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

CSS Reference	LH100823-VEGSSBLEN1
Product line	Solid Shampoo Bars
Product fragrance variations	1. Orange, Patchouli and Lavender 2. Lavender and Cedarwood 3. Tea Tree and Rosemary 4. Peppermint and Eucalyptus 5. Geranium and Patchouli 6. Lemon, Black Pepper and Litsea Cubeba 7. Unscented
Product category	Surfactant based solid hair shampoos - rinse off products
Responsible person	Lois Himpe Burgemeester g. Dussartlaan 52 8860 Lendelede

Report content

Report Validity Conditions

Report Part A

1. Quantitative formulations and concentration ranges (CPNP)
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 and concentration ranges (CPNP)

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%

Product Formulations:

1. Orange, Patchouli and Lavender

INCI	Max. weight, %	Concentration Range (CPNP)
Sodium Cocoyl Isethionate	68.41	B
BTMS 25 (Cetearyl Alcohol, Behentrimonium Methosulfate)	7.24	E
CAPB (Aqua, Cocamidopropyl Betaine)	5.03	E
Aqua	4.53	F
Cetyl Alcohol	2.62	F
Panthenol - Panthenol, Aqua, Citric Acid / Panthenol, Aqua, Pantolactone	2.01	F
Cocos Nucifera Oil	1.51	F
Theobroma Cacao Seed Butter	1.51	F
Argania Spinosa Kernel Oil	1.21	F
Olea Europaea Fruit Oil	1.21	F
Simmondsia Chinensis Seed Oil	1.01	F
Stearic Acid	0.91	G
Phytokeratin (Aqua, Hydrolyzed Soy Protein, Hydrolyzed Corn Protein, Hydrolyzed Wheat Protein, Phenoxyethanol)	0.80	G
Citrus Aurantium Dulcis (Sinensis) Peel Oil	0.67	G
Pogostemon Cablin Leaf Oil	0.67	G
Lavandula Angustifolia Oil	0.67	G
+/- CI 77004 (Cosmetic Grade Clays - Kaolin, French Green, Red, Yellow, Pink, Purple - flexible)	Up to 3.87	F

2. Lavender and Cedarwood

INCI	Max. weight, %	Concentration Range (CPNP)
Sodium Cocoyl Isethionate	68.41	B
BTMS 25 (Cetearyl Alcohol, Behentrimonium Methosulfate)	7.24	E
CAPB (Aqua, Cocamidopropyl Betaine)	5.03	E
Aqua	4.53	F
Cetyl Alcohol	2.62	F
Panthenol - Panthenol, Aqua, Citric Acid / Panthenol, Aqua, Pantolactone	2.01	F
Cocos Nucifera Oil	1.51	F
Theobroma Cacao Seed Butter	1.51	F
Argania Spinosa Kernel Oil	1.21	F
Olea Europaea Fruit Oil	1.21	F
Simmondsia Chinensis Seed Oil	1.01	F
Stearic Acid	0.91	G
Phytokeratin (Aqua, Hydrolyzed Soy Protein, Hydrolyzed Corn Protein, Hydrolyzed Wheat Protein, Phenoxyethanol)	0.80	G
Lavandula Angustifolia Oil	1.00	G
Cedrus Atlantica Wood Oil	1.00	G
+/- CI 77004 (Cosmetic Grade Clays - Kaolin, French Green, Red, Yellow, Pink, Purple - flexible)	Up to 3.87	F

3. Tea Tree and Rosemary

INCI	Max. weight, %	Concentration Range (CPNP)
Sodium Cocoyl Isethionate	68.41	B
BTMS 25 (Cetearyl Alcohol, Behentrimonium Methosulfate)	7.24	E
CAPB (Aqua, Cocamidopropyl Betaine)	5.03	E
Aqua	4.53	F
Cetyl Alcohol	2.62	F
Panthenol - Panthenol, Aqua, Citric Acid / Panthenol, Aqua, Pantolactone	2.01	F
Cocos Nucifera Oil	1.51	F
Theobroma Cacao Seed Butter	1.51	F
Argania Spinosa Kernel Oil	1.21	F
Olea Europaea Fruit Oil	1.21	F
Simmondsia Chinensis Seed Oil	1.01	F
Stearic Acid	0.91	G
Phytokeratin (Aqua, Hydrolyzed Soy Protein, Hydrolyzed Corn Protein, Hydrolyzed Wheat Protein, Phenoxyethanol)	0.80	G
Melaleuca Alternifolia Leaf Oil	1.33	F
Rosmarinus Officinalis Leaf Oil	0.67	G
+/- CI 77004 (Cosmetic Grade Clays - Kaolin, French Green, Red, Yellow, Pink, Purple - flexible)	Up to 3.87	F

4. Peppermint and Eucalyptus

INCI	Max. weight, %	Concentration Range (CPNP)
Sodium Cocoyl Isethionate	68.41	B
BTMS 25 (Cetearyl Alcohol, Behentrimonium Methosulfate)	7.24	E
CAPB (Aqua, Cocamidopropyl Betaine)	5.03	E
Aqua	4.53	F
Cetyl Alcohol	2.62	F
Panthenol - Panthenol, Aqua, Citric Acid / Panthenol, Aqua, Pantolactone	2.01	F
Cocos Nucifera Oil	1.51	F
Theobroma Cacao Seed Butter	1.51	F
Argania Spinosa Kernel Oil	1.21	F
Olea Europaea Fruit Oil	1.21	F
Simmondsia Chinensis Seed Oil	1.01	F
Stearic Acid	0.91	G
Phytokeratin (Aqua, Hydrolyzed Soy Protein, Hydrolyzed Corn Protein, Hydrolyzed Wheat Protein, Phenoxyethanol)	0.80	G
Mentha Piperita Oil	1.17	F
Eucalyptus Globulus Leaf Oil	0.83	F
+/- CI 77004 (Cosmetic Grade Clays - Kaolin, French Green, Red, Yellow, Pink, Purple - flexible)	Up to 3.87	F

5. Geranium and Patchouli

INCI	Max. weight, %	Concentration Range (CPNP)
Sodium Cocoyl Isethionate	68.41	B
BTMS 25 (Cetearyl Alcohol, Behentrimonium Methosulfate)	7.24	E
CAPB (Aqua, Cocamidopropyl Betaine)	5.03	E
Aqua	4.53	F
Cetyl Alcohol	2.62	F
Panthenol - Panthenol, Aqua, Citric Acid / Panthenol, Aqua, Pantolactone	2.01	F
Cocos Nucifera Oil	1.51	F
Theobroma Cacao Seed Butter	1.51	F
Argania Spinosa Kernel Oil	1.21	F
Olea Europaea Fruit Oil	1.21	F
Simmondsia Chinensis Seed Oil	1.01	F
Stearic Acid	0.91	G
Phytokeratin (Aqua, Hydrolyzed Soy Protein, Hydrolyzed Corn Protein, Hydrolyzed Wheat Protein, Phenoxyethanol)	0.80	G
Pelargonium Graveolens / Roseum Flower Oil	1.00	G
Pogostemon Cablin Leaf Oil	1.00	G
+/- CI 77004 (Cosmetic Grade Clays - Kaolin, French Green, Red, Yellow, Pink, Purple - flexible)	Up to 3.87	F

6. Lemon, Black Pepper and Litsea Cubeba

INCI	Max. weight, %	Concentration Range (CPNP)
Sodium Cocoyl Isethionate	68.41	B
BTMS 25 (Cetearyl Alcohol, Behentrimonium Methosulfate)	7.24	E
CAPB (Aqua, Cocamidopropyl Betaine)	5.03	E
Aqua	4.53	F
Cetyl Alcohol	2.62	F
Panthenol - Panthenol, Aqua, Citric Acid / Panthenol, Aqua, Pantolactone	2.01	F
Cocos Nucifera Oil	1.51	F
Theobroma Cacao Seed Butter	1.51	F
Argania Spinosa Kernel Oil	1.21	F
Olea Europaea Fruit Oil	1.21	F
Simmondsia Chinensis Seed Oil	1.01	F
Stearic Acid	0.91	G
Phytokeratin (Aqua, Hydrolyzed Soy Protein, Hydrolyzed Corn Protein, Hydrolyzed Wheat Protein, Phenoxyethanol)	0.80	G
Citrus Limon Peel Oil	1.33	F
Piper Nigrum Fruit Oil	0.33	F
Litsea Cubeba Fruit Oil	0.33	F
+/- CI 77004 (Cosmetic Grade Clays - Kaolin, French Green, Red, Yellow, Pink, Purple - flexible)	Up to 3.87	F

7. Unscented

INCI	Max. weight, %	Concentration Range (CPNP)
Sodium Cocoyl Isethionate	69.82	B
BTMS 25 (Cetearyl Alcohol, Behentrimonium Methosulfate)	7.39	E
CAPB (Aqua, Cocamidopropyl Betaine)	5.13	E
Aqua	4.62	F
Cetyl Alcohol	2.67	F
Panthenol - Panthenol, Aqua, Citric Acid / Panthenol, Aqua, Pantolactone	2.05	F
Cocos Nucifera Oil	1.54	F
Theobroma Cacao Seed Butter	1.54	F
Argania Spinosa Kernel Oil	1.23	F
Olea Europaea Fruit Oil	1.23	F
Simmondsia Chinensis Seed Oil	1.03	F
Stearic Acid	0.92	G
Phytokeratin (Aqua, Hydrolyzed Soy Protein, Hydrolyzed Corn Protein, Hydrolyzed Wheat Protein, Phenoxyethanol)	0.82	G
+/- CI 77004 (Cosmetic Grade Clays - Kaolin, French Green, Red, Yellow, Pink, Purple - flexible)	Up to 3.94	F

2. Final product characteristics

Physical and Chemical Properties:
Solid bar, fragrance characteristic of essential oils used.

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:
The product does not support microbial growth under normal storage conditions due to high concentration of surfactant and limited water availability.

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

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 solid hair shampoo 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).

	Shampoo Maximum amount per application / g	Potential frequency of application	g / day applied	Retention factor	g / day exposure	Surface area cm^2	Systemic Exposure Dose (SED) mg/kgbw/day (based on 60 kg avg.)	Specific Exposure mg/cm^2
CPNP Concentration Ranges	20.0	1	20.0	1 %	0.20	1440	3.333	0.1389
A – >75% - ≤100%	20.000	1	20.000	1 %	0.20000	1440	3.333	0.1389
B – >50% - ≤75%	15.000	1	15.000	1 %	0.15000	1440	2.500	0.1042
C – >25% - ≤50%	10.000	1	10.000	1 %	0.10000	1440	1.667	0.0694
D – >10% - ≤25%	5.000	1	5.000	1 %	0.05000	1440	0.833	0.0347
E – >5% - ≤10%	2.000	1	2.000	1 %	0.02000	1440	0.333	0.0139
F – >1% - ≤5%	1.000	1	1.000	1 %	0.01000	1440	0.167	0.0069
G – >0.1% - ≤1%	0.200	1	0.200	1 %	0.00200	1440	0.033	0.0014
H – ≤0.1%	0.020	1	0.020	1 %	0.00020	1440	0.003	0.0001

Please note – the above exposure values are based on standard values for a liquid shampoo – solid shampoos are highly concentrated and only a small fraction of the product is used – typically 2-3 g max. which is diluted at the time of application. Please also note – the concentrated product does not come into direct contact with the scalp, due to the physical nature of the product (solid) and the application process (rubbed onto wet hair).

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

INCI	SED	CAS	EINECS	Description	Functions	Toxicity profile	MOS	Cosmetic restriction	SCCS Opinions
Sodium Cocoyl Isethionate	2.500	61789-32-0 / 58969-27-0	263-052-5	Fatty acids, coco, 2-sulfoethyl esters, sodium salts	CLEANSING HAIR CONDITIONING SURFACTANT	Safe up to 49.4% in rinse-off products. Amended Safety Assessment of Isethionate Salts as Used in Cosmetics. IJT 36(Suppl. 1):5-16, 2017 No safety concerns at the current level of inclusion due to the nature of the product - solid shampoos are highly concentrated and only a small fraction of the product is used which is diluted at the time of application. The concentrated product does not come into direct contact with the scalp.	>100		
Cetearyl Alcohol	0.333	67762-27-0 / 8005-44-5	267-008-6 / -	Alcohols, C16-18 Ph. Eur. Name. alcohol cetylicus et stearylicus	EMOLLIENT EMULSIFYING EMULSION STABILISING FOAM BOOSTING OPACIFYING SURFACTANT VISCOSITY CONTROLLING	Fatty alcohols are metabolic intermediates of fatty acids. No safety concerns. 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.	>100		
Behentrimonium Methosulfate	0.333	81646-13-1 / 241148-21-0	279-791-1	Docosyltrimethylammonium methyl sulphate	ANTISTATIC HAIR CONDITIONING SURFACTANT	CIR - Safe up to 10% in hair conditioners. IJT 31(Suppl. 3):296-341, 2012 Present below 10%.	>100 (assuming MOS 100 at 10%)		
Cocamidopropyl Betaine	0.333	61789-40-0	263-058-8/931-296-8	1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-coco acyl derivs., hydroxides, inner salts	ANTISTATIC CLEANSING FOAM BOOSTING HAIR CONDITIONING SURFACTANT VISCOSITY CONTROLLING	NOAEL value of 1000 mg/kg bw /day for 30% active solution (based on sub-chronic systemic toxicity, rats) 300 mg / kg bw / day for 100% CAPB HERA June 2005 Human and Environmental Risk Assessment on ingredients of household cleaning products Cocamidopropyl betaine (CAPB)	300/0.333 = 900		
Aqua	0.333	7732-18-5	231-791-2	Water	SOLVENT	Universal solvent – no toxicological significance.	>100		

Cetyl Alcohol	0.167	36653-82-4	253-149-0	INN Name cetyl alcohol Ph. Eur. Name alcohol cetylicus	EMOLLIENT EMULSIFIER/ EMULSION STABILISING, OPACIFYING SURFACTANT VISCOSITY CONTROLLING	This component is essentially a metabolic product of naturally occurring edible triglycerides, found in oils/fats – there are no significant toxicological issues with this ingredient and NOAEL data do not exist. For this reason, assumed NOAEL value >5000 mg/kgbw/day.	>100		
Panthenol	0.167	81-13-0 / 16485-10-2	201-327-3 / 240-540-6	INN Name dexpanthenol Ph. Eur. Name dexpanthenolum IUPAC Name Butanamide, 2,4-dihydroxy-N-(3-hydroxypropyl)-3,3-dimethyl-, (2R)-; dl-Panthenol	ANTISTATIC HAIR CONDITIONING SKIN CONDITIONING	Lowest reported NOAEL - 200 mg/kgbw/day. Max. dermal penetration of 30% results in SED of 0.05 mg/kgbw/day. Cosmetic Ingredient Review (CIR). Safety Assessment of Panthenol, Pantothenic Acid, and Derivatives as Used in Cosmetics. 12/05/2017.	200 / 0.05 = 4000		
Pantolactone	0.167	599-04-2; 79-50-5	209-963-3; 201-210-7	Pantolactone	HUMECTANT SKIN CONDITIONING	ECHA - Not sensitising, irritating or genotoxic. Read across from panthenol: Lowest reported NOAEL - 200 mg/kgbw/day. Max. dermal penetration of 30% results in SED of 0.05 mg/kgbw/day. Cosmetic Ingredient Review (CIR). Safety Assessment of Panthenol, Pantothenic Acid, and Derivatives as Used in Cosmetics. 12/05/2017.	200 / 0.05 = 4000		
Citric Acid	0.167	77-92-9 / 5949-29-1	201-069-1	Citric acid Ph. Eur. Name acidicum citricum 2-Hydroxy-1,2,3-propanetricarboxylic acid	BUFFERING CHELATING MASKING	Citric acid is a food grade ingredient and occurs naturally in living organisms as part of the metabolic process – at this level of inclusion NOAEL data is not available or required and no toxicological risks are apparent.	>100		0370/00 - Position paper on the Safety of alpha-Hydroxy Acids 0799/04 - Updated position paper concerning consumer Safety of alpha-hydroxy acids

Cocos Nucifera Oil	0.167	8001-31-8	232-282-8	Cocos Nucifera Oil is the fixed oil obtained by expression of the kernels of the seeds of the Coconut, Cocos nucifera L., Palmaceae	HAIR CONDITIONING MASKING PERFUMING SKIN CONDITIONING	No toxicological significance. Safety Assessment of Plant-Derived Fatty Acid Oils. International Journal of Toxicology. 2017, Vol. 36 (Supplement 3) 51-129.	>100		
Theobroma Cacao Seed Butter	0.167	84649-99-0 / 8002-31-1	283-480-6 / -	Theobroma Cacao Seed Butter is a yellowish white solid material obtained from the roasted seeds of the Cocoa, Theobroma cacao L., Sterculiaceae	EMOLLIENT MASKING SKIN CONDITIONING SKIN PROTECTING	No toxicological significance. Safety Assessment of Plant-Derived Fatty Acid Oils. International Journal of Toxicology. 2017, Vol. 36 (Supplement 3) 51-129.	>100		
Argania Spinosa Kernel Oil	0.167	223747-87-3; 299184-75-1	-	Argania Spinosa Kernel Oil is the fixed oil expressed from the kernels, Argania Spinosa (L.), Sapotaceae	EMOLLIENT SKIN CONDITIONING	No toxicological significance. Safety Assessment of Plant-Derived Fatty Acid Oils. International Journal of Toxicology. 2017, Vol. 36 (Supplement 3) 51-129.	>100		
Olea Europaea Fruit Oil	0.167	8001-25-0	232-277-0	Olea Europaea Fruit Oil is the fixed oil obtained from the ripe fruit of the Olive, Olea europaea L., Oleaceae. It consists primarily of the glycerides of the fatty acids linoleic, oleic and palmitic	MASKING PERFUMING SKIN CONDITIONING	No toxicological significance. Safety Assessment of Plant-Derived Fatty Acid Oils. International Journal of Toxicology. 2017, Vol. 36 (Supplement 3) 51-129.	>100		
Simmondsia Chinensis Seed Oil	0.167	90045-98-0	289-964-3	Simmondsia Chinensis Seed Oil is the fixed oil expressed or extracted from seeds of the desert shrub, Jojoba, Simmondsia chinensis, Buxaceae	EMOLLIENT	Plant-derived fixed oil. 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.	>100		

Stearic Acid	0.033	57-11-4	200-313-4	INN Name stearic acid IUPAC stearic acid	CLEANSING EMULSIFYING EMULSION STABILISING MASKING REFATTING SURFACTANT	There are no significant toxicological issues with this ingredient and NOAEL data do not exist for this reason. 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.	>100		
CI 77004	0.167	1302-78-9 / 1327-36-2 / 1332-58-7	215-108-5 / 215-475-1 / 310-194-1	CI 77004 is classed chemically as an inorganic colour. It consists of a natural hydrated aluminum silicate.	COLORANT	Approval for colourant presence is governed by EU Regulation 1223/2009 Annex IV LIST OF COLORANTS ALLOWED IN COSMETIC PRODUCTS Systemic absorption is effectively zero due to particle size. However, the certificates of analysis MUST confirm the presence of heavy metals is below acceptable limits.	>100	IV/119	
Hydrolyzed Soy Protein	0.033	68607-88-5	271-770-5	Protein hydrolyzates, soya. Substance obtained by acidic, alkaline, or enzymatic hydrolysis of soya composed primarily of amino acids, peptides, and proteins. It may contain impurities consisting chiefly of carbohydrates and lipids along with smaller quantities of miscellaneous organic substances of biological origin	ANTISTATIC HAIR CONDITIONING HUMECTANT SKIN CONDITIONING	Hydrolyzed protein from edible source results in a mixture of amino acids which are abundant in living organisms and are important part of a diet. No safety concerns at this level of inclusion.	>100		

Hydrolyzed Corn Protein	0.033	100209-41-4	309-349-6	Protein hydrolyzates, corn. Substance obtained by acidic, alkaline, or enzymatic hydrolysis of Zea mays composed primarily of amino acids, peptides, and proteins. It may contain impurities consisting chiefly of carbohydrates and lipids along with smaller quantities of miscellaneous organic substances of biological origin.	ANTISTATIC HAIR CONDITIONING SKIN CONDITIONING	Hydrolyzed protein from edible source results in a mixture of amino acids which are abundant in living organisms and are important part of a diet. No safety concerns at this level of inclusion.	>100		
Hydrolyzed Wheat Protein	0.033	94350-06-8 / 222400-28-4 / 70084-87-6 / 100209-50-5	305-225-0 / - / 309-358-5	Protein hydrolyzates, wheat germ. Substance obtained by acidic, alkaline, or enzymatic hydrolysis of wheat germ composed primarily of amino acids, peptides, and proteins. It may contain impurities consisting chiefly of carbohydrates and lipids along with smaller quantities of miscellaneous organic substances of biological origin	ANTISTATIC HAIR CONDITIONING SKIN CONDITIONING	Regulation (EU) 2017/2228 Annex/Ref # III/307 Maximum molecular weight average of the peptides in hydrolysates: 3,5 kDa. Hydrolyzed protein from edible source results in a mixture of amino acids which are abundant in living organisms and are important part of a diet. No safety concerns at this level of inclusion.	>100	III/307	
Phenoxyethanol	0.033	122-99-6	204-589-7	Ph. Eur. Name phenoxyethanolum Chemical/IUPAC Name 2-Phenoxyethanol	PRESERVATIVE	Regulation (EC) No 1223/2009 Regulated by 2007/17/EC Annex/Ref# V/29 Maximum concentration in ready for use preparation 1%	Complies with the requirements of Cosmetic Restrictions	Cosmetic Restriction Regulation (EC) No 1223/2009 Annex V/29	0125/99 - Opinion concerning Restrictions on Materials listed in annex VI of Directive 76/768/EEC

Essential Oils:

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 / NOAEL values	MOS
Black Pepper Essential Oil	INCI Name PIPER NIGRUM FRUIT OIL Description Piper Nigrum Fruit Oil is the volatile oil distilled from the dried ripe fruit of Black Pepper, Piper nigrum L., Piperaceae INN Name Ph. Eur. Name CAS # 84929-41-9 EINECS/ELINCS # 284-524-7 Chemical/IUPAC Name Cosmetic Restriction Other Restriction(s) Functions MASKING, PERFUMING	0.167	Not likely at concentration used - Essential Oil Safety, Tisserand 2014	No	In the absence of category III substances above the level of Toxicological concern, or restricted or toxicologically important components (Methyleugenol, safrole, estragole) MOS is based on read across data for major components and camphor. Assuming 50% maximum terpenoid and related components, SED = 0.084 mg/kgbw/day. The literature (reference below) recommends a group NOAEL for cyclic and non-cyclic terpene alcohols of at least 50 mg/kg, however the presence of sclareol in the test group with a NOAEL value of just 8 mg/kg is a significant factor in the reduction of the group NOAEL minimum value – in the absence of sclareol, a realistic NOAEL value of minimum 100 mg/kg is appropriate. Margin of Safety = NOAEL / SED MOS = 100/0.084 = 1190 Assuming 50% maximum aliphatic branched-chain saturated and unsaturated alcohols, aldehydes, acids, related esters and other similar structural components, SED = 0.084 mg/kgbw/day. WHO food series group ADI = 0.5 mg/kgbw/day (when taken internally). Worst case scenario of 100% dermal absorption and systemic availability would give MOS = 0.5 x 100 / 0.084 = 595 MOS statement based on other minor components (NOAEL data derived from SCCP/1155/08 Opinion on Tea Tree oil). Compound established or estimated NOAEL (mg/kgbw/day): Terpinen-4-ol 400 1,8-Cineole (eucalyptol) 300 α-Terpinene 60 Cumene / p-Cymene 75 α-Terpineol 500 α-Pinene 250 MOS calculation – at 20% maximum content in the essential oil, the SED would be 0.033 mg/kgbw/day, indicating a minimum MOS of 1818 for minor components. D. Belsito, D. Bickers, M. Bruze, P. Calow, H. Greim, J.M. Hanifin, A.E. Rogers, J.H. Saurat, I.G. Sipes, H. Tagami. A toxicologic and dermatologic assessment of cyclic and non-cyclic terpene alcohols when used as fragrance ingredients. Food and Chemical Toxicology 46 (2008), Supplement 11. WHO FOOD ADDITIVES SERIES: 52 Aliphatic Branched-Chain Saturated and Unsaturated Alcohols, Aldehydes, Acids, and Related Esters. W. Jäger, G. Buchbauer, L. Jirovetz, M. Fritzer. Percutaneous absorption of lavender oil from a massage oil. Journal of the Society of Cosmetic Chemists 43, 49–54 (1992).	595

Cedarwood Essential Oil	INCI Name CEDRUS ATLANTICA WOOD OIL Description "Cedarwood Oil (Atlas or Moroccan)". Cedrus Atlantica Wood Olis is an essential oil obtained from the wood of the tree, Cedrus atlantica, Pinaceae INN Name Ph. Eur. Name CAS # 92201-55-3 EINECS/ELINCS # 295-985-9 Chemical/IUPAC Name Cosmetic Restriction III/122 Other Restriction(s) Functions PERFUMING	0.167	Not likely at concentration used - Essential Oil Safety, Tisserand 2014	No	**Peroxide value less than 10 mmoles/L(*) - manufacturer is responsible for ensuring compliance with this specification.** The main components of Cedarwood Essential Oil are sesquiterpenes and sesquiterpene alcohols - NOAEL published data (various toxicological endpoints) for structurally related compounds: Dermally applied a-Bisabolol the NOAEL was 200 mg/kg Orally administered Geraniol the NOAEL was 1000 mg/kg Orally administered Farnesol the NOAEL was 1000 mg/kg The literature (reference below) recommends a group NOAEL (lowest values based on numerous endpoints) for cyclic and non-cyclic terpene alcohols of at least 50 mg/kg, however the presence of sclareol in the test group with a NOAEL value of just 8 mg/kg is a significant factor in the reduction of the group NOAEL minimum value – in the absence of sclareol, a realistic NOAEL value of minimum 100 mg/kgbw/day is appropriate (sclareol is not found in Cedarwood Essential Oil). Margin of Safety = NOAEL / SED MOS = 100/0.167 = 599 D. Belsito, D. Bickers, M. Bruze, P. Calow, H. Greim, J.M. Hanifin, A.E. Rogers, J.H. Saurat, I.G. Sipes, H. Tagami. A toxicologic and dermatologic assessment of cyclic and non-cyclic terpene alcohols when used as fragrance ingredients. Food and Chemical Toxicology 46 (2008), Supplement 11.	599
Geranium Essential Oil	INCI Name PELARGONIUM GRAVEOLENS FLOWER OIL Description Pelargonium Graveolens Flower Oil is the volatile oil obtained from the flowers of the Bourbon Geranium, Pelargonium graveolens (L.), Geraniaceae INN Name Ph. Eur. Name CAS # 90082-51-2 / 8000-46-2 EINECS/ELINCS # 290-140-0 / - Chemical/IUPAC Name Cosmetic Restriction Other Restriction(s) Functions MASKING	0.167	Not likely at concentration used - Essential Oil Safety, Tisserand 2014	No	In the absence of category III substances above the level of Toxicological concern, or restricted or toxicologically important components (Methyleugenol, safrole, estragole, camphor) MOS is based on read across data for major components. Assuming 50% maximum terpenoid and related components, SED = 0.084 mg/kgbw/day. The literature (reference below) recommends a group NOAEL for cyclic and non-cyclic terpene alcohols of at least 50 mg/kg, however the presence of sclareol in the test group with a NOAEL value of just 8 mg/kg is a significant factor in the reduction of the group NOAEL minimum value – in the absence of sclareol, a realistic NOAEL value of minimum 100 mg/kg is appropriate. Margin of Safety = NOAEL / SED MOS = 100/0.084 = 1190 Assuming 50% maximum aliphatic branched-chain saturated and unsaturated alcohols, aldehydes, acids, related esters and other similar structural components, SED = 0.084 mg/kgbw/day. WHO food series group ADI = 0.5 mg/kgbw/day (when taken internally). Worst case scenario of 100% dermal absorption and systemic availability would give MOS = 0.5 x 100 / 0.084 = 595 MOS statement based on other minor components (NOAEL data derived from SCCP/1155/08 Opinion on Tea Tree oil). Compound established or estimated NOAEL (mg/kgbw/day): Terpinen-4-ol 400 1,8-Cineole (eucalyptol) 300 α-Terpinene 60 Cumene / p-Cymene 75 α-Terpineol 500 α-Pinene 250 MOS calculation – at 20% maximum content in the essential oil, the SED would be 0.033 mg/kgbw/day, indicating a minimum MOS of 1818 for minor components.	595

					D. Belsito, D. Bickers, M. Bruze, P. Calow, H. Greim, J.M. Hanifin, A.E. Rogers, J.H. Saurat, I.G. Sipes, H. Tagami. A toxicologic and dermatologic assessment of cyclic and non-cyclic terpene alcohols when used as fragrance ingredients. Food and Chemical Toxicology 46 (2008), Supplement 11. WHO FOOD ADDITIVES SERIES: 52 Aliphatic Branched-Chain Saturated and Unsaturated Alcohols, Aldehydes, Acids, and Related Esters. W. Jäger, G. Buchbauer, L. Jirovetz, M. Fritzer. Percutaneous absorption of lavender oil from a massage oil. Journal of the Society of Cosmetic Chemists 43, 49–54 (1992).	
Lavender Essential Oil	INCI Name LAVANDULA ANGUSTIFOLIA OIL Description Lavandula Angustifolia Oil is the volatile oil obtained from the flowers of the Lavender, Lavandula angustifolia, Labiatae. ISO 8902:2009 INN Name Ph. Eur. Name CAS # 8000-28-0 / 90063-37-9 EINECS/ELINCS # - / 289-995-2 Chemical/IUPAC Name Cosmetic Restriction Other Restriction(s) Functions MASKING, TONIC	0.167	Not likely at concentration used - Essential Oil Safety, Tisserand 2014	Yes - Camphor <5%	Based on linalool / linalyl acetate model – OECD SIDS Lowest NOAEL (several endpoints considered including reproductive, maternal, mutagenicity and immunotoxicity) is 160 mg/kg (based on liver and kidney weight increase). Linalyl acetate is metabolised to linalool, producing a total linalool equivalent content of 45 + (25 x 0.78) = 65% 0.167 x 0.65 = SED of 0.109 mg/kgbw/day for linalool. MOS = 160/0.109 = 1468 MOS calculation based on Camphor (5%): SED = 0.008 mg/kgbw/day. NOAEL = 100 mg/kgbw/day – critical effect – maternal toxicity (NTP 1992). MOS = 100/0.008 = >10000	1468
Lemon Essential Oil	INCI Name CITRUS LIMON PEEL OIL Description Citrus Limon Peel Oil is the volatile oil obtained from the fresh peel of the Lemon, Citrus limon (L.), Rutaceae INN Name Ph. Eur. Name CAS # 8008-56-8 / 84929-31-7 EC # - / 284-515-8 Chemical/IUPAC Name Cosmetic Restriction II/358 Other Restriction(s) Functions MASKING, PERFUMING, SKIN CONDITIONING	0.167	Phototoxic if cold pressed - limit of 2% in final product - formulation complies with IFRA recommendations	No	In the absence of category III substances above the level of Toxicological concern, or restricted or toxicologically important components (Methyleugenol, safrole, estragole, camphor) MOS is based on read across data for major components. Assuming 90% maximum terpenoid and related components, SED = 0.15 mg/kgbw/day. The literature (reference below) recommends a group NOAEL for cyclic and non-cyclic terpene alcohols of at least 50 mg/kg, however the presence of sclareol in the test group with a NOAEL value of just 8 mg/kg is a significant factor in the reduction of the group NOAEL minimum value – in the absence of sclareol, a realistic NOAEL value of minimum 100 mg/kg is appropriate. Margin of Safety = NOAEL / SED MOS= 100/0.15 = 667 Assuming 10% maximum Aliphatic Branched-Chain Saturated and Unsaturated Alcohols, Aldehydes, Acids, related Esters and other similar structural components, SED = 0.017 mg/kgbw/day. WHO food series group ADI = 0.5 mg/kgbw/day (when taken internally). Worst case scenario of 100% dermal absorption and systemic availability would give MOS = 0.5 x 100 / 0.017 = 2941 MOS statement based on other minor components (NOAEL data derived from SCCP/1155/08 Opinion on Tea Tree oil). Compound Established or Estimated NOAEL (mg/kg bw/day): Terpinen-4-ol 400 1,8-Cineole (eucalyptol) 300 α-Terpinene 60 Cumene / p-Cymene 75 α-Terpineol 500 α-Pinene 250	667

					MOS calculation – at 10% maximum content in the fragrance, the SED would be 0.017 mg/kgbw/day, indicating a minimum MOS of 3529 for minor components. D. Belsito, D. Bickers, M. Bruze, P. Calow, H. Greim, J.M. Hanifin, A.E. Rogers, J.H. Saurat, I.G. Sipes, H. Tagami. A toxicologic and dermatologic assessment of cyclic and non-cyclic terpene alcohols when used as fragrance ingredients. Food and Chemical Toxicology 46 (2008), Supplement 11. WHO FOOD ADDITIVES SERIES: 52 Aliphatic Branched-Chain Saturated and Unsaturated Alcohols, Aldehydes, Acids, and Related Esters. W. Jäger, G. Buchbauer, L. Jirovetz, M. Fritzer. Percutaneous absorption of lavender oil from a massage oil. Journal of the Society of Cosmetic Chemists 43, 49–54 (1992).	
May Chang Essential Oil	INCI Name LITSEA CUBEBA FRUIT OIL Description Litsea Cubeba Fruit Oil is the volatile oil obtained from the berries of the Litsea cubeba, Lauraceae INN Name Ph. Eur. Name CAS # 68855-99-2 / 90063-59-5 EINECS/ELINCS # - / 290-018-7 Chemical/IUPAC Name Cosmetic Restriction Other Restriction(s) Functions MASKING, PERFUMING, TONIC	0.167	Dermal sensitisation due to citral content - limited to 1.5% in rinse off products	Potential Safrole content ≤0.05%. Safrole present at <100 ppm in final product - complies with regulations.	In the absence of other category III substances above the level of Toxicological concern, or restricted or toxicologically important components (Methyleugenol, estragole, camphor) MOS is based on read across data for major components. Assuming 90% maximum terpenoid and related components, SED = 0.15 mg/kgbw/day. The literature (reference below) recommends a group NOAEL for cyclic and non-cyclic terpene alcohols of at least 50 mg/kg, however the presence of sclareol in the test group with a NOAEL value of just 8 mg/kg is a significant factor in the reduction of the group NOAEL minimum value – in the absence of sclareol, a realistic NOAEL value of minimum 100 mg/kg is appropriate. Margin of Safety = NOAEL / SED MOS= 100/0.15 = 667 Assuming 10% maximum Aliphatic Branched-Chain Saturated and Unsaturated Alcohols, Aldehydes, Acids, related Esters and other similar structural components, SED = 0.017 mg/kgbw/day. WHO food series group ADI = 0.5 mg/kgbw/day (when taken internally). Worst case scenario of 100% dermal absorption and systemic availability would give MOS = 0.5 x 100 / 0.017 = 2941 MOS statement based on other minor components (NOAEL data derived from SCCP/1155/08 Opinion on Tea Tree oil). Compound Established or Estimated NOAEL (mg/kg bw/day): Terpinen-4-ol 400 1,8-Cineole (eucalyptol) 300 α-Terpinene 60 Cumene / p-Cymene 75 α-Terpineol 500 α-Pinene 250 MOS calculation – at 10% maximum content in the fragrance, the SED would be 0.017 mg/kgbw/day, indicating a minimum MOS of 3529 for minor components. D. Belsito, D. Bickers, M. Bruze, P. Calow, H. Greim, J.M. Hanifin, A.E. Rogers, J.H. Saurat, I.G. Sipes, H. Tagami. A toxicologic and dermatologic assessment of cyclic and non-cyclic terpene alcohols when used as fragrance ingredients. Food and Chemical Toxicology 46 (2008), Supplement 11. WHO FOOD ADDITIVES SERIES: 52 Aliphatic Branched-Chain Saturated and Unsaturated Alcohols, Aldehydes, Acids, and Related Esters. W. Jäger, G. Buchbauer, L. Jirovetz, M. Fritzer. Percutaneous absorption of lavender oil from a massage oil. Journal of the Society of Cosmetic Chemists 43, 49–54 (1992).	667

Orange - Sweet / Blood Essential Oil	INCI Name CITRUS AURANTIUM DULCIS PEEL OIL Description Citrus Aurantium Dulcis (Orange) Peel Oil is the volatile oil obtained by expression from the peel of Citrus sinensis, Rutaceae INN Name Ph. Eur. Name CAS # 8008-57-9 EC # Chemical/IUPAC Name Citrus Sinensis Oil, Orange Oil, Orange oil terpeneless (Citrus sinensis (L.) Osbeck) (RIFM), Orange peel oil, sweet (Citrus sinensis (L.) Osbeck) (RIFM),Orange Yu (JPN) Cosmetic Restriction Other Restriction(s) Functions MASKING, SKIN CONDITIONING	0.167	Not likely at concentration used - Essential Oil Safety, Tisserand 2014	No	In the absence of category III substances above the level of Toxicological concern, or restricted or toxicologically important components (Methyleugenol, safrole, estragole, camphor) MOS is based on read across data for major components. Assuming 90% maximum terpenoid and related components, SED = 0.15 mg/kgbw/day. The literature (reference below) recommends a group NOAEL for cyclic and non-cyclic terpene alcohols of at least 50 mg/kg, however the presence of sclareol in the test group with a NOAEL value of just 8 mg/kg is a significant factor in the reduction of the group NOAEL minimum value – in the absence of sclareol, a realistic NOAEL value of minimum 100 mg/kg is appropriate. Margin of Safety = NOAEL / SED MOS= 100/0.15 = 667 Assuming 10% maximum Aliphatic Branched-Chain Saturated and Unsaturated Alcohols, Aldehydes, Acids, related Esters and other similar structural components, SED = 0.017 mg/kgbw/day. WHO food series group ADI = 0.5 mg/kgbw/day (when taken internally). Worst case scenario of 100% dermal absorption and systemic availability would give MOS = 0.5 x 100 / 0.017 = 2941 MOS statement based on other minor components (NOAEL data derived from SCCP/1155/08 Opinion on Tea Tree oil). Compound Established or Estimated NOAEL (mg/kg bw/day): Terpinen-4-ol 400 1,8-Cineole (eucalyptol) 300 α-Terpinene 60 Cumene / p-Cymene 75 α-Terpineol 500 α-Pinene 250 MOS calculation – at 10% maximum content in the fragrance, the SED would be 0.017 mg/kgbw/day, indicating a minimum MOS of 3529 for minor components. D. Belsito, D. Bickers, M. Bruze, P. Calow, H. Greim, J.M. Hanifin, A.E. Rogers, J.H. Saurat, I.G. Sipes, H. Tagami. A toxicologic and dermatologic assessment of cyclic and non-cyclic terpene alcohols when used as fragrance ingredients. Food and Chemical Toxicology 46 (2008), Supplement 11. WHO FOOD ADDITIVES SERIES: 52 Aliphatic Branched-Chain Saturated and Unsaturated Alcohols, Aldehydes, Acids, and Related Esters. W. Jäger, G. Buchbauer, L. Jirovetz, M. Fritzer. Percutaneous absorption of lavender oil from a massage oil. Journal of the Society of Cosmetic Chemists 43, 49–54 (1992).	667
Patchouli Essential Oil	INCI Name POGOSTEMON CABLIN OIL Description Pogostemon Cablin Oil is the volatile oil obtained from the Patchouli, Pogostemon cablin, Labiatae INN Name Ph. Eur. Name CAS # 8014-09-3 / 84238-39-1 EINECS/ELINCS # - / 282-493-4 Chemical/IUPAC Name Cosmetic Restriction Other Restriction(s) Functions MASKING	0.167	Not likely at concentration used - Essential Oil Safety, Tisserand 2014	No	In the absence of category III substances above the level of Toxicological concern, or restricted or toxicologically important components (Methyleugenol, safrole, estragole) MOS is based on read across data for major components and camphor. Assuming 50% maximum terpenoid and related components, SED = 0.084 mg/kgbw/day. The literature (reference below) recommends a group NOAEL for cyclic and non-cyclic terpene alcohols of at least 50 mg/kg, however the presence of sclareol in the test group with a NOAEL value of just 8 mg/kg is a significant factor in the reduction of the group NOAEL minimum value – in the absence of sclareol, a realistic NOAEL value of minimum 100 mg/kg is appropriate. Margin of Safety = NOAEL / SED MOS = 100/0.084 = 1190	595

					Assuming 50% maximum aliphatic branched-chain saturated and unsaturated alcohols, aldehydes, acids, related esters and other similar structural components, SED = 0.084 mg/kgbw/day. WHO food series group ADI = 0.5 mg/kgbw/day (when taken internally). Worst case scenario of 100% dermal absorption and systemic availability would give MOS = 0.5 x 100 / 0.084 = 595 MOS statement based on other minor components (NOAEL data derived from SCCP/1155/08 Opinion on Tea Tree oil). Compound established or estimated NOAEL (mg/kgbw/day): Terpinen-4-ol 400 1,8-Cineole (eucalyptol) 300 α-Terpinene 60 Cumene / p-Cymene 75 α-Terpineol 500 α-Pinene 250 MOS calculation – at 20% maximum content in the essential oil, the SED would be 0.033 mg/kgbw/day, indicating a minimum MOS of 1818 for minor components. D. Belsito, D. Bickers, M. Bruze, P. Calow, H. Greim, J.M. Hanifin, A.E. Rogers, J.H. Saurat, I.G. Sipes, H. Tagami. A toxicologic and dermatologic assessment of cyclic and non-cyclic terpene alcohols when used as fragrance ingredients. Food and Chemical Toxicology 46 (2008), Supplement 11. WHO FOOD ADDITIVES SERIES: 52 Aliphatic Branched-Chain Saturated and Unsaturated Alcohols, Aldehydes, Acids, and Related Esters. W. Jäger, G. Buchbauer, L. Jirovetz, M. Fritzer. Percutaneous absorption of lavender oil from a massage oil. Journal of the Society of Cosmetic Chemists 43, 49–54 (1992).	
Peppermint Essential Oil	INCI Name MENTHA PIPERITA OIL Description Mentha Piperita Oil is the volatile oil obtained from the whole plant of the Peppermint, Mentha piperita (L.), Labiatae INN Name Ph. Eur. Name CAS # 8006-90-4 / 84082-70-2 EINECS/ELINCS # - / 282-015-4 Chemical/IUPAC Name Cosmetic Restriction Other Restriction(s) Functions MASKING, PERFUMING, REFRESHING, TONIC	0.167	Not likely at concentration used - Essential Oil Safety, Tisserand 2014	No	Peppermint Essential oil is an established and approved flavouring agent in the food industry – it is ubiquitous in confectionery, drinks and other foods. The primary components are menthol and substances derived or structurally related to menthol. The Joint FAO/WHO Expert Committee on Food Additives derived in their 51st meeting in 1998 an acceptable daily intake (ADI) for L-menthol and D/L-menthol in the range of 0 - 4 mg/kg bodyweight (FAO/WHO 1999). Converted to NOAEL data, this equates to a NOAEL value of 400 mg/kgbw/day. Menthone is the oxidation product of menthol, and is quoted in JEFCA WHO FOOD ADDITIVES SERIES: 42 (SUBSTANCES STRUCTURALLY RELATED TO MENTHOL) of having a NOAEL value of 400 mg/kgbw/day. Taking into consideration a small percentage of other components (not closely structurally related to menthol), sesquiterpenes and sesquiterpene alcohols, for example an additional NOAEL of 100 mg/kg for this minor (<10%) component. CALCULATION OF THE MARGIN OF SAFETY SED 0.15 mg/kgbw/day (based on 90% menthol and structurally related to menthol). Margin of Safety NOAEL / SED MOS= 400/0.15 = 2667	2667
Rose Geranium Essential Oil	INCI Name PELARGONIUM ROSEUM LEAF OIL Description "Geranium Oil; Rose Geranium Oil". Pelargonium Roseum Leaf Oil is an essential oil obtained from the leaves of	0.167	Not likely at concentration used - Essential Oil Safety,	No	In the absence of category III substances above the level of Toxicological concern, or restricted or toxicologically important components (Methyleugenol, safrole, estragole, camphor) MOS is based on read across data for major components. Assuming 50% maximum terpenoid and related components, SED = 0.084 mg/kgbw/day.	595

	the plant, Pelargonium roseum, Geraniaceae INN Name Ph. Eur. Name CAS # 90082-55-6 EC # 290-144-2 Chemical/IUPAC Name Cosmetic Restriction Other Restriction(s) Functions PERFUMING		Tisserand 2014		The literature (reference below) recommends a group NOAEL for cyclic and non-cyclic terpene alcohols of at least 50 mg/kg, however the presence of sclareol in the test group with a NOAEL value of just 8 mg/kg is a significant factor in the reduction of the group NOAEL minimum value – in the absence of sclareol, a realistic NOAEL value of minimum 100 mg/kg is appropriate. Margin of Safety = NOAEL / SED MOS = 100/0.084 = 1190 Assuming 50% maximum aliphatic branched-chain saturated and unsaturated alcohols, aldehydes, acids, related esters and other similar structural components, SED = 0.084 mg/kgbw/day. WHO food series group ADI = 0.5 mg/kgbw/day (when taken internally). Worst case scenario of 100% dermal absorption and systemic availability would give MOS = 0.5 x 100 / 0.084 = 595 MOS statement based on other minor components (NOAEL data derived from SCCP/1155/08 Opinion on Tea Tree oil). Compound established or estimated NOAEL (mg/kgbw/day): Terpinen-4-ol 400 1,8-Cineole (eucalyptol) 300 α-Terpinene 60 Cumene / p-Cymene 75 α-Terpineol 500 α-Pinene 250 MOS calculation – at 20% maximum content in the essential oil, the SED would be 0.033 mg/kgbw/day, indicating a minimum MOS of 1818 for minor components. D. Belsito, D. Bickers, M. Bruze, P. Calow, H. Greim, J.M. Hanifin, A.E. Rogers, J.H. Saurat, I.G. Sipes, H. Tagami. A toxicologic and dermatologic assessment of cyclic and non-cyclic terpene alcohols when used as fragrance ingredients. Food and Chemical Toxicology 46 (2008), Supplement 11. WHO FOOD ADDITIVES SERIES: 52 Aliphatic Branched-Chain Saturated and Unsaturated Alcohols, Aldehydes, Acids, and Related Esters. W. Jäger, G. Buchbauer, L. Jirovetz, M. Fritzer. Percutaneous absorption of lavender oil from a massage oil. Journal of the Society of Cosmetic Chemists 43, 49–54 (1992).	
Rosemary Essential Oil	INCI Name ROSMARINUS OFFICINALIS LEAF OIL Description Rosmarinus Officinalis Leaf Oil is the essential oil obtained from the flowering tops and leaves of the Rosemary, Rosmarinus officinalis L., Lamiaceae INN Name Ph. Eur. Name CAS # 84604-14-8 / 8000-25-7 EINECS/ELINCS # 283-291-9 Chemical/IUPAC Name Cosmetic Restriction Other Restriction(s) Functions MASKING, SKIN CONDITIONING	0.167	Not likely at concentration used - Essential Oil Safety, Tisserand 2014	Yes, Camphor <10%	In the absence of category III substances above the level of Toxicological concern, or restricted or toxicologically important components (Methyleugenol, safrole, estragole) MOS is based on read across data for major components and camphor. Assuming 50% maximum terpenoid and related components, SED = 0.084 mg/kgbw/day. The literature (reference below) recommends a group NOAEL for cyclic and non-cyclic terpene alcohols of at least 50 mg/kg, however the presence of sclareol in the test group with a NOAEL value of just 8 mg/kg is a significant factor in the reduction of the group NOAEL minimum value – in the absence of sclareol, a realistic NOAEL value of minimum 100 mg/kg is appropriate. Margin of Safety = NOAEL / SED MOS = 100/0.084 = 1190 Assuming 50% maximum aliphatic branched-chain saturated and unsaturated alcohols, aldehydes, acids, related esters and other similar structural components, SED = 0.084 mg/kgbw/day. WHO food series group ADI = 0.5 mg/kgbw/day (when taken internally). Worst case scenario of 100% dermal absorption and systemic availability would give MOS = 0.5 x 100 / 0.084 = 595	595

					MOS statement based on other minor components (NOAEL data derived from SCCP/1155/08 Opinion on Tea Tree oil). Compound established or estimated NOAEL (mg/kgbw/day): Terpinen-4-ol 400 1,8-Cineole (eucalyptol) 300 α-Terpinene 60 Cumene / p-Cymene 75 α-Terpineol 500 α-Pinene 250 MOS calculation – at 20% maximum content in the essential oil, the SED would be 0.033 mg/kgbw/day, indicating a minimum MOS of 1818 for minor components. D. Belsito, D. Bickers, M. Bruze, P. Calow, H. Greim, J.M. Hanifin, A.E. Rogers, J.H. Saurat, I.G. Sipes, H. Tagami. A toxicologic and dermatologic assessment of cyclic and non-cyclic terpene alcohols when used as fragrance ingredients. Food and Chemical Toxicology 46 (2008), Supplement 11. WHO FOOD ADDITIVES SERIES: 52 Aliphatic Branched-Chain Saturated and Unsaturated Alcohols, Aldehydes, Acids, and Related Esters. W. Jäger, G. Buchbauer, L. Jirovetz, M. Fritzer. Percutaneous absorption of lavender oil from a massage oil. Journal of the Society of Cosmetic Chemists 43, 49–54 (1992). MOS calculation based on Camphor (10%): SED = 0.017 mg/kgbw/day. NOAEL = 100 mg/kgbw/day – critical effect – maternal toxicity (NTP 1992). MOS = 100/0.017 = 5882	
Eucalyptus Essential Oil	INCI Name EUCALYPTUS GLOBULUS LEAF OIL Description Eucalyptus Globulus Leaf Oil is the volatile oil obtained from the fresh leaves of the Eucaluptus, Eucalyptus globulus and other species of Eucalyptus, Myrtaceae. Syn. Yuukari Yu (Japanese) INN Name Ph. Eur. Name CAS # 8000-48-4 / 84625-32-1 EINECS/ELINCS # - / 283-406-2 Chemical/IUPAC Name Cosmetic Restriction Other Restriction(s) Functions PERFUMING, SKIN CONDITIONING	0.167	Not likely at concentration used - Essential Oil Safety, Tisserand 2014	No	NOAEL data derived from SCCP/1155/08 Opinion on Tea Tree oil. Compound Established or Estimated NOAEL: Terpinen-4-ol 400 (mg/kg bw/day) 1,8-Cineole (eucalyptol) 300 (mg/kg bw/day) α-Terpinene 60 (mg/kg bw/day) Cumene /p-Cymene 75 (mg/kg bw/day) α-Terpineol 500 (mg/kg bw/day) α-Pinene 250 (mg/kg bw/day) Calculated MOS based on Eucalyptol content at 80%. 300 / (0.167*0.8) = 2250	2250

Tea Tree Essential Oil	INCI Name MELALEUCA ALTERNIFOLIA LEAF OIL Description Melaleuca Alternifolia Leaf Oil is the oil distilled from the leaves of the Tea Tree, Melaleuca alternifolia, Myrtaceae INN Name Ph. Eur. Name CAS # 85085-48-9 / 8022-72-8 / 68647-73-4 EINECS/ELINCS # 285-377-1 / - / - Chemical/IUPAC Name Cosmetic Restriction Other Restriction(s) Functions ANTIOXIDANT, PERFUMING	0.167	Not likely at concentration used - Essential Oil Safety, Tisserand 2014	No	Published NOAEL values for components of Tea Tree essential oil derived from SCCP/1155/08 Opinion on Tea Tree oil). Compound Max. Content in TTO (%) Established or Estimated NOAEL (mg/kg bw/day): Terpinen-4-ol 48; 400 1,8-Cineole (eucalyptol) 15; 300 α-Terpinene 13; 60 Cumene /p-Cymene 8; 75 α-Terpineol 8; 500 α-Pinene 6; 250 α-Terpinene and p-Cymene are the principle components of concern - the derived mean NOAEL for Tea Tree oil, based on aggregate compositional NOAEL values is 510 mg/kg, however incorporating data for renal and reproductive toxicity, a value of 100 mg/kg is more conservative. CALCULATION OF THE MARGIN OF SAFETY Margin of Safety NOAEL / SED MOS = 100/0.167 = 599	599

Safety Report Part B

CSS Reference	LH100823-VEGSSBLEN1
Product line	Solid Shampoo Bars
Product fragrance variations	1. Orange, Patchouli and Lavender 2. Lavender and Cedarwood 3. Tea Tree and Rosemary 4. Peppermint and Eucalyptus 5. Geranium and Patchouli 6. Lemon, Black Pepper and Litsea Cubeba 7. Unscented
Product category	Surfactant based solid hair shampoos - rinse off products
Responsible person	Lois Himpe Burgemeester g. Dussartlaan 52 8860 Lendelede

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.

Declarable allergens*:
1. Orange, Patchouli and Lavender - Limonene, Linalool.
2. Lavender and Cedarwood - Geraniol, Limonene, Linalool.
3. Tea Tree and Rosemary - Limonene.
4. Peppermint and Eucalyptus - Limonene.
5. Geranium and Patchouli - Citral, Citronellol, Geraniol, Limonene, Linalool.
6. Lemon, Black Pepper and Litsea Cubeba - Citral, Limonene, Linalool.
7. Unscented - none present.

*allergens noted are based on published general data. However, these should be checked against the allergen statements provided by the supplier.

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 x 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.

10/08/2023

	
Joanne Priestley CBiol MRSB Managing Director, Safety Assessor ☒	Simas Kazlauskas CBiol MRSB Safety Assessor ☒

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

- 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

- 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.

Royal Society of Biology

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

Royal Society of Biology

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
Registered Charity No: 277981