals for the carcinogenicity of titanium dioxide. Both nano and non nano size Titanium dioxide was classified as a Group 2B carcinogen (Possibly carcinogenic to humans). Titanium dioxide particles have shown to lead to carcinogenic effects after inhalation. Therefore the SCCS does not recommend the use of nano titanium dioxide in applications that might lead to inhalation exposure to the nanoparticles (such as powders or sprayable products). However, due to the lack of penetration of titanium dioxide nanoparticles through human skin, systemic exposure of the titanium dioxide to reach viable cells of the epidermis, dermis, or other organs is unlikely. Therefore, the SCCS considers that the use of nano titanium dioxide in dermally applied cosmetic products should not pose any significant risk to the consumer. The EU Cosmetic Regulation currently allows the safe use of titanium dioxide as a UV-filter at a maximum concentration of 25% in cosmetic products. In light of the SCCS opinions mentioned above, titanium dioxide (nano), according to the SCCS's specifications, should be authorised for use as a UV-filter in cosmetic products at a maximum concentration of 25 % w/w, except in applications that may lead to exposure of the end-user's lungs by inhalation.
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.

9. 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 to be used up to 59%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 1000 mg/kg bw/day (Read across to Isononyl Benzoate)
SED: 2.6061735 mg/kg bw/day
MOS: 192

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.

10. Benzophenone-3

CAS No.: 131-57-7

EINECS/ELINCS: 205-031-5

CLP Classification: N/A

EU Cosmetic Regulation: Annex VI: Maximum authorized concentration in ready for use preparation is 6%

SCCS opinion: the use of benzophenone-3 as a UV-filter up to 6% in cosmetic sunscreen products and up to 0.5% in all types of cosmetic products to protect the formulation does not pose a risk to the health of the consumer, apart from its contact allergenic and photoallergenic potential.

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: 0.39092602 mg/kg bw/day (10% dermal absorption)

MOS: 255

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 up to 6%, but not more than 0.5% to protect product formulation, according to the EU Cosmetic Regulation with warning “Contains Benzophenone-3”. The warning can be exempted if the concentration is 0.5% or less and when it is used only for product protection purpose.

11. 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: 1.9546301 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 Certificate of Analysis (COA) of the ingredient with product name Ceteth-25 has been provided by the supplier. It indicates that the 1,4-dioxane content in the product is not detected. The ingredient shall be of

acceptable purity and free from technically unavoidable amount of contaminants as a cosmetic ingredient. If it is not the case, it will void this assessment.

12. 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 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: 1.9546301 mg/kg bw/day
MOS: 640
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).

13. Parfum (MY11-S089 Vanilla)

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, H411
NOAEL: --
SED: 0.1954630 mg/kg bw/day
MOS: --
Parfum MY11-S089 Vanilla as supplied by Meiyi Flavor Fragrance Co., Ltd and the corresponding IFRA certificate of 48th amendment, allergen declaration and MSDS, was used at 0.3% in the formulation. The industry recommendations are applicable and the submitted IFRA Certificate indicates up to 15.67% of this parfum can be used in leave on lotion product (Class 3C 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: 0.1628858 mg/kg bw/day
MOS: 1351
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.
The Certificate of quality analysis of this ingredient with trade name K2000 Preservative indicates the raw material contains 0.20% free formaldehyde and 17.75% total formaldehyde.

15. 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: 0.0048214182 mg/kg bw/day (3.7% dermal absorption as suggested in SCC)
MOS: 207
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- 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.

16. 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: 0.0651543 mg/kg bw/day

MOS: 7674

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).

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