MAF COSMETIC CONSULTANTS LTD

COSMETIC PRODUCT SAFETY REPORT

Conforming to

Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 and SCHEDULE 34 OF THE PRODUCT SAFETY AND METROLOGY ETC. (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019

REPORT REFERENCE NUMBER: MAF-AP-1023-01 CPSO

RESPONSIBLE INDIVIDUAL: **ALBENA PANTELEEVA**

Health from the Nature

26 The Larches

Carterton

Oxfordshire

OX18 3GH

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PRODUCT BEING ASSESSED: Soap Bar

CATEGORY OF PRODUCT & INTENDED USE: Solid, cold process soap bar for use on the skin of the whole body. Rinse off product.

REPORT PART A

1. Quantitative and qualitative composition of the cosmetic product(s) (including the chemical identity of substances in the formulation).
2. Physical/chemical characteristics and stability of the cosmetic product(s), including impurities, traces, and packaging material information.
3. Microbiological quality of the product(s).
4. Normal and reasonably foreseeable use of the product(s), target populations and warnings.
5. Product and substance exposure information.
6. Undesirable and serious undesirable effects.
7. Toxicological profile and analysis of substance – including MoS.
8. Information on the cosmetic product(s).

REPORT PART B

9. Assessment conclusions.
10. Labelled warnings and instructions of use.
11. Reasoning.
12. Assessor's credentials and approval of Part B

This report is valid only for the use by the person named as the Responsible Person for the products specified in the assessment. Any deviations from the formulations specified in this report ARE NOT VALID and will not be covered by this assessment.

All manufacture of products must comply with standard of good manufacturing practice as detailed in the relevant legislation.

All raw material specifications and finished product specifications must comply with any restrictions (purity etc.) detailed in REGULATION (EC) No 1223/2009

Any deviation from the prescribed formulation and list of permitted ingredients is NOT covered by this safety report.

MSDS sheets for all materials used must be included by the manufacturer as part of Safety Report Part A – additional information on raw materials (Identification and function) - http://ec.europa.eu/consumers/cosmetics/cosing/

MAF Cosmetic Consultants and the assessor named within accept no responsibility or liability for the misuse of this document or for any product produced outside of the specified formulation.

REPORT PART A

1. QUANTITATIVE AND QUALITATIVE COMPOSITION OF THE COSMETIC PRODUCT(S) (INCLUDING THE CHEMICAL IDENTITY OF SUBSTANCES IN THE FORMULATION)

PRODUCT INITIAL FORMULATION: The following table details the initial formulation of the product., i.e., prior to saponification.

INITIAL PRODUCT FORMULATION			
INGREDIENT NAME	**INCI NAME**	**CONC. BAND**	**MAX CONC. (w/w %)**
LARD	LARD	C	[redacted]
WATER	AQUA	D	[redacted]
COCONUT OIL	COCOS NUCIFERA OIL	D	[redacted]
SODIUM HYDROXIDE	SODIUM HYDROXIDE	E	[redacted]
CASTOR OIL	RICINUS COMMUNIS SEED OIL	E	[redacted]
SUNFLOWER SEED OIL	HELIANTHUS ANNUUS SEED OIL	E	[redacted]
COCOA BUTTER	THEOBROMA CACAO SEED BUTTER	E	[redacted]
GLYCERIN	GLYCERIN	F	[redacted]
LAVENDER ESSENTIAL OIL	LAVANDULA INTERMEDIA FLOWER/LEAF/STEM OIL	F	[redacted]
TITANIUM DIOXIDE	CI 77891	G	[redacted]
MICA	CI 77019	G	[redacted]
LAVENDER (FLOWER, DRY)	LAVANDULA ANGUSTIFOLIA FLOWER	G	[redacted]

PRODUCT FINAL FORMULATION: The following table details the formulation of the final product., i.e., after saponification.

FINAL PRODUCT FORMULATION			
INGREDIENT NAME	**INCI NAME**	**CONC. BAND**	**MAX CONC. (w/w %)**
LARD	SODIUM LARDATE	C	[redacted]
COCONUT OIL	SODIUM COCOATE	D	[redacted]
GLYCERIN	GLYCERIN	D	[redacted]
WATER	AQUA	E	[redacted]
CASTOR OIL	SODIUM CASTORATE	E	[redacted]
SUNFLOWER SEED OIL	SODIUM SUNFLOWERSEEDATE	E	[redacted]
COCOA BUTTER	SODIUM COCOABUTTERATE	E	[redacted]
LAVENDER ESSENTIAL OIL	LAVANDULA INTERMEDIA FLOWER/LEAF/STEM OIL	F	[redacted]
TITANIUM DIOXIDE	CI 77891	G	[redacted]
MICA	CI 77019	G	[redacted]
LAVENDER (FLOWER, DRY)	LAVANDULA ANGUSTIFOLIA FLOWER	G	[redacted]

2. PHYSICAL/CHEMICAL CHARACTERISTICS AND STABILITY OF THE COSMETIC PRODUCT(S) INCLUDING IMPURITIES, TRACES, AND PACKAGING MATERIAL INFORMATION.

PHYSICAL AND CHEMICAL PROPERTIES:

The colour and fragrance are characteristic of the fragrance and colourants used in the formulation (if any).

For detailed information regarding the physical and chemical characteristics of the raw materials please refer to the MSDS in the product information file (PIF) and Section 7 of this document.

The exact pH of the product has not been empirically determined but based on the understanding of similar products the expected pH is 10.5-11.5.

STABILITY AND REACTIVITY:

The product is expected to be nominally stable at ambient storage conditions – to be confirmed by manufacturer based on observation of previous products made.

No major interactions are expected - possible interaction between labile components of fragrance materials (esters, alcohols) - no resulting components that are likely to alter the toxicity profile of the initial ingredients.

A suggested shelf life of at least 30 months applies to the product. A suggested PAO of 6 months applies to this product.

INGREDIENT PURITY:

Specific purity criteria do not apply. The purity of the ingredients in the formulation(s) is specified – where appropriate – in the MSDS documents in PIF. Pharmaceutical, food or cosmetic grade ingredients are used in the manufacture of the product(s). The manufacturer is responsible for ensuring the purity of the ingredients used and the quality of the raw materials.

PACKAGING MATERIAL:

No specific requirements. Inert cosmetic/food grade packaging must be used. The manufacturer is responsible for ensuring the suitability and quality of the packaging material.

3. MICROBIOLOGICAL QUALITY OF THE PRODUCT(S).

The product(s) is anhydrous and has a low activity of water, and – under normal conditions of storage and/or use – does not support microbial growth. Product(s) is a Category 2 product:

For any cosmetic product classified as a "Category 2 Product", the total viable count (TVC) the TVC for aerobic mesophilic microorganisms should not exceed 1000cfu/g or mL of product. In addition, the pathogens Pseudomonas aeruginosa, Staphylococcus aureus and Candida albicans should not be detectable in 1g or 1mL of the product.

Microbiological quality testing was performed on the raw materials by the primary manufacturer. Further, specific microbiological testing is not required, nor recommended for this product(s).

4. NORMAL AND REASONABLY FORESEEABLE USE OF THE PRODUCT(S), TARGET POPULATIONS AND WARNINGS.

The product is a solid soap bar. It is intended to be used on the skin of the whole body.

It is a rinse off product.

It is intended to be used by the general population.

The product is not intended for, nor is marketed for use on babies, infants, and children under 3 years of age.

The product(s) is not intended to be used on mucous membranes or on the eye area. There is no other reasonable or foreseeable use for this product(s).

There is no specific requirement for warnings required for the product labelling, however a general statement that these products are for external use only, should not be applied to the eye area, mucous membranes, broken or irritated skin is recommended. It is also recommended that a statement advising to discontinue use in the case of irritation should also be include.

5. PRODUCT AND SUBSTANCE EXPOSURE INFORMATION.

Exposure (under foreseeable conditional use) is by dermal absorption only. The retention factor of 1% has been applied (as per The SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation 10th Revision), and all calculations have been based on typical exposure values (as per RIVM Report 320104001/2006).

AREAS OF SPECIFIC EXPOSURE

Inhalation – not relevant for this type of product.

Dermal – this product is intended for use on the skin of the whole body.

Eye – not relevant for this type of product. Use on the eye area should be avoided.

Ingestion – not relevant for this type of product.

EXPOSURE OF PRODUCT; SKIN OF THE BODY					
PRODUCT AMOUNT PER APPLICATION[1] (G)	**POTENTIAL FREQUENCY OF USE[1] (PER DAY)**	**MAXIMUM DAILY PRODUCT USE (G)**	**RETENTION FACTOR[2]**	**MAXIMUM DAILY PRODUCT EXPOSURE (MG)**	**DAILY SYSTEMIC EXPOSURE DOSE (SED)† (MG/KG/DAY)**
7.00	1.00	7.00	0.01	70	**1.166666667**

SUBSTANCE EXPOSURE DATA: BODY			
CONCENTRATION BAND	**CONCENTRATION (%)**	**DAILY SUBSTANCE EXPOSURE (mg/day)**	**SED (mg/kg/day)**
A (75-100)	100.00	70	**1.166666667**
B (50-75)	75.00	52.5	**0.875**
C (25-50)	50.00	35	**0.583333333**
D (10-25)	25.00	17.5	**0.291666667**
E (5-10)	10.00	7	**0.116666667**
F (1-5)	5.00	3.5	**0.058333333**
G (0.1-1)	1.00	0.7	**0.011666667**
H (<0.1)	0.10	0.07	**0.001166667**

1: Product amount per application, frequency of use and surface area exposed RIVM report 320104001/2006, H. J., Bremmer. 2: Retention factor THE SCCS NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION 11TH REVISION. †: Mean body weight used 60kg. ‡: Based on the product amount per application

6. UNDESIRABLE AND SERIOUS UNDESIRABLE EFFECTS

There were no undesirable or serious undesirable effects reported at the time this report was prepared. A record must be kept of any reported undesirable effects, and they must be notified to the relevant competent authority.

Based on the understanding of products of this type (and the raw materials used to produce them) it is not expected that any adverse effects will occur as a result of the normal, prescribed use of this product.

7. TOXICOLOGICAL PROFILE AND ANALYSIS OF SUBSTANCES – INCLUDING MoS.

The NOAEL values for each ingredient in the products assessed within this report were obtained. The margin of safety (MoS) value was determined for each ingredient using the following formula (as defined by the SCCS):

$$MoS = \frac{NOAEL}{SED}$$

For the purposes of this toxicological assessment, a MoS of >100 is considered acceptable. Any ingredients with a MoS of less than 100 will have specific justification for their approval (if such approval is granted).

NOAEL values were obtained from published, repeat dose toxicity studies.

The following table details the NOAEL and MoS values for each relevant substance included in the formulations.

In addition to calculating the MoS, the TTC (threshold of toxicological concern) was determined where relevant. The following TTC apply to compounds, where relevant:

Cramer Class I	30ug/kg/day
Cramer Class II	9ug/kg/day
Cramer Class III	1.5ug/kg/day

Where the TTC is exceeded for a specific substance, justification for deeming it “safe” will be provided.

MoS OF SUBSTANCES ASSESSED IN THIS REPORT.

The MoS was calculated for each substance used in each of the formulations covered in this assessment; the MoS for each substance was >100; the assessment determined that each of the substances was satisfactorily safe when used as specified by each of the formulations detailed in this report. Any substance with a MoS of >1000 is considered safe and non-toxic.

PROHIBITED AND RESTRICTED SUBSTANCES, AND ALLERGENS:

There are no substances in the formulations of each of the products defined as prohibited by Annex VI of Regulation (EC) No. 1223/2009.

Any allergens present in the essential and/or fragrance oils used in any of the formulations that exceed 0.01% must be indicated on the labelling of the product(s). The manufacturer is responsible for calculating the allergens present and determining which – if any – must be included on the labelling.

8. INFORMATION ON THE COSMETIC PRODUCT(S).

There are no specific or medicinal claims made by the products. The product is intended for general cosmetic use by general consumers and does not contain any novel or previously unused cosmetic ingredients. All the ingredients used in the formulation for each of the products are widely used in cosmetic preparations and are generally considered safe for use in this type of cosmetic product.

TOXICOLOGICAL PROFILE OF INGREDIENTS		
INCI NAME	**TOXICOLOGICAL PROFILE**	**MoS**
AQUA	MOLECULAR FORMULA: H2O CHEMICAL (IUPAC) NAME: Water CAS#: 7732-18-5 EC#: 231-791-2 FUNCTION: Solvent No toxicological significance.	>100
CI 77019	MOLECULAR FORMULA: AB2–3(X, Si)4O10(O, F, OH)2 CHEMICAL (IUPAC) NAME: Mica CAS#: 12001-26-2 EC#: 601-648-2 FUNCTION: Bulking Micas are listed as CI77019 in the Cosmetics Directive of the European Union (Annex IV/120) and may be used in cosmetics and personal care products without limitation.	>100
CI 77891	MOLECULAR FORMULA: TiO2 CHEMICAL (IUPAC) NAME: Titanium dioxide CAS#: 13463-67-7 EC#: 236-675-5 FUNCTION: Colourant Acute toxicity, oral: LD50 > 5000mg/kg bw Acute toxicity, inhalation: LC50 > 6,82mg/L (MMAD=1.55 µm, GSD=1.70 µm) Acute toxicity, dermal: Conduct of an acute dermal toxicity study is unjustified as inhalation of the substance is considered as major route of exposure and physicochemical properties and dermal absorption data of the substance do not suggest a significant rate of absorption through the skin (cf. Annex VIII section 8.5 Column 2 of regulation (EC) 1907/2006). Titanium dioxide has been tested in various in vivo skin and eye irritation studies. All tests show a negative response, thus titanium dioxide does not require classification either as skin or as eye irritant Titanium dioxide did not show any adverse effects in 90-day and 28-day oral repeated dose toxicity studies in rats with a NOAEL of 1000 and 24,000 mg/kg bw/day, respectively. No adverse effects were observed in rats and mice orally exposed up to a dose of 3500 mg/kg bw/day over a period of 103 weeks in a carcinogenicity bioassay. Titanium dioxide is not absorbed to any relevant extent through human skin, thus no toxic effects can be expected via the dermal route of exposure. Titanium dioxide showed adverse pulmonary effects in chronic inhalation studies only at concentrations above the maximum tolerated dose (MTD).	>100
GLYCERIN	MOLECULAR FORMULA: C3H8O3 CHEMICAL (IUPAC) NAME: propane-1,2,3-triol (Glycerin / Glycerol) CAS#: 56-81-5	>100

EC#: 200-289-5
FUNCTION: Humectant, Skin Conditioning, Skin controlling (reaction product of NaOH & Fatty acids)

Glycerin (Glycerol) is a polyol (polyhydric alcohol) that functions as a humectant, crystallization modifier, and plasticizer. it is a bit- tersweet liquid which has a high solubility of 71 g/100 g of water at 25°c. it is 75% as sweet as sugar. it is a fair oil solvent and has a medium to high hygroscopicity. it is used to maintain a certain moisture content to prevent the drying-out of foods; at 10–15% in raisins, it keeps them from drying out and prevents their moisture from migrating into cereal. it is used in confections to maintain the initial level of crystallization of the soft sugar. in reduced-fat frozen desserts, it helps prevent ice crystal formation. it also functions as a flavor solvent. applications include marshmallows, candy, and baked goods.

CAS Number: 56-81-5
Molecular formula: C3H8O3

The acute oral LD50 was determined in three species, rat, mice and guinea pigs. In all three species the oral LD50 was >/= 11,500 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, rats were exposed to aerosol from test material at targeted concentrations of 1.0, 2.0, or 4.0 mg glycerol/L for 6 hours. The 4 h inhalation LC50 was determined to be above 5.85 mg/L in rats.

A round-robin testing program was conducted in 14 laboratories.
The dermal irritation potential was examined.
Glycerin was considered to be non irritating to the skin in rabbit irritation studies in 14 testing laboratories.
In another study with rabbits, glycerin was considered to be non-irritating also.

Glycerol was applied to the skin of 33 humans for 24 hours on a semi-occluded patch and the response to the test material was observed. Under the conditions of the study, Glycerine USP (25% concentration) exhibited no clinical irritation when tested in humans.

not sensitising, OECD 429: S.I. of 1.1, 0.7 and 0.5 at 25%, 50% and 100% v/v

not sensitising based on human data

In the best available dietary study, groups of 22 rats (Long-Evans)/sex/treatment received 5, 10 and 20% glycerol (natural or synthetic) in their diet (males 2000, 4000 and 8000 mg/kg bw; females 2500, 5000 and 10000 mg/kg bw) for 2 years. Although the results were not described in detail, based on this limited dietary study it can be concluded that no adverse effects were observed at up to 10,000 mg/kg bw.

The effect of glycerine following administration for 90 days in a subchronic toxicity study was examined. Rats fed 5 or 20% glycerine in the diet for 90 days gained weight at a faster rate than control animals. There were no adverse treatment related effects noted in male or female rats fed 5% glycerine in the diet. In the male rats which received 20 percent glycerine, there was an increase in the final liver/body weight ratio and upon microscopic examination generalized cloudy swelling and hypertrophy of the parenchymal cells was observed. The only effect in the female rats on this level was some generalized cloudy selling upon microscopic examination of the liver. A 5% glycerol in the diet corresponded to 4580 and 6450 mg/kg/day for male and female rats, respectively, after 4 weeks and a 20% glycerol in the diet corresponded to 18,750 and 25,800 mg/kg/day for male and female rats, respectively, after 4 weeks.

	A number of other studies have been incorporated in the dossier. These studies are considered less reliable indicators of the systemic effects of glycerol following repeated administration, mainly because of limited toxicity assessments and/or deficient experimental design. The effects they do report are consistent with those observed in the key studies and as such they may contribute to the overall assessment of toxicity of glycerol. The acute oral LD50 was determined in three species, rat, mice and guinea pigs. In all three species the oral LD50 was >/= 11,500 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, rats were exposed to aerosol from test material at targeted concentrations of 1.0, 2.0, or 4.0 mg glycerol/L for 6 hours. The 4 h inhalation LC50 was determined to be above 5.85 mg/L in rats. A round-robin testing program was conducted in 14 laboratories. The dermal irritation potential was examined. Glycerin was considered to be non irritating to the skin in rabbit irritation studies in 14 testing laboratories. In another study with rabbits, glycerin was considered to be non-irritating also. Glycerol was applied to the skin of 33 humans for 24 hours on a semi-occluded patch and the response to the test material was observed. Under the conditions of the study, Glycerine USP (25% concentration) exhibited no clinical irritation when tested in humans. not sensitising, OECD 429: S.I. of 1.1, 0.7 and 0.5 at 25%, 50% and 100% v/v not sensitising based on human data In the best available dietary study, groups of 22 rats (Long-Evans)/sex/treatment received 5, 10 and 20% glycerol (natural or synthetic) in their diet (males 2000, 4000 and 8000 mg/kg bw; females 2500, 5000 and 10000 mg/kg bw) for 2 years. Although the results were not described in detail, based on this limited dietary study it can be concluded that no adverse effects were observed at up to 10,000 mg/kg bw. A number of other studies have been incorporated in the dossier. These studies are considered less reliable indicators of the systemic effects of glycerol following repeated administration, mainly because of limited toxicity assessments and/or deficient experimental design. The effects they do report are consistent with those observed in the key studies and as such they may contribute to the overall assessment of toxicity of glycerol.	
LAVANDULA ANGUSTIFOLIA FLOWER	No toxicological significance.	>100
LAVANDULA INTERMEDIA FLOWER/LEAF/STEM OIL	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: Lavender, Lavandula hbrida, ext. CAS#: 93455-97-1 EC#: 297-385-2 FUNCTION: Perfuming Lavandula Angustifolia Oil is the volatile oil obtained from the flowers of the Lavender, Lavandula angustifolia, Labiatae. ISO 8902:2009 Physical Properties:	>100

Appearance: colorless to pale yellow clear liquid (est)
Food Chemicals Codex Listed: No
Specific Gravity: 0.87700 to 0.89200 @ 25.00 °C.
Pounds per Gallon - (est).: 7.298 to 7.422
Refractive Index: 1.45700 to 1.46400 @ 20.00 °C.
Boiling Point: 204.00 °C. @ 760.00 mm Hg
Flash Point: 182.00 °F. TCC (83.33 °C.)
Soluble in:
alcohol
Insoluble in:
water

Organoleptic Properties:
Odor Type: floral
Odor Strength:medium
Substantivity:12 hour(s) at 100.00 %
herbal lavender
Odor Description:at 100.00 %. herbal lavender
Flavor Type: herbal
lavender
Taste Description: lavender
Odor and/or flavor descriptions from others (if found).

Organ-specific effects
Adverse skin reactions: Undiluted lavender absolute was slightly irritating to rabbits; tested at 10% on 25 volunteers it was neither irritating nor ensitizing (Opdyke 1976 p. 449). Tested at 2, 5 and 10% on 25 volunteers with a previous history of reaction to fragrance materials, lavender absolute produced allergic reactions in 7, 11 and 13 individuals, respectively. In this high-risk group, 0.12% was the concentration at which any observable reaction disappears (Bouhlal et al 1988b). The cause of facial dermatitis in a physiotherapist was due to a pharmaceutical gel she often used on patients. She also reacted to 2% lavender absolute, which was present in the gel (Rademaker 1995). Two cases of facial dermatitis are reported following the nightly application of a few drops of undiluted lavender oil to the bed pillow as a sedative; both tested positive to 2% lavender absolute (Coulson and Khan 1999). An eczema patient using an aromatherapy lavender gel tested positive to 10% lavender absolute, but not to 2% (Varma et al 2000). Carcinogenic/anticarcinogenic potential: No information found. Coumarin is carcinogenic in rodents, but is anticarcinogenic in umans (Felter et al 2006).
Systemic effects Acute toxicity: Lavender absolute acute oral LD50 in rats 4.25 g/
kg; acute dermal LD50 in guinea pigs >5 g/kg (Opdyke 1976
p. 449).

Safety in Use Information:
Category:
flavor and fragrance agents
IFRA Code of Practice Notification of the 49th Amendment to the IFRA Code of Practice
IFRA fragrance material specification:
Linalool and natural products known to be rich in linalool, such as bois de rose, coriander or ho wood oil, should only be used when the level of

	peroxides is kept to the lowest practical level. It is recommended to add antioxidants at the time of production of the raw material. The addition of 0.1% BHT or alpha-tocopherol for example has shown great efficiency. The maximum peroxide level for products in use should be 20 mmol/l. contains the following IFRA (Annex) restricted components: (non-analysis max. level reference only) 7-methoxycoumarin Max. Found: <0.02 % and Reason: Sentitization / Photo Sensitization geraniol Max. Found: trace to <0.10 % and Reason: Sensitization Recommendation for lavender oil CO2 extract usage levels up to: 16.0000 % in the fragrance concentrate.	
SODIUM CASTORATE	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: Fatty acids, castor, sodium salts CAS#: 8013-06-7 EC#: 232-390-5 FUNCTION: Surfactant Fatty acid sodium salts are metabolic products of the starting fatty acids. Read across from the following data: Oleic Acid (C18:1) NOAEL >7,500 mg/kg body weight per day (24-week oral study in Wister Rats), IUCLID 2000e. Lauric Acid NOEL >6000 mg/kg was reported for lauric acid (18-week oral study, male rats). Palmitic acid NOEL >5000 mg/kg (150 days oral study in wister Rats). Burdock GA, Carabin IG. Food Chem Toxicol. 2007 Apr;45(4):517-29. Safety assessment of myristic acid as a food ingredient. Caprenin (mixture of caprylic (C8), capric (C10), and behenic (C22) acids) - NOAEL 15% w/w i.e. 150000 mg/kg body weight per day. Webb, D.R., Wood, F.E., Bertram, T.A., and Fortier, N.E. (1993). A 91-day feeding study in rats with caprenin. Food and Chemical Toxicology, 31(12): 935-946. WHO Acceptable Considered safe as a cosmetic ingredient: (https://www.cir-safety.org/ingredient/sodium-olivate)	>100
SODIUM COCOABUTTERATE	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: Fatty acids, cocoa, sodium salts CAS#: N/A EC#: N/A FUNCTION: Surfactant Fatty acid sodium salts are metabolic products of the starting fatty acids. Read across from the following data: Oleic Acid (C18:1) NOAEL >7,500 mg/kg body weight per day (24-week oral study in Wister Rats), IUCLID 2000e. Lauric Acid NOEL >6000 mg/kg was reported for lauric acid (18-week oral study, male rats). Palmitic acid NOEL >5000 mg/kg (150 days oral study in wister Rats). Burdock GA, Carabin IG. Food Chem Toxicol. 2007 Apr;45(4):517-29. Safety assessment of myristic acid as a food ingredient. Caprenin (mixture of caprylic (C8), capric (C10), and behenic (C22) acids) - NOAEL 15% w/w i.e. 150000 mg/kg body weight per day. Webb, D.R., Wood, F.E., Bertram, T.A., and Fortier, N.E. (1993). A 91-day feeding study in rats with caprenin. Food and Chemical Toxicology, 31(12): 935-946. WHO Acceptable	>100

	Considered safe as a cosmetic ingredient: (https://www.cir-safety.org/ingredient/sodium-olivate)	
SODIUM COCOATE	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: Fatty acids, coco, sodium salts CAS#: 61789-31-9 EC#: 263-050-4 FUNCTION: Surfactant Fatty acid sodium salts are metabolic products of the starting fatty acids. Read across from the following data: Oleic Acid (C18:1) NOAEL >7,500 mg/kg body weight per day (24-week oral study in Wister Rats), IUCLID 2000e. Lauric Acid NOEL >6000 mg/kg was reported for lauric acid (18-week oral study, male rats). Palmitic acid NOEL >5000 mg/kg (150 days oral study in wister Rats). Burdock GA, Carabin IG. Food Chem Toxicol. 2007 Apr;45(4):517-29. Safety assessment of myristic acid as a food ingredient. Caprenin (mixture of caprylic (C8), capric (C10), and behenic (C22) acids) - NOAEL 15% w/w i.e. 150000 mg/kg body weight per day. Webb, D.R., Wood, F.E., Bertram, T.A., and Fortier, N.E. (1993). A 91-day feeding study in rats with caprenin. Food and Chemical Toxicology, 31(12): 935-946. WHO Acceptable Considered safe as a cosmetic ingredient: (https://www.cir-safety.org/ingredient/sodium-olivate)	>100
SODIUM LARDATE	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: Fatty acids, lard, sodium salts CAS#: N/A EC#: N/A FUNCTION: Surfactant Fatty acid sodium salts are metabolic products of the starting fatty acids. Read across from the following data: Oleic Acid (C18:1) NOAEL >7,500 mg/kg body weight per day (24-week oral study in Wister Rats), IUCLID 2000e. Lauric Acid NOEL >6000 mg/kg was reported for lauric acid (18-week oral study, male rats). Palmitic acid NOEL >5000 mg/kg (150 days oral study in wister Rats). Burdock GA, Carabin IG. Food Chem Toxicol. 2007 Apr;45(4):517-29. Safety assessment of myristic acid as a food ingredient. Caprenin (mixture of caprylic (C8), capric (C10), and behenic (C22) acids) - NOAEL 15% w/w i.e. 150000 mg/kg body weight per day. Webb, D.R., Wood, F.E., Bertram, T.A., and Fortier, N.E. (1993). A 91-day feeding study in rats with caprenin. Food and Chemical Toxicology, 31(12): 935-946. WHO Acceptable Considered safe as a cosmetic ingredient: (https://www.cir-safety.org/ingredient/sodium-olivate)	>100
SODIUM SUNFLOWERSEEDATE	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: Fatty acids, sunflower, sodium salts CAS#: N/A EC#: N/A	>100

	FUNCTION: Surfactant Fatty acid sodium salts are metabolic products of the starting fatty acids. Read across from the following data: Oleic Acid (C18:1) NOAEL >7,500 mg/kg body weight per day (24-week oral study in Wister Rats), IUCLID 2000e. Lauric Acid NOEL >6000 mg/kg was reported for lauric acid (18-week oral study, male rats). Palmitic acid NOEL >5000 mg/kg (150 days oral study in wister Rats). Burdock GA, Carabin IG. Food Chem Toxicol. 2007 Apr;45(4):517-29. Safety assessment of myristic acid as a food ingredient. Caprenin (mixture of caprylic (C8), capric (C10), and behenic (C22) acids) - NOAEL 15% w/w i.e. 150000 mg/kg body weight per day. Webb, D.R., Wood, F.E., Bertram, T.A., and Fortier, N.E. (1993). A 91-day feeding study in rats with caprenin. Food and Chemical Toxicology, 31(12): 935-946. WHO Acceptable Considered safe as a cosmetic ingredient: (https://www.cir-safety.org/ingredient/sodium-olivate)	

There are no substances contained within the formulation considered to be acutely toxic (either via dermal and/or oral exposure). There are no know dermal or ocular irritants or sensitisers. There are no phototoxic compounds. There are no known CMR compounds.

[1]: Toxicological risk is calculated using a number of parameters and is determined either by using published, peer-reviewed studies or determined computationally. The TTC values, presence of Cramer Compounds and the CMR activity of the compounds are assessed to assign a "toxicological risk category" to each component of the product(s):

1) Low/limited toxicological significance: edible and inert substances with a NOAEL value of >1000mg/kg/day (or with no NOAEL value determined due to limited toxicological concern). Includes Cramer Class I compounds, no structural alerts and no CMR activity.

2) Limited toxicological significance: Functional components with a NOAEL of 100-500mg/kg/day. Cramer classes I and II, with limited structural alerts. No determined CMR activity.

3) Moderate toxicological significance: Functional and active components with a NOAEL of 50-100mg/kg/day. Cramer classes I and II with no structural alerts. No CMR activity at the levels used in the formulation.

4) High toxicological concern: components with NOAEL of <50mg/kg/day. Cramer class II and III compounds and compounds with known or potential CMR activity.

REPORT PART B – *APPROVAL OF SOAP BAR(S)*

RESPONSIBLE PERSON DETAILS:

ALBENA PANTELEEVA

Health from the Nature

26 The Larches

Carterton

Oxfordshire

OX18 3GH

United Kingdom

9. ASSESSMENT CONCLUSIONS

Each of the products assessed by this report (specified in Part A) have been deemed safe for the prescribed use (**as a soap bar**). These products satisfy the requirements as specified in Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019.

10. LABELLED WARNINGS AND INSTRUCTIONS OF USE

No specific requirements for product labelling (other than as described in the next section). Labelling must comply with Regulation (EC) No. 1223/2009 as amended. It is recommended that general safety guidelines are included, e.g., avoid contact with the eyes, if irritation occurs discontinue use, do not use on broken or irritated skin etc.

ALLERGENS – LABELLING DECLARATION

If any of the 26 allergens specified in the EC Directive 2003/15/EC are present in a rinse off product (as is the case for these products) in a concentration of 0.01% or greater, then they must be specified on the product label.

11. REASONING

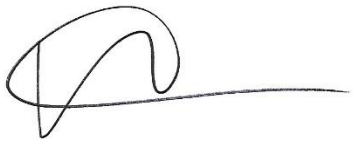
All available data for each component were reviewed for an assessment to be made. Minimally, the following criteria were considered for each product in this assessment:

- The quantitative and qualitative composition
- Physical/chemical characteristics and stability of substances
- Microbiological quality
- Impurities, trace materials and packaging used
- The normal and reasonably foreseeable use of the product(s)
- Exposure to the product(s) (local and systemic)
- Exposure to the substances (local and systemic)
- Toxicological profile of the substances – including MoS and NOAEL values
- Undesirable and serious undesirable effects
- Any other information relevant to the product

The NOAEL and MoS were calculated using published, peer-reviewed studies of oral, dermal, systemic etc. toxicity of each of the ingredients included in the formulation(s). Where no peer reviewed data were available, suitable cross-over data were obtained. Various sources were used to obtain the required data, including PubMed, COSMO database, CIR and SCSS etc. Full details of the sources used can be provided upon request.

12. ASSESSORS CREDENTIALS AND APPROVAL OF PART B

This product meets the requirements of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 and SCHEDULE 34 OF THE PRODUCT SAFETY AND METROLOGY ETC. (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019 and is approved.



Michael Ford, **BSc (Hons), MRes, AMRSB**

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QUALIFICATIONS:	BSc (Hons) Biochemistry, MRes Biochemistry, AMRSB
ADDRESS:	18 Campion Close, Newport, NP20 5DR
DATE:	17/10/2023

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

It is hereby certified that

Michael Peter David Ford

has been conferred the award of
Bachelor of Science
in Biochemistry

Second Class Honours Division One

21 July 2020

Ardystir drwy hyn fod

Michael Peter David Ford

wedi cael dyfarniad
Baglor mewn Gwyddoniaeth
mewn Biocemeg

Anrhydedd Ail Ddosbarth, Adran Un

21 Gorffennaf 2020

Vice Chancellor
Is-Ganghellor

05391641-01-DEUG

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CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

It is hereby certified that

Michael Peter David Ford

has been conferred the award of
Master of Research

Distinction

07 October 2021

Ardystir drwy hyn fod

Michael Peter David Ford

wedi cael dyfarniad
Athro Mewn Ymchwil

Rhagoriaeth

07 Hydref 2021

Vice Chancellor
Is-Ganghellor

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