TECHNICAL REPORT – CPSR REPORT

Report No. （6624）032-0221 **Date 2024-03-05**

Client:	Mid Ocean Brands B.V.		
Address:	7/F, Kings Tower, 111 King Lam Street, Cheung Sha Wan, Kowloon, Hong Kong.		
Sample name:	Hand cleaner (Hand cleanser gel) (1 formulation)		
Net weight:	30 ml per consumer product		
Style/ Item No.:	MO6130, MO9952	Country of Origin:	China
Manufacturer:	Vendor code:113285	Expiry Date:	/
Production Date :	/	Date of Receipt:	2024-02-01
Sample Source:	/	Assessment Period:	2024-02-01 to 2024-02-29
Status of Sample:	/	Appropriate Age Grade:	/
Client Specified Age Grade:	/	Tested Age Grade:	/

Test specification:
Cosmetic Product Safety Assessment

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

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

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

HBH Department

BUREAU VERITAS TESTING TECHNICAL SERVICE (ZHEJIANG) CO.,LTD SHANGHAI BRANCH 检测技术服务(浙江)有限公司上海分公司 报告专用章

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PART A – Cosmetic product safety information

A.1 Quantitative and Qualitative Composition of Products

A.1.1 Nominal Composition

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

INCI Name	CAS No.	Conc. (%)	Function
AQUA	7732-18-5	90.10	Solvent
GLYCERIN	56-81-5	5.0	Humectant
PROPYLENE GLYCOL	57-55-6	3.0	Humectant
ALOE BARBADENSIS LEAF EXTRACT	85507-69-3	1.0	Skin conditioning - emollient
CARBOMER	9007-16-3	0.50	Gel forming
TRIETHANOLAMINE	102-71-6	0.20	Buffering
BENZALKONIUM CHLORIDE	68424-85-1	0.10	Antimicrobial
TOCOPHERYL ACETATE	58-95-7	0.10	Antioxidant

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

A.2.1 Physical/chemical characteristics of Raw Materials

The raw materials specifications are available upon request.

A.2.2 Physical chemical specifications of the end product

The finished product isa transparent colourless gel with pH 6.0-8.5.

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, 40°C, and with light exposure for 12 weeks and together with cycle test for 3 cycles. The organoleptic, physico-chemical and microbiological examinations (including appearance, colour, odour, pH value, TVC bacteria, appearance of package) were carried out.

The compatibility between the formula and the packaging was also evaluated.

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

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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 10.0 2.6.12 & 2.6.13 were listed below.

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

According to Appendix 9 of the 12th Revision of the NoG (SCCS/1647/22), the microbiological quality of this product was considered as **acceptable** for **Category 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.

Micoorganisms	**D7**	**D14**	**D28**
	Log reduction values		
Escherichia coli	> 5.8	> 5.8	> 5.8
Staphylococcus aureus	> 5.6	> 5.6	> 5.6
Pseudomonas aeruginosa	> 5.4	> 5.4	> 5.4
Candida albicans	> 5.5	> 5.5	> 5.5
Aspergillus niger	> 5.4	> 5.4	> 5.4

According to EP 10.0 Table 5.1.3-2B, the preservation challenge test result of this formulation was considered as

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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 specification are available upon request. This product does not contain any relevant impurity at significant levels, and the analytical testing results of heavy metals (below table) indicated the content of As, Hg, Pb, Sb, Cd and Ni (soluble) in this product were undetected and considered to be **acceptable** according to German Health Authority BgA recommendations form German Health Journal No.28, July 1985 and German Health Journal No.7/1992,Session 45 from November 14,1991. Furthermore, in conformity with the article 3 of the regulation, the safety evaluation of this impurity and trace of prohibited substances is part of the safety evaluation of the cosmetic product.

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

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	PET
2	Lid	PP

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

A.5 Normal and Reasonably Foreseeable Use

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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 no-rinse hand cleanser. Application of this product to other parts of body is not foreseeable.

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

As this product contains benzalkonium chloride, the product should be labelled with "Avoid contact with eyes" according to European Cosmetics Regulation (EC) No 1223/2009. And the precautionary statement "If accidental contact occurs rinse immediately with water" shall also need for safe handling in case of misuse.

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 no-rinse hand cleanser.

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: hands

Application Surface area: 305 cm^2

A.6.4 Routes of Exposure

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

Routes of Exposure: Dermal

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A.6.5 Amount per daily application

The following product quantity used per application has been used in the Exposure calculations:

Product Exposure: 5 g

A.6.6 Duration and Frequency

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

Frequency of use: 5 times per day

Exposure duration: leave-on

A.7 Exposure to the substances/impurities

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

A.7.1 Exposure to the substance

INCI Name	Inclusion level (% w/w)	Total Systemic (SED) mg/kg bw/day	Local Dermal (CEL) μg/cm²
GLYCERIN	5.0	16.5565	819.672
PROPYLENE GLYCOL	3.0	9.9339	491.8032
ALOE BARBADENSIS LEAF EXTRACT	1.0	3.3113	163.9344
CARBOMER	0.50	1.65565	81.9672
TRIETHANOLAMINE	0.20	0.66226	32.78688
BENZALKONIUM CHLORIDE	0.10	0.33113	16.39344
TOCOPHERYL ACETATE	0.10	0.33113	16.39344

A.7.2 Exposure to impurities

As there is no impurity at significant levels, there is no exposure calculation.

A.8 Toxicological Profile of the Substances

Toxicological Profiles are provided for all substances apart from those that are fragrances, regulated ingredients, substances assessed by external authoritative body (for example Cosmetic Ingredient Review (CIR), SCCS, etc), aqua or substances present at levels below a threshold of toxicological concern.

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Accordingly, no toxicological profiles are included here.

A.9 Undesirable effects and serious undesirable effects

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

A.10 Information on the Cosmetic Product

This product is indicated to be manufactured by in a manufacturing setting according to ISO 22716:2007, with scope of compliance on manufacturing of general liquid unit, including hair care & cleansing products, skin care liquid products # and gel products #; cream & lotion unit, including skin care & cleansing products # and hair care products; powder unit, including loose powder products and pressed powder products; wax base unit, including wax base products; eye care products and skincare products for children by third party laboratory (Intertek Certificate SZ2210D6 which is valid until 18 Oct, 2025).

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PART B – Cosmetic Product Safety Assessment

B.1 Assessment conclusion

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

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

B.2 Labelled warnings and instructions of use

As this product contains benzalkonium chloride, the product should be labelled with "Avoid contact with eyes" according to European Cosmetics Regulation (EC) No 1223/2009. And the precautionary statement "If accidental contact occurs rinse immediately with water" shall also need for safe handling in case of misuse.

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	Inclusion Level(%)	Use conc. (%)	Margin of Safety	Assessment Conclusion	Reference
GLYCERIN	5.0	79.2	NA	Conforms to accepted external review in a cosmetic product.	IJT 38(Suppl. 3): 6-22, 2019.
PROPYLENE GLYCOL	3.0	50	NA	Conforms to accepted external review in a cosmetic product.	JACT 13(6): 437-491, 1994.
ALOE BARBADENSIS LEAF EXTRACT	1.0	6	NA	Conforms to accepted external review in a cosmetic product.	IJT 26(Suppl. 2): 1-50, 2007.

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CARBOMER	0.50	15	NA	Conforms to accepted external review in a cosmetic product.	CIR Expert Panel. 2018. Amended Safety Assessment of Acrylates Copolymers as Used in Cosmetics.
TRIETHANOLAMINE	0.20	2.5	NA	Conforms to regulated usage.	CosReg Annex III, entry No.62.
BENZALKONIUM CHLORIDE	0.10	0.1	NA	Conforms to regulated usage.	CosReg Annex V, entry No.54.
TOCOPHERYL ACETATE	0.10	36	NA	Conforms to accepted external review in a cosmetic product.	IJT 37(Suppl. 2): 61-94, 2018.

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B.3.2 Safety Evaluation of the Product

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

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

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

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

Dr. Raul Xin, EUROTOX Registered Toxicologist (ERT)
Authorized external expert of Bureau Veritas

*** End of Report ***

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