TECHNICAL REPORT – CPSR REPORT

Report No. （6625）286-0291 R1 **Date 2025-11-26**

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Client:	Mid Ocean Brands B.V		
Address:	Unit 711-716, 7/F., Tower A, 83 King Lam Street, Cheung Sha Wan, Kowloon, Hong Kong		
Sample name:	Aloe After Sun Gel (1 formulation)		
Net weight:	30ml, 50ml, 60ml per consumer product		
Style/ Item No.:	MO2911	Country of Origin:	China
Buyer:	/	Expiry Date:	/
Manufacturer:	vendor code: 113285	Date of Receipt:	2025-10-13
Production Date:	/	Assessment Period:	2025-10-13 to 2025-11-24
Sample Source:	/	Appropriate Age Grade:	/
Status of Sample:	/		
Client Specified Age Grade:	/	Tested Age Grade:	/

Test specification:

Cosmetic Product Safety Assessment

Test result*:

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

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

2.This report replaces the original report, and the original report (6625)286-0291 is void.

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

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PART A – Cosmetic product safety information

A.1 Quantitative and qualitative Composition of Products

A.1.1 Nominal Composition

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

INCI Name	CAS No.	EC No.	Conc. (%, w/w)	Function
AQUA	7732-18-5	231-791-2	91.897	Solvent
PROPYLENE GLYCOL	57-55-6	200-338-0	3.000	Humectant
GLYCERIN	56-81-5	200-289-5	3.000	Humectant
ALOE BARBADENSIS LEAF EXTRACT	85507-69-3	287-390-8	0.500	Skin conditioning - emollient
PHENOXYETHANOL	122-99-6	204-589-7	0.500	Preservative
CARBOMER	9007-16-3	/	0.500	Gel forming
PARFUM (Aloes OW-0751)	Mixture	/	0.300	Perfuming
TRIETHANOLAMINE	102-71-6	203-049-8	0.200	Buffering
TOCOPHERYL ACETATE	58-95-7	200-405-4	0.100	Antioxidant
CI 19140	1934-21-0	217-699-5	0.002	Colorant
CI 42090	3844-45-9	223-339-8	0.001	Colorant

FRAGRANCE ALLERGENS

Fragrance allergen **Eugenol, Geraniol, Linalool, Hexyl Cinnamal, Limonene** must be declared on the product label in the ingredients section according to EU Cosmetic Regulation.

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

A.2.1 Physical/chemical characteristics of Raw Materials

The raw materials specifications are available upon request.

A.2.2 Physical chemical specifications of the end product

The finished product is green gel with aloe scent.

A.2.3 End product stability

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

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

A.2.4 Durability (PAO)

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

A.3 Microbiological quality

A.3.1 The microbiological specifications of the substance or mixture

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

A.3.2 The microbiological testing results of end product

The microbiological testing results of end product according to European Pharmacopoeia 9.0 2.6.12 & 2.6.13 were listed below.

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

Conclusion: According to Appendix 9 of the 12th Revision of the NoG (SCCS/1647/22) and ISO 17516:2014, the microbiological quality of this product was considered as **acceptable** for **Category 2 products**.

A.3.3 Results of preservation challenge test

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

Microorganisms	**D7**	**D14**	**D28**
	Log reduction values		
Escherichia coli	>5.8	>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

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

A.4 Impurities, traces and information about the packaging material

A.4.1 Impurities and Traces of prohibited substances

The potential impurities and traces relevant for the raw materials were controlled via the raw material specifications. And the raw material specifications are available upon request. This product does not contain any relevant impurity at significant levels, and the analytical testing results of heavy metals (below table) indicated the

content of As, Hg, Pb, Sb, Cd and Ni (soluble) in this product were undetected and considered to be **acceptable** according to German Health Authority BgA recommendations form German Health Journal No.28, July 1985 and German Health Journal No.7/1992, Session 45 from November 14,1991. Furthermore, in conformity with the article 3 of the regulation, the safety evaluation of this impurity and trace of prohibited substances is part of the safety evaluation of the cosmetic product.

Items	Testing Results	German Health Authority BgA(Recommendation form German Health Journal No.28, July 1985)	German Health Journal No.7/1992, Session 45 from November 14,1991
Pb, mg/kg	<0.1	≤20	-
Hg, mg/kg	<0.1	≤1	-
As, mg/kg	<0.1	≤5	-
Sb, mg/kg	<0.1	≤10	-
Cd, mg/kg	<0.1	≤5	-
Ni (soluble), mg/kg	<0.1	-	≤0

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

A.4.2 Information about the Packaging Material

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

No.	Part	Material
1	Bottle	PETG
2	Cover	PP
3	Carabiner	Aluminum alloy

A.4.3 Chemical purity of the packaging materials

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

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

A.4.4 Compatibility of package

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

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

A.5 Normal and reasonably foreseeable use

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

A.5.1 Normal use and reasonably foreseeable use conditions:

The normal use of this product is intended to be applied as after sun gel by the population of 3 years old and above. Other usage is not foreseeable.

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

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

A.6 Exposure to the cosmetic product

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

A.6.1 Product Type

This cosmetic product is applied as after sun gel

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: whole body skin

Application Surface area: 565 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: 1.5 g

A.6.6 Duration and Frequency

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

Frequency of use: infrequent

Exposure duration: leave-on

A.7 Exposure to the substances

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

A.7.1 Exposure to the substance

INCI Name	Inclusion level (% w/w)	Total Systemic (SED) mg/kg bw/day	Local Dermal (CEL) µg/cm²
AQUA	91.897	91.2904798	2439.86535
PROPYLENE GLYCOL	3.000	2.9802	79.65
GLYCERIN	3.000	2.9802	79.65
ALOE BARBADENSIS LEAF EXTRACT	0.500	0.4967	13.275
PHENOXYETHANOL	0.500	0.4967	13.275
CARBOMER	0.500	0.4967	13.275
PARFUM (Aloes OW-0751)	0.300	0.29802	7.965
TRIETHANOLAMINE	0.200	0.19868	5.31
TOCOPHERYL ACETATE	0.100	0.09934	2.655
CI 19140	0.002	0.0019868	0.0531
CI 42090	0.001	0.0009934	0.02655

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 PROPYLENE GLYCOL, GLYCERIN, ALOE BARBADENSIS LEAF EXTRACT, CARBOMER, and TOCOPHERYL ACETATE are included here.

Toxicological profile of PROPYLENE GLYCOL (CAS# 57-55-6)

Toxicological endpoints:

Acute toxicity: Its acute oral toxicity was practically non-toxic with the lowest oral LD_{50} values range between 18 and 23.9 g/ kg bw (5 different species) and the reported dermal LD_{50} is 20.8 g/kg bw in rabbits [1-3].

Skin irritation: In one primary skin irritation test according to OECD TG 404, it was found to be not irritating to the rabbit skin [1-3].

Eye irritation: It was found to be not irritating to eyes in acute eye irritation test in rabbits according to OECD TG 405 [1-3].

Skin sensitization: Based on the several animal studies and the data from human study, it is concluded that its skin sensitization potential was very low.

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

Repeated dose 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/d) for periods up to 2 years [1, 3].

Mutagenicity/Genotoxicity: 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 [1, 3, 4].

Carcinogenicity: No increase in tumors was found in all tissues examined when propylene glycol was administered in the diet of rats (2.5 g/kg bw/d for 2 years), or applied to the skin of female rats (100% PG; total dose not reported; 14 months) or mice (mouse dose estimated at about 2 g/kg bw/week; lifetime) [1, 3, 4].

Reproductive toxicity: Based on the absence of adverse effects on reproduction and development in available continuous breeding study and developmental toxicity studies, it shall not be recognized as a reproductive or developmental toxicant.

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	2500 mg/kg bw/d
Exposure Estimate	2.9802 mg/kg bw/d
Margin of Safety (MoS)	839

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 99% [2].

Conclusion

It is authorised as a food additive in EU and other regions with ADI of 25 mg/kg bw/d set by both EFSA and JECFA. It was recognized to pose no unreasonable risk to human health based on Tier I assessment under the NICNAS IMAP assessment framework. 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 ofPropane-1,2-diol (CAS No. 57-55-6). Last accessed on 2022-10-22@ https://echa.europa.eu/registration-dossier/-/registered-dossier/16001.

[2] CIR Expert Panel. Safety Assessment of Propylene Glycol, Tripropylene Glycol, and PPGs as Used in Cosmetics. IJT 31(Suppl 2):245-260, 2012.

[3] SIDS INITIAL ASSESSMENT PROFILE of Propylene glycol (1,2-dihydroxypropane). SIAM 11, 23-26 January 2001.

[4] EFSA. Re-evaluation of propane-1,2-diol (E 1520) as a food additive. EFSA Journal 2018;16(4):5235.

Toxicological profile of GLYCERIN (CAS# 56-81-5)

Toxicological endpoints:

Acute toxicity: Its acute toxicity was practically non-toxic [1, 2].The oral LD_{LO} of glycerin was reported to be 1428 mg/kg for humans [3].

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

Eye irritation: It is not considered as an eye irritant [1].

Skin sensitization: Based on the available information, there is no human or animal data that indicates glycerol to be a skin sensitiser.

Phototoxicity: Weight of evidence indicated it was not phototoxic.

Repeated dose toxicity: Repeated oral exposure to glycerin does not induce adverse effects other than local irritation of the gastro-intestinal tract. And in one 2-year chronic diet feeding study in rats, NOAEL was considered as10,000 mg/kg bw/day (20% in diet) [1-3].

Mutagenicity/Genotoxicity: It'snot considered to possess genotoxic potential.

Carcinogenicity: Glycerin administered in the feed of rats at concentrations up to 20% for 2 years did not increase the incidence of tumors. Hence, it's considered to be of no concern with regard to carcinogenicity [1-3].

Reproductive toxicity: No effects on fertility and reproductive performance were observed in a two generation reproductive toxicity study with glycerin administered by gavage (NOAEL 2000 mg/kg bw/day) [1-3].

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	10000 mg/kg bw/d
Exposure Estimate	2.9802 mg/kg bw/d
Margin of Safety (MoS)	3355

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 79.2% and 99.4% respectively [3]. Glycerin was on the restriction list of Cosmetic Ingredient Hotlist in Canada and Conditions of Use was "Manufacturers of oral and leave-on products containing glycerin must ensure the raw material used is within the specifications of an accepted pharmacopoeia with respect to diethylene glycol (DEG) impurities (e.g. Glycerin Official Monograph in the most current edition of the USP)".

Conclusion

Glycerin is a clear, syrupy liquid and is naturally occurring in all animals and plant matter in combined form as glycerides in fats and oils, or, in intracellular spaces as lipids. Natural glycerin is obtained as a byproduct in the conversion of fats and oils to fatty acids or fatty acid methyl esters. The U.S. Pharmacopeia-National Formulary (USP-NF) standards state that the amount of any individual impurity in glycerin cannot exceed 0.1%, and that the total for all impurities, including diethylene glycol and ethylene glycol, must not exceed 1%. Glycerin is considered generally recognized as safe (GRAS) by the FDA for its use in food packaging and it is a multiple-purpose GRAS food substance when used in accordance with good manufacturing practices [21CFR182.90; 21CFR182.1320]. 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 Glycerol (CAS No. 56-81-5). Last accessed on 2024-09-12@

https://echa.europa.eu/registration-dossier/-/registered-dossier/14481.
[2] OECD SIDS. INITIAL ASSESSMENT PROFILE of Glycerol. SIAM 14 Paris, France, 26-28 March 2002.
[3] CIR Expert Panel. Safety Assessment of Glycerin as Used in Cosmetics. IJT 38(Suppl. 3): 6-22, 2019.

Toxicological profile of ALOE BARBADENSIS LEAF EXTRACT (CAS# 85507-69-3/ 94349-62-9)

Toxicological endpoints:

Acute toxicity: Its acute toxicity was assumed to be practically non-toxic as Aloe barbadensis–derived ingredients (also known as Aloe vera) were not toxic in acute oral studies using mice (at doses up to 3 g/kg) [1].

Skin irritation: It was not a skin irritant [2].

Eye irritation: It was not an eye irritant [2].

Skin sensitization: It was assumed to be non-sensitizing as one 0.5% Aloe extract was non-photosensitizing [1] and the content of anthraquinone in this ingredient is below 0.2 ppm from the submitted technical data.

Phototoxicity: No data. But it was considered acceptable as it was demonstrated not to have significant UV absorption capacity.

Repeated dose toxicity: No data. But it was considered acceptable as Aloe barbadensis was the food additives permitted for direct addition to food for human consumption as natural flavoring substances (21CFR 172.510) [1]. In addition, in one 13-week repeated dose oral toxicity study in rats, Qmatrix® (a white to light tan powder derived from mucilaginous parenchymal cells found in the inner central area of the Aloe barbadensis leaf) produced no significant adverse effects and the NOAEL was recognized as 2000 mg/kg bw/d [3].

Mutagenicity/Genotoxicity: No data. But it was considered acceptable as Qmatrix® was non-mutagenic in an Ames test and a chromosomal aberration test at concentrations up to 10,000 μg/plate, and in an in vivo bone marrow micronucleus test at doses up to 5000 mg/kg bw/day [3].

Carcinogenicity: No data. But it was considered acceptablethe content of anthraquinone in this ingredient is below 0.2 ppm and recognized to lack genotoxicity potential.

Reproductive toxicity: No data and the observed reproductive/developmental toxicity effects in experimental animals were related with the high concentration of anthraquinone. But this ingredient was considered to lack reproductive toxicity potential as the content of anthraquinone in this ingredient is below 0.2 ppm.

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	2000 mg/kg bw/d
Exposure Estimate	0.4967 mg/kg bw/d
Margin of Safety (MoS)	4027

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 cosmetic products at the concentration up to 6% as Aloe extract [1].

Conclusion

Aloe Barbadensis Leaf Extract is an extract of the leaves of the aloe, Aloe barbadensis, Liliaceae. The Aloe

Barbadensis plant has a long history of safe use for oral and topical applications. Based on the above information, 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 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. International Journal of Toxicology, 26(Suppl. 2):1–50, 2007.
[2] SDS of this ingredient from the supplier.
[3] Williams LD, et al. Safety studies conducted on a proprietary high-purity aloe vera inner leaf fillet preparation, Qmatrix. Regul Toxicol Pharmacol. 2010, 57(1):90-8.

Toxicological profile of CARBOMER (CAS No.9007-20-9 / 9003-01-4 / 76050-42-5 / 9062-04-8 / 9007-16-3 / 9007-17-4)

Toxicological endpoints:

Acute toxicity: Its acute toxicity was considered to be very low based on its relatively large molecular size and read-across to suitable analogues [1, 2].

Skin irritation: It was considered to be not irritating based on its relatively large molecular size and it was found to be not a skin irritant in the acute irritation test in rabbits [1,2].

Eye irritation: It was considered to be not irritating based on its relatively large molecular size [1].

Skin sensitization: It was considered to be not sensitizing based on its relatively large molecular size and by read-across to suitable analogues [1].

Phototoxicity: No photosensitization data on this polymer were available for review, but the UV absorption characteristics suggest that phototoxicity is unlikely [1].

Repeated dose toxicity: Subchronic feeding of rats and dogs with up to 5.0% Carbomer in the diet (90 days) resulted in lower than normal body weights. In rats fed Carbomer at dietary levels of 5.0% for 90 days, absolute liver weights and liver to body and brain weight ratios were reduced, but no pathological changes were observed, and NOAEL can be recognized as 5% diet level (ca. 2500 mg/kg bw/d) [2].

Mutagenicity/Genotoxicity: It was considered to be not mutagenic based on its relatively large molecular size and by read-across to suitable analogues [1].

Carcinogenicity: It was considered to lack carcinogenicity potential based on its relatively large molecular size and by read-across to suitable analogues [1].

Reproductive toxicity: No data. But it was considered to lack reproductive toxicity potential because a stable high molecular weight polymer is biologically inert as its large size precludes any significant bioavailability.

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	2500 mg/kg bw/d
Exposure Estimate	0.4967 mg/kg bw/d
Margin of Safety (MoS)	5033

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 15% and 2.5% respectively [1].

Conclusion

Carbomer is a homopolymer of acrylic acid crosslinked with an allyl ether of pentaerythritol, an allyl ether of sucrose, or an allyl ether of propylene. As a stable high molecular weight polymer itself is generally inert because its large size precludes any significant bioavailability, hence it is concluded that it is sufficient to consider it safe to be used as intended in this product.

Reference list:

[1] ECHA. Substance Infocard of Carbomer (CAS No. 9007-20-9). Last accessed on 2024-01-222 https://echa.europa.eu/registration-dossier/-/registered-dossier/22071

[2] CIR Expert Panel. 2018. Amended Safety Assessment of Acrylates Copolymers as Used in Cosmetics.

Toxicological profile of TOCOPHERYL ACETATE (CAS# 7695-91-2 / 58-95-7)

Toxicological endpoints:

Acute toxicity: Its acute toxicity was practically non-toxic with oral LD_{50} > 10000 mg/kg bw in rats and dermal LD_{50} > 3000 mg/kg bw in rabbits [1, 2].

Skin irritation:It was found to be not irritating in one primary irritation test in rabbits according to OECD TG 404 [1, 2].

Eye irritation: It was found to be not irritating in one acute eye irritation test in rabbits according to OECD TG 405 [1, 2].

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

Phototoxicity: Weight of evidence indicated it lacked phototoxicity potential [1, 2].

Repeated dose toxicity: In one subchronic oral toxicity study, the rats were dosed at 125, 500 and 2000 mg/kg. The relative liver weight was significantly increased in high dose females. Administration of 2000 mg/kg bw/d caused hematological changes: prolongation of prothrombin and activated partial thromboblastin (APTT) times and an increase in fibrinogen value, reticulocytosis and a decrease in hematocrit values and hemoglobin concentrations was observed in males; APTT times were also increased in females. Hemorrhagic diathesis was observed in males and females of the high dose group; and increased medullary erythropoiesis was seen in the spleen of one high dose male. The test substance at all dose levels tested caused interstitial inflammation and adenomatous hyperplasia of the

lung. The lung lesions were observed in all vitamin E-treated groups, and the incidence and severity increased in a dose-dependent manner. These lesions were characterized by increased cellularity, vascular congestion, thickened alveolar walls and the presence of foamy macrophages (some of which had undergone cell death and degeneration) in the alveolar spaces. A lipid-like yellow pigmentation was often present within either the macrophages or alveoli. These effects were attributed (as in the other oral gavage 90-day in minipigs study) to local aspiration of the test substance, which would not occur under normal circumstances. Furthermore, these effects were not seen in the chronic feed study (Wheldon, 1978). Therefore, for the NOAEL derivation the effects in the lungs were not considered. Because at 500 mg/kg only APTT values were increased in absence of an increase in PT and fibrinogen value, the NOAEL is set at 500 mg/kg bw/d [1]. In addition, in a 4-month clinical study as well as other well-designed clinical studies conducted in humans with DL-Alpha Tocopheryl acetate. Based on the absence of adverse effects up to the highest dose, the NOAEL was established at a dose of 540 mg alpha-tocopherol equivalents (TE)/day.

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

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

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

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	500 mg/kg bw/d
Exposure Estimate	0.09934 mg/kg bw/d
Margin of Safety (MoS)	5033

Regulatory Status: Not Regulated in Regulation (EC) No 1223/2009 with the assessment opinion from SCCNFP that alpha-tocopherol acetate does not pose a threat to the health of the consumer and therefore does not propose any restrictions or conditions on the use of alpha-tocopherol acetate in cosmetic products [3]. CIR also concluded that it can be safely used in leave-on and rinse-off cosmetics at the concentration up to 36% and 10% respectively [2].

Conclusion

It is the acetate ester of tocopherol. It is prepared by esterification of dl-*α* tocopherol with acetic acid. *α*-TA is mainly used in cosmetics as humectants, skin protectant or conditioning agent up to concentration of ≤36%. Further, it is functionally used as a nutrient, dietary supplement and antioxidant. *α*-Tocopherol and *α*-tocopheryl acetate are GRAS food ingredients when used as a nutrient, and a-tocopherol is GRAS as a chemical preservative in food when used in accordance with good manufacturing practices (21CFR182.8890; 21CFR182.8892; 21CFR182.8390). A group ADI of 0.15-2 mg/kg bw/d for dl-alpha-tocopherol and d-alpha-tocopherol concentrate, singly or in combination was set by JECFA. The tolerable upper intake level (UL) for vitamin E from all dietary sources, which were previously established by the Scientific Committee on Food, are 300 mg/day for adults, including pregnant and lactating women, 100 mg/day for children aged 1–3 years, 120 mg/day for 4–6 years, 160 mg/day for 7–10 years, 220 mg/day for 11–14 years and 260 mg/day for 15–17 years. From the currently available data, it was shown to be of low acute and repeated dose toxicity potential together with low skin/eye irritation and sensitization potential. There is no concern that tocopherols are genotoxic, carcinogenic, or teratogenic. 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. Registration dossier of 3,4-dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-yl acetate (CAS No. 7695-91-2). Last accessed on 2024-09-12@ https://echa.europa.eu/registration-dossier/-/registered-dossier/13377.
[2] CIR Expert Panel. Safety Assessment of Tocopherols and Tocotrienols as Used in Cosmetics. IJT 37(Suppl. 2): 61-94, 2018.
[3] SCCNFP. THE USE OF ALPHA-TOCOPHEROL ACETATE IN COSMETIC PRODUCTS. SCCNFP/0494/01, final.

A.9 Undesirable effects and serious undesirable effects

As at the date of this report the product has not yet been commercialized, therefore there are no data available from post marketing surveillance on undesirable effects or serious undesirable effects to the cosmetic product.

No relevant data on other cosmetic product are available.

A.10 Information on the Cosmetic Product

No other relevant information was submitted.

PART B – Cosmetic Product Safety Assessment

B.1 Assessment conclusion

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

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

B.2 Labelled warnings and instructions of use

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

B.3 Reasoning

B.3.1 Safety Evaluation of the Substances

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

Substance Name	Conc. (% w/w)	Max. allowed conc. (%)	Margin of Safety	Assessment Conclusion
PROPYLENE GLYCOL	3.000	NA	839	Safe for human health under normal and reasonably foreseeable conditions of use.
GLYCERIN	3.000	NA	3355	Safe for human health under normal and reasonably foreseeable conditions of use..
ALOE BARBADENSIS LEAF EXTRACT	0.500	NA	4027	Safe for human health under normal and reasonably foreseeable conditions of use.
PHENOXYETHANOL	0.500	1	NA	Conforms to regulated usage.
CARBOMER	0.500	NA	5033	Safe for human health under normal and reasonably foreseeable conditions of use.
PARFUM (Aloes OW-0751)	0.300	14.6	NA	conforms to IFRA standards
TRIETHANOLAMINE	0.200	2.5	NA	Conforms to regulated usage.
TOCOPHERYL ACETATE	0.100	NA	5033	Safe for human health under normal and reasonably foreseeable conditions of use.
CI 19140	0.002	NA	NA	Conforms to regulated usage.
CI 42090	0.001	NA	NA	Conforms to regulated usage.

B.3.2 Safety Evaluation of the Product

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

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

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

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

Dr. Raul Xin, EUROTOX Registered Toxicologist (ERT)

Authorized external expert of Bureau Veritas

*** End of Report ***