



Report No.: 66261100587R1

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TECHNICAL REPORT – CPSR

Applicant: Mid Ocean Brands B.V.
Address: Unit 711-716, 7/F., Tower A, 83 King Lam Street, Cheung Sha Wan, Kowloon, Hong Kong

PRODUCT INFORMATION

Product Name:	Lip Balm		
Style/Item No.	IT2698, MO6752, MO6753, MO9373, MO9374, MO9407, MO9586, MO2213, MO2214, MO2215		
Colors:	White	Physical Form:	Solid
Net Weight or Volume:	4.5g, 6.5g, 7g, 12g	Manufacturer:	Vendor code:113285
Country of Origin:	CHINA	Buyer:	/
Region of Destination:	EU	Expiry Date:	/
Date of Receipt:	April 20, 2026	Assessment Period:	April 20, 2026 – June 18, 2026

Test Requested:

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

Test Results:

Please refer to the following pages.

Note:

The revised report version 66261100587R1 replaces the original version 66261100587. The previous version is hereby declared null and void and shall no longer be used or referenced.



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PART A – Cosmetic product safety information

A.1 Quantitative and qualitative composition of the cosmetic product

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.	Function	Amount [%]
Paraffinum Liquidum	8012-95-1	Skin conditioning -emollient	37.10
Petrolatum	8009-03-8	Skin conditioning -emollient	20
Ozokerite	64742-33-2	Viscosity controlling	15
Polyisobutene	9003-27-4	Binding	5
Ethylhexyl Palmitate	29806-73-3	Skin conditioning -emollient	5
Beeswax	8006-40-4	Viscosity controlling	5
Butyrospermum Parkii Butter	194043-92-0	Skin conditioning	5
Microcrystalline Wax	63231-60-7	Viscosity controlling	3
Ethylhexyl Methoxycinnamate	5466-77-3	UV Absorber	2
Butyl Methoxydibenzoylmethane	70356-09-1	UV Absorber	1
Ethylhexyl Salicylate	118-60-5	UV Absorber	1
Phenoxyethanol	122-99-6	Preservative	0.5
Parfum	/	Perfuming	0.3
BHT	128-37-0	Antioxidant	0.1

*FRAGRANCE ALLERGENS FOR OW-0759 Vanilla Flavor:

Fragrance allergen VANILLIN may be declared on the product label.

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 product.

The finished product is white solid.

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 was conducted. The organoleptic, physico-chemical (appearance, colour, odor, 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 testing results of the product



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The microbiological testing results of the product according to European Pharmacopoeia 9.0 2.6.12 & 2.6.13 were listed below based on report issued by

Items		Testing Results	Unit
Aerobic mesophilic microorganisms	Total yeasts and moulds count (TAMC)	<10	CFU/g
	Total yeasts and moulds count (TYMC)	<10	CFU/g
Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia Coli, Candida albicans, Fecal Coliform Group, Burkholderia Cepacia, Clostridia, Salmonella, Bile-tolerant gram-negative bacteria		Undetected	/g or /10g

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 **acceptable** for **Category 1 products**.

Category 1: Products specifically intended for children under 3 years, to be used in the eye area and on mucous membranes.

Category 2: Other products.

A.3.2 Results of preservation challenge test

A preservation efficacy test (PET) test has to be undertaken. Antimicrobial effectiveness testing was conducted with reference to European Pharmacopoeia 12.0. Efficacy of Antimicrobial Preservation, and the results are listed below based on the report issued by

Criteria	Lod value of Inoculum	Log reduction (count)		
		7 days	14 days	28 days
Staphylococcus aureus (ATCC no. 6538)	8.1	>5.3	>5.3	>5.3
Escherichia coli (ATCC no. 8739)	8.3	>5.2	>5.2	>5.2
Pseudomonas aeruginosa (ATCC no. 9027)	8.4	>5.4	>5.4	>5.4
Candida albicans (ATCC no. 10231)	8.2	>5.1	>5.1	>5.1
Aspergillus niger (ATCC no. 16404)	8.4	>5.3	>5.3	>5.3

Conclusion: The preservative effectiveness requirements of client's specification with reference to the United States Pharmacopoeia, USP-NF 2023, Issue 3, chapter 51.

Note: Microbiological specifications of the substances and mixtures used within the product are not available for review. Responsible person/manufacturer must ensure that all production batches of raw materials and finished products are met with microbiological requirements that would not contribute a microbial risk to consumers.

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 has passed according to the TESTS FOR HHEAVY METALS report issued

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	The Federal Office of Consumer Protection and Food Safety (BVL, 16 Oct 2016)
Pb, mg/kg	<0.1	$\leq 2^a$
Hg, mg/kg	<0.1	≤ 0.1
As, mg/kg	<0.1	$\leq 0.5^b$
Sb, mg/kg	<0.1	≤ 0.5
Cd, mg/kg	<0.1	≤ 0.1
Ni (soluble), mg/kg	<0.1	10

a. For the product groups make-up-powder, rouge, eye shadow, eyeliner, kajal as well as theater, fan and carnival make up: 5 mg/kg

b. For theater, fan and carnival make up: 2.5 mg/kg

Conclusion: The heavy metal content of the formulation is **acceptable** according to the test report provided by the applicant.

A.4.2 Information about Packaging Material

The relevant characteristics of packaging material and in-depth knowledge of its raw materials are based on supplier data. There are two types of packaging and the material information about packaging was listed below provided by the TESTS FOR HHEAVY METALS report issued by applicant.

No.	Part	Material
1	Cap	ABS
2	lining	PP
3	Base	GPPS

A.4.3 Chemical purity of the packaging materials

The analytical testing results of immediate containers indicated Pb, Cd, Hg and Cr (VI) were undetected with total amount less than 100 ppm based on report issued by Ningbo GIG Testing Co., Ltd.. (Report No.: GNBC21051111EN).

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 was conducted. The appearance of packaging was carried out.

Conclusion: The overall results of these examinations allow it to be stated that the compatibility tests are **acceptable** according to the test report provided by the applicant.

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 moisturizing oil by people over 3 year old. 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 are clear to describe the product usage and appropriate enough to avoid



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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 Moisturizing Oil.

Product Type: leave-on

Product residence factor: 1.0

A.6.2 Target Group

The target user for this product is ≥ 3 years. And the default body weight use for margin of safety calculation is 15.20 kg.

A.6.3 Area of application

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

Area of application: Lips

A.6.4 Routes of Exposure

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

Routes of Exposure: Dermal, Oral

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 (The data is sourced from SCCS)

A.6.6 Frequency

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

Frequency of use: Four times a hour

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

$SED = E_{\text{product}} (\text{mg/kg bw/day}) \times C (\%) / 100 \times DAp (\%) / 100$

SED: Systemic Exposure Dosage

$E_{\text{product}} (\text{mg/kg bw/day})$: Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application.

$C (\%)$: Concentration of the substance under study in the finished cosmetic product on the application site.

$DAp (\%)$: Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions.

INCI Name	Inclusion level (% w/w) Max.	Total Systemic (SED) mg/kg bw/day (Max)
Paraffinum Liquidum	37.10	1.3913
Petrolatum	20	0.7500
Ozokerite	15	0.5625
Polyisobutene	5	0.1875

Ethylhexyl Palmitate	5	0.1875
Beeswax	5	0.1875
Butyrospermum Parkii Butter	5	0.1875
Microcrystalline Wax	3	0.1125
Ethylhexyl Methoxycinnamate	2	0.0750
Butyl Methoxydibenzoylmethane	1	0.0375
Ethylhexyl Salicylate	1	0.0375
Phenoxyethanol	0.5	0.0188
Fragrance (Parfum)	0.3	0.0113
BHT	0.1	0.0038

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, Ozokerite, Polyisobutene, Ethylhexyl Palmitate, Beeswax, Butyrospermum Parkii Butter, Microcrystalline Wax, Ethylhexyl Methoxycinnamate, Butyl Methoxydibenzoylmethane, Ethylhexyl Salicylate, Phenoxyethanol, and BHT are included here.

Margin of Safety calculation: $MOS = NOAEL / SED$

Paraffinum Liquidum(CAS NO.8012-95- 1)	
Regulatory requirements	The substance 'Paraffinum Liquidum' is not EU regulated.
Conclusion Summary	White mineral oil (petroleum) a highly refined petroleum mineral oil consisting of a complex combination of hydrocarbons obtained from the intensive treatment of a petroleum fraction with sulfuric acid and oleum, or by hydrogenation, or by a combination of hydrogenation and acid treatment. Additional washing and treating steps maybe included in the processing operation. It consists of saturated hydrocarbons having carbon numbers predominantly in the range of C15 through C50. Mineral oil (US) ;Oral route: No adverse effect observed NOAEL 1 000 mg/kgbw/day (subchronic, rat). This ingredient in this product is considered safe under normal and reasonably foreseeable conditions of use.
Reference:	
1. REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products	

Petrolatum(CAS NO.8009-03-8)	
Regulatory requirements	No threshold defined in the relevant Annex. Conditions: "Prohibited for use in cosmetic products, except if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen."



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Conclusion Summary	<p>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. Substance purity and purification history must be evaluated. Insufficiently purified substance could contain unwanted petroleum residues like benzene and PAHs. For high viscosity and medium viscosity mineral oils (Class I), the EFSA ANS Panel established a group ADI of 12 mg/kg bw/day on the basis of a 2-year feeding study on chronic toxicity and carcinogenicity in F344 rats (considered the most sensitive species and strain). In this pivotal study, the NOAEL was defined at 1200 mg/kg bw/day, the highest dose tested. Based on the results of the study, the EFSA ANS Panel concluded that no carcinogenic effect was observed.</p> <p>This ingredient in this product is considered safe under normal and reasonably foreseeable conditions of use.</p>
Reference:	
<ol style="list-style-type: none">1. REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products2. The EFSA ANS Panel- Petrolatum.	

Ozokerite (CAS NO.64742-33-2)	
Regulatory requirements	The substance 'Ozokerite' is not EU regulated.
Conclusion Summary	<p>Hydrocarbon waxes (petroleum), chemically neutralized. A complex combination of hydrocarbons produced by a treating process to remove acidic materials. It consists predominantly of saturated straight chain hydrocarbons having carbon numbers predominantly in the range of C20 through C50. In the 52-week chronic toxicity study, the NOAEL of ozokerite was estimated to be less than 25,5 mg/kg/day based on xenobiotic reactions and the secondary effects.</p> <p>This ingredient in this product is considered safe under normal and reasonably foreseeable conditions of use.</p>
Reference:	
<ol style="list-style-type: none">1. JACT 3(3):43 99, 1984; IJT 24(Suppl. 1):1 102, 20052. REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products3. CIR 2025 - Safety Assessment of Fossil and Synthetic Waxes as Used in Cosmetics.	

Polyisobutene(CAS NO.9003-27-4)	
Regulatory requirements	The substance 'Polyisobutene' is not EU regulated.
Conclusion Summary	<p>The Cosmetic Ingredient Review Expert Panel (Panel) reviewed the safety of polyenes (2015), which function in cosmetics primarily as film formers and viscosity increasing agents. The Panel reviewed relevant data related to these ingredients, noting gaps in the available safety data for some of the polyenes in this safety assessment. The Panel concluded that available data on many of the ingredients are sufficient, and similarity between structural</p>



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	<p>activity relationships and biologic functions in cosmetic concentrations of use and can be extrapolated to support the safety of the entire group. The Panel concluded that polyenes were safe in cosmetics in the present practices of use and concentration described in the safety assessment. The oral LD50 of 100% hydrogenated polyisobutene in rats was greater than 5 g/kg (molecular weight range 187-468; no further details provided). Overall toxicity was very low. The evaluated substances (or their analogues) were not irritating, sensitizing, mutagenic or carcinogenic. The overall lowest NOAEL for the evaluated group of substances was 1000 mg/kgbw/d which, based on structural-activity similarities, can be applied as the systemic toxicity threshold for all substances for the calculation of MoS. This ingredient in this product is considered safe under normal and reasonably foreseeable conditions of use.</p>
<p>Reference:</p> <ol style="list-style-type: none"> 1. IJT 27 (Suppl. 4):83 106, 2008;IJT 39(S2):59 90,2020 2. REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products 	

Ethylhexyl Palmitate(CAS NO.5466-77-3/83834-59-7 (trans-))	
Regulatory requirements	The substance 'Ethylhexyl Palmitate' is not EU regulated.
Conclusion Summary	<p>The CIR Expert Panel assessed the safety of 237 alkyl esters for use in cosmetics, concluding that these ingredients are safe in cosmetic formulations in the present practices of use and concentration when formulated to be non-irritating. The alkyl esters included in this assessment have a variety of reported functions in cosmetics, with skin conditioning agent being the most common function. The Panel reviewed available animal and clinical data in making its determination of safety on these ingredients, and, where there were data gaps, similarity in structure, properties, functions and uses of these ingredients allowed for extrapolation of the available toxicological data to assess the safety of the entire group. Most of these alkyl esters are produced synthetically via classical Fischer type esterification methods.</p> <p>However, some of the natural source ingredients in this review maybe produced by transesterification. Alkyl esters are hydrophobic materials that range from oils, at the lowest molecular weights/shortest chain-lengths, to waxy solids, at the highest molecular weights/longest chain-lengths. The alkyl esters are reported to function in cosmetics mostly as skin conditioning agents. In general, Alkyl Esters have low toxicity. In repeated dose studies in rats, toxic effects were not observed with oral administration of up to 1000 mg/kg ethylhexyl laurate or 4500 mg/kg/day isodecyl laurate for 4 wks or with up to 1000 mg/kgbw/day propylheptylcaprylate for 90 days. The Panel was also concerned that the potential exists for dermal irritation with the use of products formulated using some of the alkyl esters. The Panel thus specified that products must be formulated to be non-irritating and the skin compatability testing (Human Patch Test) is advised for products containing Alkyl Esters. The Panel also noted that although no carcinogenicity data were available, the</p>



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	<p>negative genotoxicity data coupled with the fact that dermal penetration is expected to below led the Panel to conclude that carcinogenicity would not be a concern with cosmetic use. these ingredients are large molecules and most are quite insoluble in water, which supports the view that they are unlikely to be absorbed or cause local effects in the respiratory tract. The Panel also considered the data available to characterize the potential for alkyl esters to cause systemic toxicity, irritation, sensitization, or other effects, and concluded that ingredients of this family tend not to produce systemic toxicity at high doses in single-dose oral, dermal, or inhalation studies and not to produce significant systemic toxicity in oral repeated- dose studies. For the purpose of MoS calculation a general group NOAEL of 1000 mg/kgbw/day can be applied as read-across for all substances included in the assessment.</p> <p>This ingredient in this product is considered safe under normal and reasonably foreseeable conditions of use.</p>
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Reference:

1. Safety Assessment of Alkyl Esters. JACT 4(5):107,146, 1985; IJT 24(Suppl. 1):1,102, 2005; IJT 34(Suppl.2):5,69, 2015
2. REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products

Beeswax(CAS NO.8006-40-4,8012-89-3)	
Regulatory requirements	The substance 'Beeswax' is not EU regulated.
Conclusion Summary	<p>Beeswax is the purified wax from the honeycomb of the bee, <i>Apis mellifera</i> , free from all other waxes.</p> <p>Beeswax is a complex mixture of saturated and unsaturated linear and complex monoesters (see below), hydrocarbons, free fatty acids, free fatty alcohols and other minor exogenous substances. It is an approved EU Food Additive. In the USA, beeswax (yellow and white) is affirmed as GRAS. It is used as a flavoring agent and adjuvant, as a lubricant, and as a surface-finishing agent.</p> <p>This ingredient in this product is considered safe under normal and reasonably foreseeable conditions of use.</p>

Reference:

1. JACT 3(3):1,41, 1984; IJT 24(Suppl. 1):1,102, 2005
2. REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products

Butyrospermum Parkii Butter(CAS NO.194043-92-0,91080-23-8)	
Regulatory requirements	The substance 'Butyrospermum Parkii Butter' is not EU regulated.
Conclusion Summary	<p>The CIR Expert Panel assessed the safety of 244 Plant-Derived Fatty Acid Oils (including oils which have been hydrogenated to reduce or eliminate unsaturation, fatty acid salts, and oil unsaponifiables) as used in cosmetics. Oils are used in a wide variety of cosmetic products for their skin conditioning, occlusive, emollient, and moisturizing properties. Since</p>



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	<p>many of these oils are edible, and their systemic toxicity potential low, the review of the Panel focused on their potential dermal effects. The Expert Panel concluded that the 244 Plant-Derived Fatty Acid Oils are safe as used in cosmetics.</p> <p>Based on the structure-activity relationship it is justified to use read-across data for all substances evaluated in this group. A general NOAEL of 5000 mg/kgbw/day (read-across from corn oil) can be used for calculation of MoS.</p> <p>This ingredient in this product is considered safe under normal and reasonably foreseeable conditions of use.</p>
<p>Reference:</p> <ol style="list-style-type: none"> 1. Safety Assessment of Plant-Derived Fatty Acid Oils. IJT 36(Suppl.3):51-129, 2017 2. REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products 	

Microcrystalline Wax(CAS NO.63231-60-7)	
Regulatory requirements	The substance 'Microcrystalline Wax' is not EU regulated.
Conclusion Summary	<p>NOAEL rats 1.10 g/kg bw/day (sub?chronic) U.S. EPA September, 2011 Paraffin waxes andHydrocarbon waxes, microcryst. A combination of long, branched chain hydrocarbons obtained fromresidual oils by solvent crystallization. It consists of saturated straight and branched chain hydrocarbonsgreater than C35.</p> <p>Read accross reference</p> <p>The NOAEL and Assessment info are based on the analogue substance Cera Microcristallina.</p> <p>Toxicological data has been extrapolated from an analogue substance based on the structure-activityrelationship.</p> <p>This ingredient in this product is considered safe under normal and reasonably foreseeable conditions of use.</p>
<p>Reference:</p> <ol style="list-style-type: none"> 1. JACT 3(3):43-99, 1984; IJT 24(Suppl. 1):1-102, 2005 2. REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products 	

Ethylhexyl Methoxycinnamate (CAS NO.5466-77-3)	
Regulatory requirements	The percentage (2,0000%) conforms to the maximum legal threshold of 10,0000% based on the product category 'Lip Balm'. NOAEL : 450,00 mg/kg bw/day(Repeated dose, Rat, Oral.
Conclusion Summary	This ingredient in this product is considered safe under normal and reasonably foreseeable conditions of use.
<p>Reference:</p> <ol style="list-style-type: none"> 1. REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products 	



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Butyl Methoxydibenzoylmethane, CAS NO.70356-09-1	
Regulatory requirements	The percentage (1,0000%) conforms to the maximum legal threshold of 5,0000% based on the product category 'Lip Balm'.
Conclusion Summary	TDI: 360,00 mg/kgbw/day(Repeated dose, Rabbit, Oral) This ingredient in this product is considered safe under normal and reasonably foreseeable conditions of use.
Reference: 1. REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products	

Ethylhexyl Salicylate (CAS NO.118-60-5)	
Regulatory requirements	The percentage (1,0000%) conforms to the maximum legal threshold of 5,0000% based on the product category 'Lip Balm'.
Conclusion Summary	DNEL: 79,10 mg/kgbw/day (Repeated dose, Dermal) This ingredient in this product is considered safe under normal and reasonably foreseeable conditions of use.
Reference: 1. REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products	

Phenoxyethanol (CAS NO.122-99-6)	
Regulatory requirements	The percentage (0,5000%) conforms to the maximum legal threshold of 1,0000% based on the product category 'Foot Cream/Gel/Lotion'.
Conclusion Summary	Phenoxyethanol is a glycol ether (aromatic ether alcohol) used in cosmetics primarily for antimicrobial preservation and secondarily as a solvent/co-solvent for fragrance and other ingredients. ECHA Oral Systemic Effects Long-term - General population: (DNEL) 9.23 mg/kg bw/day. DNEL: 9,23 mg/kgbw/day (Repeated dose, Ra, Oral) This ingredient in this product is considered safe under normal and reasonably foreseeable conditions of use.
Reference: 1. JACT 9(2):259-277, 1990;IJT 30(Suppl. 2):73-127, 2011 2. REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products	

BHT (CAS NO.128-37-0)	
Regulatory requirements	The percentage (0,1000%) conforms to the maximum legal threshold of 0,8000% based on



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	the product category 'Concealer'.
Conclusion Summary	<p>SCCS evaluated BHT for use in cosmetic products and in relation to its possible ED properties.</p> <p>Based on the data available for BHT SCCS concluded that BHT is safe for use in mouthwash up to 0,001%, toothpaste up to 0,1% and all other products (leave-on and rinse-off) up to 0,8%. A NOAEL of 25 mg/kgbw/day for non-neoplastic effects was used as the relevant toxicological end-point for the calculations of MoS in the SCCS report.</p> <p>NOAEL: 25,00 mg/kgbw/day (Chronic, Rat, Oral)</p> <p>This ingredient in this product is considered safe under normal and reasonably foreseeable conditions of use.</p>
Reference:	
<ol style="list-style-type: none">1. IJT 21(Suppl.2):19,94, 20022. REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products	

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 products are available.

A.10 Information on the Cosmetic Product

Supplier declared that the raw material(s) used in the product and the finished product itself have not been subjected to any animals testing to meet the requirements of EU Cosmetic Regulation (EC) No 1223/2009.

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

Substance Name	Conc. (% w/w)	Margin of Safety	Assessment Conclusion
Paraffinum Liquidum	37.10	718.78	Safe for human health under normal and reasonably foreseeable conditions of use.
Petrolatum	20	1600.00	Safe for human health under normal and reasonably foreseeable conditions of use.
Ozokerite	15	45.33	Safe for human health under normal and reasonably foreseeable conditions of use.
Polyisobutene	5	5333.33	Safe for human health under normal and reasonably foreseeable conditions of use.
Ethylhexyl Palmitate	5	5333.33	Safe for human health under normal and reasonably foreseeable conditions of use.
Beeswax	5	8000.00	Safe for human health under normal and reasonably foreseeable conditions of use.
Butyrospermum Parkii Butter	5	53333.33	Safe for human health under normal and reasonably foreseeable conditions of use.



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Substance Name	Conc. (% w/w)	Margin of Safety	Assessment Conclusion
Microcrystalline Wax	3	9777.78	Safe for human health under normal and reasonably foreseeable conditions of use.
Ethylhexyl Methoxycinnamate	2	6000.00	Safe for human health under normal and reasonably foreseeable conditions of use.
Butyl Methoxydibenzoylmethane,	1	9600.00	Safe for human health under normal and reasonably foreseeable conditions of use.
Ethylhexyl Salicylate	1	2109.33	Safe for human health under normal and reasonably foreseeable conditions of use.
Phenoxyethanol	0.5	492.27	Conforms to regulated usage.
Fragrance (Parfum)	0.3	/	Fragrance conforms to IFRA standards.
BHT	0.1	6666.67	Safe for human health under normal and reasonably foreseeable conditions of use.

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 should 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



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Xiuming Du

2026.06.18

Xiuming Du

DABT, Diplomate of American Board of Toxicology

DCST, Diplomate of Chinese Society of Toxicology

UKRT, UK Register of Toxicologists

ERT, Europe Registered Toxicologist

Education background:

2013.9 - 2016.6 Second military medical university Master of Public Health

2009.9 - 2013.6 Qilu industrial university Bachelor of pharmaceutical preparations

*** End of Report ***