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

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

Net Weight	:	5 g per consumer product
Style/Item No.	:	MO9890/IT2698/MO9407/KC7094/MO9373/MO9374/MO8740/ KC6655/MO9586/MO9807/CX1470
SGS Report No.	:	HKHC2007005709HC
SGS Case No.	:	HKHC200700002518 – 101 (XMCPCH200701225)
Buyer	:	MID OCEAN BRANDS B. V
Manufacturer	:	113285
Region of Origin	:	China
Region of Destination	:	EU
Sample Receiving Date	:	Jul 16 – Aug 18, 2020
Test Period	:	Jul 16 – Aug 25, 2020

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

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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 formula LIP BALM for consumer health and no other part of the product. The product is for EU market and intended for application on lips for keeping it in good condition by children of 3 years old above.
The net weight of this product (The formulation under assessment) is 5 g 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
Paraffinum Liquidum	8042-47-5	232-455-8	30.0000	Antistatic / emollient / skin protecting / solvent
Petrolatum	8009-03-8	232-373-2	22.3600	Antistatic / emollient
Ceresin	8001-75-0	232-290-1	15.0000	Antistatic / binding / emulsion stabilising / hair conditioning / opacifying / viscosity controlling
Polyisobutene	9003-27-4	N/A	10.0000	Binding / film forming / viscosiity controlling
Beeswax	8012-89-3	232-383-7	5.0000	Emollient / emulsifying / film forming / perfuming
Butyrospermum Parkii Butter	194043-92-0	N/A	5.0000	Skin conditioning
Benzophenone-3	131-57-7	205-031-5	4.0000	Uv absorber / uv filter
Microcrystalline Wax	63231-60-7	264-038-1	4.0000	Binding / bulking / emulsion stabilising / viscosity controlling
Ethylhexyl Methoxycinnamate	5466-77-3	226-775-7	2.0000	Uv absorber / uv filter
Ethylhexyl Salicylate	118-60-5	204-263-4	2.0000	Uv absorber / uv filter
Phenoxyethanol	122-99-6	204-589-7	0.5000	Preservative
Tocopherol	59-02-9	200-412-2	0.1000	Antioxidant / masking / skin conditioning
Parfum (Vanilla MY12-B018)	N/A (mixture)	N/A (mixture)	0.0400	Perfuming

FRAGRANCE ALLERGENS

None of the 26 fragrance allergens was present in the parfum as indicated by the supplier declaration.

2 Physical/chemical characteristics and stability of the formulation

2.1 The product is white colored solid with the fragrance (Vanilla MY12-B018) and pH value of 7.06.

2.2 The stability test result on formulation, by in house method of manufacturer Yuyao Jessie Commodity Co., Ltd. (item no. JS-02028), on product name LIP BALM, with a testing period Apr 17 – Jul 17, 2019, 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.

Testing conditions : -5°C, -15°C, 25°C, 40°C, light exposure for 12 weeks; Cycle test (40°C(8hrs) >4°C(8hrs)> 40°C(8hrs)> 4°C(8hrs)> room temperature (4hrs))

Testing parameters : Appearance, colour, odour, pH value 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 Pharmacopeia 9.0 2.6.12 and 2.6.13, by third party laboratory (SGS report no. XMCPCH180901035.1), with a testing period of Sep 13 – 21, 2018, was submitted and reviewed based on following criteria as required by SCCS Notes of Guidance.
Product Category of this product: 1

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 a third-party laboratory (SGS report no. XMCPCH180901035.3), on product name Lip balm, 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 results on formulation, by a third party laboratory (SGS report no. CANCPCH2012084101), with testing period of Jul 17 – 23, 2020, 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	ABS

4.3 For packaging material, test results of lead, cadmium, mercury and chromium (VI) of immediate container by a third party laboratory (SGS report no. XMCPCH2000942901), with a testing period of Jul 16 – 21, 2020, indicate the total amount is less than 100ppm.
Conclusion: The heavy metal content of the packaging material is acceptable.

4.4 Packaging compatibility test results on packaging material, by in house method of manufacturer Yuyao Jessie Commodity Co., Ltd. (item no. JS-02028), on product name LIP BALM, with a testing period Apr 17 – Jul 17, 2019, was submitted and reviewed.

Testing conditions	:	-5°C, -15°C, 25°C, 40°C, light exposure for 12 weeks; cycle test (40°C(8hrs) >4°C(8hrs)> 40°C(8hrs)> 4°C(8hrs)> room temperature (4hrs))
Testing parameters	:	Appearance, 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 lips by children of 3 years old above. The application to other parts of the body is unlikely. Ingestion of small amount of this product would be possible.

6 Exposure to the cosmetic product

Product type: Makeup cosmetics
Use category: Lip balm
Physical form: Solid
The site(s) of application: Lips
The surface area(s) of application: 4.8 square centimeter
The amount per application: 0.0285 g
The duration of exposure: 360 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 3 years old or above
The body weight: 15.1 kg
Estimated daily amount applied: 57 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 by Yuyao Jessie Commodity Co., Ltd., in a manufacturing setting according to Cosmetic Good Manufacturing Practice Guidelines (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-2-0076 which is valid until Jun 03, 2021).

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
Keep it out of reach of children unless use under adult supervision.

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.
As there is a chance of ingestion of this lip product with customary use, the ingredients used should be of food grade or any appropriate grade.
The formulation is not expected to be irritating to the eye, skin and respiratory tract, be sensitizing, phototoxic, and is unlikely to cause damage to internal organs through ingestion, skin and inhalation in the majority of consumers under normal and reasonably foreseeable conditions of use. Accidental exposure to eyes may cause slight irritation.
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 Cosmetic GMP guidelines as published by US FDA.

4. Assessor's credentials and approval of Part B

Date: Aug 25, 2020

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.

herein. The opinions provided by the Company are not a substitute for professional legal advice and Client should seek legal review to ensure compliance with any applicable laws and regulations.

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

ANNEX 1 TOXICOLOGICAL PROFILE OF INDIVIDUAL INGREDIENT

1. Paraffinum Liquidum

CAS No.: 8012-95-1 / 8042-47-5 / 8020-83-5
EINECS/ELINCS: 232-384-2 / 232-455-8
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: 1200 mg/kg bw/day (only high viscosity MHC applied)
SED: 0.1425000 mg/kg bw/day
MOS: 4211

Paraffinum Liquidum / 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.

It is the responsibility of the manufacturer to ensure the ingredient used is of acceptable chemical purity and does not contain hazardous amounts of residue and contaminants as well as the physicochemical properties conforming to the recommendation of Cosmetic Europe to substantiate the safety of the product and complies with the EU Cosmetic Regulation. If it is not the case, it will void the assessment. Studies found that only less than 0.1% of applied dose was found in the dermis of guinea pigs skin after application of hexadecane in mineral oil topically; 0% and less than 0.01% of the applied dose has been reported in an In vitro human skin penetration studies with topical application of [14C]n-pentadecane and [14C]n-undecane in chlorinated paraffins respectively. It was found that the depth of penetration of hydrocarbons is limited to the stratum corneum in human skin. Therefore, it is concluded that these data support the view that mineral oil does not effectively penetrate the skin beyond the stratum corneum, resulting in minimal (<1%) absorption of white minerals oils after topical exposure (Nash et al., 1996). Petrolatum does not appear to penetrate beneath the stratum corneum at time points when physiologic lipids of comparable chain length are rapidly absorbed, such penetration was also insignificant when it is applied on damaged skin (about 90% of the applied petrolatum remained on the surface of the damaged skin after 2.5 hours). Therefore, it is very unlikely that relevant quantities of white mineral hydrocarbons enter the general circulation after intermittent topical administration to either intact or damaged skin; i.e., relevant toxicological effects should not occur under these conditions. (Brown et al., 1995). A 10% dermal absorption was taking into account in calculating the SED to demonstrate the actual scenario.

The submitted document for the ingredient, in the product name PIONIER 1204 MINERAL OIL, as supplied by H&R China (Daxie) Co., Ltd, indicates the PAHs is not detected.

2. Petrolatum

CAS No.: 8009-03-8
EINECS/ELINCS: 232-373-2
CLP Classification: Carc. 1B, H350

EU Cosmetic Regulation: Annex II (except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen)
SCCS opinion: None
CIR recommendation: None
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 5000 mg/kg bw/day
SED: 0.1062100 mg/kg bw/day
MOS: 23538
Petrolatum is a complex combination of hydrocarbons obtained as a semi-solid from dewaxing paraffinic residual oil. It consists predominantly of saturated crystalline and liquid hydrocarbons having carbon numbers predominantly greater than C25. It is used as hair conditioning agents, skin protectants, skin conditioning agents in cosmetic. It cannot be used as a cosmetic ingredient except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen according to the EU Cosmetic Regulation. It is not irritating to eye and skin. With an estimated Oral LD50 of >5000mg/kg of body weight, the test material is considered practically nontoxic. White petrolatum when applied undiluted was not observed to be a dermal sensitizer in male and female guinea pigs.
It is the responsibility of the manufacturer to ensure the ingredient used is of acceptable chemical purity and does not contain hazardous amounts of residue and contaminants as well as the physicochemical properties conforming to the recommendation of Cosmetic Europe, from batch to batch, to substantiate the safety of the product and complies with the EU Cosmetic Regulation. If it is not the case, it will void the assessment.
The submitted document for the ingredient, in the product name Petrolatum, as supplied by H&R China (Ningbo) Co., Ltd, indicates the PAH is not detected.

3. Ceresin
CAS No.: 8001-75-0
EINECS/ELINCS: 232-290-1
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 20%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 0.0712500 mg/kg bw/day
MOS: --
Ceresin is a complex combination of hydrocarbons produced by the purification of ozocerite with sulfuric acid and filtration through bone black to form waxy cakes. It is used as antistatic, binding, emulsion stabilising, hair conditioning, opacifying and viscosity controlling in cosmetic. No death in rats given 80ml/kg orally of a cosmetic formulation containing 6% beeswax and 6% ceresin and the formulation were neither cause irritation nor sensitization as indicated by CIR.
It is the responsibility of the manufacturer to ensure the ingredient used is of acceptable chemical purity and does not contain hazardous amounts of residue and contaminants as well as the physicochemical properties conforming to the recommendation of Cosmetic Europe to substantiate the safety of the product and complies with the EU Cosmetic Regulation. If it is not the case, it will void the assessment.

The submitted document for the ingredient, in the product name Ceresin, as supplied by KahlWax, indicates the PAH is not detected.

4. Polyisobutene

CAS No.: 9003-27-4
EINECS/ELINCS: N/A
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 40%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 0.0475000 mg/kg bw/day
MOS: --

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

5. Beeswax

CAS No.: 8006-40-4 (white) / 8012-89-3
EINECS/ELINCS: 232-383-7
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 56%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 0.0237500 mg/kg bw/day
MOS: --

Beeswax is the wax obtained from the honeycomb of the bee. It consists primarily of myricyl palmitate, cerotic acid and esters and some high-carbon paraffins. It is used as emollient, emulsifying, film forming and perfuming in cosmetics. Beeswax was not phototoxic in hairless mice and swine. It caused minimal irritation in human patch test and was non-sensitizing when tested under open or closed conditions. It was also not mutagenic in Ames test with and without metabolic activation. Beeswax is a GRAS food ingredient

and is used in cosmetics at concentration of less than 0.1% to greater than 50%. The CIR Expert Panel concluded this ingredient is safe as cosmetic ingredient in the present practices of use and concentration.

6. Butyrospermum Parkii Butter

CAS No.: 91080-23-8 / 194043-92-0 / 68920-03-6
EINECS/ELINCS: 293-515-7 / - / 272-911-3
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used from 0.0005 to 60%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 0.0237500 mg/kg bw/day
MOS: --
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. Butyrospermum Parkii (Shea) Butter at 45% and 60% are 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.

7. 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: 0.0190000 mg/kg bw/day
MOS: 5263
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.

8. Microcrystalline Wax

CAS No.: 63231-60-7
EINECS/ELINCS: 264-038-1
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 50%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: 1100 mg/kg bw/day
SED: 0.0190000 mg/kg bw/day
MOS: 28947
Microcrystalline Wax is a wax derived from petroleum and characterized by the fineness of its crystals in contrast to the larger crystals of paraffin wax. It consists of high molecular weight saturated aliphatic hydrocarbons. It is used as emulsion stabilizers, viscosity controlling, binding and bulking agents in cosmetics. Based on the available documented animal and clinical test data, the CIR concluded that it is safe for use as cosmetic ingredients in the present practices of concentration and use.
It is the responsibility of the manufacturer to ensure the ingredient used is of acceptable chemical purity and does not contain hazardous amounts of residue and contaminants as well as the physicochemical properties conforming to the recommendation of Cosmetic Europe to substantiate the safety of the product and complies with the EU Cosmetic Regulation. If it is not the case, it will void the assessment.
The submitted document for the ingredient, in the product name Hydrogenated Microcrystalline Cera, as supplied by KahlWax, indicates the PAH is not detected.

9. 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: 0.0095000 mg/kg bw/day
MOS: 27474
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.

10. 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: 0.0095000 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.

11. Phenoxyethanol
CAS No.: 122-99-6
EINECS/ELINCS: 204-589-7
CLP Classification: Acute Tox. 4 H302; Eye Irrit. 2 H319
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: 0.0023750 mg/kg bw/day
MOS: 75158
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.

12. Tocopherol

CAS No.: 54-28-4 / 16698-35-4 / 10191-41-0 / 119-13-1 / 1406-18-4 / 1406-66-2 / 2074-53-5 / 59-02-9 /7616-22-0

EINECS/ELINCS: 200-201-5 / 240-747-1 / 233-466-0 / 204-299-0 /215-798-8 / - / 218-197-9 / 200-412-2 / -

CLP Classification: N/A

EU Cosmetic Regulation: None

SCCS opinion: None

CIR recommendation: Safe to be used up to 5%

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 500 mg/kg bw/day (Read across to Tocopheryl Acetate)

SED: 0.0004750 mg/kg bw/day

MOS: 526316

Tocopherol (Vitamin E) consists of alpha-tocopherol, beta-tocopherol, delta-tocopherol and/or gamma-tocopherol. It generally functions as antioxidant, masking and skin conditioning in cosmetics. It is a natural component of cell membranes thought to protect against oxidative damage, and was reported to protect against ultraviolet radiation induced skin damage. Tocopherol is generally not toxic in animal feeding studies, although very high doses (2 g/kg/day) have hemorrhagic activity. It is not irritating or sensitizing to skin or irritating to eyes. Reproductive and developmental toxicity tests in animals using Tocopherol were all negative or showed some effect of reducing toxicity. It was also uniformly negative in genotoxicity tests, exhibited anti-mutagenic activity consistent with its antioxidant properties, not carcinogenic and inhibited tumor promotion. Because methylhydroquinone is used in the chemical synthesis of Tocopherol, there was concern that hydroquinone may be present as an impurity. However, residual levels of hydroquinone would be expected to be limited to those achieved by good manufacturing practices. The CIR Expert Panel concluded up to 5% of this ingredient can be used in cosmetics.

13. Parfum (Vanilla MY12-B018)

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: None

NOAEL: --

SED: 0.0001900 mg/kg bw/day

MOS: --

Parfum Vanilla MY12-B018 as supplied by MEIYI Flavor Fragrance CO., LTD and the corresponding IFRA certificate of 48th amendment, allergen declaration and MSDS, was used at 0.04% in the formulation. The industry recommendations are applicable and the submitted IFRA Certificate indicates up to 20% of this parfum can be used in leave on lip balm product (Class 1 product).

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