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-PA-0523-01 WSS

RESPONSIBLE INDIVIDUAL: **STACEY CHARLES**

MILL FARM

CHEPSTOW, NP166QN

UNITED KINGDOM

PRODUCT BEING ASSESSED: CP / HP SOAP – Solid Soap Bars

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

CONTENT OF THIS REPORT

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

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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 BASE FORMULATION: The following table(s) details the base formulation(s) of the product.

PRODUCT BASE FORMULATION			
INGREDIENT NAME	**INCI NAME**	**CONC. BAND**	**MAX. CONC. (%)**
COCONUT OIL	COCOS NUCIFERA OIL	D	**23.21**
OLIVE OIL	OLEA EUROPAEA FRUIT OIL	D	**22.11**
WATER	AQUA	D	**21.89**
OIL	SEE OPTION TABLE	D	**11.05**
COCOA BUTTER / SHEA BUTTER	THEOBROMA CACAO SEED BUTTER / BUTYROSPERMUM PARKII BUTTER	E	**9.95**
SODIUM HYDROXIDE	SODIUM HYDROXIDE	E	**9.58**
FRAGRANCE / ESSENTIAL OIL	SEE OPTION TABLE	F	**2.21**

PRODUCT BASE FORMULATION (FINAL)			
INGREDIENT NAME	**INCI NAME**	**CONC. BAND**	**MAX. CONC. (%)**
COCONUT OIL	SODIUM COCOATE	C	**27.56**
OLIVE OIL	SODIUM OLIVATE	C	**26.25**
OIL	SEE OPTION TABLE	D	**13.12**
COCOA BUTTER / SHEA BUTTER	SODIUM COCOABUTTERATE / SODIUM SHEABUTTERATE	D	**11.81**
WATER	AQUA	E	**9.84**
GLYCERIN	GLYCERIN	E	**8.76**
FRAGRANCE / ESSENTIAL OIL	SEE OPTION TABLE	F	**2.62**

PRODUCT BASE FORMULATION (UNFRAGRANCED)			
INGREDIENT NAME	**INCI NAME**	**CONC. BAND**	**MAX. CONC. (%)**
COCONUT OIL	COCOS NUCIFERA OIL	D	**23.74**
OLIVE OIL	OLEA EUROPAEA FRUIT OIL	D	**22.61**
WATER	AQUA	D	**22.38**
OIL	SEE OPTION TABLE	D	**11.30**
COCOA BUTTER / SHEA BUTTER	THEOBROMA CACAO SEED BUTTER / BUTYROSPERMUM PARKII BUTTER	E	**10.17**
SODIUM HYDROXIDE	SODIUM HYDROXIDE	E	**9.80**

PRODUCT BASE FORMULATION (UNFRAGRANCED) (FINAL)			
INGREDIENT NAME	**INCI NAME**	**CONC. BAND**	**MAX. CONC. (%)**
COCONUT OIL	SODIUM COCOATE	C	**28.30**
OLIVE OIL	SODIUM OLIVATE	C	**26.95**
OIL	SEE OPTION TABLE	D	**13.48**
COCOA BUTTER / SHEA BUTTER	SODIUM COCOABUTTERATE / SODIUM SHEABUTTERATE	D	**12.13**
WATER	AQUA	E	**10.11**
GLYCERIN	GLYCERIN	E	**8.99**

LIQUID OIL / BUTTER OPTIONS: The following table details the oils that may be used in the formulation of the product.

OIL OPTION TABLE				
INGREDIENT NAME	**INCI NAME (SAPONIFIED)**	**INCI NAME**	**CONC. BAND**	**MAX. CONC. (%)**
APRICOT KERNEL OIL	SODIUM APRICOT KERNELATE	PRUNUS ARMENIACA KERNEL OIL	D	**11.05**
ARGAN OIL	SODIUM ARGANATE	ARGANIA SPINOSA KERNEL OIL	D	**11.05**
AVOCADO OIL	SODIUM AVOCADOATE	PERSEA GRATISSIMA OIL	D	**11.05**
BLACK CUMIN / NIGELLA OIL	SODIUM NIGELLATE	NIGELLA SATIVA SEED OIL	D	**11.05**
BROCCOLI SEED OIL	SODIUM BROCCOLISEEDATE	BRASSICA OLERACEA ITALICA SEED OIL	D	**11.05**
CASTOR OIL	SODIUM CASTORATE	RICINUS COMMUNIS SEED OIL	D	**11.05**
GRAPESEED	SODIUM GRAPESEEDATE	VITIS VINIFERA SEED OIL	D	**11.05**
HEMPSEED OIL	SODIUM HEMPSEEDATE	CANNABIS SATIVA SEED OIL	D	**11.05**
JOJOBA OIL	SODIUM JOJOBATE	SIMMONDSIA CHINENSIS SEED OIL	D	**11.05**
KUKUI NUT OIL	SODIUM KUKUIATE	ALEURITES MOLUCCANUS SEED OIL	D	**11.05**
MACADAMIA OIL	SODIUM MACADAMIATE	MACADAMIA TERNIFOLIA KERNEL OIL	D	**11.05**
MANGO BUTTER	SODIUM MANGOSEEDATE	MANGIFERA INDICA SEED BUTTER	D	**11.05**
MEADOWFOAM SEED OIL	SODIUM MAEDOWFOAM SEEDATE	LIMNANTHES ALBA SEED OIL	D	**11.05**
MORINGA OIL	SODIUM MORINGATE	MORINGA OLEIFERA SEED OIL	D	**11.05**
NEEM OIL	SODIUM NEEMATE	MELIA AZADIRACHTA SEED OIL	D	**11.05**
OAT OIL	SODIUM OAT KERNELATE	AVENA SATIVA KERNEL OIL	D	**11.05**
OLIVE OIL	SODIUM OLIVATE	OLEA EUROPAEA FRUIT OIL	D	**11.05**
PUMPKIN SEED OIL	SODIUM PUMPKINSEEDATE	CUCURBITA PEPO SEED OIL	D	**11.05**
RAPESEED OIL	SODIUM RAPESEEDATE	BRASSICA CAMPESTRIS SEED OIL	D	**11.05**
RASPBERRY SEED OIL	SODIUM RASPBERRY SEEDATE	RUBUS IDAEUS SEED OIL	D	**11.05**
RICE BRAN OIL	SODIUM RICE BRANATE	ORYZA SATIVA BRAN OIL	D	**11.05**
ROSEHIP OIL	SODIUM ROSEHIPATE	ROSA CANINA FRUIT / SEED OIL	D	**11.05**
SAFFLOWER OIL	SODIUM SAFFLOWER SEEDATE	CARTHAMUS TINCTORIUS SEED OIL	D	**11.05**
SUNFLOWER SEED OIL	SODIUM SUNFLOWERSEEDATE	HELIANTHUS ANNUUS SEED OIL	D	**11.05**
SWEET ALMOND OIL	SODIUM SWEET ALMONDATE	PRUNUS AMYGDALUS DULCIS OIL	D	**11.05**

PRODUCT COLOURANT OPTIONS: The following table details the substances that may be used to colour the product(s). Any one, or combination of one or more of the following substances may be used to colour the product. The maximum concentration of colourant permitted for use in this product is 2.5% (w/w).

A commercially manufactured blend containing one, or any combination of one or more of the substances shown in the following tables may be used to colour the product.

Each of the following substances (with CI numbers) are listed in Annex IV of Regulation 1223/2009 and Annex IV of Regulation (EC) No 1223/2009 on Cosmetic Products as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019.

These substances are considered safe for use in cosmetic products, without restriction and when used in the manner described in this assessment they do not alter the toxicology of the product and have no impact on the safety of the product.

SUBSTANCE NAME	CI NUMBER
ACID RED 18, CI 11710, CI 15985, CURRY RED, ACID RED 33, ACID YELLOW 23, SOLVENT RED 23, FOOD BLACK 2, CI 28440, CI 40215, BETA CAROTENE, ACID BLUE 1, ACID BLUE 3, FAST GREEN FCF, ACID BLUE 9, ACID BLUE 9 ALUMINIUM LAKE, CI 42170, BASIC VIOLET 2, CI 44090, ACID RED 52, BASIC RED 1, BASIC VIOLET 11:1, ACID YELLOW 73, ACID RED 92, NIGROSINE, CI 71105, ACID BLUE 74, ACID BLUE 74 ALUMINIUM LAKE, CI 73360, CI 73385, PIGMENT VIOLET 19, CI 74260, ANNATTO, PIGMENT BLUE 27, CI 75125, CI FOOD ORANGE 5, CARMINES, ALUMINIUM, CI 77002, KAOLIN / BENTONITE / ILLITE / MONTMORILLONITE, ULTRAMARINES, CI 77015, MICA, CARBON BLACK, CHARCOAL, CHROMIUM (III) OXIDE, CHROMIUM (III) HYDROXIDE, COPPER, GOLD, IRON OXIDE, IRON OXIDE RED, IRON OXIDE YELLOW, IRON OXIDE BLACK, MANGANESE VIOLET, MAGNESIUM CARBONATE, SILVER, TIN OXIDE, TITANIUM DIOXIDE, COKE BLACK	**16255, 11710, 15985, 16035, 17200, 19140, 26100, 27755, 28440, 40215, 40800, 42045, 42051, 42053, 42090, 42090:1, 42170, 42520, 44090, 45100, 45160, 45174, 45350, 45410, 50420, 71105, 73015, 73015:1, 73360, 73385, 73900, 74260, 75120, 77510, 75125, 75130, 75470, 77000, 77002, 77004, 77007, 77015, 77019, 77266, 77267, 77288, 77289, 77400, 77480, 77489, 77491, 77492, 77499, 77742, 77713, 77820, 77861, 77891, 77268:1.**

SUBSTANCE NAME	INCI NAME	CAS NUMBER
SYNTHETIC MICA	SYNTHETIC FLUORPHLOGOPITE	12003-38-2
STYRENE/ACRYLATE COPOLYMER	STYRENE/ACRYLATE COPOLYMER	9010-92-8
POLYURETHANE-11	POLYURETHANE-11	N/A
RAYON	RAYON	270-493-7
RAYON (CELLULOSE REGENERATED)	RAYON (CELLULOSE REGENERATED)	270-493-7
GLYCERIN	GLYCERIN	56-81-5
AQUA	AQUA	7732-18-5
UREA	UREA	57-13-6
SHELLAC	SHELLAC	9000-59-3
ALKANET ROOT	ALKANNA TINCTORIA ROOT POWDER	N/A
ANNATTO SEED POWDER	BIXA ORELLANA SEED POWDER	N/A
BEETROOT POWDER	BETA VULGARIS ROOT POWDER	N/A
CINNAMON POWDER	CINNAMOMUM ZEYLANICUM BARK POWDER	N/A
GREEN TEA POWDER	CAMELLIA SINENSIS LEAF POWDER	N/A
MADDER ROOT POWDER	RUBIA TINCTORIA ROOT POWDER	N/A
PAPRIKA POWDER	CAPSICUM ANNUUM FRUIT POWDER	N/A
SPINACH POWDER	SPINACIA OLERACEA LEAF POWDER	N/A
SPIRULINA POWDER	SPIRULINA PLATENSIS POWDER	N/A
TURMERIC POWDER	CURCUMA LONGA ROOT POWDER	N/A
COCOA POWDER	THEOBROMA CACAO FRUIT POWDER	N/A

OPTIONAL ADDITIVES: The following table details the optional additives that may be used in the formulation of the product. One, or any combination of one or more may be used up to the maximum concentration shown below.

ADDITIONAL / DECORATIVE EXTRA OPTIONS			
INGREDIENT NAME	**INCI NAME**	**CONC. BAND**	**MAX. CONC. (%)**
CALENDULA PETALS	CALENDULA OFFICINALIS FLOWER	F	**5.00**
COFFEE BEANS	COFFEA ARABICA SEED	F	**5.00**
COFFEE GROUNDS	COFFEA ARABICA SEED POWDER	F	**5.00**
CORNFLOWERS	CENTAUREA CYANUS FLOWER	F	**5.00**
HEATHER	CALLUNA VULGARIS FLOWER	F	**5.00**
LAVENDER FLOWER / BUDS	LAVANDULA ANGUSTIFOLIA FLOWER	F	**5.00**
LEMON PEEL / SLICE	CITRUS LIMON FRUIT	F	**5.00**
LIME PEEL / SLICE	CITRUS AURANTIFOLIA FRUIT	F	**5.00**
MINT LEAF	MENTHA PIPERITA LEAF	F	**5.00**
OAT FLOUR	AVENA SATIVA KERNEL FLOUR	F	**5.00**
OATS	AVENA SATIVA KERNEL MEAL	F	**5.00**
ORANGE PEEL / SLICE	CITRUS SINENSIS FRUIT	F	**5.00**
ORANGE PEEL POWDER	CITRUS SINENSIS PEEL POWDER	F	**5.00**
PEPPERCORNS (BLACK & PINK)	PIPER NIGRUM FRUIT OIL	F	**5.00**
POPPYSEEDS	*PAPAVER SOMNIFERUM SEED*	F	**5.00**
PUMICE (FINE)	PUMICE	F	**5.00**
ROSE PETALS	ROSA DAMASCENA FLOWER / ROSA GALLICA FLOWER	F	**5.00**
SALT / PINK SALT / HIMALAYAN SALT	SODIUM CHLORIDE	F	**5.00**
SEA SALT	MARIS SAL	F	**5.00**
STAR ANISE (WHOLE)	ILLICIUM VERUM FRUIT	F	**5.00**
VITAMIN E	TOCOPHEROL	F	**5.00**
NETTLE LEAF	URTICA DIOICA LEAF	F	**5.00**
NETTLE LEAF POWDER	URTICA DIOICA LEAF POWDER	F	**5.00**

PRODUCT FRAGRANCE VARIANTS: The following table details the essential oils that may be used in the formulation of the product(s). These essential oils may be blended in any ratio, but the overall concentration of essential oils may not exceed 3% (3g in 100g of product).

ESSENTIAL OIL OPTIONS			
INGREDIENT NAME	**INCI NAME**	**CONCENTRATION BAND**	**MAX CONCENTRATION (W/W%)**
BERGAMOT ESSENTIAL OIL	CITRUS AURANTIUM BERGAMIA PEEL OIL / CITRUS AURANTIUM BERGAMIA FRUIT OIL	F	**3.00**
CLARY SAGE ESSENTIAL OIL	SALVIA SCLAREA OIL	F	**3.00**
EUCALYPTUS ESSENTIAL OIL	EUCALYPTUS GLOBULUS LEAF OIL	F	**3.00**
FRANKINCENSE ESSENTIAL OIL	BOSWELLIA CARTERII OIL	F	**3.00**
LAVENDER ESSENTIAL OIL	LAVANDULA ANGUSTIFOLIA OIL	F	**3.00**
MAY CHANG ESSENTIAL OIL	LITSEA CUBEBA FRUIT OIL	F	**1.60**
PATCHOULI ESSENTIAL OIL	POGOSTEMON CABLIN LEAF OIL	F	**3.00**
ROSEMARY ESSENTIAL OIL	ROSMARINUS OFFICINALIS LEAF OIL	F	**3.00**
SANDALWOOD ESSENTIAL OIL	AMYRIS BALSAMIFERA BARK OIL	F	**3.00**
SPEARMINT ESSENTIAL OIL	MENTHA SPICATA HERB OIL	F	**3.00**

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. Based on our understanding of products of a similar nature, the pH can be expected to be between 10.5-11.5.

STABILITY AND REACTIVITY:

Based on our understanding of products of a similar nature, it can reasonable be assumed that the product will remain nominally stable at ambient storage conditions – to be confirmed by manufacturer based on observation of previous products made. At the point of completing this assessment, no results of stability tests have been made available; the manufacturer is obligated to perform stability tests and record the observations in their product information file.

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 PAO of 12 months applies to this product. This shelf life may have to be re-evaluated depending on the results of the stability testing performed by the manufacturer.

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).

Assessment of the microbiological quality and risk of the product has been assessed using the guidelines specified in ISO 29621 and as described in NoG (SCCS/1647/22).

NoG (SCCS/1647/22) / ISO 29621 specifies the minimum microbiological standards of cosmetic products (i.e., the qualitative limits in a finished cosmetic product of the specified microorganisms):

TYPE OF MICROORGANISM	PRODUCTS SPECIFICALLY INTENDED FOR CHILDREN UNDER 3 YEARS OF AGE, THE EYE AREA OR MUCOUS MEMBRANES (Category 1)	OTHER PRODUCTS (Category 2)
TOTAL AEROBIC MESOPHILIC MICROORGANISMS (BACTERIA PLUS YEAST AND MOULD)	**≤ 1 x10² CFU per g or ml**	**≤ 1 x10³ CFU per g or ml**
Escherichia coli	Absence in 1g or 1ml	Absence in 1g or 1ml
Pseudomonas aeruginosa	Absence in 1g or 1ml	Absence in 1g or 1ml
Staphylococcus aureus	Absence in 1g or 1ml	Absence in 1g or 1ml
Candida albicans	Absence in 1g or 1ml	Absence in 1g or 1ml

The product is a Category 2 product.

Low microbiological risk products are not required to have specific microbiological quality testing or preservative efficacy testing. Low risk products are defined (in ISO 29621) as:

- Product with a pH of more than 10 or less than 3.
- Products that are anhydrous.
- Products that have significant content of alcohol (>20%), polar solvents (>10%) or other substances that create a hostile environment that inhibits the growth or survival of microbes.

This product is anhydrous & has a low activity of water. These conditions are considered to create an environment sufficiently hostile to inhibit the survival and growth of microbes.

The area of application of the product is not considered to increase the microbiological risk of the product, i.e., it is not applied on mucous membranes, it is not applied to the eye area and is not intended to be applied on broken or irritated skin.

Based on the above we have deemed the product to be of a sufficiently low risk that specific testing of the microbiological quality of the product is not required.

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 & the face.

It is a rinse off product.

It is intended to be used by the general population.

The product is not intended for, nor is suitable 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 12th 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 & the face.

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 12TH 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
AVENA SATIVA KERNEL FLOUR	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: N/A CAS#: 84012-26-0 EC#: 281-672-4 FUNCTION: BULKING, SOOTHING NO TOXICOLOGICAL SIGNIFICANCE – OAT IS A WIDELY USED FOOD PRODUCT. CONSIDERED SAFE AS A COSMETIC INGREDIENT: (HTTPS://DOI.ORG/10.1177%2F1091581819889904)	>100
AVENA SATIVA KERNEL MEAL	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: N/A CAS#: 84012-26-0 EC#: 281-672-4 FUNCTION: BULKING, SOOTHING NO TOXICOLOGICAL SIGNIFICANCE – OAT IS A WIDELY USED FOOD PRODUCT. CONSIDERED SAFE AS A COSMETIC INGREDIENT: (HTTPS://DOI.ORG/10.1177%2F1091581819889904)	>100
CALENDULA OFFICINALIS FLOWER	NO TOXICOLOGICAL SIGNIFICANCE.	>100
CALLUNA VULGARIS FLOWER	NO TOXICOLOGICAL SIGNIFICANCE.	>100
CENTAUREA CYANUS FLOWER	NO TOXICOLOGICAL SIGNIFICANCE.	>100
CITRUS AURANTIFOLIA FRUIT	EC NUMBER:290-010-3 EC NAME: LIME (CITRUS AURANTIFOLIA), EXT. CAS NUMBER: 90063-52-8 MOLECULAR FORMULA: THIS REFERENCE SUBSTANCE IS A UVCB OF THE NCS TYPE. IT IS A COMPLEX MIXTURE OF COMPOUNDS AND THEREFORE MOLECULAR FORMULA, MOLCULAR WEIGHT, AND STRUCTURAL FORMULA CANNOT BE GIVEN. IUPAC NAME: (4S)-1-METHYL-4-(PROP-1-EN-2-YL)CYCLOHEX-1-ENE; 1-METHYL-4-(PROPAN-2-YL)CYCLOHEXA-1,4-DIENE; 1-METHYL-4-(PROPAN-2-YLIDENE)CYCLOHEX-1-ENE; 2-(4-METHYLCYCLOHEX-3-EN-1-YL)PROPAN-2-OL; 6,6-DIMETHYL-2-METHYLIDENEBICYCLO[3.1.1]HEPTANE ACUTE ORAL TOXICITY: LD50 > 4.367 G/KG BW (5 ML/KG BW) (STANDARD ACUTE METHOD, LIMIT TEST; SIMILAR TO OECD 401) ACUTE DERMAL TOXICITY: LD50 > 4.367 G/KG BW (5 ML/KG BW) (STANDARD ACUTE METHOD, LIMIT TEST; SIMILAR TO OECD 402) SKIN IRRITATION: READ ACROSS WITHIN CITRUS OILS AND MAJOR CONSTITUENT LIMONENE: IRRITATING EYE IRRITATION: READ ACROSS WITHIN CITRUS OILS AND MAJOR CONSTITUENT LIMONENE: NOT IRRITATING READ ACROSS BASED ON D-LIMONENE CONTENT: SENSITISING NO NOAEL DATA AVAILABLE FOR LIME ESSENTIAL OIL; WE HAVE USED LIMONENE AS A READ-ACROSS (MAJOR COMPONENT, UP TO 94% CONTENT): THERE WAS NO DATA ON L-LIMONENE REPEATED DOSE TOXICITY. THEREFORE, THE READ-ACROSS FROM THE ANALOGUE SUBSTANCE D-LIMONENE IS APPLIED. WHEN ADMINISTERED ORALLY BY GAVAGE FOR AT LEAST 6 MONTHS, D-LIMONENE INDUCES SOME TOXICOLOGICAL EFFECTS FROM 1000 MG/KG BW/D. AT THIS DOSE LEVEL, FOLLOWING 90 DAYS OF EXPOSURE, D-LIMONENE INDUCES DECREASED BODYWEIGHT GAIN AND CLINICAL SIGNS IN MICE. 180 DAYS OF EXPOSURE TO D-LIMONENE AT THIS DOSE LEVEL DECREASED BODYWEIGHT GAIN AND INCREASED RELATIVE AND ABSOLUTE KIDNEY WEIGHTS OF DOGS (WITH PROTEIN CASTS IN THE RENAL TUBULES OF FEMALES). THE MOST RELEVANT LOAEL VALUE TO DERIVE THE DNEL IS CONSIDERED TO BE 1000 MG/KG BW FROM THE 180-D DOG STUDY.	>100

CITRUS LIMON FRUIT	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: CITRUS LIMON PEEL OIL (LEMON) CAS#: 8008-56-8 / 84929-31-7 EC#: - / 284-515-8 FUNCTION: PERFUMING BASED ON ITS PHYSICAL CHEMICAL PROPERTIES, LEMON OIL IS CLASSIFIED AS FLAMMABLE, R10 ACCORDING TO THE CRITERIA OF DIRECTIVE 67/548/EEC. BASED ON ITS PHYSICAL CHEMICAL PROPERTIES, LEMON OIL IS CLASSIFIED AS FLAMMABLE LIQUID, CATEGORY 3 ACCORDING TO THE CRITERIA OF REGULATION 1272/2008/EC (CLP). THE SUBSTANCE IS A LIQUID. THE SUBSTANCE IS A CLEAR MOBILE LIQUID AT 20 DEGREES CELSIUS AND A SLIGHTLY TURBID MOBILE LIQUID AT -25°C AFTER 72H. THE SUBSTANCE STARTS TO BOIL AT 160°C. THE SUBSTANCE HAS A RELATIVE DENSITY OF 0.8527 AT 20°C. THE VAPOUR PRESSURE OF THE SUBSTANCE IS 218.8 PA AT 25°C. THE PARTITIONING COEFFICIENT OCTANOL-WATER OF THE CONSTITUENTS OF LEMON OIL RANGES FROM 3.33 - 6.3. THE LOG KOW OF THE CONSTITUENTS OF IS ABOVE 4.0 FOR 91% OF THE COMPOSITION. WITH LOG KOW 4.83 (PREDICTED) OR 4.38 (MEASURED), LIMONENE REPRESENTS THE GROUP WITH A HIGH LOG KOW. THE RANGE OF WATER SOLUBILITIES FOR THE KNOWN CONSTITUENTS OF LEMON OIL WAS ESTIMATED TO BE 0.5 - 1767 MG/L AT 25°C. THE DYNAMIC AND KINEMATIC VISCOSITY OF THE SUBSTANCE ARE 1.09 MPA*S AND 1.28 MM^2/S AT 20°C RESPECTIVELY. THE FLASHPOINT OF THE SUBSTANCE IS 53.5°C. THE AUTO-IGNITION TEMPERATURE OF THE SUBSTANCE IS 235°C. THE DYNAMIC AND KINEMATIC VISCOSITY WERE FOUND TO BE 0.99 MPA*S AND 1.17 MM^2/S AT 20°C RESPECTIVELY. ACUTE ORAL TOXICITY: LD50>5000 MG/KG BW (STANDARD ACUTE METHOD, LIMIT TEST) ACUTE DERMAL TOXICITY: LD50>10000 MG/KG BW (STANDARD ACUTE METHOD, LIMIT TEST) SKIN IRRITATION: IRRITATING EYE IRRITATION: NOT IRRITATING THE KEY STUDY IS A LOCAL LYMPH NODE ASSAY PERFORMED WITH MAJOR CONSTITUENT LIMONENE WHICH WAS READ ACROSS TO LEMON OIL. THE STUDY WAS PERFORMED IN CBA/CA STRAIN MICE ACCORDING TO OECD GUIDELINE 429 AND IN COMPLIANCE WITH GLP. MEAN DPM FOR 0, 10, 25, 50, 75 OR 100% D-LIMONENE WERE OBSERVED TO BE 2511, 3319, 8554, 9916, 22063 OR 16259 DPM, RESPECTIVELY. STIMULATION INDEX FOR 10, 25, 50, 75 OR 100% D-LIMONENE WERE CALCULATED TO BE 1.3, 3.4, 4.0, 8.8 OR 6.5, RESPECTIVELY. THE ESTIMATED CONCENTRATION GIVING RISE TO A 3 FOLD INCREASE IN LYMPHOCYTE PROLIFERATION (EC3) WAS 22% V/V (5500 µG/CM2). NO INCREASE IN VISUAL LEVELS OF IRRITANCY TO THE EAR SKIN WAS OBSERVED DURING THE STUDY. UNDER THE TEST CONDITIONS, D-LIMONENE IS CLASSIFIED AS 'R43 MAY CAUSE SENSITISATION BY SKIN CONTACT', ACCORDING TO THE CRITERIA OF ANNEX VI TO THE DIRECTIVE 67/548/EEC AND 'CATEGORY 1' ACCORDING TO THE CLP REGULATION (EC) Nº (1272-2008). IN A SUPPORTING STUDY, A HUMAN PATCH TEST WAS PERFORMED IN WHICH HUMAN VOLUNTEERS WERE EXPOSED TO LEMON OIL REPEATEDLY DURING THREE WEEKS (STUDY SUMMARY INCLUDED IN 7.10.4). SKIN REACTIONS WERE NOTED IN 4% OF THE SUBJECTS AT 24 HR, NO REACTION WAS NOTED AT ANY OTHER READING (48 HR, 72 HR) OR IN THE CONTROL GROUP. IT CAN BE CONCLUDED THAT LEMON OIL DOES NOT HAVE SIN SENSITISING PROPERTIES. HOWEVER, AS THE MAJOR CONSTITUENT OF LEMON OIL IS LIMONENE, WHICH IS CLASSIFIED FOR SKIN SENSITISATION, LEMON OIL WILL BE CLASSIFIED FOR SKIN SENSITISATION. MIGRATED FROM SHORT DESCRIPTION OF KEY INFORMATION: READ ACROSS BASED ON D-LIMONENE CONTENT: SENSITISING A 28-DAY REPEATED DOSE ORAL TOXICITY STUDY IS NOT REQUIRED BASED ON THE INFORMATION REQUIREMENTS	>100

	OUTLINED IN THE ECHA REACH FACT SHEET OF 15/09/2009 (REF: ECHA-09-FS-05-EN), AS A PROPOSAL TO ADDRESS THE 90-DAY REPEATED DOSE ORAL TOXICITY STUDY IN RATS IS INCLUDED IN THE DOSSIER. THE TEST PROPOSAL FOR A 90-DAY REPEATED DOSE TOXICITY STUDY IS PART OF AN INTEGRATED TEST STRATEGY (ITS), WHICH COMPRISES THE FOLLOWING STEPS: 1. DATA FOR ALL MAJOR CONSTITUENTS OF LEMON OIL SHOULD BE CONSIDERED AS A FIRST STEP: - THE CURRENTLY AVAILABLE DATA (AVAILABLE DATA ON MAIN CONSTITUENT D-LIMONENE ALREADY INCLUDED IN THIS DOSSIER) - DATA WHICH ARE EXPECTED TO BECOME AVAILABLE AS A RESULT OF THE REACH REGISTRATION OF THE CONSTITUENTS AS SUCH, LATER DURING THE PHASE-IN PERIOD 2. WHEN DATA FROM CONSTITUENTS ARE NOT SUFFICIENT, TESTING WITH LIME OIL SHOULD BE CONSIDERED.	
CITRUS SINENSIS FRUIT	ACUTE ORAL TOXICITY: LD50>5000 MG/KG BW (STANDARD ACUTE METHOD, LIMIT TEST) ACUTE DERMAL TOXICITY: LD50>5000 MG/KG BW (STANDARD ACUTE METHOD, LIMIT TEST) SKIN IRRITATION: NOT IRRITATING (OECD404), ALTHOUGH SOME EFFECTS WERE NOTED. EYE IRRITATION: NOT IRRITATING (OECD405) READ ACROSS BASED ON D-LIMONENE CONTENT: SENSITISING REPEATED DOSE TOXICITY: ORAL WEIGHT OF EVIDENCE APPROACH 6-MONTH REPEATED DOSE TOXICITY STUDY IN DOGS: LOAEL 1000 MG/KG BW/DAY 90-DAY REPEATED DOSE TOXICITY STUDY IN MICE: LOAEL 1000 MG/KG BW/DAY 90-DAY REPEATED DOSE TOXICITY STUDY IN RATS: LOAEL 1200 MG/KG BW/DAY SUPPORTING 6-MONTH REPEATED DOSE TOXICITY STUDY IN DOGS: LOAEL 1000 MG/KG BW/DAY - GENE MUTATION IN BACTERIA: (BACTERIAL REVERSE MUTATION ASSAY/AMES) (ACCORDING TO OECD 471): NOT MUTAGENIC. - IN VITRO MAMMALIAN CHROMOSOME ABERRATION TEST (EQUIVALENT OR SIMILAR TO OECD 473): NOT CLASTOGENIC WITHOUT METABOLIC ACTIVATION. - IN VITRO MAMMALIAN CELL GENE MUTATION TEST (ACCORDING TO OECD 476): NEGATIVE. DEVELOPMENTAL TOXICITY STUDY IN RATS: NOT TERATOGENIC, NOAELMATERNAL AND DEVELOPMENTAL 591 MG/KG BW/DAY DEVELOPMENTAL TOXICITY STUDY IN RABBITS: NOT TERATOGENIC, NOAELMATERNAL 250 MG/KG BW/DAY, NOEAL DEVELOPMENTAL 1000 MG/KG BW/DAY DEVELOPMENTAL TOXICITY STUDY IN MICE: NOT TERATOGENIC, NOAELMATERNAL AND DEVELOPMENTAL 591 MG/KG BW/DAY	>100
CITRUS SINENSIS PEEL POWDER	ACUTE ORAL TOXICITY: LD50>5000 MG/KG BW (STANDARD ACUTE METHOD, LIMIT TEST) ACUTE DERMAL TOXICITY: LD50>5000 MG/KG BW (STANDARD ACUTE METHOD, LIMIT TEST) SKIN IRRITATION: NOT IRRITATING (OECD404), ALTHOUGH SOME EFFECTS WERE NOTED. EYE IRRITATION: NOT IRRITATING (OECD405) READ ACROSS BASED ON D-LIMONENE CONTENT: SENSITISING REPEATED DOSE TOXICITY: ORAL WEIGHT OF EVIDENCE APPROACH 6-MONTH REPEATED DOSE TOXICITY STUDY IN DOGS: LOAEL 1000 MG/KG BW/DAY 90-DAY REPEATED DOSE TOXICITY STUDY IN MICE: LOAEL 1000 MG/KG BW/DAY 90-DAY REPEATED DOSE TOXICITY STUDY IN RATS: LOAEL 1200 MG/KG BW/DAY SUPPORTING 6-MONTH REPEATED DOSE TOXICITY STUDY IN DOGS: LOAEL 1000 MG/KG BW/DAY - GENE MUTATION IN BACTERIA: (BACTERIAL REVERSE MUTATION ASSAY/AMES) (ACCORDING TO OECD 471): NOT MUTAGENIC. - IN VITRO MAMMALIAN CHROMOSOME ABERRATION TEST (EQUIVALENT OR SIMILAR TO OECD 473): NOT CLASTOGENIC WITHOUT METABOLIC ACTIVATION. - IN VITRO MAMMALIAN CELL GENE MUTATION TEST (ACCORDING TO OECD 476): NEGATIVE. DEVELOPMENTAL TOXICITY STUDY IN RATS: NOT TERATOGENIC, NOAELMATERNAL AND DEVELOPMENTAL 591 MG/KG BW/DAY DEVELOPMENTAL TOXICITY STUDY IN RABBITS: NOT TERATOGENIC, NOAELMATERNAL 250 MG/KG BW/DAY, NOEAL DEVELOPMENTAL 1000 MG/KG BW/DAY DEVELOPMENTAL TOXICITY STUDY IN MICE: NOT TERATOGENIC, NOAELMATERNAL AND DEVELOPMENTAL 591 MG/KG BW/DAY	>100
COFFEA ARABICA SEED	NO TOXICOLOGICAL SIGNIFICANCE.	>100
COFFEA ARABICA SEED POWDER	NO TOXICOLOGICAL SIGNIFICANCE.	>100

GLYCERIN	MOLECULAR FORMULA: C3H8O3 CHEMICAL (IUPAC) NAME: PROPANE-1,2,3-TRIOL (GLYCERIN / GLYCEROL) CAS#: 56-81-5 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.	>100

	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.	
ILLICIUM VERUM FRUIT	NO TOXICOLOGICAL SIGNIFICANCE.	>100
LAVANDULA ANGUSTIFOLIA FLOWER	NO TOXICOLOGICAL SIGNIFICANCE.	>100
MARIS SAL	NO TOXICOLOGICAL SIGNIFICANCE.	>100
MENTHA PIPERITA LEAF	EC NUMBER: 282-015-4 EC NAME: PEPPERMINT, EXT. CAS NUMBER: 84082-70-2 MOLECULAR FORMULA: NOT APPLICABLE (UVCB SUBSTANCE) ACUTE TOXICITY ORAL: - STANDARD ACUTE METHOD (RAT): LD50 = 2650 MG/KG (95% CI >= 2300 - <= 3000) (SIMILAR TO OECD GUIDELINE 401) ACUTE TOXICITY DERMAL: - STANDARD ACTUE METHOD (RABBIT): LD50 > 5000 MG/KG BW (SIMILAR TO OECD GUIDELINE 402) SKIN IRRITATION: - IN VIVO (RABBIT): SLIGHTLY/MODERATELY IRRITATING EYE IRRITATION: - WOE: NOT IRRITATING SEVERAL STUDIES ON THE SKIN SENSITISING POTENTIAL OF CORNMINT OIL WERE AVAILABLE FOR THE DOSSIER, WHICH ARE READ ACROSS TO PEPPERMINT OIL. BECAUSE OF THE COMPARABLE RELIABILITY BETWEEN THE STUDIES AND THE DIFFERING OUTCOMES, A WEIGHT OF EVIDENCE APPROACH WAS USED TO DESCRIBE THE ENDPOINT OF SKIN SENSITISATION. FOUR GUINEA PIG MAXIMISATION TESTS WERE AVAILABLE WITH DIFFERENT FORMS OF CORNMINT OIL, ONE USING PEPPERMINT ARVENSIS (65% PEPPERMINT BRAZILIAN AND 35% PEPPERMINT CHINESE), ONE USING PEPPERMINT CHINESE, AND TWO USING PEPPERMINT BRAZILIAN. IN ALL TESTS THREE CHALLENGES WITH THE TEST SUBSTANCE WERE PERFORMED. THE FIRST TWO CHALLENGES WITH PEPPERMINT ARVENSIS INDICATED NO SKIN SENSITISATION, ONLY AFTER THREE CHALLENGES SENSITISATION WAS INDICATED. THE FIRST CHALLENGE WITH PEPPERMINT CHINESE INDICATED SKINS SENSITISATION. HOWEVER, THE SECOND AND THIRD CHALLENGE DID NOT INDICATE SKIN SENSITISATION. IN BOTH STUDIES CONDUCTED WITH PEPPERMINT BRAZILIAN, THE FIRST AND THIRD CHALLENGE INDICATED SKIN SENSITISATION.	>100

	ADDITIONALLY TOT THE GUINEA PIG MAXIMISATION TESTS, A HUMAN REPEATED OCCLUDED PATCH TEST WAS AVAILABLE WHICH INDICATED ALLERGIC CONTACT SENSITISATION IN 2 OUT OF 22 MALE SUBJECTS. BASED ON THE ABOVE INFORMATION, IT WAS CONCLUDED THAT PEPPERMINT OIL IS A SUBSTANCE THAT POSSESSES THE ABILITY TO INDUCE SKIN SENSITISATION. THREE OF THE FOUR ANIMAL STUDIES INDICATED SENSITISATION AND THE HUMAN STUDY INDICATED SKIN SENSITISATION IN TWO SUBJECTS. MIGRATED FROM SHORT DESCRIPTION OF KEY INFORMATION: SKIN SENSITISATION (WEIGHT OF EVIDENCE, READ ACROSS FROM CORNMINT OIL): - GPMT (5% PEPPERMINT ARVENSIS): NOT SENSITISING (METHOD SIMILAR TO OECD 406) - GPMT (5% PEPPERMINT CHINESE): SENSITISING (METHOD SIMILAR TO OECD 406) - GPMT (5% PEPPERMINT BRAZILIAN): SENSITISING (METHOD SIMILAR TO OECD 406) - GPMT (5% PEPPERMINT BRAZILIAN): SENSITISING (METHOD SIMILAR TO OECD 406) - MAXIMIZATION TEST (HUMANS): SENSITISING JUSTIFICATION FOR SELECTION OF SKIN SENSITISATION ENDPOINT: NO SELECTION IS MADE AS A WEIGHT OF EVIDENCE APPROACH WAS FOLLOWED WHICH IS DESCRIBED BELOW. 28-D ORAL REPEATED DOSE TOXICITY STUDY WITH PEPPERMINT OIL: NOAEL 400 MG/KG BW/DAY BASED ON ABSENCE OF EFFECTS AT THE HIGHEST DOSE TESTED (SEROTA, 1990)	
PAPAVER SOMNIFERUM SEED	NO TOXICOLOGICAL SIGNIFICANCE.	>100
PUMICE	NO TOXICOLOGICAL SIGNIFICANCE.	>100
ROSA DAMASCENA FLOWER / ROSA GALLICA FLOWER	NO TOXICOLOGICAL SIGNIFICANCE.	>100
SODIUM APRICOT KERNELATE	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
SODIUM ARGANATE	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
SODIUM AVOCADOATE	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
SODIUM BROCCOLISEEDATE	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

SODIUM CHLORIDE	MOLECULAR FORMULA: NACL CHEMICAL (IUPAC) NAME: SODIUM CHLORIDE CAS#: 7647-14-5 EC#: 231-598-3 FUNCTION: ABRASIVE, VISCOSITY CONTROLLING THE ACUTE ORAL LD50 TO RATS IS GREATER THAN 3550 MG/KG (95% FIDUCIAL LIMITS 3040 - 4140), THE ACUTE DERMAL LD50 TO RABBITS IS 10000 MG/KG AND THE ACUTE INHALATION LC50 TO RATS IS GREATER THAN 42 MG/L (42000 MG/M3) A DERMAL TOXICITY STUDY WAS CONDUCTED IN RABBITS AND THE LD50 VALUE WAS GREATER THAN 10000 MG/KG AND HENCE NOT CLASSIFIED ACCORDING TO EU ANNEX VI SODIUM CHLORIDE IS CONSIDERED TO BE SLIGHTLY TO NOT IRRITATING TO THE SKIN, AND MODERATELY IRRITATING TO THE EYES SODIUM CHLORIDE IS CATEGORISED UNDER GRAS (GENERALLY RECOGNISED AS SAFE) BY THE FDA (U.S. FOOD AND DRUG ADMINISTRATION) AND BASED ON THE RESULTS OF THE IN-VITRO STUDY, SODIUM CHLORIDE CAN BE CONSIDERED AS A NON-SENSITIZER. CHRONIC ADMINISTRATION AT DOSES OF 4% SODIUM CHLORIDE IN THE DIET OVER A PERIOD OF 2 YEARS INDUCED ELEVATED BLOOD PRESSURE IN THE RATS. THIS DOSE CAN BE CONSIDERED AS AN EXCESSIVE EXPOSURE. REPEATED DOSE ORAL: HISTORICALLY, SODIUM CHLORIDE (AS A MAJOR INGREDIENT IN EDIBLE SALT) HAS BEEN COMMONLY USED IN COOKING AND AS A CONDIMENT AND FOOD PRESERVATIVE. SODIUM CHLORIDE IS CATEGORISED UNDER GRAS (GENERALLY RECOGNISED AS SAFE) BY THE FDA (U.S. FOOD AND DRUG ADMINISTRATION) AND THE AVERAGE DAILY LEVELS OF SODIUM INTAKE FOR ADULTS RANGE FROM 2 TO 5 GRAMS. A TECHNICAL REPORT BY WHO AND THE FOOD AND AGRICULTURE ORGANIZATION (FAO) RECOMMENDED THE CONSUMPTION OF LESS THAN 5 GRAMS SODIUM CHLORIDE (OR 2 GRAMS SODIUM) PER DAY AS A POPULATION NUTRIENT INTAKE GOAL, WHILE ENSURING THAT THE SALT IS IODIZED (WHO, 2003). THE ESTIMATED FATAL DOSE OF SODIUM CHLORIDE IS APPROXIMATELY 0.75 TO 3.00 G/KG (HSDB - HAZARD SUBSTANCE DATA BANK - 750 TO 3000 MG/KG). THE LOWEST TOXIC DOSE (TDLO) FOR AN ADULT MAN WITH NORMAL BLOOD PRESSURE IS 8200 MG/KG (PATTY'S HANDBOOK OF TOXICOLOGY, 5TH ED.; VOL. 3, 375). HIGH ORAL SODIUM CHLORIDE INTAKE IS ASSOCIATED WITH INCREASED RISK OF HYPERTENSION; HOWEVER, THIS IS A WELL STUDIED FIELD IN HUMANS AND ADDITIONAL ANIMAL TESTING DATA WOULD NOT ADD VALUE. BASED ON THE STUDIES, SODIUM CHLORIDE IS NOT CLASSIFIED FOR ANY REPEATED DOSE EFFECTS. THE LOEL FROM THE KEY STUDY IDENTIFIED A DOSE LEVEL OF < 4% VIA THE DIET AND THE CALCULATED LOEL WOULD BE 2533 MG/KG/DAY. REPEATED DOSE DERMAL: OVER AND ABOVE THE CONSUMPTION OF SALT, HUMANS (INCLUDING PREGNANT WOMEN) HAVE THE POTENTIAL TO HAVE A A DERMAL EXPOSURE TO 2 -3% SODIUM CHLORIDE IN SALTWATER WHEN BATHING IN THE OCEAN. DUE TO THE UBIQUITOUS HUMAN EXPOSURE TO SODIUM CHLORIDE WITHOUT CAUSALLY ANY EFFECTS, ANIMAL TESTING IS NOT NECESSARY. REPEATED DOSE INHALATION: THE TOXICITY OF SODIUM CHLORIDE IS SO LOW THAT ONLY MILD NASAL IRRITATION IS EXPERIENCED BY DRILLERS IN SALT MINES EVEN WHEN DUST LEVELS EXCEED THE NUISANCE DUST ACGIH TLV OF 10 MG/CU M. THE MAIN SYSTEMIC EFFECT OF EXCESS SODIUM CHLORIDE INTAKE IS ON BLOOD PRESSURE ELEVATION. DUE TO THE UBIQUITOUS HUMAN EXPOSURE TO SODIUM CHLORIDE WITHOUT CAUSALLY ANY EFFECTS, ANIMAL TESTING IS NOT NECESSARY.	>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 SHEABUTTERATE	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: FATTY ACIDS, SHEA, 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 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 GRAPESEEDATE	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
SODIUM HEMPSEEDATE	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
SODIUM MACADAMIATE	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	>100

	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	
SODIUM MAEDOWFOAM SEEDATE	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
SODIUM MANGOSEEDATE	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 MORINGATE	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
SODIUM NEEMATE	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
SODIUM NIGELLATE	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
SODIUM OAT KERNELATE	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

SODIUM OLIVATE	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: FATTY ACIDS, OLIVE-OIL, SODIUM SALTS CAS#: 61789-88-6 EC#: 263-096-5 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 PUMPKINSEEDATE	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
SODIUM RAPESEEDATE	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
SODIUM RASPBERRY SEEDATE	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
SODIUM RICE BRANATE	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
SODIUM ROSEHIPATE	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	>100

	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	
SODIUM SAFFLOWER SEEDATE	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
SODIUM SUNFLOWERSEEDATE	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: FATTY ACIDS, SUNFLOWER, 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 SWEET ALMONDATE	MOLECULAR FORMULA: N/A CHEMICAL (IUPAC) NAME: FATTY ACIDS, ALMOND, 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
TOCOPHEROL	EC NUMBER: 604-195-9 CAS NUMBER: 1406-66-2 MOLECULAR FORMULA: NOT APPLICABLE IUPAC NAME: TOCOPHEROLS ORAL LD50 (OECD GUIDELINE 401), RAT = 7500 MG/KG BW RA: CAS 7695-91-2, LD50 (OECD GUIDELINE 401), RAT > 10000 MG/KG BW DERMAL LD50 (OECD GUIDELINE 402), RABBIT > 1000 MG/KG BW READ-ACROSS CAS: 59-02-9: DERMAL LD50 (OECD GUIDELINE 402), RABBIT = 5000 MG/KG BW ACUTE TOXICITY BY INHALATION WAS NOT TESTED ACCORDING TO REGULATION (EC) NO 1907/2006, ANNEX VIII, SECTION 8.5, COLUMN 2. ACUTE ORAL TOXICITY THE KEY STUDY WAS PERFORMED WITH "MIXED TOCOPHEROLS". THE ACUTE ORAL TOXICITY OF "MIXED TOCOPHEROLS" WAS INVESTIGATED IN FIVE SPRAGUE-DAWLEY RATS OF EACH SEX. THE STUDY REVEALED NO SIGNIFICANT TREATMENT-RELATED FINDINGS EXCEPT DIARRHEA IN TWO ANIMALS ON DAY 2 AFTER ADMINISTRATION. THE ACUTE ORAL MEDIAN LETHAL DOSE (LD50) OF THE TEST ITEM (50% A.I.) IN THE RAT WAS ESTIMATED TO BE GREATER THAN 15000 MG/KG BODY WEIGHT AND THUS THE LD50 OF THE A.I. WAS CALCULATED TO BE GREATER THAN 7500 MG/KG BW.	>100

THE SUPPORTING STUDY WAS PERFORMED WITH D,L-ALPHA-TOCOPHERYL ACETATE SIMILAR TO THE OECD GUIDELINE 401 (LIMIT TEST) IN SPRAGUE-DAWLEY RATS. THE TEST MATERIAL WAS APPLIED AS A 50% SOLUTION IN OLIVE OIL. THE ANIMALS RECEIVED A SINGLE APPLICATION OF 10000 MG/KG BW (50% A.I.) BY GAVAGE. THE MEDIAN LETHAL DOSE (LD50) OF THE A.I. WAS CACULATED TO BE >5000 MG/KG BW FOR MALES AND FEMALES.

ANOTHER STUDY WAS PERFORMED WITH THE CLOSE HOMOLOG "DL-ALPHA-TOCOPHEROL". THE ACUTE ORAL TOXICITY OF "DL-ALPHA-TOCOPHEROL" WAS INVESTIGATED IN WISTAR RATS EQUIVALENT OR SIMILAR TO THE OECD GUIDELINE 401 FOR ACUTE ORAL TOXICITY STUDIES (LIMIT TEST).

THE ACUTE ORAL MEDIAN LETHAL DOSE (LD50) OF THE TEST ITEM IN THE RAT WAS ESTIMATED TO BE GREATER THAN 4000 MG/KG BODY WEIGHT (SEE ECHA DISSIMINATED DOSSIER CAS: 10191 -41 -0).

IT IS CONCLUDED THAT THE MEDIAN LETHAL DOSE (LD50) OF "RRR-(ALPHA-, BETA-, GAMMA-, DELTA)-TOCOPHEROL IS ≥ 5000MG/KG.

ACUTE DERMAL TOXICITY

THERE IS ONE RELIABLE STUDY AVAILABLE CONCERNING ACUTE ORAL TOXICITY OF THE TEST ITEM ITSELF. THE EVALUATION IS BASED ON THE RESULTS OF THIS STUDY AND A STUDY WHICH IS PERFORMED WITH THE CLOSE HOMOLOG "RRR-ALPHA-TOCOPHEROL".

THE ACUTE DERMAL TOXICITY STUDY WAS PERFORMED WITH THE TEST ITEM "RRR-(ALPHA, BETA-, GAMMA-, DELTA)-TOCOPHEROL". THE ACUTE DERMAL TOXICITY OF THE TEST ITEM WAS INVESTIGATED IN FIVE FEMALE AND 5 MALE NEW ZEALAND WHITE RABBITS. NO MORTALITY OCCURRED. SOME ANIMALS SHOWED DECREASED ACITIVITY, LOSS OF APPETITE AND DIARRHEA. ALL SIGNS VANISHED UNTIL DAY 14. ONE ANIMAL SHOWED WEIGHT LOSS.

THE ACUTE DERMAL MEDIAN LETHAL DOSE (LD50) OF THE TEST ITEM (50% A.I.) IN THE RABBIT WAS ESTIMATED TO BE GREATER THAN 2000 MG/KG BODY WEIGHT. THE LD50 OF THE A.I. WAS CALCULATED TO BE GREATER THAN 1000 MG/KG BW.

ANOTHER STUDY WAS PERFORMED WITH THE STRUCTURAL HOMOLOG "RRR-ALPHA-TOCOPHEROL". THE ACUTE DERMAL TOXICITY OF THE TEST ITEM WAS INVESTIGATED IN FIVE FEMALE AND 5 MALE NEW ZEALAND WHITE RABBITS. ONE ANIMAL WAS FOUND DEAD ON DAY 14. SOME ANIMALS SHOWED DECREASED ACITIVITY, LOSS OF APPETITE, NASAL DISCHARGE AND DIARRHEA. THREE ANIMALS SHOWED WEIGHT LOSS.

THE ACUTE DERMAL MEDIAN LETHAL DOSE (LD50) OF THE TEST ITEM IN THE RABBIT WAS ESTIMATED TO BE GREATER THAN 5000 MG/KG BODY WEIGHT.

AS NO MORTALITIES AND ONLY SOME MINOR TREATMENT-RELATED EFFECTS (DIARRHEA, LOSS OF APETITE, DECREASED ACTIVITY, NASAL DISCHARGE) OCCURRED IN SOME ANIMALS DOSED WITH THE TEST ITEM "RRR-(ALPHA, BETA-, GAMMA-, DELTA)-TOCOPHEROL" (50% A.I.) AND ADDITIONALLY THE LD50 OF A VERY CLOSE HOMOLOG "RRR-ALPHA-TOCOPHEROL" WAS ESTIMATED TO BE GREATER THAN 5000 MG/KG BW. THEREFORE

IT IS CONCLUDED THAT THE MEDIAN LETHAL DOSE (LD50) OF "RRR-(ALPHA-, BEA-, GAMMA-, DELTA)-TOCOPHEROL" IS 2000MG/KG.

JUSTIFICATION FOR SELECTION OF ACUTE TOXICITY – ORAL ENDPOINT
RELIABLE GUIDELINE STUDY WHICH IS THE BASIS FOR CLASSIFICATION.

SKIN IRRITATION: NOT IRRITATING
- RA: 10191-41-0, OECD 404, NOT IRRITATING
- RA: 59-02-9, OECD 404, NOT IRRITATING (24 H EXPOSURE TIME, ABRADED SKIN, OCCLUSIVE DRESSING)
- RA: 59-02-9, OECD 404, NOT IRRITATING (OCCLUSIVE)
EYE IRRITATION: NOT IRRITATING
- RA: 59-02-9, OECD 405, NOT IRRITATING
- RA: 59-02-9, OECD 405, NOT IRRITATING

THE EVALUATION OF THE SKIN SENSITIZING POTENTIAL OF RRR-(ALPHA-, BETA-, GAMMA-, DELTA)-TOCOPHEROL IS BASED ON ONE IN-VIVO STUDY WITH THE TEST SUBSTANCE AND THREE IN-VIVO STUDIES WITH THE A CLOSE HOMOLOG (RRR-ALPHA-TOCOPHEROL) AND A RELIABLE PUBLICATION.

THE SKIN SENSITISING POTENTIAL OF THE TEST ITEM WAS ASSESSED USING THE GUINEA PIG MAXIMIZATION TEST. THE ASSAYS ARE DONE ACCORDING TO THE OECD GUIDELINE 406.

KEY STUDY:

THE TEST SUBSTANCE, RRR-(ALPHA-, BETA-, GAMMA-, DELTA)-TOCOPHEROL, WAS TESTED FOR ITS SENSITISATION POTENTIAL IN GUINEA PIGS, USING THE METHOD OF B. MAGNUSSON AND A. M. KLIGMAN, J. INVEST. DERMATOL. 52, 268 -276 (1969). THE TEST SUBSTANCE WAS APPLIED IN OILY DILUTIONS. 24 AND 48 HOURS AFTER REMOVING OF THE PATCHES OF THE CHALLENGE APPLICATION NO SKIN REACTIONS WERE OBSERVED ON THE TEST ANIMALS AS WELL AS ON THE CONTROL ANIMALS. ACCORDING TO THESE TEST RESULTS THE TEST SUBSTANCE CAN BE REGARDED AS A

"NON-SENSITISER" FOR ALBINO GUINEA PIGS.

SUPPORTING STUDY:

THE STUDY IS DONE WITH A CLOSE HOMOLOG OF THE TEST SUBSTANCE, RRR-ALPHA-TOCOPHEROL.

FOR THE GPMT 20 FEMALE TEST ANIMALS AND 20 CONTROLS, PIRBRIGHT WHITE STRAIN, WERE USED. FOR THE DILUTION OF THE TEST CONCENTRATION OF THE INTRACUTANEOUS TEST SOYBEAN OIL AND FOR THE EPICUTANEOUS APPLICATION PARAFFINUM ALBUM WERE USED.

24 AND 48 HOURS AFTER THE REMOVING OF THE PATCHES OF THE CHALLENGE APPLICATION NEITHER THE TEST NOR THE CONTROL ANIMALS SHOWED ANY SKIN REACTIONS ON THE TREATED SKIN AREAS.

ACCORDING TO THESE TEST RESULTS THE TEST ITEM CAN BE CLASSIFIED AS "NO SKIN SENSITIZER" IN THE MAGNUSSON-KLIGMAN TEST ON GUINEA PIGS.

SUPPORTING STUDY:

THE SECOND SUPPORTING STUDY WAS DONE WITH A CLOSE HOMOLOG OF THE TEST SUBSTANCE, RRR-ALPHA-TOCOPHEROL, ACCORDING TO THE KEY STUDY. 24 AND 48 HOURS AFTER THE REMOVING OF THE PATCHES OF THE CHALLENGE APPLICATION NEITHER THE TEST NOR THE CONTROL ANIMALS SHOWED ANY SKIN REACTIONS ON THE TREATED SKIN AREAS.

ACCORDING TO THESE TEST RESULTS THE TEST ITEM CAN BE CLASSIFIED AS "NO SKIN SENSITIZER" IN THE MAGNUSSON-KLIGMAN TEST ON GUINEA PIGS.

SUPPORTING STUDY:

THIS STUDY WAS ALSO DONE WITH A CLOSE HOMOLOG OF THE TEST SUBSTANCE, RRR-ALPHA-TOCOPHEROL.

THE SENSITISING PROPERTIES OF RRR-ALPHA-TOCOPHEROL (PURITY 87%) WERE EVALUATED IN THE GUINEA PIG MAXIMIZATION TEST.

20 GUINEA PIGS WERE USED FOR THE TEST GROUP AND 19 GUINEA PIGS WERE USED FOR THE CONTROL GROUP.

SENSITISATION RATES WERE 0/20 AND 0/19 IN THE TEST AND CONTROL GROUP, RESPECTIVELY. THE TEST SUBSTANCE WAS NOT A SENSITISER UNDER THE CONDITIONS OF THIS STUDY.
THE INFORMATION AVAILABLE ON THE SKIN SENSITIZING POTENTIAL OF THE TEST ITEM SHOW NO NEED FOR A CLASSIFICATION OF THE TEST ITEM CONCERNING SKIN SENSITIZATION.

MIGRATED FROM SHORT DESCRIPTION OF KEY INFORMATION:
SKIN SENSITISATION:
KEY: NOT SENSITISING (GPMT)
SUPPORTING: RA: 59-02-9, NOT SENSITISING (GPMT)
SUPPORTING STUDY: RA: 59-02-9, NOT SENSITISING (GPMT)
SUPPORTING STUDY: RA: 59-02-9, NOT SENSITISING (GPMT, PUBLICATION)

REPEATED ORAL DOSE TOXICITY:
- SUBCHRONIC (90-DAY), RAT (ORAL, GAVAGE), NOAEL = 500 MG/KG BW
- SUBACUTE (28-DAY), RAT (ORAL, FEEDING), NOAEL CA. 1111 MG/KG BW
- SUBACUTE (28-DAY), DOG (ORAL, FEEDING), NOAEL >= 360 MG/KG BW

NOAEL = 360MG/KG

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 SOLID SOAP*

RESPONSIBLE PERSON DETAILS:

STACEY CHARLES

MILL FARM

CHEPSTOW, NP166QN

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 solid soap**). 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

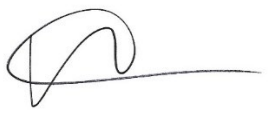
All available data for each component were reviewed for an assessment to be made. Minimally, the following criteria were considered for each product in this assessment:

- 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**

NAME:	Michael Ford, MAF Cosmetic Consultants
QUALIFICATIONS:	BSc (Hons) Biochemistry, MRes Biochemistry, AMRSB
ADDRESS:	5 Market Arcade, Newport, NP20 1FS
DATE:	20/07/2024

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

62739650-01-A6DF

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