TECHNICAL REPORT – CPSR REPORT

Report No.	**（6624）032-0225 Revision**	**Date**	**2024-03-28**

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Client:	Mid Ocean Brands B.V.		
Address:	7/F, Kings Tower, 111 King Lam Street, Cheung Sha Wan, Kowloon, Hong Kong.		
Sample name:	Lip Balm (1 formulation)		
Net weight:	4.5 g, 6.5 g, 7 g, 12 g per consumer product		
Style/ Item No.:	IT2698, MO6752, MO6753, MO9373, MO9374, MO9407, MO9586, MO2213, MO2214, MO2215	Country of Origin:	China
Manufacturer:	Vendor code:113285	Expiry Date:	/
Production Date :	/	Date of Receipt:	2024-02-01
Sample Source:	/	Assessment Period:	2024-02-01 to 2024-02-29
Status of Sample:	/	Appropriate Age Grade:	/
Client Specified Age Grade:	/	Tested Age Grade:	/

Test specification:

Cosmetic Product Safety Assessment

Test result*:

Please refer to the assessment based on the EU Cosmetic Regulation (EC) No 1223/2009 issued by Toxicological & Regulatory Assessor.

Note: 1、*: The results were performed at external authorized lab.

2、This report replaces the original report（6624）032-0225, which be invalidated

Bureau Veritas Testing Technical Service (Zhejiang) Co., Ltd Shanghai Branch

HBH Department

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PART A – Cosmetic product safety information

A.1 Quantitative and Qualitative Composition of Products

A.1.1 Nominal Composition

The table below shows the aggregated break-down components of all raw materials from the product. Substances may have more than one function in the product. If so, the main function is given.

INCI Name	CAS No.	Conc. (%)	Function
PARAFFINUM LIQUIDUM	8012-95-1	37.1	Skin conditioning - emollient
PETROLATUM	8009-03-8	20	Skin conditioning - emollient
OZOKERITE	64742-33-2	15	Viscosity controlling
POLYISOBUTENE	9003-27-4	5	Binding
ETHYLHEXYL PALMITATE	29806-73-3	5	Skin conditioning - emollient
BEESWAX	8006-40-4	5	Viscosity controlling
BUTYROSPERMUM PARKII BUTTER	194043-92-0	5	Skin conditioning
MICROCRYSTALLINE WAX	63231-60-7	3	Viscosity controlling
ETHYLHEXYL METHOXYCINNAMATE	5466-77-3	2	UV absorber
BUTYL METHOXYDIBENZOYLMETHANE	70356-09-1	1	UV absorber
ETHYLHEXYL SALICYLATE	118-60-5	1	UV absorber
PHENOXYETHANOL	122-99-6	0.5	Preservative
PARFUM (Vanilla MY12-B018)	Mixture	0.3	Perfuming
BHT	128-37-0	0.1	Antioxidant

A.2 Physical chemical characteristics and stability of the cosmetic product

A.2.1 Physical/chemical characteristics of Raw Materials

The raw materials specifications are available upon request.

A.2.2 Physical chemical specifications of the end product

The finished product is a white solid with vanilla scented.

A.2.3 End product stability

The stability evaluation of the above formula was conducted under different operating conditions in an appropriate

packaging at -15°C, -5°C, 25°C, 40°C, and with light exposure for 12 weeks together with cycle test for 3 cycles. The organoleptic, physico-chemical and microbiological examinations (including appearance, colour, odour, TVC bacteria, appearance of package) were carried out.

The compatibility between the formula and the packaging was also evaluated.

The overall results of these examinations allow it to be stated that the stability tests and compatibility tests are **acceptable**.

A.2.4 Durability (PAO)

It lies with the responsibility of manufacturer or responsible person to determine the product's minimum durability and period-after-opening (PAO) based on the above results from the product stability testing.

A.3 Microbiological quality

A.3.1 The microbiological specifications of the substance or mixture

The microbiological specifications of all raw materials are available upon request.

A.3.2 The microbiological testing results of end product

The microbiological testing results of end product according to European Pharmacopoeia 10.0 2.6.12 & 2.6.13 were listed below.

Items	**Testing Results**	**Unit**
Aerobic Plate Count	<10	CFU/g
Yeasts and Moulds	<10	CFU/g
E. Coli, P. aeruginosa, S. aureus, C. albicans, Bile-tolerant gram-negative bacteria, S. typhimurium, C.tetani	Undetected	/g

According to Appendix 9 of the 12th Revision of the NoG (SCCS/1647/22), the microbiological quality of this product was considered as **acceptable** for **Category 1 products.**

A.3.3 Results of preservation challenge test

The preservation challenge test result of this formulation according to European Pharmacopoeia 10.0 5.1.3 was listed below.

Micoorganisms	D7	D14	D28
	Log reduction values		
Escherichia coli	> 5.8	> 5.8	> 5.8
Staphylococcus aureus	> 5.6	> 5.6	> 5.6
Pseudomonas aeruginosa	> 5.4	> 5.4	> 5.4
Candida albicans	> 5.5	> 5.5	> 5.5
Aspergillus niger	> 5.4	> 5.4	> 5.4

According to EP 10.0 Table 5.1.3-2B, the preservation challenge test result of this formulation was considered as **acceptable**.

A.4 Impurities, traces and Information about the Packaging Material

A.4.1 Impurities and Traces of prohibited substances

The potential impurities and traces relevant for the raw materials were controlled via the raw material specifications. And the raw material specification are available upon request. This product does not contain any relevant impurity at significant levels, and the analytical testing results of heavy metals (below table) indicated the content of As, Hg, Pb, Sb, Cd and Ni (soluble) in this product were undetected and considered to be **acceptable** according to German Health Authority BgA recommendations form German Health Journal No.28, July 1985 and German Health Journal No.7/1992,Session 45 from November 14,1991. Furthermore, in conformity with the article 3 of the regulation, the safety evaluation of this impurity and trace of prohibited substances is part of the safety evaluation of the cosmetic product.

Items	Testing Results	German Health Authority BgA(Recommendation form German Health Journal No.28, July 1985)	German Health Journal No.7/1992, Session 45 from November 14,1991 (mg/kg)
Pb	< 0.1 mg/kg	≤20 mg/kg	-
Hg	< 0.1 mg/kg	≤ mg/kg	-
As	< 0.1 mg/kg	≤5 mg/kg	-
Sb	< 0.1 mg/kg	≤0 mg/kg	-
Cd	< 0.1 mg/kg	≤5 mg/kg	-
Ni (soluble)	< 0.1 mg/kg	-	≤0 mg/kg

A.4.2 Information about the Packaging Material

The relevant characteristics of packaging material and in-depth knowledge of its raw materials is based on supplier data. The material information of packaging was listed below.

No.	Part	Material
1	Cap	ABS
2	Pipe	PP
3	Pipe seat	GPPS

The analytical testing results of immediate container indicated Pb, Cd, Hg and Cr (VI) were undetected with total amount less than 100 ppm.

A.5 Normal and Reasonably Foreseeable Use

The normal use and reasonably foreseeable uses of the product are described for the product type and determine the exposure and hazards used in the safety assessment. Product misuse is not considered.

A.5.1 Normal use and reasonably foreseeable use conditions:

The normal use of this product is intended to be applied as lip balm. Application of this product to other parts of body is not foreseeable.

A.5.2 Warning and other explanation in the product labelling of the product category relevant for safety evaluation.

As the printed instructions of use and warning is clear to describe the product usage and appropriate enough to avoid misuse, no special warnings or instructions of use are further required.

A.6 Exposure to the product

The exposure to the cosmetic product is described by the following items:

A.6.1 Product Type

This cosmetic product is applied as lip balm

Product Type: Leave-on

A.6.2 Target Group

The target users for this product are: the population of 3 years old and above. And the default body weight use for margin of safety calculation is 15.1 kg.

A.6.3 Area of application

The following exposure areas have been used in the Exposure calculations:

Area of application: lips

Application Surface area: 4.8 cm^2

A.6.4 Routes of Exposure

The following exposure routes have been used in the Exposure calculations:

Routes of Exposure: Dermal

A.6.5 Amount per daily application

The following product quantity used per application has been used in the Exposure calculations:
Product Exposure: 0.057 g

A.6.6 Duration and Frequency

The following product use conditions have been used in the Exposure calculations:

Frequency of use: twice per day

Exposure duration: leave-on

A.7 Exposure to the substances/impurities

Exposure to the substances/impurities has been calculated taking into account the potential exposure of product and the concentration of substances/impurities in the product. And exposure to aqua and sea water is not calculated as it is an innocuous and ubiquitous substance.

A.7.1 Exposure to the substance

INCI Name	Inclusion level (% w/w)	Total Systemic (SED) mg/kg bw/day	Local Dermal (CEL) µg/cm^2
PARAFFINUM LIQUIDUM	37.1	1.39867	4405.625
PETROLATUM	20	0.754	2375
OZOKERITE	15	0.5655	1781.25
POLYISOBUTENE	5	0.1885	593.75
ETHYLHEXYL PALMITATE	5	0.1885	593.75
BEESWAX	5	0.1885	593.75

BUTYROSPERMUM PARKII BUTTER	5	0.1885	593.75
MICROCRYSTALLINE WAX	3	0.1131	356.25
ETHYLHEXYL METHOXYCINNAMATE	2	0.0754	237.5
BUTYL METHOXYDIBENZOYLMETHANE	1	0.0377	118.75
ETHYLHEXYL SALICYLATE	1	0.0377	118.75
PHENOXYETHANOL	0.5	0.01885	59.375
PARFUM (Vanilla MY12-B018)	0.3	0.01131	35.625
BHT	0.1	0.00377	11.875

A.7.2 Exposure to impurities

As there is no impurity at significant levels, there is no exposure calculation.

A.8 Toxicological Profile of the Substances

Toxicological Profiles are provided for all substances apart from those that are fragrances, regulated ingredients, substances assessed by external authoritative body (for example Cosmetic Ingredient Review (CIR), SCCS, etc), aqua or substances present at levels below a threshold of toxicological concern.

Accordingly, toxicological profiles of PARAFFINUM LIQUIDUM and PETROLATUM are included here.

Toxicological profile of Paraffinum Liquidum (CAS# 8012-95-1)

Toxicological endpoints:

Acute toxicity: Its acute toxicity was practically non-toxic with oral LD_{50} > 5000 mg/kg bw in rats and dermal LD_{50} > 2000 mg/kg bw in rabbits [1].

Skin irritation: According to the acute irritation test in rabbits, it was found to be non-irritating to rabbit skin [1].

Eye irritation: According to the acute irritation test in rabbits, it was found to be non-irritating to eyes [1].

Skin sensitization: Overall weight of evidence indicated it was not a skin sensitizer.

Phototoxicity: Weight of evidence indicated it was not phototoxic with the absence of UV absorbance.

Repeated dose toxicity: No studies were available to evaluate the repeated dose toxicity effects of mineral oils via dermal administration. However, based upon the fact that there is no evidence to suggest significant percutaneous absorption, adverse effects are not expected following repeated dermal exposure. An ADI of 12 mg/kg bw/d for medium viscosity white mineral oils (kinematic viscosity between 8.5 - 11 mm²/s at 100 ℃) was set by JECFA based on a 2-year feeding study in the rats with

NOAEL of 1200 mg/kg bw/d [2].

Mutagenicity/Genotoxicity: Highly refined mineral oils are not considered to be mutagenic/genotoxic [1].

Carcinogenicity: It was found to be not carcinogenic in the chronic feeding study in rats [2].

Reproductive toxicity: The data available from short-term and long-term toxicity studies in the experimental animals exposed to mineral oil via oral, inhalation or skin exposure routes provided no evidence of reproduction/developmental toxicity. Moreover, mineral oil has not been detected in the reproductive organs [1].

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	1200 mg/kg bw/d
Exposure Estimate	1.40 mg/kg bw/d
Margin of Safety (MoS)	857

Regulatory Status – Not regulated in (EC) No 1223/2009 and without the assessment opinion from SCCS or CIR.

Conclusion

It was highly refined white mineral oil that are removed aromatic hydrocarbon during the refinery process, which was not classified as CMR substance according to EU Regulation No. 1272/2008. And it is concluded that the currently available data is sufficient to consider it safe to be used as intended in this product.

Reference list:

[1] ECHA. Registration dossier of White mineral oil (petroleum) (CAS No. 8012-95-1). Last accessed on 2022-10-22@ https://echa.europa.eu/registration-dossier/-/registered-dossier/15514.

[2] EFSA. Scientific opinion on the safety assessment of medium viscosity white mineral oils with a kinematic viscosity between 8.5 – 11 mm²/s at 100 °C for the proposed uses as a food additive. EFSA Journal 2013;11(1):3073.

Toxicological profile of Petrolatum（CAS# 8009-03-8）

Toxicological endpoints:

Acute toxicity: Its acute toxicity was assumed to be practically nontoxic with oral LD_{50} > 5000 mg/kg bw in rats and dermal LD_{50} > 2000 mg/kg bw in rabbits [1,2].

Skin irritation: It is not a dermal irritant [1,2].

Eye irritation: It was considered to be not irritating to rabbit eyes [1,2].

Skin sensitization: It is not sensitizing in one Buehler test in guinea pigs[1,2].

Phototoxicity: Weight of evidence indicated it was not phototoxic.

Repeated dose toxicity: In one chronic oral toxicity study in rats, the NOAEL was deemed to be 2500 mg/kg bw/d [1].

Mutagenicity/Genotoxicity: Weight of evidence indicated it lacked genotoxicity potential [1,2].

Carcinogenicity: It was found to lack carcinogenicity potential [1,2].

Reproductive toxicity: It was found to lack reproductive or developmental toxicity potential [1, 2].

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	2500 mg/kg bw/d
Exposure Estimate	0.754 mg/kg bw/d
Margin of Safety (MoS)	3316

Regulatory Status: – Not regulated in (EC) No 1223/2009 and without the assessment opinion from SCCS or CIR.

Conclusion

It was 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. In addition, as indicated from the submitted technical data, the full refining history of this material is known and it can be shown that the substance from which it is produced is not a carcinogen. The purity of this ingredient complies with Pharmacopoeia Eur. The NOAEL of 2500 mg/kg bw/d from one chronic oral toxicity in rats was chosen for MoS calculation. In addition, there is no evidence from the various studies that mineral oils and waxes are percutaneously absorbed and become systemically available [3]. Hence the absorption rate of 1% was employed for systemic exposure dose calculation. And it is concluded that the currently available data is sufficient to consider it safe to be used as intended in this product.

Reference list:

[1] ECHA. Registration dossier of Petroleum (CAS # 8009-03-8). Last accessed on 2022-04-24@ https://echa.europa.eu/registration-dossier/-/registered-dossier/15353.

[2] Safety data sheet of this substance.

[3] Petry T, et al. Review of data on the dermal penetration of mineral oils and waxes used in cosmetic applications. Toxicol Lett. 2017 Oct 5;280:70-78. doi: 10.1016/j.toxlet.2017.07.899. Epub 2017 Aug 5. PMID: 28789996.

A.9 Undesirable effects and serious undesirable effects

As at the date of this report the product has not yet been commercialized, therefore there are no data available

from post marketing surveillance on undesirable effects or serious undesirable effects to the cosmetic product. No relevant data on other cosmetic product are available.

A.10 Information on the Cosmetic Product

This product is indicated to be manufactured by Cosmuses Cosmetics (Ningbo) Co., Ltd., 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 #; cream & lotion unit, including skin care & cleansing products # and hair care products; powder unit, including loose powder products and pressed powder products; wax base unit, including wax base products; eye care products and skincare products for children by third party laboratory (Intertek Certificate SZ2210D6 which is valid until 18 Oct, 2025).

PART B – Cosmetic Product Safety Assessment

B.1 Assessment conclusion

The formulation does not contain forbidden or banned ingredients per European Cosmetics Regulation (EC) No 1223/2009 and its amendments, and the safety assessment has been carried out in accordance with this regulation and its subsequent amendments.

After overall evaluation, this product can be considered as safe to be placed on the market without posing a foreseeable risk to the health of consumers under normal or reasonably foreseeable conditions of use.

B.2 Labelled warnings and instructions of use

As the printed instructions of use and warning is clear to describe the product usage and appropriate enough to avoid misuse, no special warnings or instructions of use are further required.

B.3 Reasoning

B.3.1 Safety Evaluation of the Substances

All of the following ingredients have been assessed as safe for human health under normal and reasonably foreseeable conditions of use.

Substance Name	Inclusion Level(%)	Use conc. (%)	Margin of Safety	Assessment Conclusion	Reference
PARAFFINUM LIQUIDUM	37.1	NA	857	Safe for human health under normal and reasonably foreseeable conditions of use.	See Section A.8.
PETROLATUM	20	NA	3316	Safe for human health under normal and reasonably foreseeable conditions of use.	See Section A.8.
OZOKERITE	15	22	NA	Conforms to accepted external review in a cosmetic product.	IJT 24(Suppl. 1): 1-102, 2005.

POLYISOBUTENE	5	40	NA	Conforms to accepted external review in a cosmetic product.	IJT 39(Suppl. 2): 59-90, 2020.
ETHYLHEXYL PALMITATE	5	78	NA	Conforms to accepted external review in a cosmetic product.	IJT 34(Suppl. 2): 5-69, 2015.
BEESWAX	5	56	NA	Conforms to accepted external review in a cosmetic product.	IJT 24(Suppl. 1): 1-102, 2005.
BUTYROSPERMUM PARKII BUTTER	5	60	NA	Conforms to accepted external review in a cosmetic product.	IJT 36(Suppl. 3): 51-129, 2017.
MICROCRYSTALLINE WAX	3	50	NA	Conforms to accepted external review in a cosmetic product.	IJT 24(Suppl. 1): 1-102, 2005.
ETHYLHEXYL METHOXYCINNAMATE	2	10	NA	Conforms to regulated usage.	CosReg Annex VI, entry No. 12
BUTYL METHOXYDIBENZOYLMETHANE	1	5	NA	Conforms to regulated usage.	CosReg Annex VI, entry No. 8.
ETHYLHEXYL SALICYLATE	1	5	NA	Conforms to regulated usage.	CosReg Annex VI, entry No. 20.
PHENOXYETHANOL	0.5	1	NA	Conforms to regulated usage.	CosReg Annex V, entry No. 29.
PARFUM (MY12-B018 Vanilla)	0.3	100	NA	Fragrance conforms to IFRA standards	see IFRA 51th certificate.
BHT	0.1	0.5	NA	Conforms to accepted external review in a cosmetic product.	IJT 42(Suppl. 3):17-19, 2023.

B.3.2 Safety Evaluation of the Product

This product along with all substances contained within the formulation of the product has been evaluated and found to be safe for its normal and reasonably foreseeable use based on submitted product information and other information publicly available.

The product will be produced with certified Good Manufacturing Practices for cosmetics. And the stability, microbiological quality, packaging, warnings and use instructions have been considered and taken into account as part of safety evaluation of this product. These aspects are covered under Sections A2, A3, A4 & A5 of the report.

Based upon the information supplied, unless otherwise stated in this report, it was assumed that neither this product, nor the ingredients used in the product, contained any impurities/contaminants that would cause harm to the health of a consumer. And this evaluation result is valid only to the conditions described herein. And any deviation from the above disclosed conditions will necessitate a new evaluation. Furthermore, if any serious undesirable effects attributed to the use of this product occurred, the safety assessor shall be informed immediately. Under such circumstances, a new safety assessment will be conducted, and conclusions may be revised.

B.4 Assessor´s credentials and approval of part B

Dr. Raul Xin, EUROTOX Registered Toxicologist (ERT)
Authorized external expert of Bureau Veritas

*** End of Report ***