MID OCEAN BRANDS B.V.
ADDRESS 7/F., KINGS TOWER, 111 KING LAM STREET, CHEUNG SHA WAN, KOWLOON, HONG KONG

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

Net Weight	:	4.5g or 12g per consumer product
Style/Item No.	:	MO6809-13, MO6809-06, MO6809-09, MO6809-11, MO6809-66, MO6943
SGS Report No.	:	HKHC2308006242HC
SGS Case No.	:	HKHC221000003178 – 101 (XMCPCH221001726)
Buyer	:	Mid Ocean Brands B.V.
Manufacturer	:	
Region of Origin	:	China
Region of Destination	:	EU
Sample Receiving Date	:	Aug 09 – 15, 2023
Test Period	:	Aug 09 – 15, 2023
Reference Report No. / Issue Date	:	HKHC2211008467HC / Nov 25, 2022

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

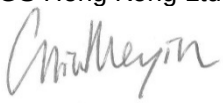
Test Results
Please refer to the following pages.

Summary
It is my opinion that this cosmetic formulation is safe to use under normal or reasonably foreseeable conditions of use.
This assessment takes account of:

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

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

Signed for and on behalf of
SGS Hong Kong Ltd.



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

This document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

PART A - COSMETIC PRODUCT SAFETY INFORMATION

INTRODUCTION

SGS is requested to review the safety of the product formula VEGAN LIP BALM (Item no.: MO6809-13, MO6809-06, MO6809-09, MO6809-11, MO6809-66, MO6943) 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 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	8012-95-1	232-384-2	31.1500000000	Skin Protecting
Petrolatum	8009-03-8	232-373-2	30.0000000000	Antistatic / Emollient
Ozokerite	64742-33-2	265-134-6	20.0000000000	Binding / Emulsion Stabilising / Opacifying / Viscosity Controlling
Polyisobutene	9003-27-4	N/A	5.0000000000	Binding / Film Forming / Viscosiity Controlling
Butyrospermum Parkii Butter	194043-92-0	293-515-7	5.0000000000	Skin Conditioning
Ethylhexyl Palmitate	29806-73-3	249-862-1	5.0000000000	Emollient
Microcrystalline Wax	63231-60-7	264-038-1	3.0000000000	Binding / Bulking / Emulsion Stabilising / Viscosity Controlling
Phenoxyethanol	122-99-6	204-589-7	0.5000000000	Preservative
Parfum (Vanilla MY12-B018)	N/A (Mixture)	N/A (Mixture)	0.3000000000	Perfuming
BHT	128-37-0	204-881-4	0.0500000000	Antioxidant

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 the fragrance (Vanilla MY12-B018).

2.2 The stability test result on formulation, by in house method of Ltd., on product name vegan lip balm and vegan lip balm (item no. MO6943), with testing period of Apr 08 – Jul 08, 2022 and Mar 08 – Jun 08, 2023, respectively, 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/8hr; 4°C/8hr; 40°C/8hr; 4°C/8hr; room temperature/4hr) for 3 cycles

Testing parameters : Appearance, colour, odour, and TVC bacteria (cfu/g)

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

3. Microbiological quality

3.1 The microbiological test results on formulation, with reference to European Pharmacopoeia 9.0 2.6.12 & 13, by in house method of on product name vegan lip

This document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

balm, with testing period of Jul 12 – 19, 2022, 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 10.0, 5.1.3, by in house method of on product name vegan lip balm, with testing period of Jun 08 – Jul 08, 2022, 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 criteria B and is acceptable for this application.

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

4.1 The heavy metal test results on formulation, by in house method of Co., Ltd., on product name vegan lip balm, with testing period of Jul 10 – 17, 2022, was submitted and reviewed based on following criteria.

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

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

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

No.	Immediate Container	Material
1.	Box	Aluminum

No.	Immediate Container	Material
1.	Shell	R-ABS
2.	Inner tank	R-ABS

4.3 For the packaging materials, the test results of total Lead (Pb), Cadmium (Cd), Mercury (Hg), Chromium VI (Cr (VI)), by third party laboratory (Ningbo GIG Testing Co., Ltd. report no. GNBC22111113-02EN for box and GNBC23071213EN for shell and inner tank), with testing period of Nov 11 – 15, 2022 and

This document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx **and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at** http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx**. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.**

Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Jul 13 – 24, 2023, respectively, indicates the total amount of lead, cadmium, mercury and chromium (VI) is less than 100mg/kg.
Conclusion: The heavy metal content of the packaging material is acceptable.

4.4 Packaging compatibility test results on packaging material, tested together with the formulation, by in house method of on product name vegan lip balm, with testing period of Apr 08 – Jul 08, 2022, was submitted and reviewed.
Testing conditions : -15°C, -5°C, 25°C, 40°C, light exposure for 12 weeks; cycle test (40°C/8hr; 4°C/8hr; 40°C/8hr; 4°C/8hr; room temperature/4hr) for 3 cycles
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 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 cm^2
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)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 in a manufacturing setting according to ISO 22716:2007, with scope of compliance on 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, by third party laboratory (Intertek Certificate SZ2210D6 which is valid until Oct 18, 2025).

This document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx **and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at** http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx**. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.**

Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

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

Stop using the product if it disagrees with you.
Keep out of reach of children except 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 skin and respiratory tract, phototoxic, and is unlikely to cause damage to internal organs through skin in the majority of consumers under normal and reasonably foreseeable conditions of use. Accidental exposure to eyes may cause slight irritation. There are substances of allergenic potential but at low level that is not expected to induce an allergenic reaction in most of the users under normal and reasonably foreseeable conditions of use. However, sensitized people can react to allergen present at extremely low concentrations.
The potential interactions between ingredients have been considered. The submitted test results indicate the product will be safe for intended use concerning the impurity, stability, microbiological quality, and preservative efficacy while the product was manufactured in accordance with ISO 22716:2007 Cosmetic GMP.

4. Assessor's credentials and approval of Part B

Date: Aug 15, 2023

Mei-Yin CHIU, Sondy MSc, FRSB, CBiol, DABT, EUROTOX Registered Toxicologist

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.

Disclaimer ©2023 SGS SA. All rights reserved. The Company's consulting services, including compilations(s) of data and any review of cosmetic label and formulation, are based upon the Company's know-how and on publicly available sources available at the time the services were provided. The Company disclaims any and all liability for the accuracy of any such publicly available information or any legal interpretation of such

This document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

information. The Company provides its services in a consulting capacity only and offers no legal opinion(s) 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 ********

This document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

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: 0.5191666667 mg/kg bw/day
MOS: 1155
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.
The submitted inspection certificate (Batch number: 1985624), on the trade name PIONIER 1204 Paraffinum Liquidum, as supplied by indicates the kinematic viscosity at 100°C, MOSH (C10-C25), and purity of the product are detected at 9.945 mm²/s, 1.7% and 99.85% respectively, while the residual PAH content is not detected, with the detection limit 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: 0.5000000000 mg/kg bw/day
MOS: 4999
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

This document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

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.
The submitted inspection certificate (Batch number: 1378878), on the trade name PIONIER 3476 Petrolatum, as supplied by indicates the kinematic viscosity at 100°C, MOSH (C10-C25), and purity of the product are detected at 11.945 mm²/s, 1.2% and 99.9% respectively, while the residual PAH content is controlled at ≤0.1 mg/kg. Besides, the submitted declaration letter indicates the product has a known full refining history and can be shown that the substance from which it is produced is not a carcinogen. 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. Ozokerite
CAS No.: 12198-93-5 / 64742-33-2
EINECS/ELINCS: - / 265-134-6
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe to be used up to 22%
Food additive recommendation: None
Toxicological profile by chemical supplier: None
NOAEL: --
SED: 0.3333333333 mg/kg bw/day
MOS: --
Ozokerite is a naturally occurring fossil wax which consists of aliphatic series of straight-chain, cyclic hydrocarbons, and some oxygenated resinous bodies. It has a delicate needle or short plate microcrystalline structure. Ozokerite is found near soft shale, which acts as a molecular filter and condenser. It has been suggested that the wax was produced into large ones. Wax from different deposits has somewhat different chemical compositions and physical properties. No toxic effects were reported after gastric administration to mice of up to 200 mg/kg of a 0.2% solution of Ozokerite, or to rabbits of up to 200 mg/kg of a 2.0% solution of the wax. Rabbit skin test and ocular irritation test showed that Ozokerite was mild/non-irritating. The available human clinical data indicated mild to minimal reactions. The CIR Expert Panel concluded this ingredient is safe as cosmetic ingredient in the present practices of use and concentration.
The submitted inspection certificate of quality (Lot no. 201112), on the trade name Kahlwax 4511, as supplied by , indicates the kinematic viscosity at 100°C is detected at 13 cSt, MOSH(C10 – C25) is detected at 1.5%, purity is detected at 100%, and the residual PAH content is 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.

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: 0.0833333333 mg/kg bw/day

This document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

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.
The submitted certificate of analysis (Lot number: 200712104), on the trade name POLYBUTENE PB2400, as supplied by indicates the POSH/MOSH (C1-C25) content is controlled at max 5.0%. 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. Ethylhexyl Palmitate
CAS No.: 29806-73-3
EINECS/ELINCS: 249-862-1
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe as used in rinse off product up to 50% and safe at concentration up to 78% in leave on products
Food additive recommendation: None

This document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Toxicological profile by chemical supplier: None
NOAEL: 1000 mg/kg bw/day (Read across to 2-ethylhexyl stearate)
SED: 0.0833333333 mg/kg bw/day
MOS: 5999
Ethylhexyl Palmitate is the ester of 2-ethylhexyl alcohol and palmitic acid. It is used as emollient and perfuming in cosmetics. The acute oral LD50 in rats is estimated to be greater than 64.0 ml/kg. It was also shown to be nontoxic in sub-chronic dermal studies. Rabbit skin tests with the Palmitates showed that they were non-irritating and non-sensitizing. Also, Draize rabbit eye irritation tests produced either no or only very slight ocular irritation. A body lotion containing 77.9% of Ethylhexyl Palmitate is not an irritant or a sensitizer when applied neat on 104 subjects in a HRIPT test (24-h semi-occlusive). Up to 45% of ethylhexyl palmitate is reported to be used in indoor tanning preparation which could be inhaled. There were no repeated-dose inhalation toxicity data available for the alkyl esters, but the actual exposure in the breathing zone is small and given the concentrations at which the ingredients are used, the available information indicates that incidental inhalation would not be a significant route of exposure that might lead to local respiratory or systemic effects. Also, this ingredient is large molecule and insoluble in water, which supports the view that it is unlikely to be absorbed or cause local effects in the respiratory tract. The CIR states concluded that alkyl esters tend not to produce systemic toxicity at high does in single-dose oral, dermal, or inhalation studies and not to produce significant system toxicity in oral repeated-dose studies. The CIR Expert Panel concluded that Ethylhexyl Palmitate is safe in the present practices of use and concentration when formulated to be non-irritating.

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: 0.0500000000 mg/kg bw/day
MOS: 11000
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 (Lot no. 201118), on the trade name Kahlwax 1847, as supplied by indicates the kinematic viscosity at 100°C is detected at 12 cSt, MOSH(C10 – C25) is detected at 1.2%, purity is detected at 100%, and the residual PAH content is 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. Phenoxyethanol
CAS No.: 122-99-6
EINECS/ELINCS: 204-589-7
CLP Classification: Acute Tox. 4 H302; Eye Dam. 1 H318; STOT SE 3 H335
EU Cosmetic Regulation: Annex V/29: Maximum authorized concentration is 1.0%

This document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

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.

9. 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: H315, H317, H319 and H411
NOAEL: --
SED: 0.0050000000 mg/kg bw/day
MOS: --
Parfum with code number Vanilla MY12-B018 as supplied by and the corresponding IFRA certificate of 50th amendment, MSDS and allergen list were provided, was used at 0.3% in the formulation. The industry recommendations are applicable and the submitted IFRA Certificate indicates up to 0.82552% of this parfum can be used in leave on lip balm product (Class 1 product).

10. BHT
CAS No.: 128-37-0
EINECS/ELINCS: 204-881-4
CLP Classification: N/A
EU Cosmetic Regulation: None
SCCS opinion: None
CIR recommendation: Safe as used at concentration up to 0.5% in both rinse off and leave on products
Food additive recommendation: ADI of 0 - 0.3 mg/kg bw/day

This document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Toxicological profile by chemical supplier: None
NOAEL: 25 mg/kg bw/day
SED: 0.0008333333 mg/kg bw/day
MOS: 14999
Butylated hydroxytoluene (BHT) is a substituted toluene that functions as antioxidant and masking in cosmetics. BHT is used in cosmetic formulations in the range of 0.01 to 0.1%. Human studies and literature data indicated that BHT produced no significant irritation, sensitization or photosensitization on skin. BHT is of low acute toxicity. It caused acute toxic effects in mammalians but there were no specific clinical symptoms. In rats, the oral LD50 was >2930 mg/kg bw, the LD50 after dermal exposure was >2000 mg/kg bw. On chronic oral exposure of rats, liver and thyroid are the main targets. Doses above 25 mg/kg bw/day BHT resulted in thyroid hyperactivity, enlargement of the liver, induction of several liver enzymes. 25 mg/kg bw/day BHT can be considered as NOAEL for chronic exposure. BHT is not a genotoxic carcinogen. For the use of BHT as antioxidant in foodstuff an acceptable daily intake (ADI) of 0 - 0.3 mg/kg bw/day has been established.

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

This document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at http://www.sgs.com/en/Terms-and-Conditions.aspx and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Document.aspx. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.