TECHNICAL REPORT – CPSR REPORT

Report No. （6624）310-0154 R1 **Date 2024-11-29**

Page 1 of 24

Client:	Mid Ocean Brands B.V.		
Address:	7/F, Kings Tower, 111 King Lam Street, Cheung Sha Wan, Kowloon, Hong Kong.		
Sample name:	Vegan Lip Balm (1 formulation)		
Net weight:	3.8 g per consumer product		
Style/ Item No.:	MO2525	Country of Origin:	China
Manufacturer:	vendor code： 113285	Expiry Date:	/
Production Date :	/	Date of Receipt:	2024-11-05
Sample Source:	/	Assessment Period:	2024-11-05 to 2024-11-14
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, and the original report (6624) 310-0154 is invalidated.

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

HBH Department

Approved by

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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	31.15	Skin conditioning - emollient
PETROLATUM	8009-03-8	30.00	Skin conditioning - emollient
OZOKERITE	64742-33-2	20.00	Viscosity controlling
POLYISOBUTENE	9003-27-4	5.00	Binding
ETHYLHEXYL PALMITATE	29806-73-3	5.00	Skin conditioning - emollient
BUTYROSPERMUM PARKII BUTTER	194043-92-0	5.00	Skin conditioning
MICROCRYSTALLINE WAX	63231-60-7	3.00	Viscosity controlling
PHENOXYETHANOL	122-99-6	0.50	Preservative
PARFUM (Vanilla MY12-B018)	Mixture	0.30	Perfuming
BHT	128-37-0	0.05	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 odour.

A.2.3 End product stability

The stability evaluation of the above formula was conducted under different operating conditions in an appropriate packaging at -5 °C , -15 °C, 25 °C, and 40 °C for 12 weeks. Light compatibility test and cycling test (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.

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)

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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 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 Table 5.1.3.-2. criteria B in EP 10.0 5.1.3, 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

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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
Pb	Not detected	≤20	-
Hg	Not detected	≤1	-
As	Not detected	≤5	-
Sb	Not detected	≤10	-
Cd	Not detected	≤5	-
Ni (soluble)	Not detected	-	≤10

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	Body	R-PP
2	Cap	R-PP

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 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

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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 per day

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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/cm2
PARAFFINUM LIQUIDUM	31.15	1.170585	3687.1875
PETROLATUM	30.00	1.131	3562.5
OZOKERITE	20.00	0.754	2375
POLYISOBUTENE	5.00	0.1885	593.75
ETHYLHEXYL PALMITATE	5.00	0.1885	593.75
BUTYROSPERMUM PARKII BUTTER	5.00	0.1885	593.75
MICROCRYSTALLINE WAX	3.00	0.1131	356.25
PHENOXYETHANOL	0.50	0.01885	59.375
PARFUM (Vanilla MY12-B018)	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, 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, PETROLATUM, OZOKERITE, POLYISOBUTENE, ETHYLHEXYL PALMITATE, BUTYROSPERMUM PARKII BUTTER, MICROCRYSTALLINE WAX PARFUM (Vanilla MY12-B018), and BHT are included here.

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

Toxicological endpoints:

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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 mm^2/s at 100 $_oC$) 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	1.17 mg/kg bw/d
Margin of Safety (MoS)	1026

Regulatory Status – Not regulated in Regulation (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 complies with purity requirements of USP/NF/BP/JP/Ph.Eur. for Mineral Oil. And it is concluded that the currently available data is sufficient to consider it safe to be used as intended in this product.

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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	1.13 mg/kg bw/d
Margin of Safety (MoS)	3563

Regulatory Status: – Not regulated in Regulation (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

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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]. 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.

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]. It was found to be at most slightly irritating in one 24 h patch test on 20 human subjects when applied as neat [2].

Eye irritation: It was considered to be non-irritating to eyes [1, 2]. 50% concentration was found to be non-irritating to eyes in the Draize tests [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 °C) was set by JECFA based on a 2-year feeding study in the rats with NOAEL of 1200 mg/kg bw/d [3].

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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	11 mg/kg bw/d
Margin of Safety (MoS)	109

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

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.

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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]. In a 3-generation reproductive toxicity study, an unreported number of Charles River rats received 0, 800, or 20,000 ppm 100% Polyisobutene in their feed (molecular weight range 654-2,168 Da).37,38 No further details about dosing were provided. Weight gain was slightly reduced in the second generation high-dose male rats, but the changes were within normal control ranges. No other effects on body weights, clinical signs, organ weights, or histopathology were observed. No treatment-related reproductive effects were noted in any of the parameters measured (no furthered details provided). No differences were observed in offspring survival, litter size, number of stillborn pups, and number of viable pups in any generation of the treated groups when compared to controls. And No remarkable postmortem findings were reported [2].

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	1000 mg/kg bw/d
Exposure Estimate	0.19 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 and rinse-off cosmetics at the concentration up to 40% and 3.5% respectively [2].

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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 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), NOEL 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].

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Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	1000 mg/kg bw/d
Exposure Estimate	0.19 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 Butyrospermum Parkii (Shea) Butter (CAS# 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]. While mild conjunctival reactions were observed, undiluted Butyrospermum Parkii (Shea) Butter was considered not irritating when tested in the eyes of male rabbits [2].

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%. No sensitization was observed in multiple HRIPTs with products containing Butyrospermum Parkii (Shea) Butter at the concentrations up to 60% [2].

Phototoxicity: Butyrospermum Parkii (Shea) Butter was not phototoxic in guinea pigs when tested at 10 and 20% in

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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	0.19 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 ◦C (reported range: 28-46 ◦C). 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%).20 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

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(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]. Microcrystalline Wax, tested in a 21-day cumulative irritancy test on eight subjects, produced no irritation [1]. In addition, in a primary skin irritation study, the intact skin of three male New Zealand albino rabbits was exposed to 0.5 milligrams of paraffin wax under semi-occlusive conditions for 4 hours. Animals were observed for 72 hours, and skin irritation or corrosion was scored by the method of Draize at 1, 24, 48, and 72 hours. At the end of the 4 -hour test period, excess paraffin wax was removed with water. Slight erythema was observed at 1 hour in all three animals which was fully reversible by 24 hours. Therefore, under conditions of the study, paraffin wax is considered not irritating. Data from multiple skin irritation studies (NOTOX, 2003b; BIBRA Toxicology International, 1993c; CFTA, 1980a; Elder, 1984; CTFA, 1972a; CTFA, 1972 b; CFTA, 1980b; CFTA, 1977a; CFTA, 1977b; CFTA, 1977c) indicate that paraffin and hydrocarbon waxes are not irritating to the skin of rabbits [2]. Based on the data available, the chemicals in this group were considered to be non-irritating to skin.

Eye irritation:0.1 g sample of 100% Microcrystalline Wax was applied to the left eye of each of six albino rabbits and the right eye was left untreated. After 24, 48, and 72 h, five of the six animals showed no irritation. One animal showed slight conjunctival erythema and edema after 24 h [1]. In addition, in a primary eye irritation study (SafePharm

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Laboratories Limited, 2007b), 0.1 ml of paraffin wax was instilled into the conjunctival sac of three male New Zealand White rabbits whose eyes were unwashed. Animals then were observed for 72 hours. Irritation was scored by the method of Draize and a modified Kay and Calandra interpretation of the eye irritation test. Results are presented in the Draize method of scoring. Slight conjunctival irritation was observed at 1 and 24 hours after treatment but was fully reversible after the 24 hour timepoint. In this study, paraffin wax is therefore not considered to be an eye irritant, based on minimal conjunctival irritation (maximum score of 2 based on redness in each animal) at 24 hours which was fully reversible after the 24 -hour observation. Data from multiple supporting studies (CFTA, 1980a; CFTA, 1972a; CFTA, 1972b; Elder, 1984; BIBRA Toxicology International, 1993d) indicate that paraffin and hydrocarbon waxes are not irritating when applied to the eyes of rabbits [2]. Based on the data available, the chemicals in this group were considered to be, at most, slightly irritating to the eyes.

Skin sensitization: Paraffin waxes and hydrocarbon waxes (CAS No. 8002-74-2), was not a dermal sensitiser in the guinea pig maximisation test [2]. And petrolatum (CAS No. 8009-03-8) was not a dermal sensitiser in guinea pigs when tested using a modified Buehler method [2]. In addition, in a human maximization test on 25 subjects, a lipstick formulation containing 15% (0.3g) Microcrystalline Wax caused no contact sensitization reactions [2]. Based on the data available, the chemicals in this group are not considered to be skin sensitisers.

Phototoxicity: No photosensitization data on this chemical were available for review, but the UV absorption characteristics suggest that phototoxicity is unlikely. In addition, a lipstick formulation containing 15% Microcrystalline Wax was applied under occlusion to the lower backs of 10 panelists for 24 h. The patches were then removed and the sites were irradiated for 12 min with filtered light from a Xenon Arc Solar Simulator emitting in the range of 320-400 nm. An untreated site was also irradiated as a control. After 24 and 48 h, both test and control sites showed minimal reactions. This product did not produce phototoxicity [1].

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: In a chronic toxicity/carcinogenicity study in which rats were fed 5 types of refined waxes (three of the waxes were microcrystalline and the other two were refined paraffin waxes, not further specified) at a dietary concentration of 10% (about 5000 mg/kg b.w. per day) the incidence of tumours was comparable in test animals and

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controls. Both JECFA and the SCF concluded that (microcrystalline) paraffin wax is not carcinogenic, based on the results of this study. EFSA has also concluded that, in chronic toxicity/carcinogenicity studies conducted with high viscosity and medium viscosity white oils, no carcinogenic effects were observed in any of the studies in F344 rats or in skin painting studies in mice [2, 3].

Reproductive toxicity: No data are available on the reproductive and developmental toxicity of paraffin wax or microcrystalline wax. In addition, several reproductive and developmental toxicity studies using low viscosity mineral oils as a solvent are available, suggesting 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	0.11 mg/kg bw/d
Margin of Safety (MoS)	13636

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. In toxicokinetic studies analyzing tissue distribution paraffin and hydrocarbon waxes accumulated in the greatest amounts in the liver and mesenteric lymph nodes. The majority of the administered dose of these substances is excreted in the urine and faeces. Microcrystalline wax (E 905) is authorized as food additive in EU and other region. The JECFA established a group ADI of 20 mg/kg bw/day for mineral oils, paraffins and microcrystalline waxes. The EFSA Panel noted that all mineral oil products accumulated in tissues in a dose- and time-dependent manner with the exception of

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microcrystalline waxes. 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.

Assessment of PARFUM (Vanilla MY12-B018) was based on the submitted IFRA certificate according to the Standards of the INTERNATIONALFRAGRANCE ASSOCIATION (IFRA-51th Amendment /published June 30, 2023), which indicated it can be safely used in Category 1 products without concentration limits. Based on the above information, it is considered to be safe at the stated concentration in the formulation under normal and reasonably foreseeable conditions of use.

Toxicological profile of BHT (CAS# 128-37-0)

Toxicological endpoints:

Acute toxicity: Its acute oral toxicity was very low with oral LD_{50} > 6000 mg/kg bw in rats and dermal LD_{50} > 2000 mg/kg bw in rats [1, 2].

Skin irritation: After 24-hour semi-occlusive application of BHT (500 mg undiluted) to the intact and scarified skin, respectively, a very slight irritation could be noted. On the intact skin, erythemas occurred in 3/6 and 2/6 animals after 24 hours and 72 hours, respectively; edemas occurred in 1/6 animals after 24 hours and none after 72 hours. On the abraded skin, erythemas and edemas occurred in 1/6 animals after 24 hours and none after 72 hours [1, 2]. And it was concluded to be slightly irritating to the skin of rabbits under the experimental conditions.

Eye irritation: When tested in the Draize test (Bomhard 1996), 6 of 6 rabbits showed slight conjunctivitis 24 hours after application of 100 mg BHT (undiluted). Symptoms were completely reversible after 72 hours [1, 2]. And it was concluded to be slightly irritating to the eyes of rabbits under the experimental conditions.

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Skin sensitization: Limited studies with guinea pigs showed no indications of a sensitizing potential.From a range of human clinical studies there is no evidence to suggest that BHT is a significant human skin sensitiser or contact allergen. A few positive patch-test reactions were considered to reflect cross-reactivity with tert-butylhydroquinone [1-3]. And it's considered its skin sensitization potential was very low and the risk of skin sensitisation from current use levels is negligible.

Phototoxicity: Weight of evidence indicated it was not phototoxic as it was demonstrated not to have significant UV absorption capacity.

Repeated dose toxicity: Long-term exposure to BHT can result in functional and histological changes of lung, liver, kidneys and thyroid. Higher sub-acute and sub-chronic doses of BHT can cause death of mice or rats, either due to severe lung damage or massive haemorrhages. In the case of chronic oral exposure, liver and thyroid are the main targets. Doses above 25 mg BHT/kg bw/day result in thyroid hyperactivity, enlargement of the liver, induction of several liver enzymes. These hepatic effects, together with the formation of preneoplastic foci and nodules are discussed as causative factors in the mechanism of non-genotoxic carcinogenicity of BHT. As derived from rat studies, a dose of 25 mg BHT/kg bw/day can be considered as reliable NOAEL for chronic exposure. The haemorrhagic effects of high repeated doses of BHT seen in certain strains of mice and rats, but not in other species, may be related to its ability to interact with prothrombin and vitamin K [1- 3].

Mutagenicity/Genotoxicity: BHT showed no potential to cause point mutations in several bacterial and mammalian in vitro test systems. Overall, the available studies demonstrate that BHT has no clastogenic activity in vitro or in vivo. Most in vitro chromosome aberration assays were negative as were sister chromatid exchange assays and DNA damage and repair assays. In vivo, micronucleus assays with mice, cytogenetic assays with rats and mice, dominant lethal assays with rats and mice, and the heritable translocation assay with mice were also negative [1-3]. Positive genotoxicity results obtained in vitro with BHT and BHT metabolites may be due to pro-oxidative chemistry, giving rise to formation of quinones and reactive oxygen species. Such a mechanism of genotoxicity is generally considered to have a threshold. The SCCS concurs with the conclusions of EFSA (2012) and VKM (2019) that BHT is not of concern with regard to genotoxicity [3].

Carcinogenicity: BHT is not a genotoxic carcinogen. lung or liver tumours have been seen in some studies in mice or rats exposed orally to BHT as the single test substance. BMD analyses of the data reported by Brooks et al. (1976) on the incidence of lung neoplasia in mice induced by BHT revealed a BMDL10 of 38 mg/kg bw/day, and of the data reported by Olsen et al. (1986) on the incidence of hepatocellular carcinomas in male rats induced by BHT a BMDL10 of 247 mg/kg bw/day. The NOAEL for non-neoplastic effects in the study of Olsen et al. (1986) was 25 mg/kg bw/day, based on the effects on litter size, sex ratio and pup body weight gain during the lactation period in the reproduction segment of the study [1-3]. The International Agency for Research on Cancer (IARC) evaluated BHT (1987) and

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classified it in group 3, since no evaluation of the carcinogenicity of BHT in humans could be made, and there was limited evidence for the carcinogenicity in experimental animals.

Reproductive toxicity: In a three-generation study (Tanaka et al. 1993), Crj:CD-1 mice (F0 and F1 generations) received ca. 0, 23, 68, 203 or 608 mg/kg bw/day BHT in the diet during premating, mating, gestation and lactation periods (ca. 11 weeks). There were no effects on the number of litters, number of pups, litter size, litter weight and sex ratio in any dose group of F1 and F2 animals or on neurobehavioural parameters in F1 and F2 generation. The body weight of pups was increased at the lowest dose at birth and during lactation period for each generation. And in the two-generation oral carcinogenicity study with Wistar rats, the NOAEL for maternal toxicity was 100 mg/kg bw/day; body weight gain of the F0 animals was significantly reduced in the high-dose group (500 mg/kg bw/day). Gestation rate was not affected by the treatment. The Armitage-Cochran test for linear trend in proportions demonstrated that the fraction of litters with ten or more pups decreased significantly with BHT dose ($P < 0.001$). bw/day At weaning, these pups, particularly males, showed a dose-related reduction of body weight being clearly statistically significant at 100 and 500 mg/kg bw/day. The findings of the other two-generation feeding study with Wistar rats revealed slightly less maternal toxicity (NOAEL parental: females 500; males 100 mg/kg bw/day). Consequently, the NOEL for pup body weight and development (weight gain reduction during lactation) was higher, i.e. 100 mg/kg bw/day, than in the above study. No adverse effects on reproductive performance were observed [1-3]. And in one prenatal developmental study in mice or rats, no teratogenic effects were observed, and the NOALE for developmental toxicity was established as 800 mg/kg bw/d and 500 mg/kg bw/d in mice and rats respectively [2].

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	25 mg/kg bw/d
Exposure Estimate	0.0019 mg/kg bw/d
Margin of Safety (MoS)	13263

Regulatory Status: **Regulated** in Regulation (EC) No 1223/2009 (Annex III/ 325, the maximum allowed concentration in Mouthwash was 0.001%, in toothpaste was 0.1%, in other leave-on and rinse-off products was 0.8%) and with the assessment opinion from CIR that it can be safely used in cosmetics at the concentration up to 0.5% [4].

Conclusion

BHT (E 321) is a synthetic antioxidant authorised as a food additive in the EU. JECFA allocated an ADI of 0-0.3 mg/kg bw/day for BHT based on NOAEL of 25 mg/kg bw/d in 2-generation studies in rats. With the same NOAEL, an ADI of 0.25 mg/kg bw/day was established by EFSA with uncertain factor of 100. In one in vitro skin absorption study according to OECD TG 428 and SCCS/1358/10 (SCCS Basic criteria for the in vitro assessment of dermal absorption of cosmetic ingredient) with dermatomed human abdominal skin,the dermal absorption rate of 0.4% (mean + 1SD:

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0.20±0.20%) was derived. It is not acutely toxic and is essentially nonirritating to the skin and non- irritating to the eyes. Numerous studies support that it is also not a skin sensitizer. The available data did not raise concern with respect to genotoxicity or reproductive toxicity. Carcinogenic effects observed in chronic experimental animal studieswere caused by the specific study conditions and assumed to be with threshold. 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 BHT (CAS No. 128-37-0). Last accessed on 2022-10-22@ https://echa.europa.eu/registration-dossier/-/registered-dossier/15975.

[2] SIDS INITIAL ASSESSMENT PROFILE of Butylated Hydroxytoluene. SIAM 14, 26-28 March 2002.

[3] SCCS. OPINION on Butylated Hydroxytoluene (BHT). SCCS/1636/21 Final version.

[4] CIR Expert Panel. BHT – Butylated Hydroxytoluene. IJT 42(Suppl. 3):17-19, 2023.

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).

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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. (%)	Max. allowed Usage conc. (%)	Margin of Safety	Assessment Conclusion
PARAFFINUM LIQUIDUM	31.15	NA	1026	Safe for human health under normal and reasonably foreseeable conditions of use.
PETROLATUM	30.00	NA	2210	Safe for human health under normal and reasonably foreseeable conditions of use.
OZOKERITE	20.00	NA	1592	Safe for human health under normal and reasonably foreseeable conditions of use.
POLYISOBUTENE	5.00	NA	5305	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.

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BUTYROSPERMUM PARKII BUTTER	5.00	NA	53050	Safe for human health under normal and reasonably foreseeable conditions of use.
MICROCRYSTALLINE WAX	3.00	NA	13636	Safe for human health under normal and reasonably foreseeable conditions of use.
PHENOXYETHANOL	0.50	1	NA	Conforms to regulated usage and Safe for human health under normal and reasonably foreseeable conditions of use.
PARFUM (Vanilla MY12-B018)	0.30	100	NA	Fragrance conforms to IFRA standards and Safe for human health under normal and reasonably foreseeable conditions of use.
BHT	0.05	NA	13263	Safe for human health under normal and reasonably foreseeable conditions of use.

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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 ***

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