TECHNICAL REPORT – CPSR REPORT

Report No. （6625）240-1289 **Date 2025-10-10**

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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:	Sunscreen Lotion (1 formulation)		
Net weight:	30ml, 45ml per consumer product		
Style/ Item No.:	MO6115, MO8512	Country of Origin:	China
Buyer:	/	Expiry Date:	/
Manufacturer:	vendor code: 113285	Date of Receipt:	2025-08-28
Production Date:	/	Assessment Period:	2025-08-28 to 2025-10-09
Sample Source:	/	Appropriate Age Grade:	/
Status of Sample:	/		
Client Specified Age Grade:	/	Tested Age Grade:	/

Test specification:

Cosmetic Product Safety Assessment

Test result*:

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

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

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

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PART A – Cosmetic product safety information

A.1 Quantitative and qualitative Composition of Products

A.1.1 Nominal Composition

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

INCI Name	CAS No.	EC No.	Conc. (%, w/w)	Function
AQUA	7732-18-5	231-791-2	53.10	Solvent
ETHYLHEXYL METHOXYCINNAMATE	5466-77-3	226-775-7	7.00	UV filter
ISOPROPYL MYRISTATE	110-27-0	203-751-4	5.00	Skin conditioning - emollient
CAPRYLIC/CAPRIC TRIGLYCERIDE	73398-61-5	277-452-2	5.00	Skin conditioning - occlusive
CETEARYL ALCOHOL	8005-44-5	267-008-6	5.00	Surfactant - emulsifying
GLYCERIN	56-81-5	200-289-5	5.00	Humectant
ETHYLHEXYL SALICYLATE	118-60-5	204-263-4	5.00	UV filter
C12-15 ALKYL BENZOATE	68411-27-8	270-112-4	4.00	Skin conditioning - emollient
CETETH-25	9004-95-9	/	3.00	Surfactant - emulsifying
GLYCERYL STEARATE	31566-31-1	250-705-4	3.00	Skin conditioning - emollient
BENZOPHENONE-3	131-57-7	205-031-5	2.00	UV filter
TITANIUM DIOXIDE	13463-67-7	236-675-5	2.00	UV absorber
PARFUM (Vanilla MY11-S089)	Mixture	/	0.30	Perfuming
DMDM HYDANTOIN	6440-58-0	229-222-8	0.30	Preservative
METHYLPARABEN	99-76-3	202-785-7	0.20	Preservative
PROPYLPARABEN	94-13-3	202-307-7	0.10	Preservative

FRAGRANCE ALLERGENS

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

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

A.2.1 Physical/chemical characteristics of Raw Materials

The raw materials specifications are available upon request.

A.2.2 Physical chemical specifications of the end product

The finished product is white lotion with vanilla scent.

A.2.3 End product stability

The stability evaluation of the above formula was conducted under different operating conditions in an appropriate packaging at -15°C, -5°C, 25°C, and 40°C for 12 weeks, light exposure for 12 weeks, and cycling test (3 cycle freeze thaw 40°C/RT/4°C) were also conducted. The organoleptic, physico-chemical and microbiological examinations (including appearance, colour, odour, 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	>5.6	>5.6	>5.6
Staphylococcus aureus	>5.2	>5.2	>5.2
Pseudomonas aeruginosa	>5.3	>5.3	>5.3

Candida albicans	>5.4	>5.4	>5.4
Aspergillus niger	>5.5	>5.5	>5.5

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	-	≤10

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	PP
2	Tube	PE
3	Cap	PP

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 sunscreen lotion 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

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: 6200 cm^2 (child); 17500 cm^2 (adult)

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: 6.38 g (child); 18 g (adult)

A.6.6 Duration and Frequency

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

Frequency of use: twice per day

Exposure duration: leave-on

A.7 Exposure to the substances

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

A.7.1 Exposure to the substance

INCI Name	Inclusion level (% w/w)	Total Systemic (SED) mg/kg bw/day	Local Dermal (CEL) μg/cm2
AQUA	53.10	224.613	546.399
ETHYLHEXYL METHOXYCINNAMATE	7.00	29.61	72.03
ISOPROPYL MYRISTATE	5.00	2.115	5.145
CAPRYLIC/CAPRIC TRIGLYCERIDE	5.00	21.15	51.45
CETEARYL ALCOHOL	5.00	2.115	5.145
GLYCERIN	5.00	21.15	51.45
ETHYLHEXYL SALICYLATE	5.00	21.15	51.45
C12-15 ALKYL BENZOATE	4.00	1.692	4.116
CETETH-25	3.00	0.1269	0.3087
GLYCERYL STEARATE	3.00	12.69	30.87
BENZOPHENONE-3	2.00	8.46	20.58
TITANIUM DIOXIDE	2.00	8.46	20.58
PARFUM (Vanilla MY11-S089)	0.30	1.269	3.087
DMDM HYDANTOIN	0.30	1.269	3.087
METHYLPARABEN	0.20	0.846	2.058
PROPYLPARABEN	0.10	0.423	1.029

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 ISOPROPYL MYRISTATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, CETEARYL ALCOHOL, GLYCERIN, C12-15 ALKYL BENZOATE, CETETH-25 and GLYCERYL STEARATE are included here.

Toxicological profile of ISOPROPYL MYRISTATE (CAS# 110-27-0)

Toxicological endpoints:

Acute toxicity: Its acute toxicity was considered to be very low with oral LD_{50} > 2000 mg/kg bw in rats and dermal LD_{50} > 5000 mg/kg bw in rabbits [1, 2].

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

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

Skin sensitization: It was not skin sensitizing in one guinea pig maximisation test [1, 2].

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

Repeated dose toxicity: In a 28-day oral gavage study a NOAEL of 1000 mg/kg bw/d was found for male and female Wistar rats [1].

Mutagenicity/Genotoxicity: Based on the available information, it can be concluded that there is no concern with respect to genotoxicity [1, 2].

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

Reproductive toxicity: Weigt of evidence indicated it will not be classified as a reproductive or developmental toxicant [1, 2].

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	1000 mg/kg bw/d
Exposure Estimate	2.115 mg/kg bw/d
Margin of Safety (MoS)	473

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 77.3% and 67% respectively [2].

Conclusion

It was the ester of isopropyl alcohol and myristic acid. The ester obtained from the reaction of isopropyl alcohol with myristic acid. 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. Weight of evidence indicated it's unlikely to possess genotoxicity, carcinogenicity and reproductive/developmental toxicity potential. Considering its molecular weight, log Pow and water solubility, it's expected to have a very low dermal absorption potential, and dermal absorption rate of 10% was employed for systemic exposure amount calculation. 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 Isopropyl myristate (CAS No. 110-27-0). Last accessed on 2024-09-12@ https://echa.europa.eu/registration-dossier/-/registered-dossier/16077.

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

Toxicological profile of CAPRYLIC/CAPRIC TRIGLYCERIDE (CAS# 73398-61-5; 65381-09-1)

Toxicological endpoints:

Acute toxicity: It was not an acute oral toxicant to mice or rats (Acute oral LD_{50} values for Caprylic/Capric Triglyceride were > 25 ml/kg in mice and >5 g/kg in rats) [1, 2].

Skin irritation: It's not considered to be a skin irritant in one primary skin irritation test according to EPA OPP 81-5 method [1, 2].

Eye irritation: It is not considered to be irritating to eyes in one acute eye irritation test according to EPA OPP 81-4 method [1, 2]

Skin sensitization: It's not found to be sensitizing to guinea pig skin in one Buehler test [1, 2].

Phototoxicity: One facial cream oil containing 95.51% Caprylic/Capric Triglyceride was found to be not phototoxic or non-photoallergenic in a RIPT photocontact allergenicity assay completed in 27 human subjects [2].

Repeated dose toxicity:Three-month feeding studies were performed with Caprylic/Capric Triglyceride in rats and dogs. The NOAELs were 5% (ca. 5000 mg/kg bw/d) and 15% (ca. 3750 mg/kg bw/d) in diet, respectively, and no toxicologically-relevant signs of toxicity were observed at the highest doses [1, 2].

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

Carcinogenicity: No data, but it was considered unlikely to be carcinogenic under current condition of use [1].

Reproductive toxicity: It was considered as neither a reproductive nor a developmental toxicant [1, 2].

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	5000 mg/kg bw/d
Exposure Estimate	21.15 mg/kg bw/d
Margin of Safety (MoS)	236

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 95.6% and 89.2% respectively [2].

Conclusion

Caprylic/Capric Triglyceride is the mixed triester of glycerin and caprylic and capric acids. 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 Glycerides, mixed decanoyl and octanoyl. Last accessed on 2024-09-26@ https://echa.europa.eu/registration-dossier/-/registered-dossier/16019.

[2] CIR Expert Panel. Amended Safety Assessment of Triglycerides as Used in Cosmetics. IJT 41(Suppl. 3):22-68, 2022.

Toxicological profile of CETEARYL ALCOHOL (CAS# 67762-27-0/ 8005-44-5)

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} > 8000 mg/kg bw in rabbits [1].

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

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

Skin sensitization: Overall weight of evidence indicated it was not a skin sensitizer [1, 2]. It is not a skin sensitiser in the guinea pig when tested using the Magnusson and Kligman maximisation assay [1].

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

Repeated dose toxicity: No data. Repeated oral administration of the analog 1-hexadecanol (CAS NO. 36653-82-4) in a 90-day repeated dose feeding study in rats produced reduced food consumption and body weight gain at the higher two doses of 1,822 and 4,257 mg/kg bw/day. As a result, a NOAEL for systemic toxicity was established at the next lower dose of 750 mg/kg bw/day [1].

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

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

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

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	750 mg/kg bw/d
Exposure Estimate	2.115 mg/kg bw/d
Margin of Safety (MoS)	355

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 25% [3].

Conclusion

Cetearyl Alcohol (CAS No. 8005-44-s) is a white, waxy solid, usually in flake form. It is a mixture of mostly cetyl (hexadecanol) and stearyl (octodecanol) alcohols. Cetearyl Alcohol is also known as cetostearyl alcohol and cetyl/stearyl alcohol. It is insoluble in water and soluble in alcohol and oils. Considering its molecular weight, log Pow and water solubility, it's expected to have a very low dermal absorption potential, and dermal absorption rate of 10% was employed for systemic exposure amount calculation. And hence it is concluded that the currently available data is sufficient to consider it safe to be used as intended in this product.

Reference list:

[1] ECHA. Registration dossier of Alcohols, C16-18 (CAS No. 67762-27-0). Last accessed on 2024-10-18@ https://echa.europa.eu/registration-dossier/-/registered-dossier/16007.

[2] CIR Expert Panel. Final Report on the Safety Assessment of Cetearyl Alcohol, Cetyl Alcohol, Isostearyl

Alcohol, Myristyl Alcohol, and Behenyl Alcohol. JACT 7(3):359-413, 1988.

[3] CIR Expert Panel. Annual Review of Cosmetic Ingredient Safety Assessments: 2005/2006. IJT 27(Suppl. 1):77-142, 2008.

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

Toxicological endpoints:

Acute toxicity: Its acute toxicity was practically non-toxic [1, 2].The oral LD_{L0} 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	21.15 mg/kg bw/d
Margin of Safety (MoS)	473

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 C12-15 ALKYL BENZOATE (CAS No. 68411-27-8)

Toxicological endpoints:

Acute toxicity: Its acute oral toxicity was practically non-toxic with LD_{50} > 5000 mg/kg bw in rats and dermal LD_{50} > 2000 mg/kg bw in rabbits [1, 2].

Skin irritation: It was considered to be irritating [1].

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

Skin sensitization: It's considered to be not skin sensitizing [1, 2].

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

Repeated dose toxicity: In one Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test according to OECD Guideline 422, the NOAEL (No Observed Adverse Effect Level) for general, reproductive and developmental toxicity was considered to be 1000 mg/kg bw/d for males and females [1].

Mutagenicity/Genotoxicity: It was tested as negative in one bacterial reverse mutation assay, one in vitro micronucleus test in cultured human lymphocytes and TK locus mutation assay in mouse lymphoma L5178Y cells, indicating it lacked genotoxicity potential [1, 2].

Carcinogenicity: No data, but it is not expected to be a carcinogen.

Reproductive toxicity: In one Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test according to OECD Guideline 422, the NOAEL (No Observed Adverse Effect Level) for general, reproductive and developmental toxicity was considered to be 1000 mg/kg bw/d for males and females [1].

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	1000 mg/kg bw/d
Exposure Estimate	1.692 mg/kg bw/d

Margin of Safety (MoS)	**591**

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 59% and 50% respectively [2].

Conclusion

C12-15 alkyl benzoate is the mixture of esters of benzoic acid and C12-15 alcohols. C12-15 Alkyl benzoates applied to frozen and fresh pig skin did not penetrate the skin, indicating its skin absorption potential was very low. And the dermal absorption rate of 10% was employed for systemic exposure amount calculation. Due to the adequate margin of safety, hence it can be concluded it is safe to be used as intended in this product.

Reference list:

[1] ECHA. Registration dossier of Benzoic acid, C12-15-alkyl esters (CAS No. 68411-27-8). Last accessed on 2024-10-26@https://echa.europa.eu/registration-dossier/-/registered-dossier/14928.

[2] CIR Expert Panel. Safety Assessment of Alkyl Benzoates as Used in Cosmetics. IJT 31(Suppl.3):342-372, 2012.

Toxicological profile of CETETH-25 (CAS No. 9004-95-9)

Toxicological endpoints:

Acute toxicity: Its acute toxicity was considered to be very low with estimated oral LD_{50} in rats based on read-across to suitable analogues [1].

Skin irritation: It was not considered to be irritating to rabbit skin based on read-across to suitable analogues [1].

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

Skin sensitization: It's not considered to be skin sensitizingbased on read-across to suitable analogues [1].

Phototoxicity: Based on UV/Vis absorption spectra and existing data, it does not present a concern for phototoxicity or photoallergenicity [1, 2].

Repeated dose toxicity:Hexadecan-1-ol, ethoxylated, < 2.5 EO (CAS No. 9004-95-9, EC No. 500-014-1) was tested in Wistar Han rats in a combined repeated dose toxicity study with the reproductive / developmental toxicity screening test according to OECD guideline 422 under GLP conditions. Non-adverse test item-related morphologic changes were present in the jejunum (lymphangieactasis) starting at 300 mg/kg bw/day in both sexes and in the pituitary gland (hypertrophy and vacuolation of cells of the pars distalis) at 1000 mg/kg bw/day in males. Based on the findings of this study, No-Observed-Adverse-Effect-Levels (NOAEL) of ≥1000 mg/kg bw/day for parental systemic and 300 mg/kg bw/day for parental local toxicity were determined [1].

Mutagenicity/Genotoxicity: Based on the data available, it does not present a concern for genotoxic potential.

Carcinogenicity: No data. But it was considered acceptable as it lacked genotoxicity potential and additionally, there is no evidence from the repeated dose studies that the substance is able to induce hyperplasia and/or pre-neoplastic lesions.

Reproductive toxicity: In one Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test of Hexadecan-1-ol, ethoxylated, < 2.5 EO (CAS No. 9004-95-9, EC No. 500-014-1) in rats, no treatment-related adverse effects on reproductive or developmental parameters were observed and NOAEL ≥1000 mg/kg bw/day for reproductive toxicity (fertility) was determined [1].

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	1000 mg/kg bw/d
Exposure Estimate	0.1269 mg/kg bw/d
Margin of Safety (MoS)	7880

Regulatory Status: Not regulated in Regulation (EC) No 1223/2009 and with the assessment opinion from CIR that it can be safely used in leave-on cosmetics at the concentration up to 3% [2].

Conclusion

It was the polyethylene glycol ethers of cetyl alcohol with molecular weight of 1360 Dalton. Due to its relatively large molecular weight, dermal absorption rate of 1% was employed for systemic exposure dose calculation. Based on the adequate margin of safety, hence it can be concluded it is safe to be used as intended in this product.

Reference list:

[1] ECHA. Registration dossier of Hexadecan- l-ol, ethoxylated (CAS No. 9004-95-9). Last accessed on 2024-02-20@ https://echa.europa.eu/registration-dossier/-/registered-dossier/25379.

Toxicological profile of Glyceryl Stearate (CAS No. 11099-07-3; 123-94-4; 31566-31-1)

Toxicological endpoints:

Acute toxicity: Its acute toxicity was considered to be practically non-toxic with oral LD_{50} > 5000 mg/kg bw in rats and mice [1-3].

Skin irritation: It was considered to be not irritating according to primary skin irritation test in rabbits [1-3].

Eye irritation: It was considered to be not irritating according to Draize test in rabbits [1-3].

Skin sensitization: It was considered to be not skin sensitizing [1-2].

Phototoxicity: It was considered to lack phototoxicity potential as UV absorption characteristics suggest that phototoxicity is unlikely.

Repeated dose toxicity: Glyceryl monostearate was fed at levels of 15% and 25% as the sole source of fat in the diet to groups of 10 male and 10 female rats over three generations. Studies carried out during the rapid growth period in each generation showed no adverse effect on weight gain. Reproductive performance and lactation were also normal. In another study, 25% of the glyceryl monostearate was fed to groups of 12 male and 12 female rats for up to two years. Weight gain and survival were normal. There was a significant increase in liver weight and some renal calcification. And it belonged to Glyceride Category chemicals and Repeated dose oral (gavage or diet studies) have been located for six of the Glyceride Category members (CAS 61790-12-3 (monoglyceride), 1323-39-3 and 65381-09-

1 (diglycerides), 538-23-8, 85409-09-2 and 73398-61-5 (triglycerides). There were no adverse effects of treatment reported following repeated oral studies with rats, by either gavage or diet route. The NOAELs were =>2500 mg/kg bw, indicating the Glyceride Category members are not toxic [4].

Mutagenicity/Genotoxicity: It was considered to be not mutagenic based on read-across to suitable analogues.

Carcinogenicity: Weight of evidence it's unlikely to be carcinogenic under current condition of use [1-4].

Reproductive toxicity: Overall weight of evidence indicated it's unlikely to possess reproductive/developmental toxicity potential [1-4].

Critical Point of Departure Value for MoS calculation

Critical Point of Departure Value	2500 mg/kg bw/d
Exposure Estimate	12.69 mg/kg bw/d
Margin of Safety (MoS)	197

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 17% and 18.9% respectively [3].

Conclusion

Glyceryl stearate is the esterification product of glycerol and stearic acid. It is a white or cream-colored wax-like solid with a faint odor and an agreeable fatty taste and it is widely used in cosmetics as an opacifier, auxiliary oil/water emulsifier, acid stabilizer, and non-ionic surfactant. When applied to skin, it produces a waxy, occlusive, water-soluble film, which makes it useful for hand lotions and creams. Glyceryl stearate is considered to be a 'generally recognized as safe (GRAS)' direct food substance by US FDA (21CFR184.1324) and with a 'NOT LIMITED' ADI specified by JECFA.

It has been shown to be of low acute oral toxicity, not to mildly irritating to eyes and skin and it didn't show any potential to cause skin sensitization or photosensitization. No systemic toxicity effects were observed in the available repeated dose toxicity studies at the dosage up to 2500 mg/kg bw/d. Hence it is concluded that it is sufficient to consider it safe to be used as intended in this product.

Reference list:

[1] ECHA. Registration dossier of Stearic acid, monoester with glycerol (CAS No. 31566-31-1). Last accessed on 2024-10-18@https://echa.europa.eu/registration-dossier/-/registered-dossier/2133.

[2] CIR Expert Panel. Final Report on the Safety Assessment of Glyceryl Stearate and Glyceryl Stearate/SE. JACT 1(4):169-192, 1982.

[3] CIR Expert Panel. Safety Assessment of Monoglyceryl Monoesters as Used in Cosmetics. IJT 39(Suppl. 3):93-126, 2020.

[4] BIAC/ICCA. SIDS INITIAL ASSESSMENT PROFILE OF Glycerides Category. CoCAM 6, 30 - 03 October, 2014.

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
ETHYLHEXYL METHOXYCINNAMATE	7.00	10	NA	Conforms to regulated usage.
ISOPROPYL MYRISTATE	5.00	NA	473	Safe for human health under normal and reasonably foreseeable conditions of use.
CAPRYLIC/CAPRIC TRIGLYCERIDE	5.00	NA	236	Safe for human health under normal and reasonably foreseeable conditions of use.
CETEARYL ALCOHOL	5.00	NA	355	Safe for human health under normal and reasonably foreseeable conditions of use.
GLYCERIN	5.00	NA	473	Safe for human health under normal and reasonably foreseeable conditions of use.
ETHYLHEXYL SALICYLATE	5.00	5	NA	Conforms to regulated usage.
C12-15 ALKYL BENZOATE	4.00	NA	591	Safe for human health under normal and reasonably foreseeable conditions of use.
CETETH-25	3.00	NA	7880	Safe for human health under normal and reasonably foreseeable conditions of use.
GLYCERYL STEARATE	3.00	NA	197	Safe for human health under normal and reasonably foreseeable conditions of use.
BENZOPHENONE-3	2.00	2.2	NA	Conforms to regulated usage.

TITANIUM DIOXIDE	2.00	25	NA	Conforms to regulated usage.
PARFUM (Vanilla MY11-S089)	0.30	6.33	NA	conforms to IFRA standards
DMDM HYDANTOIN	0.30	0.6	NA	Conforms to regulated usage.
METHYLPARABEN	0.20	0.4	NA	Conforms to regulated usage.
PROPYLPARABEN	0.10	0.14	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 ***