COSMETICS PRODUCT SAFETY REPORT

PART A and PART B

Product: **MAYERI Hand Soap Ocean Fresh**

Producer: Mayeri Industries AS, Tabivere, Tartu County 49127, Estonia, www.mayeri.ee

Formula no: F6100

PART A – Cosmetic product safety information

1. Qualitative and Quantitative composition of the product, function and EU regulatory data

INCI	CAS	Function	EU Regulatory status
Aqua (77.055%)	7732-18-5	-	-
Sodium Laureth Sulfate (7.32%)	3088-31-1 / 9004-82-4 / 68891-38-3 / 1335-72-4 / 68585-34-2 / 91648-56-5	Surfactant, Foaming	CIR Expert Panel evaluated the scientific data and concluded that this ingredient was safe for use in cosmetics and personal care products in the present practices of use and concentration when formulated to be non-irritating.
Cocamidopropyl Betaine (7.73%)	61789-40-0	Surfactant, Cleansing	CIR Expert Panel evaluated the scientific data and concluded that this ingredient was safe for use in cosmetics and personal care products.
Coco-Glucoside (1%)	-	Cleansing, Surfactant, Foaming	The CIR Expert Panel evaluated the scientific data and concluded that these ingredients were safe for use in cosmetics when formulated to be non-irritating.
Glyceryl Oleate (1%)	25496-72-4 / 111-03-5	Emollient, Emulsifying	The CIR Expert Panel evaluated the scientific data and concluded that this product was safe for use as cosmetic ingredients.
Glycerin (3.5%)	56-81-5	Humectant, moisturizer	The Food and Drug Administration (FDA) includes Glycerin on its list of direct food additives considered Generally Recognized As Safe (GRAS).
Sodium Benzoate (0.5%)	532-32-1	Preservative	According to Annex V/I maximum allowed concentration is 0.5% (acid) in leave-on and 2.5% in rinse-off products. As Sodium Benzoate contains ca 84.7% of Benzoic acid the allowed concentration is not exceeded (0.29%). The CIR Expert Panel has concluded that Sodium benzoates is safe for use in

INCI	CAS	Function	EU Regulatory status
			cosmetics. The Food and Drug Administration (FDA) includes Sodium benzoate on its list of direct food additives considered Generally Recognized As Safe (GRAS).
Potassium Sorbate (0.5%)	24634-61-5	Preservative	According to Annex V/4 the maximum allowed concentration is 0.6% (Acid). The CIR Expert Panel has concluded that potassium sorbate is safe for use in cosmetics. The Food and Drug Administration (FDA) includes potassium sorbate on its list of direct food additives considered Generally Recognized As Safe (GRAS).
Parfum (0.18%)	-	Parfuming	This product conforms to the Annex I and the latest IFRA guidelines (Amendment n°48). PARFUM: - Product name and code – SPORT BLAST M_0060227 - Producer – V.Mane (France) Presence of allergens but none of the allergen exceeds 0,01% in rinse-off product.
Sodium Chloride (1.2%)	7647-14-5	Masking, bulking	-
CI 42051 (0.015%)	3536-49-0	Blue Cosmetic Colorant	"CI 42051 is listed in the Cosmetics Directive of the European Union and may be used as a coloring agent in all cosmetics and personal care products (Annex VI/60, E 131).

This product does not contain substances which are listed in following Annexes:

- Annex II of Regulation no 1223/2009 of the European Parliament and of the Council – list of substances prohibited in cosmetic products

- Annex III of Regulation no 1223/2009 of the European Parliament and of the Council – list of substances which cosmetic products must not contain except subject to the restrictions laid down
- Annex VI of Regulation no 1223/2009 of the European Parliament and of the Council – list of UV-filters which cometic products may contain

2. Physical/Chemical characteristics and stability of the cosmetic product

2.1 Physical/chemical characteristics of the ingredients (substances and mixtures)

Purity and analytical specifications of raw materials are contained on the relevant Certificates of Analysis / Sales Specifications, which are held by the manufacturer.
Raw material physical characteristics and suppliers' hazard classifications are given in the safety data sheets, which are held by manufacture.
The physical/chemical specification of the ingredients are well known and commonly used in similar products. Their inclusions in the finished product at the specified concentrations do not give rise to any concerns.

2.2 Physical/chemical characteristics of the finished cosmetic product

Appearance	Viscouse liquid
Color	Blue
Odor	Characteristic
Density	1.01 – 1.03
Viscosity	4 - 5 min.
pH	5.1 – 6.1

5.2 Stability of the cosmetic product

A shelf life of 30 months after manufacturing and 12 months after opening (PAO) is currently assigned to this product according to the stability testing, microbiological testing, the physical nature of the product, the type of packaging used, and experience with this and similar products in the market.
Store at room temperature in a dry place. Keep out of direct sunlight.

3. Microbiological quality

In order to ensure the quality of the product and the safety for the consumer, the microbiological test performed.

3.1 Microbiological quality of ingredients (substances and mixtures)

Based on available information from the ingredient specifications (see section 1. Quantitative and qualitative composition– specification of ingredients), the ingredients used can be assessed as microbiologically safe.

3.2 Microbiological quality of the finished cosmetic product

This product belongs to Category 2.

Index name	**Result**
Total aerobic microbial count	<1 cfu/g
Escherichia coli	Absent
Candida albicans	Absent
Staphylococcus aureus	Absent
Pseudomonas aeruginosa	Absent

It is generally accepted that for cosmetics classified in *Category 1*, the total viable count for aerobic mesophyllic microorganisms should not exceed 10^2 cfu/g or 10^2 cfu/ml of the product (cfu = colony forming unit).
For cosmetics classified in *Category 2*, the total viable count for aerobic mesophyllic microorganisms should not exceed 10^3 cfu/g or 10^3 cfu/ml of the product.

Escherichia Coli, Pseudomonas aeruginosa, *Staphylococcus aureus* and *Candida albicans* are considered the main potential pathogens in cosmetic products. These specific potential pathogens must not be detectable in 0.1 g or 0.1 ml of a cosmetic product of Category 2.

Results obtained on different batches comply with SCCS requirements; therefore the risk of microbial contamination is negligible.

No Challange test is carried out as the product does not pose any risk to cunsumers under normal conditions of use.

4. Impurities and information about the packaging material

Regarding any traces and impurities from the raw materials please refer to Table 1 of Part A Quantitative and qualitative composition of the cosmetic product and section 8. Toxicological Profile of the Substances.

Product is packed into plastic bottle (PET) and covered with plastic closure (PP).

We hereby confirm that PET bottles, containers and jars produced and supplied by MAYERI comply with relevant requirements as follows:
a) the Plastics Regulation No 10/20111 with all amendments: No. 321/2011, No. 1282/2011, No 1183/2012, No 202/2014, No 2015/174, No 2016/1416, No 2017/752, No 2018/79, No 2018/213, No 2018/831, No 2019/37, No 2019/1338.
b) the Framework Regulation No 1935/2004/EEC2 Article 3, 11(5), 15 and 17.
c) the Commission Regulation No 2023/20063 on good manufacturing practice (GMP).
d) Requirements of Food Safety Standard Certification (FSSC) 22000 version 5.0 (based on ISO 22000:2018 and relevant technical standards for sector specific PRPs).

The analysis result of Overall Migration Limits (OML) of our products shown to meet overall migration limits laid down in Plastics Regulation No 10/2011.

According to opinion of NIAS risk assessment our products do not intentionally contain any substances based on (are not as a part of the recipe):
- Bisphenol A (BPA), (CAS 80-05-7) (complied with EU Regulation 2018/2135)
- Primary Aromatic Amines (PAA) covered by point 2 of Annex II of the Regulation No 10/2011
- Azodicarbonamide (E927)
- Polyvinyl Chloride (PVC)
- Ba, Co, Cu, Fe, Li, Mn, Zn, Al, Ni listed in point 1 of Annex II of the Regulation No 10/2011 (fully comply with Plastics Regulations amendments: 2016/1416 and 2017/752).

Heavy metals such Pb, Hg, Cd and Cr (VI) are not intentionally added in the manufacture of products. Based on chemical analysis can confirm that content of mentioned substances does not exceed the limits laid down in 94/62/EC6 Article 11 of 100 mg/kg.

Packaging details are available by customer. These materials has proper certificate of conformity.

5. Normal and reasonably foreseeable use

This is rinse-off product intended to use on hands.

6. Exposure to the cosmetics product

- Site of application: hands
- Surface area: 860 cm2 (Bremmer et al. 2005)
- Parameters: area hands (Bremmer et al. 2005)
- Frequency of application: 10/day (Bremmer et al. 2005)
- Estimated daily amount applied: 20 g (SCCNFP/0321/02; Hall et al. 2007, 2011)
- Relative amount applied: - (SCCNFP/0321/02; Hall et al. 2007, 2011)
- Retention factor: 0,01 (SCCNFP/0321/02; Hall et al. 2007, 2011)
- Calculated daily exposure: 0,2 g/day (SCCNFP/0321/02; Hall et al. 2007, 2011)

- Calculated relative daily exposure: 3,33 mg/kg/bw/day (SCCNFP/0321/02; Hall et al. 2007, 2011)
- Dermal absorbtion **DA_P (%)**: 100% (worst case study)
- Route of application: intact skin
- Targeted population: adults
- Rinse-off

7. Exposure to the substances

Safety information for each ingredient and all available information about the exposure has been checked. Available margin of safety's has been checked and values are above 100.

Dermal absorption reported as a percentage of the amount of substance applied:

SED = **A**(mg/kg bw/day) X **C**(%) / 100 X **Dap** (%) / 100

Margin of Safety (MoS) = NOAEL/SED

MoS should at least be 100 to conclude that a substance is safe for use.

Ingredient/ Concentration	Max. Concentration (C, %)	SED (mg/kg/day)	NOAEL (mg/kg/bw/day)	Margin of Safety (%)
Sodium Laureth Sulfate	7.32	0.243756	225	923
Cocamidopropyl Betaine	7.73	0.257409	300	1165
Coco-Glucoside	1	0.0333	1000	30030
Glyceryl Oleate	1	0.0333	1000	30030
Glycerin	3.5	0.11655	10000	85800
Sodium Benzoate	0.5	0.01665	500	30030
Potassium Sorbate	0.5	0.01665	1000	60060
Parfum	0.18	0.005994	N/A	N/A
CI 42051	0.015	0.0004995	630	1261261
Sodium Chloride	1.2	0.03996	1000	25025

Substances where NOAEL value were available MoS was calculated and all values are above 100 and we can conclude that all used substances are safe for use.

8. Toxicological profile of the ingredients

Literature has been reviewed as regards of toxicology of the raw materials and following summery is provided:

Sodium Laureth Sulfate –
Acute toxicity: Low acute oral toxicity. LD50 > 5000 mg/kg
Corrosivity and irritation: Can produce eye and/or skin irritation in experimental animals. Dermal and ocular irritant in concentrate.
Skin sensitisation: Not sensitising.
Repeated toxicity: No data, read across to NaC12-14AE2S in group AES. Based on systemic toxicity from the 90 days rat study, behavioural and clinical abnormalities and other general or specific toxic effects, a no adverse effect level (NOAEL) of 225 mg/kg was established.
Mutagenicity/Genotoxicity: Read across to group AES. Negative in vitro mutagenicity tests) and in vivo chromosome aberration tests. Not clastogenic.
Carcinogenicity: Not carcinogenic
Reproductive toxicity: Read-across to AES, not reprotoxic
Phototoxicity: Not phototoxic (CIR Final Report of the Amended Safety Assessment of Sodium Laureth Sulfate (SLES) and related salts of sulfated ethoxylated alcohols; ECHA; HERA).

Cocamidopropyl Betaine - The CIR Expert Panel reviewed data that indicated that Cocamidopropyl Betaine was not a systemic toxicant, nor did it cause genotoxicity. CAPB (30% -35.61% active) is not a potent acute oral toxicant in mice or rats, with LD50 values greater than 1 g/kg. The oral LD50 of full-strength commercial samples of 30% active CAPB was 4.91 g/kg in CFR mice and 7.45 ml/kg in Wistar rats. Another study of 30% active CAPB in Wistar rats found the acute oral LD50 to be 8.55 g/kg. The oral LD50 of 30% active CAPB in albino rats of an unspecified strain was 4.9 g/kg. The acute oral LD50 for 35.61% active CAPB was >1.8 g/kg for male Sprague-Dawley rats. All female rats in this study died before study end. The acute oral LD50 was greater than 5.0 g/kg and the acute lethal dermal dose was greater than 2.0 g/kg in studies of CAPB (31% active) with CD rats. In another 28-day oral toxicity study, rats received 0, 250, 500, or 1000 mg/kg CAPB. In the 1000 mg/kg dose group, compound-related edema of the mucosa of the non-glandular stomach was observed at macroscopic examination and acanthosis of the mucosa, inflammatory edema of the submucosa, and multiple ulcerations were observed during microscopic examination. These effects were thought to be the result of the irritating properties of CAPB and not of systemic toxicity. The NOEL and LOEL for this study were 500 mg/kg/day and 1000 mg/kg/day, respectively. From subacute and subchronic studies with rats a NOAEL of 1000 mg/kg bw/day for systemic toxicity of the 30% active CAPB was derived (NOAEL 300 mf/kg/day used for MoS calculations). A subchronic oral toxicity study of CAPB rats that received 0, 250, 500, or 1000 mg/kg/day CAPB concluded that the NOEL was 250 mg/kg/day. Forestomach gastritis was observed in rats in the 500 and 1000 mg/kg/day dose groups (CIR, Draft Final Amended Report on Cocamidopropyl Betaine and Related Amidopropyl Betaines 2010).

Coco-Glucoside – alkyl glucoside.
Acute toxicity: In single dose dermal studies with caprylyl/capryl glucoside and C10-16 alkyl glucoside (both 50% a.i., n:1.6) in rabbits, the LD50 was greater than the 2000 mg/kg dose administered. In oral studies with the same test substances, none of the mice dosed with 2000 mg/kg caprylyl glucoside and none of the rats dosed with 5000 mg/kg C10-16 alkyl glucoside died during the study.
Skin irritation: slightly irritating
Skin sensitization: not sensitizing

Carcinogenicity: Published carcinogenicity studies were not found.
Lauryl Glucoside was not a reproductive or developmental toxicant.
Alkyl glucoside ingredients have not been found to be genotoxic.
Repeated dose toxicity dermal: In 2-wk repeated dose dermal studies in rabbits with 60% active caprylyl/capryl glucoside, occlusive applications produced testicular effects, while non-occlusive application did not. In the two occlusive studies, one with 0.09and 1.8 g a.i./kg and the other with 0.14-1.25 g a.i./kg, an NOEL for testicular effects could not be established. In the non-occlusive study, the NOEL for systemic toxicity was 0.18 g a.i./kg caprylyl/capryl glucoside. Severe dermal irritation was observed in both occlusive studies, while slight to moderate irritation was reported in the non-occlusive study.
Repeated dose toxicity oral: In oral repeated dose toxicity studies, moderately-dilated renal tubules were observed in 3 of 6 rats fed 20% ethyl glucoside for 39 days, but in none of the rats fed 10% ethyl glucoside. Kidney weights were statistically significantly increased in the test animals. In rats dosed orally with 250-1000 mg/kg C12/16 APG for 13 wks, reversible irritation and ulceration of the stomach mucosa was observed, but there was no systemic toxicity reported for any group.
The no-observed adverse effect level (NOAEL) for systemic toxicity was 1000 mg/kg bw (CIR, Decyl Glucosides and Other Alkyl Glucosides as Used in Cosmetics – Draft Report).

Glyceryl Oleate - According to the FDA, many of the monoglyceryl monoesters are direct food substances affirmed as GRAS in the U.S. for human and/or animal use, are permitted as direct food additives, or are permitted as indirect food additives. Monoglyceryl monoesters can act as penetration enhancers.
Acute dose toxicity: The dermal LD50 of glyceryl rosinate is >10 g/kg bw in rabbits in a 24-h patch test.25 In oral studies, the LD50 of glyceryl behenate and glyceryl hydrogenated rosin is >2 g/kg, of glyceryl stearate is >5 g/kg, and of glyceryl rosinate is >10 g/kg.
Repeated dose toxicity: In a 90-day dietary study, NOAEL for glyceryl hydrogenated rosinate in rats was 10,000 ppm. For glyceryl rosinate, the NOAEL for rats was 1% in one 90 day study, and 2500 mg/ kg bw/day in another. In a 28-day study of glycerides, C8-18 and C18-unsatd. mono- and di-, acetates in rats, the NOAEL was 1000 mg/kg bw/day.
Reproductive and Developmental toxicity: Glyceryl oleate was not a reproductive or developmental toxin in rats. The NOAELs for systemic toxicity (males and females), fertility (males and females), and development (F1 generation) were 1000 mg/kg bw/day.
Dermal Irritation/Sensitization: undiluted glyceryl behenate and glyceryl palmitate/stearate were non-irritating to rabbit eyes, and undiluted glyceryl rosinate was slight irritating.
Eye irritation: Undiluted glyceryl behenate and glyceryl palmitate/stearate were non-irritating to rabbit eyes, and undiluted glyceryl rosinate was slight irritating.
Phototoxicit: not phototoxic (CIR, Amended Safety Assessment of Monoglyceryl Monoesters as Used in Cosmetics, 2015).

Glycerin –
The acute oral toxicity: results for natural and synthetic glycerine were comparable with an oral LD50 of 27 200 mg/kg.
The acute dermal toxicity of glycerin was examined in guinea pigs. The dermal LD50 was determined to be 45 ml/kg (56 750 mg/kg) in guinea pigs.

In an inhalation study: thus the 1-hour LC50 based on nominal concentration was >1100 mg/L. Under the OECD GHS guidelines, a 4 hr LC50 can be determined from a 1-hour LC50 by dividing by 4. Thus, a calculated 4-hour LC50 value based on nominal concentration would be >275 mg/L.
Skin irritation: not irritating
Eye irritation: not irritating
Skin sensitization: not sensitizing
Repeated dose toxicity oral: NOAEL was 8000-10,000 mg/kg bw based on the absence of treatment related effects in high dose animals.
Repeated dose toxicity dermal: There were no effects noted in rabbits dosed 8 hours/day, 5 days/week for 45 weeks with dose levels as high as 4.0 ml/kg. Using a density of 1.2611 g/cm3 at 20 °C, a dose of 4.0 ml/kg corresponds to 5040 mg/kg/day.
Repeated dose toxicity inhalation: NOAEL was 167 mg/m3 based on local irritant effects on the upper respiratory tract.
Mutagenicity: not mutagenic
Carcinogenicity: there was no indication of a carcinogenic response in rats fed 8000 mg/kg/day glycerol in the diet for 2 years.
Toxicity reproduction: There was no effect noted on growth, fertility and reproductive performance through two generations at a dose level of ~2000 mg/kg/day.
Developmental toxicity / teratogenicity: There was no effect on developmental toxicity of offspring of female rats dosed with glycerin at doses as high as 1310 mg/kg/day.
The NOAEL from a 2-year study in rats is assessed to be acceptable for use in the MoS calculation NOAEL 10000 from the 2-year study in rats (https://echa.europa.eu/bg/registration-dossier/-/registered-dossier/14481/1; CIR, Safety Assessment of Glycerin as Used in Cosmetics 2014).

Sodium Benzoate - The CIR Expert Panel noted that no adverse effects of Benzyl Alcohol were seen in chronic oral exposure studies. Effects of Benzoic Acid and Sodium Benzoate in chronic oral exposure studies were limited to reduced feed intake and reduced growth.
Acute toxicity oral: Multiple studies are available with a LD50 value of >2000 mg/kg in a weight of evidence approach.
Acute toxicity dermal: An acute dermal toxicity study with rabbit (Goldenthal, 1974) which run on analog substance Benzoic acid (65-85-0) is available which is key study. The LD50 was >2000 mg/kg bodyweight.
Acute toxicity inhalation: An acute inhalation toxicity study with rat (Goldenthal, 1974) which run on analog substance Benzoic acid (65-85-0) is available which is key study. The LC50 was >12200 mg/m3
Skin irritation: not irritating
Eye irritation: slightly irritating
Skin sensitization: not sensitising
Repeated dose toxicity oral: In a chronic toxicity/carcinogenicity study in rats (Sodemoto, 1979) no signs of toxicity were reported at 2% the test substance in feed (stated to be equivalent to 1000 mg/kg bw). In mice (Toth, 1984) no effects were reported at 2% the test substance in drinking water (119-124 mg/animal/day).
Repeated dose toxicity dermal: The NOAEL was considered to be > 2500 mg/kg
Genotoxicity: All the in vivo genotoxicity tests were negative.

Carcinogenicity: was not carcinogenic (https://echa.europa.eu/et/registration-dossier/-/registered-dossier/14966/7/9/3)
Maximum use concentration in end-product can be 0.5% according to Annex V/1. NOAEL 500 mg/kg bw/day used for MoS calculations (SCCP Opinion 0891/05, https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_015.pdf).

Potassium Sorbate - Acute toxicity oral: LD50 = 10.50 g/kg bw (95% CI = 9.17-12.03 g/kg bw)
Acute toxicity dermal: LD50 (rats) > 2000 mg/kg bw
Skin irritation: not irritating
Eye irritation: irritating
Skin sensitization: not sensitizing
Repeated dose toxicity oral: LO(A)EL: Not applicable; NO(A)EL: 100 000 ppm males and females (male: 9200 mg/kg bw/d and female: 8600 mg/kg bw/d)
Repeated dose toxicity dermal: NOAEL 1000 mg/kg bw/day in 90 day study with rats (ECHA 2011; https://echa.europa.eu/documents/10162/13626/clh_potassium_sorbate_en.pdf).
Sorbic Acid and Potassium Sorbate have been tested for mutagenic effects using bacterial tests, genetic recombination tests, reversion assays, tests for chromosomal aberrations, sister chromatid exchanges and gene mutations. The weight of evidence of these tests indicates that these ingredients were not mutagenic. Sorbic Acid (Hexa-2-4-Dienoic Acid) and its salts may be used as preservatives at a maximum concentration of 0.6% in cosmetics and personal care products marketed in the European Union (Annex V/4) (https://echa.europa.eu/et/registration-dossier/-/registered-dossier/11008)

Sodium Chloride -
Acute toxicity oral: The acute oral LD50 of sodium chloride (administered as 25% water solution) was 3550 mg/kg to male rats
Acute toxicity inhalation: LC50 to rats is greater than 42 mg/l (42000 mg/m3)
Acute toxicity dermal: a dermal toxicity study was conducted in rabbits and the LD50 value was greater than 10000 mg/kg
Skin irritation: slightly to not irritating
Eye irritation: moderately irritating
Skin sensitization: not sensitizing
Repeated dose toxicity oral: Based on the results of the study, NaCl was not considered carcinogenic when administered thorugh the diet to F344/Slc rats for a period of two years (conc.4%).
Repeated dose toxicity dermal: not specified but it was estimated that toxoc dose for humans was between 1000-3000 mg/kg/day.
Sodium chloride is not classified as a carcinogen (https://echa.europa.eu/et/registration-dossier/-/registered-dossier/15467/7/9/3).

CI 42051 - The Panel concluded that the present dataset provides a rationale for a re-definition of the ADI. Using the NOAEL of 500 mg/kg bw/day derived from a chronic toxicity study in mice and applying an uncertainty factor of 100 to this NOAEL, the Panel establishes an ADI of 5 mg/kg bw/day.
Acute oral toxicity: The oral LD50 values in mice and rats were greater than 3000 and 5000 mg/kg bw respectively.

Repeated dose oral toxicity: According to the authors of the BIBRA (1982) report, the No-Observed-Adverse-Effect Level (NOAEL) of this study was 280 mg/kg bw/day, the highest dose tested.
Reproductive and developmental toxicity: The Panel agreed with the authors that the NOAEL of this study was 500 mg/kg bw/day, the highest
dose tested (https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2013.2818).
Staining and deposits in the stomach of rats were seen when Acid Blue 9 was administered orally in a concentration of 4 % in the diet (about 2 g/kg bw/day) for at least 3 weeks. No further details in the review. Original: Willheim, R. & Ivy, A.C. (1953).
Chronic toxicity: NOAEL of 631 mg/kg/bw in the rat two year study.
Skin irritation: moderate irritation occured.
Eye irritation: slightly irritating
Skin sensitisation: non sensitising
Not mutagenic/genotoxic.
Not carcinogenic
(https://ec.europa.eu/health/ph_risk/committees/sccp/documents/out261_en.pdf).

9. Undesirable effects and serious undesirable effects

This product is for adult use. The cosmetic product with a similar composition has been supplied to the market in the long term and until nowadays, no undesired effects to human health have been noticed in relation to the use of this product. Therefore, no undesired effects are anticipated at the common and reasonably predictable application of the given cosmetic product.
In case of undesirable effects or serious undesirable effects the responsible person should inform the safety assessor to evaluate the effect and update the safety report accordingly.
The product is manufactured in compliance with GMP practise.

10. Information on the cosmetic product

No animal studies have been carried out for finished products. All MSDS and TDS are available by customer.

SAFETY ASSESSMENT OÜ

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COSMETIC PRODUCT SAFETY REPORT

PART B – Cosmetic product safety assessment

Product: **MAYERI Hand Soap Ocean Fresh**

Producer: Mayeri Industries AS, Tabivere, Tartu County 49127, Estonia, www.mayeri.ee

Formula no: F6100

1. Conclusion

Considering the exposure, chemical and toxicological information of this product during the safety assessment procedure, it is concluded that the product does not cause damage to human health under normal or reasonably foreseeable conditions of use.

The safety assessment report of this product is for adult use. MoS>100 is found for raw materials where NOAEL were available. The calculation was performed assuming that dermal absorption is 100%. With this worst case study, it is evaluated that the use of this raw material in this product is safe.

The ingredients of the product are permitted ingredients for cosmetics. All raw materials are not toxic under normal or reasonably unforeseeable conditions of use at this concentration. The product does not contain prohibited substances listed in annexes of Regulation (EC) No. 1223/2009. Composition of the product complies with the requirements of the Cosmetic Regulations. Following review of the information provided for the above product and its ingredients, the **product is considered safe** for the intended application and **complies with EC Regulation 1223/2009.**

2. Labeled warnings and instruction of use

This product's presentation is in accordance with a Regulation no 1223/2009 of the European Parliament and of the Council about the labelling of cosmetic product. Restricted ingredients are properly listed on the package.

Instruction of use:
Apply product equally on your hands to cleanse it. Rinse it off with warm water. Exact instructions are written also on the label.

Claim support: All claims on the label should be in compliance with (EC) Regulation 655/2013 and the guidelines to this Regulation.

3. Reasoning

This assessment is based on:

- The chemical and physical specification of the ingredients
- The general toxicological profile of the ingredients
- The level of exposure of the ingredients
- The specific exposure characteristics of the areas to which the cosmetic product will be applied
- Margin of Safety calculations if available
- The specific exposure characteristics of the population for which the cosmetic product is intended

This assessment is conducted in accordance with the Regulation no 1223/2009 of the European Parliament and of the Council. All the ingredients in the formulation are either commonly used in rinse-off products with low toxicity or within the reccomended limit as suggested by SCCS and Cosmetic Ingredient Review (CIR), FDA etc.

Provided manufacturer's instructions are followed.

The potential interactions between ingredients have been considered. The submitted test results indicate the product will be safe for intended use concerning the impurity, stability and microbiological quality.

4. Assessor's credentials

Safety Assessor's CV and diploma are added to this report.

Meelika Koitjärv

Safety Assessor

Date: 03.03.2021

This safety assessment is based upon information available at this date. The safety of the product should be reviewed on a regular basis. Reviews of this assessment should be conducted when new information becomes available.