TECHNICAL REPORT – CPSR REPORT

Report No. **(6625) 286-0289** **Date 2025-10-21**

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Client:	Mid Ocean Brands B.V		
Address:	Unit 711-716, 7/F., Tower A, 83 King Lam Street, Cheung Sha Wan, Kowloon, Hong Kong		
Sample name:	Vegan Lip Gloss (1 formulation)		
Net weight:	10g, 12g per consumer product		
Style/ Item No.:	MO2870	Country of Origin:	China
Buyer:	/	Expiry Date:	/
Manufacturer:	vendor code: 113285	Date of Receipt:	2025-10-13
Production Date:	/	Assessment Period:	2025-10-13 to 2025-10-21
Sample Source:	/	Appropriate Age Grade:	/
Status of Sample:	/		
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: *: The results were performed at external authorized lab.

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

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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.	EC No.	Conc. (%, w/w)	Function
PARAFFINUM LIQUIDUM	8012-95-1	232-384-2	27.15	Skin protecting
PETROLATUM	8009-03-8	232-373-2	25.00	Skin conditioning - emollient
POLYISOBUTENE	9003-27-4	/	20.00	Film forming
TRIDECYL TRIMELLITATE	94109-09-8	302-446-4	5.00	Skin conditioning - emollient
ETHYLHEXYL PALMITATE	29806-73-3	249-862-1	5.00	Skin conditioning - emollient
OZOKERITE	64742-33-2	265-134-6	5.00	Binding
BUTYROSPERMUM PARKII BUTTER	194043-92-0	293-515-7	5.00	Skin conditioning
MICROCRYSTALLINE WAX	63231-60-7	264-038-1	3.00	Binding
ETHYLHEXYL METHOXYCINNAMATE	5466-77-3	226-775-7	2.00	UV filter
BUTYL METHOXYDIBENZOYLMETHANE	70356-09-1	274-581-6	1.00	UV filter
ETHYLHEXYL SALICYLATE	118-60-5	204-263-4	1.00	UV filter
PHENOXYETHANOL	122-99-6	204-589-7	0.50	Preservative
PARFUM (Vanilla OW-0759)	Mixture	/	0.30	Perfuming
BHT	128-37-0	204-881-4	0.05	Antioxidant

FRAGRANCE ALLERGENS

Fragrance allergen **Vanillin** must be declared on the product label in the ingredients section according to EU Cosmetic Regulation.

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 white solid with vanilla scent.

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, and 40°C for 12 weeks, light exposure for 12 weeks, and cycling test (3 cycle freeze thaw 40°C/RT/4°C) were also conducted. The organoleptic, physico-chemical and microbiological

examinations (including appearance, colour, odour, TVC bacteria, appearance of package) were carried out.

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

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 9.0 2.6.12 & 2.6.13 were listed below.

Items		**Testing Results**	**Unit**
Aerobic mesophilic microorganisms	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

Conclusion: According to Appendix 9 of the 12th Revision of the NoG (SCCS/1647/22) and ISO 17516:2014, 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.

Microorganisms	**D7**	**D14**	**D28**
	Log reduction values		
Escherichia coli	>5.3	>5.3	>5.3
Staphylococcus aureus	>5.2	>5.2	>5.2
Pseudomonas aeruginosa	>5.6	>5.6	>5.6
Candida albicans	>5.5	>5.5	>5.5
Aspergillus niger	>5.3	>5.3	>5.3

Conclusion: According to EP 10.0 5.1.3 Table 5.1.3.-2 B criteria, 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 specifications 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
Pb, mg/kg	<0.1	≤20	-
Hg, mg/kg	<0.1	≤1	-
As, mg/kg	<0.1	≤5	-
Sb, mg/kg	<0.1	≤10	-
Cd, mg/kg	<0.1	≤5	-
Ni (soluble), mg/kg	<0.1	-	≤0

Conclusion: The heavy metal content of the formulation is **acceptable**.

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	Hose	PE
2	Cap	PP
3	Inner plug	PE

A.4.3 Chemical purity of the packaging materials

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

Conclusion: The chemical purity of the packaging material is acceptable.

A.4.4 Compatibility of package

The compatibility evaluation of the above formula was conducted under different operating conditions in an appropriate packaging at -15°C, -5°C, 25°C, and 40°C for 12 weeks, light exposure for 12 weeks, and cycling test (3 cycle freeze thaw 40°C/RT/4°C) were also conducted. The organoleptic, physico-chemical and microbiological examinations (including appearance, colour, odour, TVC bacteria, appearance of package) were carried out.

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

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 gloss by the population of 3 years old and above. Other usage 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 cosmetic 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 gloss

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

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	27.15	1.023555	3224.0625
PETROLATUM	25.00	0.9425	2968.75
POLYISOBUTENE	20.00	0.754	2375
TRIDECYL TRIMELLITATE	5.00	0.1885	593.75
ETHYLHEXYL PALMITATE	5.00	0.1885	593.75
OZOKERITE	5.00	0.1885	593.75
BUTYROSPERMUM PARKII BUTTER	5.00	0.1885	593.75
MICROCRYSTALLINE WAX	3.00	0.1131	356.25
ETHYLHEXYL METHOXYCINNAMATE	2.00	0.0754	237.5
BUTYL METHOXYDIBENZOYLMETHANE	1.00	0.0377	118.75
ETHYLHEXYL SALICYLATE	1.00	0.0377	118.75
PHENOXYETHANOL	0.50	0.01885	59.375
PARFUM (Vanilla OW-0759)	0.30	0.01131	35.625
BHT	0.05	0.001885	5.9375

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, aqua or substances present at levels below a threshold of toxicological concern.

Accordingly, toxicological profiles of PARAFFINUM LIQUIDUM, PETROLATUM, POLYISOBUTENE, TRIDECYL TRIMELLITATE, ETHYLHEXYL PALMITATE, OZOKERITE, BUTYROSPERMUM PARKII BUTTER, and MICROCRYSTALLINE WAX 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	1.023555 mg/kg bw/d
Margin of Safety (MoS)	1172

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

Conclusion

It is highly refined white mineral oil in which aromatic hydrocarbons are removed during the refining process. 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	0.9425 mg/kg bw/d
Margin of Safety (MoS)	2653

Regulatory Status: Not regulated in Regulation (EC) No 1223/2009 as the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen.

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 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]. 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.

Toxicological profile of POLYISOBUTENE (CAS# 9003-27-4)

Toxicological endpoints:

Acute toxicity: Its acute toxicity was practically non-toxic with oral LD_{50} > 15400 mg/kg bw in rats and dermal LD_{50} > 25000 mg/kg bw in rabbits [1, 2].

Skin irritation: It was considered to be non-irritating to skin [1, 2].

Eye irritation: It was considered to be non-irritating to eyes [1, 2].

Skin sensitization: Overall weight of evidence indicated it was not a skin sensitizer [1, 2].

Phototoxicity: Weight of evidence indicated it was not phototoxic with the absence of UV absorbance [1, 2].

Repeated dose toxicity: No treatment-related gross or microscopic changes were observed following exposure to in a 2-year dietary studies of Polyisobutene (molecular weight range 654-2168 Da) in rats or dogs. And NOAEL was recognized as 2000 mg/kg bw/d and 1000 mg/kg bw/d for rats and dogs respectively [2].

Mutagenicity/Genotoxicity: Weight of evidence indicated it's unlikely to be mutagenic/genotoxic [1, 2].

Carcinogenicity: Polyisobutene (100%) was not carcinogenic in rats (dosed up to 20,000 ppm) or dogs (dosed up to 1,000 mg/kg) in oral carcinogenicity studies [2].

Reproductive toxicity: Weight of evidence indicated it's unlikely to be a specific reproductive toxicant [1, 2].

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	1000 mg/kg bw/d
Exposure Estimate	0.754 mg/kg bw/d
Margin of Safety (MoS)	1326

Regulatory Status: Not regulated in Regulation (EC) No 1223/2009 and with the assessment opinion from CIR that it can be safely used in leave-on and rinse-off cosmetics at the concentration up to 40% and 3.5% respectively [2].

Conclusion

Polyisobutene is the homopolymer of isobutylene and is used in cosmetic products as a binder, film former, and nonaqueous viscosity-increasing agent. It was also the food additives permitted for direct addition to food for human consumption—chewing gum base in U.S. (21 CFR172.61). The estimated octanol water partition coefficient for Hydrogenated Polyisobutene and Polybutene is log Kow of 13.27 and the estimated water solubility was 5.6 x 10^{-3} ng/L for Hydrogenated Polyisobutene and Polybutene. And hence 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] CIR Expert Panel. Final Report of the Cosmetic Ingredient Review Expert Panel on the Safety Assessment of Polyisobutene and Hydrogenated Polyisobutene as Used in Cosmetics. IJT 27 (Suppl. 4):83-106, 2008.
[2] CIR Expert Panel. Safety Assessment of Polyene Group as Used in Cosmetics. IJT 39(Supp. 2):59-90, 2020.

Toxicological profile of TRIDECYL TRIMELLITATE (CAS# 94109-09-8)

Toxicological endpoints:

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

Skin irritation: It's not considered to be irritating to skin in one primary skin irritation test according to OECD TG 404 [1].

Eye irritation: It is considered to be slightly irritating in one acute eye irritation test according to OECD TG 405 [1].

Skin sensitization: It was not considered as a skin sensitiser in a LLNA study or in a human repeated insult patch test when tested undiluted [1, 2].

Phototoxicity: Weight of evidence indicated it was not phototoxic.

Repeated dose toxicity: No data. The analogue, tris (2-ethylhexyl)benzene-1,2,4-tricarboxylate (CAS: 3319-31-1) is considered an acceptable analogue based on structure and properties. Based on structure, the analogue data are expected to generally represent the physicochemical and health concerns of tridecyl trimellitate. In one sub-chronic oral toxicity study of tris (2-ethylhexyl)benzene-1,2,4-tricarboxylate (CAS: 3319-31-1) in rats,a statistically significant increase in relative liver weights in high dose males and females and some microscopic lesions in the liver and spleen were observed. The NOAEL was recognized as 225 mg/kg bw/d [1, 2].

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

Carcinogenicity: No data. However, with regard to the molecular structure of the substance, no carcinogenic potential is expected. Moreover, in investigations on mutagenicity (in vitro and in vivo) as well as in read across repeated dose toxicity studies (oral route and via inhalation), neither genotoxicity nor an indication for neoplastic lesions was observed [1, 2].

Reproductive toxicity: Weight of evidence indicated it lacked reproductive or developmental toxicity potential [1, 2].

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	225 mg/kg bw/d
Exposure Estimate	0.1885 mg/kg bw/d
Margin of Safety (MoS)	1194

Regulatory Status: Not regulated in Regulation (EC) No 1223/2009 and with the assessment opinion from CIR that it can be safely used in leave-on and rinse-off cosmetics at the concentration up to 57.1% and 12.8% respectively [3].

Conclusion

The relatively high molecular weight of the notified chemical (757 Da), low water solubility (< 0.13 mg/L) and high logP value (> 5.94) indicate that the it will have limited absorption capacity through skin and the GI tract. Due to the adequate margin of safety, hence it can be concluded it is safe to be used as intended in this product.

Reference list:

[1] ECHA. Registration dossier of Tri(tridecyl) benzene-1,2,4-tricarboxylate (CAS# 94109-09-8). Last accessed on 2022-04-24@ https://echa.europa.eu/registration-dossier/-/registered-dossier/28373.

[2] CIR Expert Panel. Safety Assessment of Trialkyl Trimellitates as Used in Cosmetics. IJT 43(Suppl. 1):96-120, 2024.

Toxicological profile of ETHYLHEXYL PALMITATE (CAS# 29806-73-3)

Toxicological endpoints:

Acute toxicity: Its acute oral toxicity was assumed to be practically non-toxic with LD_{50} > 5000 mg/kg bw in rats [1].In addition, all available acute dermal toxicity studies within the chemical of this category resulted in acute dermal LD_{50} > 2000 mg/kg bw [1].

Skin irritation: It is not considered as a dermal irritant in one acute skin irritation test in rabbits [1].

Eye irritation: It is not considered as an eye irritantin one acute eye irritation test in rabbits [1].

Skin sensitization: Weight of evidence indicated it was not skin sensitizing [1].

Phototoxicity: Weight of evidence indicated it was not phototoxic.

Repeated dose toxicity: No data was available, while in a repeated dose 28-day oral toxicity study of Fatty acids, C16-18, 2-Ethylhexyl Esters (CAS# 91031-48-0),NOAEL was determined to be 1000 mg/kg bw/d [1].

Mutagenicity/Genotoxicity: Weight of evidence indicated it lacked mutagenicity potential [1].

Carcinogenicity: While no specific data are available for the chemicals in this category, it was not expected to be carcinogenic [1].

Reproductive toxicity: Weight of evidence indicated it lacked reproductive or developmental toxicity potential [1].

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	1000 mg/kg bw/d
Exposure Estimate	0.1885 mg/kg bw/d
Margin of Safety (MoS)	5305

Regulatory Status: Not regulated in Regulation (EC) No 1223/2009 and with the assessment opinion from CIR that it can be safely used in leave-on cosmetics at the concentration up to 78% [2].

Conclusion

It belonged to the Short Chain Alcohol Esters (SCAE C2-C8) category, which covers esters from a fatty acid (C8-C29) and a C2-C8 alcohol (ethanol, isopropanol, butanol, isobutanol, pentanol, iso-pentanol, hexanol, 2-ethylhexanol or octanol). This category includes both well-defined mono-constituent substances as well as related UVCB substances with varying fatty acid chain lengths. Due to the adequate margin of safety, hence it can be concluded it is safe to be used as intended in this product.

Reference list:

[1] ECHA. Registration dossier of 2-ethylhexyl palmitate (CAS#29806-73-3). Last accessed on 2022-04-24@ https://echa.europa.eu/registration-dossier/-/registered-dossier/15089/.

[2] CIR Expert Panel. Safety Assessment of Alkyl Esters as Used in Cosmetics. IJT 34(Suppl. 2): 5-69, 2015.

Toxicological profile of OZOKERITE (CAS# 64742-33-2)

Toxicological endpoints:

Acute toxicity: It is considered to be of low acute oral and dermal toxicity based on the data from structural analogue [1, 2].

Skin irritation: It was considered to be non-irritating to skin [1, 2].

Eye irritation:It was considered to be non-irritating to eyes [1, 2].

Skin sensitization: Overall weight of evidence indicated it was not a skin sensitizer [1, 2].

Phototoxicity: Weight of evidence indicated it was not phototoxic with the absence of UV absorbance [1, 2].

Repeated dose toxicity: No studies were available. 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 [3].

Mutagenicity/Genotoxicity: Weight of evidence indicated it's unlikely to be mutagenic/genotoxic [1, 2].

Carcinogenicity: Weight of evidence indicated it's unlikely to be carcinogenic [1, 2].

Reproductive toxicity: Weight of evidence indicated it's unlikely to be a specific reproductive toxicant [1, 2].

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	1200 mg/kg bw/d
Exposure Estimate	0.1885 mg/kg bw/d
Margin of Safety (MoS)	6366

Regulatory Status: Not regulated in Regulation (EC) No 1223/2009 and with the assessment opinion from CIR that it can be safely used in cosmetics at the concentration up to 22% [4].

Conclusion

Ozokerite is a naturally occurring fossil wax which consists of aliphatic series of straight-chain, branched-chain, and cyclic hydrocarbons, and some oxygenated resinous bodies. It has a delicate needle or short plate microcrystalline structure. It consists predominantly of saturated straight chain hydrocarbons having carbon numbers predominantly in the range of C20 through C50. And hence 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. Substance Infocard of Ozokerite (CAS # 64742-33-2). Last accessed on 2022-04-24@ https://echa.europa.eu/substance-information/-/substanceinfo/100.059.195.

[2] CIR Expert Panel. Final report on the safety assessment of fossil and synthetic waxes. Journal of the American College of Toxicology, 3(3): 43-99; 1984.

[3] 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. [4] CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. IJT 24(Suppl. 1):1-102,

2005.

Toxicological profile of Butyrospermum Parkii (Shea) Butter (CAS# 91080-23-8; 194043-92-0)

Toxicological endpoints:

Acute toxicity: Its acute oral toxicity was assumed to be very low [1, 2].

Skin irritation: It's not considered to be a skin irritant [1].

Eye irritation: It is not considered to be irritating to eyes [1].

Skin sensitization: Butyrospermum Parkii (Shea) Butter was not sensitizing in a guinea pig maximization study with the induction concentration of 75% and the challenge concentrations being 20% and 50%.

Phototoxicity: Butyrospermum Parkii (Shea) Butter was not phototoxic in guinea pigs when tested at 10 and 20% in acetone.2 The test sites were irradiated with UV-B light for 80 seconds followed by UV-A light for 80 min. In addition, a material containing Butyrospermum Parkii (Shea) Butter (70%) and Butyrospermum Parkii (Shea) Butter Unsaponifiables (30%) was considered non-phototoxic in a 3T3 NRU assay when tested at 0.005 to 1 mg/ml [2].

Repeated dose toxicity: No data was available. In a 13-week rat feeding study, groups of 15 male and 15 female Colworth-Wistar rats received a diet containing 20% (w/w; 10 to 15 g/kg/day) shea oleine or hydrogenated shea oleine. Additional groups of 15 male and 15 female rats were fed either 20% (w/w) palm oil, soy bean oil, or the hydrogenated equivalents. During the exposure period, body weight, food and water consumption, urine chemistry, and clinical pathology were assessed. Gross necropsy and microscopic examination of select tissues and organs were performed at study completion. Results showed that shea oleine diets produced biological effects similar to those of palm oil and soy bean oil diets. Based on these findings, it was concluded that shea olein given at 20% of the diet (10 to 15 g/kg bw/day) was well tolerated and appeared to have no adverse effect on the growing rat [2].

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

Carcinogenicity: It was considered unlikely to be carcinogenic since the carcinogenic potential of shea oleine and Butyrospermum Parkii (Shea) Oil were not observed in a dietary study in Colworth-Wistar rats for 104 weeks at 15% in the diet (7.5 g/kg/day) [2].

Reproductive toxicity: Available data indicated it was neither a reproductive nor a developmental toxicant [1, 2].

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	10000 mg/kg bw/d
Exposure Estimate	0.1885 mg/kg bw/d
Margin of Safety (MoS)	53050

Regulatory Status: Not Regulated in Regulation (EC) No 1223/2009 with the assessment opinion from CIR that it can be safely used in leave-on and rinse-off cosmetics at the concentration up to 100% and 10% respectively [2].

Conclusion

Butyrospermum Parkii Butter is the fat obtained from the fruit of the Shea Tree, Butyrospernum parkii, Sapotaceae. Butyrospermum Parkii (Shea) Butter, depending on level of refinement, is an off-white or grey to yellowish-cream

tallow-like solid, with a specific gravity of 0.918 at 15 ◦C and a melting point of 37.8℃ (reported range: 28-46℃). A study of Butyrospermum Parkii (Shea) Butter (described as kernel fats; n-hexane extraction) from 36 samples from seven different countries found the principal triacylglycerols to be stearic-oleic-stearic (mean 31.2% of total triacylglycerols), stearic-oleic-oleic (27.7%), and oleic-oleic-oleic (10.8%). Triterpene ester contents ranged from 0.5% to 6.5% and consisted of α-amyrin cinnamate (mean 29.3% of total triterpene esters), butyrospermol cinnamate (14.8%), α-amyrin acetate (14.1%), lupeol cinnamate (9.0%), β-amyrin cinnamate (7.6%), lupeol acetate (7.2%), butyrospermol acetate (5.8%), and β-amyrin acetate (4.9%). 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] SDS.

[2] CIR Expert Panel.Safety Assessment of Butyrospermum parkii (Shea)-Derived Ingredients as Used in Cosmetics. IJT 43(Suppl. 1):82-95, 2024.

Toxicological profile of MICROCRYSTALLINE WAX (CAS No. 63231-60-7)

Toxicological endpoints:

Acute toxicity: Its acute toxicity was very low with estimated LD_{50} > 5000 mg/kg bw and dermal LD_{50} > 2000 mg/kg bw based on read-across to available analogue data [1, 2].

Skin irritation: A single 0.5 g application of 100% Microcrystalline Wax administered to the intact and abraded skin of six albino rabbits for 24 h caused slight erythema and edema in intact and abraded sites. The primary irritation index (PII) was 0.48 out of a possible maximum score of 8.0 [1]. Therefore, under conditions of the study, paraffin wax is considered not irritating.

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

Skin sensitization: Weight of evidence indicated it was not skin sensitizing.

Phototoxicity: No photosensitization data on this chemical were available for review, but the UV absorption characteristics suggest that phototoxicity is unlikely.

Repeated dose toxicity: In a 90-day oral feeding study, three different waxes (low melting point wax, high melting point wax, and high sulphur wax) were administered to Fischer 344 rats (20/sex/dose for waxes, 60/sex for control) at dose levels of 0.002, 0.02, 0.2, or 2.0% in diet (equivalent to approximate average daily consumption values of 1.5, 15, 150, 1500 mg mineral hydrocarbon/kg body weight/day) for 90 days. A NOAEL of 0.002 % in diet (about 1.5 mg/kg b.w. per day) wasidentified for the low melting point wax, while for the microcrystalline waxes the NOAEL was ≥2% in diet (about 1500 mg/kg b.w. per day) [2-3].

Mutagenicity/Genotoxicity: Weight of evidence indicate it's unlikely to be mutagenic [1-3].

Carcinogenicity: Weight of evidence indicated it's unlikely to be carcinogenic [2, 3].

Reproductive toxicity: Weight of evidence indicated it's unlikely to possess reproductive toxicity potential [2, 3].

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	1500 mg/kg bw/d
Exposure Estimate	0.1131 mg/kg bw/d
Margin of Safety (MoS)	13263

Regulatory Status: Not regulated in Regulation (EC) No 1223/2009 and with the assessment opinion from CIR that it can be safely used in cosmetics at the concentration up to 50% [4].

Conclusion

Microcrystalline Wax, like Paraffin, is a distillation product of crude petroleum; however, this wax is distinctly different from Paraffin. The name "micro-crystalline" refers to the small, needle-like crystalline manifestations of the hydrocarbons in the wax. These crystals consist of long-chain, saturated hydrocarbons of high molecular weight. From ECHA, it was a complex combination of long, branched chain hydrocarbons obtained from residual oils by solvent crystallization. It consists predominantly of saturated straight and branched chain hydrocarbons predominantly greater than C35. It belonged to chemical group of hydrocarbon, paraffin and slack waxes that are derived from lubricating oil basestocks(also known as base oils). Waxes are predominantly saturated paraffins; solid or semi-solid at room temperature, and are classed according to their oil content and melting point. Waxes are separated from the lubricating oil basestocks by chilling or solvent extraction (dewaxing). Slack waxes can be further de-oiled to produce refined waxes (paraffin or microcrystalline) with a lower oil content. Microcrystalline Wax is a tough, flexible substance, with a high tensile strength and melting point, and a high penetration value and refractive index. It is adhesive (tacky), nonlustrous, somewhat greasy, plastic, and tends to flow under compression. This wax is compatible with other mineral waxes and with most vegetable waxes and resins. In cosmetics, Microcrystalline Wax imparts firmness to makeup, fragrance products, hair grooming products, lipsticks, and solid stick-form deodorants. Based on the data available, it was of low acute and repeated dose toxicity with low skin/eye irritation and skin sensitization potential. There is no concern for genotoxicity, carcinogenicity and reproductive toxicity from microcrystalline wax (E 905). Hence, taking the above into account, it is concluded that it is sufficient to consider it safe to be used as intended in this product.

Reference list:

[1] CIR Expert Panel. Final Report on the Safety Assessment of Fossil and Synthetic Waxes. JACT 3(3):43-99, 1984.
[2] ECHA. Registration dossier of Paraffin waxes and Hydrocarbon waxes, microcryst (CAS No. 63231-60-7). Last accessed on 2024-09-18@https://echa.europa.eu/registration-dossier/-/registered-dossier/15167.
[3] EFSA. Scientific Opinion on the re-evaluation of microcrystalline wax (E 905) as a food additive. EFSA Journal 2013;11(4):3146.
[4] CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments-2002/2003. IJT 24(Suppl. 1): 1-102, 2005.

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

No other relevant information was submitted.

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	Conc. (% w/w)	Max. allowed conc. (%)	Margin of Safety	Assessment Conclusion
PARAFFINUM LIQUIDUM	27.15	NA	1172	Safe for human health under normal and reasonably foreseeable conditions of use.
PETROLATUM	25.00	NA	2653	Safe for human health under normal and reasonably foreseeable conditions of use.
POLYISOBUTENE	20.00	NA	1326	Safe for human health under normal and reasonably foreseeable conditions of use.
TRIDECYL TRIMELLITATE	5.00	NA	1194	Safe for human health under normal and reasonably foreseeable conditions of use.
ETHYLHEXYL PALMITATE	5.00	NA	5305	Safe for human health under normal and reasonably foreseeable conditions of use.
OZOKERITE	5.00	NA	6366	Safe for human health under normal and reasonably foreseeable conditions of use.
BUTYROSPERMUM PARKII BUTTER	5.00	NA	53050	Safe for human health under normal and reasonably foreseeable conditions of use.
MICROCRYSTALLINE WAX	3.00	NA	13263	Safe for human health under normal and reasonably foreseeable conditions of use.
ETHYLHEXYL METHOXYCINNAMATE	2.00	10	NA	Conforms to regulated usage.

BUTYL METHOXYDIBENZOYLMETHANE	1.00	5	NA	Conforms to regulated usage.
ETHYLHEXYL SALICYLATE	1.00	5	NA	Conforms to regulated usage.
PHENOXYETHANOL	0.50	1	NA	Conforms to regulated usage.
PARFUM (Vanilla OW-0759)	0.30	100	NA	conforms to IFRA standards
BHT	0.05	0.8	NA	Conforms to regulated usage.

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 ***