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:	Hand cleanser gel		
Style/Item No.	MO6130, MO9952		
Colors:	Colorless	**Physical Form:**	Gel
Net Weight or Volume:	30ml	**Manufacturer:**	vendor code: 113285
Country of Origin:	CHINA	**Buyer:**	/
Region of Destination:	EU	**Assessment period:**	29-Jun-26~8-Jul-26

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 66261771529 R1 replaces the original version 66261771529. 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 [%]
AQUA	7732-18-5	Solvent	90.1
GLYCERIN	56-81-5	Humectant	5
PROPYLENE GLYCOL	57-55-6	Humectant	3
ALOE BARBADENSIS LEAF EXTRACT	85507-69-3	Skin conditioning - emollient	1
CARBOMER	9007-16-3	Gel forming	0.5
TRIETHANOLAMINE	102-71-6	Buffering	0.2
BENZALKONIUM CHLORIDE	68424-85-1	Antimicrobial	0.1
TOCOPHERYL ACETATE	58-95-7	Antioxidant	0.1

***FRAGRANCE ALLERGENS:**

The product contains no fragrance.

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 gel.

A.2.3 End product stability

The stability evaluation of the above formula was conducted under different operating conditions in an appropriate packaging at -10°C, 5°C, 25°C (roomtemperature), 40°C, 45°C and Light Exposure and Temperature Cycle Test for 12 weeks were also conducted. The organoleptic, physico-chemical (including appearance, colour, odour, pH value, microbial indexes) were carried out based on the report issued by (Date 2026-01-10).

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

The microbiological testing results of the product according to European Pharmacopoeia, 12.0 edition, method 2.6.12 & 2.6.13 were listed below based on report issued by (Date 2026.03.21).

Items		Testing Results	Unit
Aerobic mesophilic microorganisms	Total aerobic microbial count (TAMC)	<10	CFU/g
	Total yeasts and moulds count (TYMC)	<10	CFU/g
	Total viable count (TAMC + TYMC)	<100	CFU/g

Items	Testing Results	Unit
Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Salmonella, Candida albicans	Absent	/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 2 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 been completed. Antimicrobial effectiveness testing was conducted with reference to European Pharmacopoeia 12 5.1.3 Efficacy of Antimicrobial Preservation., and the results are listed below based on the report issued by (Date 2026-04-30).

Organisms		Initial count (CFU/g)	Log reduction (count)			
			2 days	7 days	14 days	28 days
Bacteria	Escherichia coli (ATCC 8739)	8.1×10^5	>4.3	>4.3	>4.3	No increase
	Staphylococcus aureus (ATCC 6538)	5.2×10^5	>4.3	>4.3	>4.3	No increase
	Pseudomonas aeruginosa (ATCC 9027)	8.2×10^5	>4.3	>4.3	>4.3	No increase
Fungi	Candida albicans (ATCC 10231)	4.1×10^5	-	-	>4.6	No increase
	Aspergillus brasiliensis (ATCC 16404)	3.8×10^5	-	-	>4.6	No increase

Conclusion: The preservative effectiveness requirements of client's specification with reference to the European Pharmacopoeia 12.0, chapter 5.1.3. is **acceptable.**

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 by the TESTS FOR HHEAVY METALS report issued by (Date 2026.03.27). 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 HealthAuthority BgA(Recommendation form German Health Journal No.28, July 1985)
Pb, mg/kg	Not detected	⩽20
Cd, mg/kg	Not detected	⩽5
Hg, mg/kg	Not detected	⩽1
As, mg/kg	Not detected	⩽5
Sb, mg/kg	Not detected	⩽10
Ni (soluble), mg/kg	Not detected	⩽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 three 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	Bottle	PET
2	Cap	PP
3	Hook	Aluminum alloy

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. (GA26070312-01EN, GA26070312-02EN)

A.4.4 Compatibility of package

The compatibility evaluation of the above formula was conducted under different operating conditions in an appropriate packaging at -10°C, 5°C, 25°C, 40°C, 45°C, Light Exposure and Temperature Cycle Test for 12 weeks was conducted. The packaging appearance and pack performance were 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 Hand cleanser gel by children 3 years 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 are 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 Hand cleanser gel.

Product Type: Leave-on

Product residence factor: 1.0

A.6.2 Target Group

The target user for this product is children 3 years and above. And the default body weight use for margin of safety calculation is 15.2 kg.

A.6.3 Area of application

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

Area of application: Hand

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:0.033 g (The data is sourced from JCAI)

A.6.6 Frequency

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

Frequency of use: Once every 4 hours

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= $E_{product}$ (mg/kg bw/day) x C (%)/100 x DAp (%)/100

SED: Systemic Exposure Dosage

$E_{product}$ (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)
AQUA	90.1	1.956118421
GLYCERIN	5	0.108552632
PROPYLENE GLYCOL	3	0.065131579
ALOE BARBADENSIS LEAF EXTRACT	1	0.021710526
CARBOMER	0.5	0.010855263

INCI Name	Inclusion level (%, w/w) Max.	Total Systemic (SED) mg/kg bw/day (Max)
TRIETHANOLAMINE	0.2	0.004342105
BENZALKONIUM CHLORIDE	0.1	0.002171053
TOCOPHERYL ACETATE	0.1	0.002171053

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 the formula ingredients are included here.

Margin of Safety calculation: MOS=NOAEL/SED

AQUA(CAS NO.7732-18-5)	
Conclusion of authoritative database:	Aqua is authorized as additive or monomer for plastic materials and articles in contact with foods (Regulation (EU) No 10/2011) with no specific restrictions[1]. Based on experimental and modeling data, the EPA has confirmed that this chemical substance poses a relatively low risk. Aqua is included in the "Information on the Use of Raw Materials in Marketed Products". The information on the use of raw materials in cosmetics is as follows: Whole body [leave-on]: 92.89% Whole body [rinse-off]: 95.09% Trunk [leave-on]: 97.15% Facial (including neck) [leave-on]: 98.85% Head [leave-on]: 98.917% Eye [leave-on]: 93.838% [2]. The content of water in this product is 90.01%. Therefore, it is concluded that the ingredient is safe for use at the proposed concentration in this product.
Regulatory requirements	NA
Conclusion Summary	This ingredient in this product is considered safe under normal and reasonably foreseeable conditions of use.
Reference: 1. EFSA 2012, Scientific Opinion on the safety evaluation of the active substances,activated carbon, water, iron powder, kaolin calcined, sulphur and sodiumchloride for use as active component in food contact materials. 2. NMPA 2024, Information on the Use of Raw Materials in Marketed Products. 3. EPA Safer Chemical Ingredients List.	

GLYCERIN(CAS NO.56-81-5)	
Acute Toxicity	The LD50 is greater than 11,500 mg/kg bw.
Dermal Irritation/Corrosion	No adverse effect observed (not irritating).
Eye Irritation/Corrosion	No adverse effect observed (not irritating).
Sensitization	No adverse effect observed (not sensitizing).
Phototoxicity	NA
Genetic toxicity	No adverse effect observed (negative).

Chronic toxicity	The chronic oral NOAEL of rat is 10000 mg/kg bw/day and the sub-chronic oral NOAEC of rat is 622 mg/m³. Thus, the NOAEL value of 1000 mg/kg bw/day be adopt as the Point of Departure.
Margin of Safety (MoS)	9212.121212
Conclusion of authoritative database:	CIR-Safe for use in leave-on and rinse-of cosmetic products at concentration no greater than 79.2%, and 99.4%.(Dermal Contact 99.4%).
Regulatory requirements	NA
Conclusion Summary	This ingredient in this product is considered safe under normal and reasonably foreseeable conditions of use.
Reference: 1. CIR 2019, Safety Assessment of Glycerin as Used in Cosmetics. 2. REACH-2,3-dihydroxypropyl 12-hydroxyoctadecanoate EC number228-507-4 CAS number6284-43-1.	

PROPYLENE GLYCOL(CAS NO.57-55-6)	
Acute Toxicity	The oral LD50 of 22000 mg/kg bw in rats, dermal LD50 > 2000 mg/kg bw in rabbits and inhalation LC50/2 h of > 317042 mg/m^{3}in rabbits.
Dermal Irritation/Corrosion	No adverse effect observed (not irritating)
Eye Irritation/Corrosion	No adverse effect observed (not irritating)
Sensitization	No adverse effect observed (not sensitising)
Phototoxicity	No phototoxicity.
Genetic toxicity	Propylene glycol was not a genetic toxicant as demonstrated by a battery of in vivo (micronucleus, dominant lethal, chromosome aberration) and in vitro (bacterial and mammalian cells and cultures) studies.
Chronic toxicity	Repeated exposures of rats to propylene glycol in drinking water or feed did not result in adverse effects at levels up to 10% in water (estimated at about 10 g/kg bw/day) or 5% in feed (dosage reported as 2.5 g/kg bw/day) for periods up to 2 years. In cats, two studies of at least 90 days duration show that a species-specific effect of increased Heinz bodies was observed (NOAEL = 80 mg/kg bw/day; LOAEL = 443 mg/kg bw/day), with other haematological effects (decrease in number of erythrocytes and erythrocyte survival) reported at higher doses (6-12% in diet, or3.7-10.1 g/cat/day). Propylene glycol did not cause fetal or developmental toxicity in rats, mice, rabbits, or hamsters (NOAELs range from 1.2 to 1.6 g/kg bw/day in four species). The WHO Committee has established an ADI of 0–25 mg/kg bw for propylene glycol as the food additive. In summary, the ADI value of 25 mg/kg bw is adopted as the Point of Departure.
Margin of Safety (MoS)	383.8383838
Conclusion of authoritative database:	The CIR safety assessment results indicate that when the formula is non-irritating, the ingredient is safe for use in cosmetics at concentrations not exceeding 99%.
Regulatory requirements	NA

Conclusion Summary	This ingredient in this product is considered safe under normal and reasonably foreseeable conditions of use.
Reference: 1. REACH 2010-Propane-1,2-diol EC number200-338-0 CAS number57-55-6. 2. WHO 1994，Propylene glycol. 3. OECD 2001, SIDS Initial Assessment Report for 11th SIAM. CIR 2012, Safety Assessment of Propylene Glycol, Tripropylene Glycol, and PPGs as Used in Cosmetics.	

ALOE BARBADENSIS EXTRACT(CAS NO.85507-69-3)	
Conclusion of authoritative database:	The CIR safety assessment results indicate that when the anthraquinone content in the ingredient does not exceed 50ppm, the ingredient is safe for use in cosmetics at a concentration not exceeding 6%.
Regulatory requirements	The FDA has determined that Aloe perryi, Aloe barbadensis, Aloe ferox, and hybrids of this species with Aloe africana and Aloe spicata are food additives permitted for direct addition to food for human consumption as natural flavoring substances (21 CFR 172.510).
Conclusion Summary	This ingredient in this product is considered safe under normal and reasonably foreseeable conditions of use.
Reference: 1. CIR 2007, Final Report on the Safety Assessment of Aloe Andongensis Extract, Aloe Andongensis Leaf Juice, Aloe Arborescens Leaf Extract, Aloe Arborescens Leaf Juice, Aloe Arborescens Leaf Protoplasts, Aloe Barbadensis Flower Extract, Aloe Barbadensis Leaf, Aloe Barbadensis Leaf Extract, Aloe Barbadensis Leaf Juice, Aloe Barbadensis Leaf Polysaccharides, Aloe Barbadensis Leaf Water, Aloe Ferox Leaf Extract, Aloe Ferox Leaf Juice, and Aloe Ferox Leaf Juice Extract.	

Carbomer (CAS NO. 9007-20-9)	
Acute Toxicity	The dermal LD50 of rats exposed to Carbomer was > 3 g/kg. And the inhalation LC50 of Carbomer in albino rats was 1.71 mg/l.
Dermal Irritation/Corrosion	Rabbits showed minimal skin irritation when tested with 100% Carbomer. Clinical studies with Carbomer and its various salts showed low potential for skin irritation and sensitization at concentrations of 0.5%, 5%, 10%, and 100%. When tested on humans at 1.0% concentration, Carbomer and its various salts also demonstrated low potential for skin irritation and sensitization. Further, formulations containing up to 0.25% Carbomer demonstrated low potential for human skin irritation, sensitization, phototoxicity, and photo-contact allergenicity.
Eye Irritation/Corrosion	Rabbits showed zero to moderate eye irritation when tested with Carbomer and/or its various salts at concentrations of 0.20-100%.
Sensitization	Clinical studies with Carbomer and its various salts showed low potential for skin irritation and sensitization at concentrations of 0.5%, 5%, 10%, and 100%. When tested on humans at 1.0% concentration, Carbomer and its various salts also demonstrated low potential for skin irritation and sensitization. Further, formulations containing up to 0.25%

	Carbomer demonstrated low potential for human skin irritation, sensitization, phototoxicity, and photo-contact allergenicity.
Phototoxicity	Clinical studies with Carbomer and its various salts showed low potential for skin irritation and sensitization at concentrations of 0.5%, 5%, 10%, and 100%. When tested on humans at 1.0% concentration, Carbomer and its various salts also demonstrated low potential for skin irritation and sensitization. Further, formulations containing up to 0.25% Carbomer demonstrated low potential for human skin irritation, sensitization, phototoxicity, and photo-contact allergenicity.
Genetic toxicity	In vivo, the analogue acrylic acid did not induce mutagenic effects in either rat bone marrow cells or mouse germ cells after oral administration.
Chronic toxicity	Following repeated oral administration of the analogue acrylic acid in drinking water to Wistar rats at the dose levels of 0, 120, 800, 2000 or 5000 ppm (equivalent to 0, 6, 40, 100 or 200 mg/kg and 0, 10, 66, 150 or 375 mg/kg, for males and females respectively) for 12 months, the dose of 800 ppm in males (equivalent to 40 mg/kg) was identified as a NOAEL based on decreased water intake and body weight at higher dose levels. No target organs were identified.
Margin of Safety (MoS)	3684.848485
Conclusion of authoritative database:	CIR: The Panel concluded the 126 acrylates copolymers named in this report are safe in cosmetics in the present practices of use and concentration described in the safety assessment when formulated to be non-irritating. (Leave-on:0.0012-15%, Rinse-off :0.00001-2.5)
Regulatory requirements	NA
Conclusion Summary	This ingredient in this product is considered safe under normal and reasonably foreseeable conditions of use.
Reference: 1. CIR 2018, Amended Safety Assessment of Acrylates Copolymers as Used in Cosmetics 2. REACH: 2-Propenoic acid, homopolymer EC number618-347-7 CAS number9007-20-9	

TRIETHANOLAMINE (CAS NO. 102-71-6)	
Acute Toxicity	Acute toxicity data indicate low toxicity: in rats the oral LD50 was 6400 mg/kg bw; in rabbits the dermal LD50 was > 2000 mg/kg bw. Inhalation exposure for 8 hours to vapour saturated with TEA failed to cause any deaths in rats (LC50 was not determined).
Dermal Irritation/Corrosion	No adverse effect observed (not irritating)
Eye Irritation/Corrosion	No adverse effect observed (not irritating)
Sensitization	No adverse effect observed (not sensitising)
Phototoxicity	NA
Genetic toxicity	TEA did not cause gene mutations in Salmonella typhimurium and Escherichia coli (Ames test), nor were chromosomal aberrations or sister chromatid exchanges induced in Chinese hamster ovary cells observed. An in vitro gene mutation assay (mouse lymphoma (L5178Y

	TK+/-) forward gene mutation assay) was also negative. All tests were performed in the absence and presence of metabolic activation.
Chronic toxicity	In a sub-chronic oral toxicity study, a NOAEL of 1000 mg/kg bw/day was established, the highest dose tested. In a sub-chronic dermal toxicity study, NOAELs of 125 and 250 mg/kg bw/day were established for local effects for males and females. Thus, the NOAEL of 125mg/kg bw/day is adopt as Point of Departure
Margin of Safety (MoS)	28787.87879
Conclusion of authoritative database:	European Union (EU) cosmetic restriction III/62: Authorised use in leave-on products at a maximum concentration of 2.5 % in the finished product. Furthermore, for both leave-on and rinse-off products the following restrictions apply: do not use with nitrosating systems; minimum purity: 99 %; maximum secondary amine content: 0.5 % (applies to raw materials); maximum nitrosamine content: 50 microgram/kg; and keep in nitrite-free containers. The CIR safety assessment indicates that when the formula is non-irritating, the concentration of this component should not exceed 6% in the leave-on products and 19% in the rinse-off products, and it is safe to use. It should not be applied in cosmetics that can form N-nitroso compounds. (Note: The content of its free diethanolamine (DEA) should not exceed the conventional usage standard of DEA itself.)
Regulatory requirements	NA
Conclusion Summary	This ingredient in this product is considered safe under normal and reasonably foreseeable conditions of use.

Reference:
1. CIR 2013, Safety Assessment of Triethanolamine and Triethanolamine-Containing Ingredients as Used in Cosmetics.
2. RECAH 2010, 2,2',2"-nitrilotriethanol EC number203-049-8 CAS number102-71-6.
3. NICNAS 2013, Ethanol, 2,2',2"-nitrilotris-: Human health tier II assessment.

BENZALKONIUM CHLORIDE (CAS NO. 68424-85-1)	
Acute Toxicity	Acute oral LD50 was 240–525 mg/kg bw for benzalkonium chloride. The dermal LD50 was 930 mg/kg bw for benzalkonium chloride when applied at a concentration of 82.26%
Dermal Irritation/Corrosion	H314 (99.4%): Causes severe skin burns and eye damage [Danger Skin corrosion/irritation]
Eye Irritation/Corrosion	H318 (55.7%): Causes serious eye damage [Danger Serious eye damage/eye irritation]
Sensitization	No adverse effect observed (not sensitising)
Phototoxicity	NA
Genetic toxicity	Negative
Chronic toxicity	Read-across: NOAELs(chronic oral, rats): 44 and 57 mg/kg bw/day for alkyldimethylbenzylammonium chloride; In a 52 week oral toxicity study, beagle dogs (3/vehicle/dose) received 12.5, 25 or 50 mg/kg bw/day benzalkonium chloride (10% solution in water or milk). One animal in the high dose(water) and 3 animals in the mid dose (water) did not survive the treatment period.

	BfR derived an ADI value of 0.1 mg/kg bw/day and an ARfD of 0.1 mg/kg bw (body weight) for benzalkonium chloride. Thus, the ADI value of 0.1 mg/kg bw/day is adopt as Point of Departure
Margin of Safety (MoS)	4606.060606
Conclusion of authoritative database:	The Cosmetic Ingredient Review (CIR) Expert Panel stated that Benzalkonium Chloride, at concentrations up to 0.1% free, active ingredient, is safe as a cosmetic ingredient as presently used.
Regulatory requirements	Benzalkonium chloride, as a food additive or ingredient, has been recognized by the FDA as a "Generally Recognized as Safe" (GRAS) substance based on long-term historical use records and scientific evaluations。
Conclusion Summary	This ingredient in this product is considered safe under normal and reasonably foreseeable conditions of use.
Reference: 1. CIR 2008, Annual Review of Cosmetic Ingredient Safety Assessments: 2005/2006. 2. FDA Generally Recognized as Safe - GRAS Notices 488. 3. NICNAS 2022, Benzalkonium halides Evaluation statement. 4. BfR 2012, Health assessment of benzalkonium chloride residues in food.	

TOCOPHERYL ACETATE (CAS NO. 7695-91-2)	
Acute Toxicity	The oral LD50 was > 10000 mg/kg bw in rats.
Dermal Irritation/Corrosion	No adverse effect observed (not irritating).
Eye Irritation/Corrosion	No adverse effect observed (not irritating).
Sensitization	No adverse effect observed (not sensitising).
Phototoxicity	NA.
Genetic toxicity	According to EU Directive 67/548/EEC and EU Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulation (EC) No. 1272/2008 classification is not warranted.
Chronic toxicity	The NOAEL of 500 mg/kg bw/day was based on a well conducted 90-day study in rat comparable to OECD guideline 408 (Abdo, 1986).
Margin of Safety (MoS)	230303.0303
Conclusion of authoritative database:	CIR-Safe for use in leave-on and rinse-of cosmetic products at concentration no greater than 36%, and 10%.
Regulatory requirements	NA.
Conclusion Summary	This ingredient in this product is considered safe under normal and reasonably foreseeable conditions of use.
Reference: 1. REACH 2015, 3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-yl acetate EC number231-710-0 CAS number7695-91-2 2. CIR 2018, Safety Assessment of Tocopherols and Tocotrienols as Used in Cosmetics	

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 and its amendments. The safety assessment has been carried out in accordance with this regulation and its subsequent amendments.

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. 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)	Max. allowed conc. (%)	Margin of Safety	Assessment Conclusion
AQUA	90.1	92.89	/	Safe for human health under normal and reasonably foreseeable conditions of use.
GLYCERIN	5	79.2	9212.121212	Safe for human health under normal and reasonably foreseeable conditions of use.
PROPYLENE GLYCOL	3	99	38383.838	Safe for human health under normal and reasonably foreseeable conditions of use.
ALOE BARBADENSIS LEAF EXTRACT	1	6	/	Conforms to regulated usage.
CARBOMER	0.5	15	3684.848485	Safe for human health under normal and reasonably foreseeable conditions of use.
TRIETHANOLAMINE	0.2	6	28787.87879	Safe for human health under normal and reasonably foreseeable conditions of use.
BENZALKONIUM CHLORIDE	0.1	0.1	4606.0606	Conforms to regulated usage.

Substance Name	Conc. (% w/w)	Max. allowed conc. (%)	Margin of Safety	Assessment Conclusion
TOCOPHERYL ACETATE	0.1	36	230303.0303	Safe for human health under normal and reasonably foreseeable conditions of use.

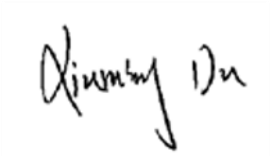
B.3.2 Safety Evaluation of the Product

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



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 Date:27-Jul-26

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

Work Experience：

2025.6 – Current BUREAU VERITAS CONSUMER PRODUCTS SERVICES.

Responsible for the toxicological safety assessment work of consumer products, including cosmetics, chemicals, toys, art materials, etc.

Evaluate the accuracy and completeness of toxicological data of different consumer products.

Write and issue TRA or CPSR of consumer products.

Provide training on toxicology-related regulations and technical support for both internal and external parties.

2023.09 –2025.05 Puni Testing Group Shanghai Co., Ltd.

Responsible for the operation and management of the Consumer Product Toxicology Department, system document construction, and overall coordination of CMA and CNAS expansion work.

As an authorized signatory, review and issue toxicology reports, including acute toxicity, local toxicity, genetic toxicity, repeated dose toxicity test, and reproductive and developmental toxicity test.

Review CPSR reports of cosmetic products.

Provide training on toxicology-related regulations and technical support for both internal and external parties.

2016.08 – 2023.08 Shanghai Research Institute of Chemical Industry

Participate in and be responsible for the expansion and review of GLP, CNAS, and CMA in the health toxicology testing department.

Conduct health hazard assessments on cosmetics, chemicals, disinfectants, pesticides, and new chemical substances, and lead and participate in project implementation, including acute toxicity, local toxicity, genetic toxicity.

Write and issue CPSR of cosmetic products and raw materials; Provide registration and filing compliance consulting services such as formula review and label review for enterprises.

APPENDIX: Toxicologist's Certificate

*** End of Report ***