



Test Report

No. HKHC2310008117HC

Date : Nov 13, 2023

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MID OCEAN BRANDS B.V.
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 LIP BALM (1 formulation).

Net Weight : 4.5g, 5g, 6.5g, 7g, 8g, 10g or 12g per consumer product
: CX1470 / IT2698 / KC6655 / KC7094 / MO8740 / MO9373 /
Style/Item No. : MO9374 / MO9407 / MO9586 / MO6752 / MO6753 / MO2213 /
: MO2214 / MO2215
SGS Report No. : HKHC2310008117HC
SGS Case No. : HKHC231000002953-101(XMCPCH220500934)
Buyer : Mid Ocean Brands B.V.
Manufacturer :
Region of Origin : China
Region of Destination : EU
Sample Receiving Date : Oct 20 – Nov 02, 2023
Test Period : Oct 20 – Nov 13, 2023
Reference Report No. / Issue Date : HKHC2205003766HC-01 / Nov 22, 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 the areas 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 LIP BALM (Style / Item no.: CX1470 / IT2698 / KC6655 / KC7094 / MO8740 / MO9373 / MO9374 / MO9407 / MO9586 / MO6752 / MO6753 / MO2213 / MO2214 / MO2215) 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 age 3 years or above.

The net weight of this product (The formula under assessment) is 4.5g, 5g, 6.5g, 7g, 8g, 10g or 12g 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	30.0000000000	Antistatic / Emollient / Skin Protecting / Solvent
Petrolatum	8009-03-8	232-373-2	22.3600000000	Antistatic / Emollient
Ceresin	8001-75-0	232-290-1	15.0000000000	Antistatic / Binding / Emulsion Stabilising / Opacifying / Viscosity Controlling
Polyisobutene	9003-27-4	N/A	10.0000000000	Binding / Film Forming / Viscosity Controlling
Butyrospermum Parkii Butter	194043-92-0	N/A	5.0000000000	Skin Conditioning
Beeswax	8012-89-3	232-383-7	5.0000000000	Emollient / Emulsifying / Film Forming / Perfuming
Microcrystalline Wax	63231-60-7	264-038-1	4.0000000000	Binding / Bulking / Emulsion Stabilising / Viscosity Controlling
Benzophenone-3	131-57-7	205-031-5	4.0000000000	UV Absorber / UV Filter
Ethylhexyl Salicylate	118-60-5	204-263-4	2.0000000000	UV Absorber / UV Filter
Ethylhexyl Methoxycinnamate	5466-77-3	226-775-7	2.0000000000	UV Absorber / UV Filter
Phenoxyethanol	122-99-6	204-589-7	0.5000000000	Preservative
Tocopherol	59-02-9	200-412-2	0.1000000000	Antioxidant / Masking / Skin Conditioning
Parfum (VANILLA MY12-B018)	N/A (Mixture)	N/A (Mixture)	0.0400000000	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 a white colored solid, with fragrance (VANILLA MY12-B018).

2.2 The stability test result on formulation, by in house method of _____ with product name Lip balm (Item no. CX1470, IT2698, KC6655, KC7094, MO8740, MO9373, MO9374, MO9407, MO9586), with testing period of Apr 08 – Jul 08, 2022 (CX1470), Apr 10 – Jul 10, 2022 (IT2698), Apr 12 – Jul 12, 2022 (KC6655), Apr 14 – Jul 14, 2022 (KC7094), Apr 16 – Jul 16, 2022 (MO8740), Apr 17 – Jul 17, 2022 (MO9373), Apr 19 – Jul 19, 2022 (MO9374), Apr 21 – Jul 21, 2022 (MO9407), and Apr 23 – Jul 23,

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2022 (MO9586), were submitted and reviewed. The stability test result on formulation, by in house method of , with product name Lip balm (Item no. MO6752, MO6753, MO2213, MO2214, MO2215), with testing period of Apr 08 – Jul 08, 2022 (MO6752), Apr 10 – Jul 10, 2022 (MO6753), and May 15 – Aug 15, 2023 (MO2213, MO2214, MO2215), 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°C, -5°C, 25°C, 40°C, Light exposure for 12 weeks; Cycle test (40°C for 8 hours > 4°C for 8 hours > 40°C for 8 hours > 4°C for 8 hours > Room temperature for over 4 hours for one cycle) for 3 cycles

Testing parameters : Appearance, colour, odour and TVC bacteria

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

3. Microbiological quality

3.1. The microbiological test result on formulation, with reference to European Pharmacopeia 9.0 2.6.12 and 9.0 2.6.13, by in house method of , on product name Lip balm, with a testing date of Jan 13 – 20, 2023, 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	<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 of formulation is not required because the product is a low microbiological risk product.

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

4.1. The heavy metal test result on formulation, by in house method of , on product name Lip Balm, with a testing period of Jan 14 – 20, 2023, was submitted and reviewed based on following criteria.

Test items	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					
	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 / Item no. CX1470

No.	Immediate Container	Material
1.	Ball	ABS

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Style / Item no. IT2698

No.	Immediate Container	Material
1.	Cap	ABS
2.	Button	ABS
3.	Inner tube (white)	PS
4.	Inner tube (transparent)	PP
5.	Base	POM

Style / Item no. KC6655

No.	Immediate Container	Material
1.	Ball	GPPS
2.	Inner sheet	PP

Style / Item no. KC7094

No.	Immediate Container	Material
1.	Cap	ABS
2.	Tube	ABS

Style / Item no. MO8740

No.	Immediate Container	Material
1.	Tin box	Tin

Style / Item no. MO9373

No.	Immediate Container	Material
1.	Cap	ABS
2.	Base	ABS

Style / Item no. MO9374

No.	Immediate Container	Material
1.	Cap	ABS
2.	Base	ABS
3.	Mirror	PS

Style / Item no. MO9407

No.	Immediate Container	Material
1.	Lid	ABS
2.	Button	ABS
3.	Inner tube (white)	PS
4.	Inner tube (transparent)	PP
5.	Base	POM

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Style / Item no. MO9586

No.	Immediate Container	Material
1.	Tub	ABS
2.	Grid	ABS

Style / Item no. MO6752

No.	Immediate Container	Material
1.	Inner Tube	PP
2.	Outer Tube/Cap	Bamboo

Style / Item no. MO6753

No.	Immediate Container	Material
1.	Inner shell	ABS
2.	Outer shell/Cap	Bamboo

Style / Item no. MO2213 / MO2214 / MO2215

No.	Immediate Container	Material
1.	Shell	ABS

4.3. For packaging material, test result of lead (Pb), cadmium (Cd), mercury (Hg), chromium VI (Cr (VI)) on immediate packaging, by third party laboratory (Ningbo GIG Testing Co., Ltd. report no.: GNBC22062411EN for item no. CX1470 / IT2698 / KC6655 / KC7094 / MO8740 / MO9373 / MO9374 / MO9407 / MO9586, GNBC22111113-01EN for item no. MO6752 / MO 6753, and GNBC23101714EN for MO2213 / MO2214 / MO2215), with testing period of Jun 29 – Jul 01, 2022, Nov 11 – 15, 2022, and Oct 20 – 24, 2023, respectively, indicate the total amount is less than 100ppm.

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

4.4. Packaging compatibility test result on packaging material, indicated to be tested together with the product, by in house method of _____, with product name Lip balm (Item no. CX1470, IT2698, KC6655, KC7094, MO8740, MO9373, MO9374, MO9407, MO9586), with testing period of Apr 08 – Jul 08, 2022 (CX1470), Apr 10 – Jul 10, 2022 (IT2698), Apr 12 – Jul 12, 2022 (KC6655), Apr 14 – Jul 14, 2022 (KC7094), Apr 16 – Jul 16, 2022 (MO8740), Apr 17 – Jul 17, 2022 (MO9373), Apr 19 – Jul 19, 2022 (MO9374), Apr 21 – Jul 21, 2022 (MO9407), and Apr 23 – Jul 23, 2022 (MO9586), were submitted and reviewed. The Packaging compatibility test result on packaging material, indicated to be tested together with the product, by in house method of _____, with product name Lip balm (Item no. MO6752, MO6753, MO2213, MO2214, MO2215), with testing period of Apr 08 – Jul 08, 2022 (MO6752), Apr 10 – Jul 10, 2022 (MO6753), and May 15 – Aug 15, 2023 (MO2213, MO2214, MO2215), were submitted and reviewed.

Testing conditions : -15°C, -5°C, 25°C, 40°C, Light exposure for 12 weeks; Cycle test (40°C for 8 hours > 4°C for 8 hours > 40°C for 8 hours > 4°C for 8 hours > Room temperature for over 4 hours for one cycle) for 3 cycles

Testing parameters : Appearance of package

Conclusion: The stability of the packaging material is acceptable.

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5. Normal and reasonably foreseeable use

The normal use of this product is for application on lips by children of age 3 years or above. Application of this product to any other parts of the body is unlikely. Ingestion of small amount of this product would be possible.

6. Exposure to 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 cm²

The amount per application: 0.1 g (Indicated by client)

The duration of exposure: 360 minutes

The frequency of use: 730 times per year

The normal and reasonably foreseeable exposure route(s): Primary via dermal contact with potential ingestion

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

The body weight: 15.1 kg

Estimated daily amount applied: 200 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.

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 ISO 22716:2007, with scope of compliance on production of manufacturing of general liquid unit, including hair care & cleansing products, skin care liquid products# and gel products#; manufacturing of cream & lotion unit, including skin care & cleansing products# and hair care products; manufacturing of powder unit, including loose powder products and pressed powder products; manufacturing of wax base unit, including wax base products (# indicated the production capability of eye care products and skincare products for children), by third party laboratory (Intertek Certificate SZ210D6 which is valid until Oct 18, 2025).

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)**

Stop using this product when it disagrees with you.

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, 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, 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 and microbiological quality, while the product was manufactured in accordance with Cosmetic GMP guidelines as published by US FDA. The preservation efficacy test of formulation is not required because the product is a low microbiological risk product.

*The COMMISSION REGULATION (EU) 2023/1545 of 26 July 2023 amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards labelling of fragrance allergens in cosmetic products has come into force on Aug 16, 2023. Only 26 allergen declaration is taken as the sole document for listing of fragrance allergen(s). The client is drawn to the attention that allergen listing shall comply with COMMISSION REGULATION (EU) 2023/1545 in due course. Cosmetic products containing the substances that do not comply with the restriction(s) may be placed on the Union market until July 31, 2026 and made available on the Union market until July 31, 2028.

The allergen declaration is still valid by the time of assessment. However, all products that do not comply with the restriction(s) should be off the shelf by July 31, 2028 or be re-assessed for compliance with EU cosmetic regulation (EC) No.1223/2009.

4. Assessor's credentials and approval of Part B

Date: Nov 13, 2023

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. 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: 0.5000000000 mg/kg bw/day

MOS: 1199

Paraffinum Liquidum is a highly refined petroleum mineral oil consisting of a complex combination of hydrocarbons obtained from the intensive treatment of a petroleum fraction with sulfuric acid and oleum, or by hydrogenation, or by a combination of hydrogenation and acid treatment. Additional washing and treating steps may be included in the processing operation. It consists of saturated hydrocarbons having carbon numbers predominantly in the range of C15 through C50. In the United States, Mineral Oil may be used as an active ingredient in OTC drug products. The EFSA Panel established an acceptable daily intake (ADI) of 12 mg/kg bw/day for high viscosity white mineral oils based on the NOAEL of 1200 mg/kg bw/day.

The submitted Inspection certificate of this ingredient (Batch number 1985624), on product name PIONIER 1204 Paraffinum Liquidum, as supplied by _____, indicated that kinematic viscosity at 100°C, MOSH(less than C25), molecular weight and purity are 9.945 mm²/s, 1.7%, 495, and 99.85% respectively, while PAHs content is not detected with specification of ≤0.1 mg/kg. 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.

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: 0.3726666667 mg/kg bw/day

MOS: 6708

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.

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The submitted Inspection certificate of this ingredient (Batch number 1378878), on product name PIONIER 3476 Petrolatum, as supplied by _____, indicated that the content of kinematic viscosity at 100° degree C, MOSH(less than C25), purity, molecular weight and residual PAH content are 11.945 mm²/s, 1.2%, 510 and 99.90% respectively, with the PAH content not detected and controlled at ≤0.1 mg/kg. 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.

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: 0.2500000000 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.

The submitted INSPECTION CERTIFICATE OF QUALITY of this ingredient, on product name Kahlwax 4511, as supplied by _____ indicated that kinematic viscosity at 100°C, MOSH(less than C25), molecular weight and purity are 13 cSt, 1.5%, 550 and 100% respectively, while PAH content is not detected with specification of ≤0.1 mg/kg. 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.

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: 0.1666666667 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

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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.

The submitted CERTIFICATE OF ANALYSIS of this ingredient (LOT NUMBER: 200712104), on product name POLYBUTENE PB2400, as supplied by _____ indicated that 1.1% of POSH/MOSH (C1 to C25) is detected. 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.

5. 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 as used in rinse off product up to 30% and safe at concentration up to 60% in leave on products

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: --

SED: 0.0833333333 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.

6. 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: 0.0833333333 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

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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.

7. 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% in leave on products

Food additive recommendation: None

Toxicological profile by chemical supplier: None

NOAEL: 1100 mg/kg bw/day

SED: 0.0666666667 mg/kg bw/day

MOS: 8249

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.

The submitted INSPECTION CERTIFICATE OF QUALITY of this ingredient (Lot no. 201118), on product name Microcrystalline Wax (Product number Kahlwax 1847), as supplied by _____ indicated that the content of kinematic viscosity at 100° degree C, MOSH(less than C25), molecular weight, and purity are 12cSt, 1.2%, 535, and 100% respectively, with the PAH content not detected and controlled at ≤0.1 mg/kg. 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.

8. 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: 0.0666666667 mg/kg bw/day

MOS: 1499

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

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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.

9. 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: 0.0333333333 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).

10. 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: 0.0333333333 mg/kg bw/day

MOS: 7829

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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 SCCS (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.

11. Phenoxyethanol

CAS No.: 122-99-6

EINECS/ELINCS: 204-589-7

CLP Classification: Acute Tox. 4 H302; Eye Dam. 1 H318

EU Cosmetic Regulation: Annex V/29: Maximum authorized concentration is 1.0%

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: 357 mg/kg bw/day (dermal, rabbit, 90-day)

SED: 0.0083333333 mg/kg bw/day

MOS: 21419

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 as used in rinse off product up to 3% and safe at concentration up to 5.4% in leave on products

Food additive recommendation: None

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Toxicological profile by chemical supplier: None
NOAEL: 500 mg/kg bw/day (Read across to Tocopheryl Acetate)
SED: 0.0016666667 mg/kg bw/day
MOS: 150000

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: 0.0006666667 mg/kg bw/day
MOS: --

Parfum (VANILLA MY12-B018) as supplied by _____ and the corresponding IFRA certificate of 51st amendment, allergen list and SDS were provided, was used at 0.04% in the formulation. The industry recommendations are applicable and the submitted IFRA Certificate indicates up to 100% of this parfum can be used in leave on lip balm product (Class 1 product).

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