

# Cosmetic Product Safety Report

Conforming to

REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on COSMETIC PRODUCTS and SCHEDULE 34 OF THE PRODUCT SAFETY AND METROLOGY ETC. (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019

By Cosmetic Safety Solutions Ltd on behalf of the named manufacturer below

<b>CSS Reference</b>	AT300922CPCPSR
<b>Product line</b>	Cold Process Soaps
<b>Product variants</b>	<ol style="list-style-type: none"><li>1. Tannenbaum</li><li>2. Winter Kiss</li><li>3. Floral Touch</li><li>4. Fruit Tree</li><li>5. Herbal Life</li><li>6. Black Rose</li><li>7. Whoville</li><li>8. Cookie</li></ol>
<b>Product category</b>	Solid soaps - rinse off products
<b>Responsible person</b>	Sense of Velvet Anastasia Tsigkrou 33 Ben Street M114EW Manchester, Uk

## **Report content**

### Report Validity Conditions

#### **Report Part A**

1. Quantitative formulations, concentration ranges (CPNP), toxicity classes and Margin of Safety summaries
2. Final Product characteristics (including stability, microbiology etc.)
3. Packaging
4. Warnings
5. Normal and reasonably foreseeable use
6. Target Population
7. Undesirable effects and serious undesirable effects
8. Information on the cosmetic product / Proof of effects
9. Product and substance exposure characteristics
10. Ingredient toxicity profiles and MOS calculations

#### **Report Part B**

1. Assessment Conclusion
2. Labelled Warnings and Instructions for Use
3. Reasoning
4. Assessor's credentials and approval of part B

## **Report Validity Conditions**

**This Safety Assessment Report is valid only for the named responsible person and is not transferable to any other party without prior written agreement from Cosmetic Safety Solutions Ltd.**

**Cosmetic Safety Solutions Ltd. and its directors will accept no liability for the misuse of this document or for any cosmetic product formulated outside the remit of this document; this includes, but is not limited to 'cupcake' type soaps or any product which may be mistaken for food and is subsequently in violation the European food imitation regulations.**

**All manufacture must comply with appropriate standards of Good Manufacturing Practice as detailed in REGULATION (EC) No 1223/2009**

**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/>**

# Safety Report Part A

## **1. Quantitative formulations, concentration ranges (CPNP), toxicity classes and Margin of Safety summaries**

Concentration ranges (CPNP):

A	>75% - ≤100%
B	>50% - ≤75%
C	>25% - ≤50%
D	>10% - ≤25%
E	>5% - ≤10%
F	>1% - ≤5%
G	>0.1% - ≤1%
H	≤0.1%

**Cosmetic Safety Solutions Ltd confirms that Sodium Hydroxide (lye) is completely neutralized in the provided formulation below (minimum 3% superfatting discount).**

**INCI names for saponified oils are used when these exist - where INCI names have not yet been registered, the names given follow the rules of nomenclature used in INCI name derivation.**

**For details of initial formulations please see attached Annex 1.**

## Product variants:

### 1. Tannenbaum

INCI	Weight, %	Concentration Range (CPNP)	Toxicity Class <sup>†</sup>	MOS Summary
Sodium Olivatate	36.41	C	A	>100
Sodium Cocoate	17.59	D	A	>100
Sodium Shea Butterate	16.18	D	A	>100
Sodium Castorate	4.05	F	A	>100
Sodium Hempseedate	3.52	F	A	>100
Sodium Cocoa Butterate	3.17	F	A	>100
Aqua	8.09	E	A	>100
Glycerin	8.16	E	A	>100
Abies Sibirica Needle Oil	0.61	G	C	>100
Boswellia Carterii Oil	0.49	G	C	>100
Cupressus Sempervirens Oil	0.24	G	C	>100
Citrus Sinensis Peel Oil	0.97	G	C	>100
Cinnamomum Zeylanicum Leaf Oil	0.12	G	C	>100
Spirulina Platensis Powder	0.14	G	A	>100
Illite	0.05	H	A	>100
Boswellia Carterii Gum	0.11	G	C	>100
Bixa Orellana Seed	0.11	G	A	>100

### 2. Winter Kiss

INCI	Weight, %	Concentration Range (CPNP)	Toxicity Class <sup>†</sup>	MOS Summary
Sodium Olivatate	36.48	C	A	>100
Sodium Cocoate	17.62	D	A	>100
Sodium Shea Butterate	16.21	D	A	>100
Sodium Castorate	4.05	F	A	>100
Sodium Hempseedate	3.52	F	A	>100
Sodium Cocoa Butterate	3.17	F	A	>100
Aqua	8.11	E	A	>100
Glycerin	8.17	E	A	>100
Juniperus Communis Fruit Oil	0.24	G	C	>100
Cupressus Sempervirens Oil	0.24	G	C	>100
Mentha Piperita Oil	0.97	G	C	>100
Salvia Sclarea Flower Oil	0.36	G	C	>100
Lavandula Latifolia Herb Oil	0.61	G	C	>100
Kaolin	0.14	G	A	>100
Hibiscus Sabdariffa Flower	0.07	H	A	>100

### 3. Floral Touch

INCI	Weight, %	Concentration Range (CPNP)	Toxicity Class <sup>†</sup>	MOS Summary
Sodium Olivatate	36.46	C	A	>100
Sodium Cocoate	17.61	D	A	>100
Sodium Shea Butterate	16.20	D	A	>100
Sodium Castorate	4.05	F	A	>100
Sodium Hempseedate	3.52	F	A	>100
Sodium Cocoa Butterate	3.17	F	A	>100
Aqua	8.10	E	A	>100
Glycerin	8.17	E	A	>100
Pogostemon Cablin Leaf Oil	0.17	G	C	>100
Cymbopogon Martini Oil	0.32	G	C	>100
Cananga Odorata Flower Oil	0.32	G	C	>100
Citrus Aurantium Bergamia Peel Oil	0.17	G	C	>100
Pelargonium Graveolens Flower Oil	0.32	G	C	>100
Lavandula Latifolia Herb Oil	1.14	F	C	>100
Montmorillonite, Illite	0.14	G	A	>100
Calluna Vulgaris Flower	0.07	H	A	>100
Calendula Officinalis Flower	0.07	H	A	>100

### 4. Fruit Tree

INCI	Weight, %	Concentration Range (CPNP)	Toxicity Class <sup>†</sup>	MOS Summary
Sodium Olivatate	36.47	C	A	>100
Sodium Cocoate	17.62	D	A	>100
Sodium Shea Butterate	16.21	D	A	>100
Sodium Castorate	4.05	F	A	>100
Sodium Hempseedate	3.52	F	A	>100
Sodium Cocoa Butterate	3.17	F	A	>100
Aqua	8.10	E	A	>100
Glycerin	8.17	E	A	>100
Citrus Sinensis Peel Oil	0.80	G	C	>100
Melaleuca Alternifolia Leaf Oil	0.80	G	C	>100
Lavandula Latifolia Herb Oil	0.83	G	C	>100
Kaolin	0.14	G	A	>100
Citrus Aurantium Dulcis Fruit	0.11	G	A	>100

## 5. Herbal Life

INCI	Weight, %	Concentration Range (CPNP)	Toxicity Class <sup>†</sup>	MOS Summary
Sodium Olivatate	36.75	C	A	>100
Sodium Cocoate	17.75	D	A	>100
Sodium Shea Butterate	16.33	D	A	>100
Sodium Castorate	4.08	F	A	>100
Sodium Hempseedate	3.55	F	A	>100
Sodium Cocoa Butterate	3.20	F	A	>100
Aqua	8.17	E	A	>100
Glycerin	8.24	E	A	>100
Foeniculum Vulgare Dulce Fruit Oil	0.07	H	D	>100
Rosmarinus Officinalis Leaf Oil	1.47	F	C	>100
Ocimum Basilicum Oil	0.02	H	D	>100
Illicium Verum Fruit Oil	0.01	H	D	>100
Montmorillonite, Illite	0.18	G	A	>100
Kaolin	0.18	G	A	>100

## 6. Black Rose

INCI	Weight, %	Concentration Range (CPNP)	Toxicity Class <sup>†</sup>	MOS Summary
Sodium Olivatate	36.43	C	A	>100
Sodium Cocoate	17.60	D	A	>100
Sodium Shea Butterate	16.19	D	A	>100
Sodium Castorate	4.05	F	A	>100
Sodium Hempseedate	3.52	F	A	>100
Sodium Cocoa Butterate	3.17	F	A	>100
Aqua	8.09	E	A	>100
Glycerin	8.16	E	A	>100
Piper Nigrum Fruit Oil	0.12	G	C	>100
Pogostemon Cablin Leaf Oil	0.58	G	C	>100
Cymbopogon Martini Oil	0.63	G	C	>100
Citrus Paradisi Peel Oil	0.46	G	C	>100
Pelargonium Graveolens Flower Oil	0.44	G	C	>100
Cinnamomum Zeylanicum Leaf Oil	0.19	G	C	>100
Papaver Somniferum Seed	0.09	H	A	>100
Charcoal Powder	0.14	G	A	>100
Kaolin	0.14	G	A	>100

## 7. Whoville

INCI	Weight, %	Concentration Range (CPNP)	Toxicity Class <sup>†</sup>	MOS Summary
Sodium Oliviate	36.43	C	A	>100
Sodium Cocoate	17.60	D	A	>100
Sodium Shea Butterate	16.19	D	A	>100
Sodium Castorate	4.05	F	A	>100
Sodium Hempseedate	3.52	F	A	>100
Sodium Cocoa Butterate	3.17	F	A	>100
Aqua	8.09	E	A	>100
Glycerin	8.16	E	A	>100
Citrus Paradisi Peel Oil	0.66	G	C	>100
Cedrus Atlantica Wood Oil	0.83	G	C	>100
Cananga Odorata Flower Oil	0.41	G	C	>100
Citrus Aurantium Bergamia Peel Oil	0.53	G	C	>100
Charcoal Powder	0.18	G	A	>100
Kaolin	0.11	G	A	>100
Maris Sal	0.09	H	A	>100

## 8. Cookie

INCI	Weight, %	Concentration Range (CPNP)	Toxicity Class <sup>†</sup>	MOS Summary
Sodium Oliviate	36.51	C	A	>100
Sodium Cocoate	17.64	D	A	>100
Sodium Shea Butterate	16.23	D	A	>100
Sodium Castorate	4.06	F	A	>100
Sodium Hempseedate	3.53	F	A	>100
Sodium Cocoa Butterate	3.17	F	A	>100
Aqua	8.11	E	A	>100
Glycerin	8.18	E	A	>100
Citrus Sinensis Peel Oil	1.95	F	C	>100
Cinnamomum Zeylanicum Leaf Oil	0.37	G	C	>100
Eugenia Caryophyllus Leaf Oil	0.12	G	C	>100
Theobroma Cacao Seed Powder	0.14	G	A	>100

<sup>†</sup> See Section 10 for detailed toxicity class information

## 2. Final product characteristics

### Physical and Chemical Properties:

Solid soap with fragrance characteristic of essential oils used.

pH – expected range 9.5-10.5 for soaps.

### Raw Materials:

Please refer to supplier MSDS and CoA information which should be used in conjunction with this report.

### 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.

### Ingredient Purity:

Approved cosmetic, pharmaceutical or food grade ingredients are used. Where specific purity criteria (e.g. secondary amine content, heavy metals content) apply (as detailed in Ingredient toxicity profiles and MOS calculations section) these remain the responsibility of the responsible person.

### Microbiological Purity:

Product does not support microbial growth under normal storage conditions due to elevated pH and limited water availability (osmotic potential).

The product is not specifically marketed as a product for use by children under 3 years, in the eye area and on mucous membranes, therefore it is classified as a Category 2 product: “Other products”.

For cosmetics classified as Category 2, the total viable count for aerobic mesophilic microorganisms (bacteria plus yeast and mould) should not exceed  $10^3$  CFU per g or ml of product (CFU - colony forming unit).

*Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans* are considered the main potential pathogens in cosmetic products. These specific potential pathogens must not be detectable in 1 g or ml of a cosmetic product.

## 3. Packaging

Wrapped in paper. No specific requirements (e.g. absence of nitrosating agents). Cosmetic / food grade packaging materials must be used.

#### **4. Warnings**

No specific warnings required other than standard product usage instructions – for external use only – avoid direct eye contact – not for application to the mucous membranes or on broken skin. If irritation occurs discontinue use.

#### **5. Normal and reasonably foreseeable use**

The product is intended for use as a traditional cleansing soap for topical application. Rinse off product.

The product is intended for external use only and is not marketed for infant use, or for application to mucous membranes, broken skin or the eye area.

#### **6. Target Population**

Marketed as products for general population – not specifically marketed for infant use.

#### **7. Undesirable effects and serious undesirable effects**

None declared at the time of preparation of this document – a separate file must be made to record any declared incidences of undesirable effects – any serious undesirable effects must be notified to the competent authority and or local poison control agency.

#### **8. Information on the cosmetic product / Proof of effects**

No specific medicinal claims are made. All constituents have been used widely in cosmetic preparations – no newly introduced or novel ingredients are used.

## 9. Product and Substance exposure characteristics

Exposure is by dermal absorption only under foreseeable conditions of use – a retention factor of 1 % has been used for all ingredients (rinse off products) and calculations are based on typical exposure values (RIVM report 320104001/2006 Cosmetics Fact Sheet. H.J. Bremmer, L.C.H. Prud'homme de Lodder, J.G.M. van Engelen).

	Soap (full body)	Potential frequency of application	g / day applied	Retention factor	g / day exposure	Surface area cm <sup>2</sup>	Systemic Exposure Dose (SED) mg/kgbw/day (based on 60 kg avg.)	Specific Exposure mg/cm <sup>2</sup>
	Maximum amount per application / g							
<b>CPNP Concentration Ranges</b>	7.0	1	7.0	1 %	0.07	17500	1.167	0.0040
A – >75% - ≤100%	7.000	1	7.000	1 %	0.07000	17500	1.167	0.0040
B – >50% - ≤75%	5.250	1	5.250	1 %	0.05250	17500	0.875	0.0030
C – >25% - ≤50%	3.500	1	3.500	1 %	0.03500	17500	0.583	0.0020
D – >10% - ≤25%	1.750	1	1.750	1 %	0.01750	17500	0.292	0.0010
E – >5% - ≤10%	0.700	1	0.700	1 %	0.00700	17500	0.117	0.0004
F – >1% - ≤5%	0.350	1	0.350	1 %	0.00350	17500	0.058	0.0002
G – >0.1% - ≤1%	0.070	1	0.070	1 %	0.00070	17500	0.012	0.0000
H – ≤0.1%	0.007	1	0.007	1 %	0.00007	17500	0.001	0.0000

## 10. Ingredient toxicity profiles and MOS calculations based on maximum percentages

### External reference for MOS summary and toxicological data:

[http://cosmetic-compliance.co.uk/web\\_documents/grainger\\_100713\\_toxicology\\_and\\_mos\\_data.xlsx](http://cosmetic-compliance.co.uk/web_documents/grainger_100713_toxicology_and_mos_data.xlsx)

### Ingredient Toxicity profile

Substance classification of toxicological significance

- A Low or limited toxicological significance – edible and inert ingredients with NOAEL values of  $>1000 \text{ mg kg bw}^{-1}\text{d}^{-1}$  or non-determined due to no toxicological concerns. Cramer class I – no structural alerts – no determined CMR activity.  
Examples – edible and/or plant-derived fixed oils and fats, water, bulking minerals, saponified oils and fats, BP grade mineral oils.  
MOS  $>100$
- B Limited toxicological significance – functional components with determined NOAEL values  $100\text{-}500 \text{ mg kg bw}^{-1}\text{d}^{-1}$ . Cramer Class I / Cramer class II – no structural alerts - no determined CMR activity.  
Examples – surfactants, emulsifiers, conditioning agents.  
SED  $<1 - 5 \text{ mg kg bw}^{-1}\text{d}^{-1} = \text{MOS } >100$
- C Moderate toxicological significance – active components with determined NOAEL values  $50\text{-}100 \text{ mg kg bw}^{-1}\text{d}^{-1}$ . Cramer Class I / Cramer class II – potential structural alerts – no determined CMR activity at concentrations used in formulation.  
Examples – essential oils\* and fragrance ingredients, plant extracts<sup>‡</sup>.  
SED  $<0.5 - 1.0 \text{ mg kg bw}^{-1}\text{d}^{-1} = \text{MOS } >100$

\* - Absence of Cramer class III components (e.g. Methyleugenol, safrole, estragole).

‡ - Absence of Cramer class III components (e.g. Pyrrolizidine alkaloids).

- D High toxicological significance – active components with determined NOAEL Values  $<50 \text{ mg kg bw}^{-1}\text{d}^{-1}$ . Cramer class II / Cramer class III – structural alerts – potential CMR activity.  
Examples – active ingredients with presence of restricted components (Rose essential oil, Basil essential oil, Comfrey extract, Peptides, skin lightening, some anti-wrinkle actives).  
MOS to be detailed specifically on report.

TTC values:

Human exposure thresholds of 1800, 540, and 90  $\mu\text{g/person/d}$  (corresponding to 30, 9, and 1.5  $\mu\text{g/kg bw/d}$ ) were proposed for Cramer Class I, II and III, respectively, using the 5th percentile value of distribution of NOELs for each class of chemicals, a body weight of 60 kg, and a safety factor of 100 (Munro *et al.*, 1996). When organophosphates were excluded from Class III, the human exposure threshold increased to 180  $\mu\text{g/person/d}$  (3.0  $\mu\text{g/kg bw/d}$ ; Munro *et al.*, 2008). Due to high potential toxicity, a specific TTC of 18  $\mu\text{g/person/d}$  may be applicable for organophosphates.

SCCP/1171/08

Scientific Committee on Consumer Safety (SCCS)

Scientific Committee on Health and Environmental Risks (SCHER)

Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)

OPINION ON Use of the Threshold of Toxicological Concern (TTC) Approach for Human Safety Assessment of Chemical Substances with focus on Cosmetics and Consumer Products

Common Name	Ingredient Information	Maximum Systemic Exposure Dose (mg/kg) (based on 60kg average)	Phototoxicity Potential / Sensitisation Potential	Documented source of Methyleugenol, safrole, estragole, camphor	Ingredient Toxicology Profile / NOEL values	MOS
Basil Essential Oil	INCI Name OCIMUM BASILICUM OIL Description Ocimum Basilicum Oil is the volatile oil obtained from the leaves of the Basil, Ocimum basilicum L., Labiatae INN Name Ph. Eur. Name CAS # 84775-71-3 / 8015-73-4 EC # 283-900-8 / - Chemical/IUPAC Name Cosmetic Restriction Other Restriction(s) Functions MASKING, TONIC	0.0002	No	Estragole - up to 35% Methyleugenol - up to 1% (provided by supplier)	Safety statement based on Methyleugenol content. Methyleugenol (ME) present at 1% (provided by supplier). Essential oil present at a maximum of 0.02% giving a potential ME content of 0.0002%. Regulation (EC) No 1223/2009 Annex/Ref # III/102 Highest concentration of methyleugenol (CAS # 93-15-2) in the finished products must not exceed: (a) 0.01 % in fine fragrance; (b) 0.004 % in eau de toilette; (c) 0.002 % in a fragrance cream; (d) 0.0002 % in other leave-on products and in oral hygiene products; <b>(e) 0.001% in rinse-off products.</b>  Safety statement based on estragole (methyl chavicol) content - 35% (provided by supplier). Estragole limits in the finished product: - 0.05% in soaps, bathing products, body washes, shampoos, face cleansers (IFRA category 9). Essential oil present at a maximum of 0.02% in the final product. $0.02/100 \times 35 = 0.007\%$ which complies with IFRA limits for category 9 products.	Total estragole content $\leq 0.05\%$ which complies with IFRA limits for category 9 products
Fennel Essential Oil	INCI Name FOENICULUM VULGARE OIL Description Foeniculum Vulgare Oil is the volatile oil obtained from the seeds of the Fennel, Foeniculum vulgare, Umbelliferae. Japanese trivial name: IKYO YU INN Name Ph. Eur. Name CAS # 8006-84-6 EC # - Chemical/IUPAC Name Functions EMOLLIENT, SKIN CONDITIONING, SOOTHING, TONIC	0.0008	Not likely at concentration used - Essential Oil Safety, Tisserand 2014	Yes - estragole - up to 6% (provided by supplier)	Safety statement based on estragole (methyl chavicol) content - 6% (provided by supplier). Estragole limits in the finished product: - 0.05% in soaps, bathing products, body washes, shampoos, face cleansers (IFRA category 9). Essential oil present at a maximum of 0.07% in the final product. $0.07/100 \times 6 = 0.004\%$ which complies with IFRA limits for category 9 products.	
Star Anise Essential Oil	INCI Name ILLICIUM VERUM FRUIT OIL Description Illicium Verum Fruit Oil is an essential oil distilled from the fruits of the Star Anise, Illicium verum, Illiciaceae INN Name Ph. Eur. Name CAS # 84650-59-9 EC # 283-518-1 Chemical/IUPAC Name Functions PERFUMING	0.0001	Not likely at concentration used - Essential Oil Safety, Tisserand 2014	Estragole - up to 5% (provided by supplier)	Safety statement based on estragole (methyl chavicol) content - 5% (provided by supplier). Estragole limits in the finished product: - 0.05% in soaps, bathing products, body washes, shampoos, face cleansers (IFRA category 9). Essential oil present at a maximum of 0.01% in the final product. $0.01/100 \times 5 = 0.0005\%$ which complies with IFRA limits for category 9 products.	

# Safety Report Part B

<b>CSS Reference</b>	AT300922CPCPSR
<b>Product line</b>	Cold Process Soaps
<b>Product variants</b>	1. Tannenbaum 2. Winter Kiss 3. Floral Touch 4. Fruit Tree 5. Herbal Life 6. Black Rose 7. Whoville 8. Cookie
<b>Product category</b>	Solid soaps - rinse off products
<b>Responsible person</b>	Sense of Velvet Anastasia Tsigkrou 33 Ben Street M114EW Manchester, Uk

## ***1. Assessment Conclusion***

This product meets the criteria for safety specified by the requirements of Article 3 of REGULATION (EC) No 1223/2009 and SCHEDULE 34 OF THE PRODUCT SAFETY AND METROLOGY ETC. (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019.

## ***2. Labelled Warnings and Instructions for Use***

No specific warnings required other than standard product usage instructions – for external use only – avoid direct eye contact – not for application to the mucous membranes or on broken skin. If irritation occurs discontinue use.

No other specific instructions for use are prescribed.

### **Allergen declaration**

In a rinse off product, any of the 26 allergens detailed in the European Commission Directive 2003/15/EC, that are present in the final product at a concentration greater than or equal to 0.01% must be declared on the product labelling.

### 3. Reasoning

**Appropriate data were available for all components and a full review of this information has been made. The following information was reviewed as a minimum requirement.**

**Relating to the final product:**

Physical and chemical properties;  
Stability and reactivity;  
Microbiological purity;  
Packaging;  
Normal and reasonably foreseeable use;  
Target population.

**And specifically:**

The general toxicological profile of each ingredient used;  
The chemical structure of each ingredient;  
The level of exposure of each ingredient;  
The specific exposure characteristics of the areas on which the cosmetic product will be applied;  
The specific exposure characteristics of the class of individuals for whom the cosmetic product is intended.

**Margins of safety have been calculated for all components, with additional safety factors applied where appropriate due to the use of data from structurally related compounds.**

**CALCULATION OF THE MARGIN OF SAFETY**

Maximum amount of ingredient applied (mg) **I**  
Typical body weight (bw) of human (kg) **60**  
Maximum absorption through the skin (%) **A**  
Systemic Exposure Dose (mg/kgbw)  $SED = I \times A / 60$   
Margin of Safety **NOAEL / SED**

Where NOAEL equals no observed adverse effect level in mg/kgbw from appropriate repeated dose studies.

MOS values for all toxicologically significant components (other than those whose presence is governed / prescribed specifically by the Annexes of Regulation (EC) No 1223/2009) have been calculated and are satisfactory (MOS >100).

**Local toxicity** – phototoxic materials are not included in this formulation at levels of concern.

**CMRs** – not included in this formulation.

**Nano materials** – not included in this formulation.

**Dermal irritants / sensitizers** – no significant exposure. Compatibility testing is generally advised if the product formulation uses ingredients at concentrations significantly greater

than in previously well tolerated formulations. This formulation is very similar to other formulations that have been marketed previously, over a number of years without report of adverse reaction.


#### **Interaction of substances**

No significant interactions expected, based on a review of the chemical properties of the species included in this formulation. There are no components present that are likely to undergo spontaneous reaction – no species are present that have structural alerts with regard to carcinogenic activity.

#### ***4. Assessor's credentials and approval of part B***

**Approved** - This product meets the criteria for safety specified by the requirements of Article 3 of REGULATION (EC) No 1223/2009 and SCHEDULE 34 OF THE PRODUCT SAFETY AND METROLOGY ETC. (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019.

**30/09/2022**

  Joanne Priestley CBiol MRSB  Managing Director, Safety Assessor  <input checked="" type="checkbox"/>	  Simas Kazlauskas CBiol MRSB  Safety Assessor  <input checked="" type="checkbox"/>
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On behalf of Cosmetic Safety Solutions Ltd, Reg. 13922324 DL14 6HE, England

**Cosmetic Safety Solutions Ltd.**

**Westlea Avenue Bishop Auckland, DL14 6HE, England**

**Safety Assessor Information**

**Joanne Priestley CBiol MRSB Bsc (Hons)**

Email [info@cosmeticsafetyassessment.com](mailto:info@cosmeticsafetyassessment.com)

**- Qualifications**

BSc (Hons) 1st Class (Biological Science)

Chartered Biologist (CBiol)

Full member of the Royal Society of Biology (MRSB)

**- Experience**

11 years in cosmetic product safety, of which cosmetic toxicology forms at least 8 years.

3 years in cardiovascular research and delivery of physiology seminars to undergraduates.

**Simas Kazlauskas CBiol MRSB**

Email [lietuva@cosmeticsafetyassessment.com](mailto:lietuva@cosmeticsafetyassessment.com)

**- Qualifications**

Bachelor's degree in Biochemistry (Vilnius University)

Master's degree in Biochemistry (Vilnius University)

Chartered Biologist (CBiol)

Full member of the Royal Society of Biology (MRSB)

**- Experience**

5+ years in cosmetic product safety and cosmetic toxicology.

3 years in applied enzymology (lipase) research.

This is to certify that

**Joanne Priestley**

has been admitted as a

**Chartered Biologist**

by resolution of the Council

Membership Number P0115871  
Election Date 2 July 2015



Dr Mark Downs CSci FRSB  
Chief Executive



Incorporated by Royal Charter  
Registered Charity No: 277981

This is to certify that

**Simas Kazlauskas**

has been admitted as a

**Chartered Biologist**

by resolution of the Council

Membership Number P0130074  
Election Date 6 April 2018



Dr Mark Downs CSci FRSB  
Chief Executive



Incorporated by Royal Charter  
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