eurofins | Consumer Product Testing

Laboratory Test Report

Prepared for:	Eresos Health + Wellbeing LTD
Address:	14 A Commercial Road London N18 1TP
Customer Sample Description:	Mandarin & Clove Hand Wash 500mg
Eurofins Registration Number:	2022-753-5058
No. of samples:	1
Assessment Performed:	Cosmetic Product Safety Report – EU/UK
Date Received:	16/11/2022
Date issued:	23/01/2023

Results and Observations

Please refer to the following page(s)

GMaeLL

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Georgia Lees-Lowe
Technical Account Executive

Date: 06/02/2023

The assessment was performed by an approved partner of the Eurofins Group.

Job No	**NCH1140**
Report No	**008248**
Issue Date	**23/01/2023**
Version No	**1**

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

Manufacturer

Eresos Health + Wellbeing LTD
14 A Commercial Road
London
N18 1TP

Cosmetic Product Safety Report

PRODUCT IDENTIFICATION

Product Category:	Cosmetic
Requirements:	Regulation (EC) 1223/2009 and UK
Reference Number:	2022-753-5058
Client Name:	Eurofins Consumer Product Testing Services
Contact Name:	Georgia Lees-Lowe

PRODUCT CHARACTERISTICS

Product Group:	Hand Wash
Type Of Product:	Rinse Off
Physical State:	Liquid
Nominal Size:	300g
Type Of Package:	PET bottle with PP pump

PHYSICAL/CHEMICAL CHARACTERISTICS

Appearence:	Yellow opaque liquid	**Specific Gravity [20°c]:**	Not Available
Odour:	Characteristic	**Particles Size:**	Not Applicable
pH:	5	**Density:**	Not Available
Viscosity[cp]:	Not Available	**Flash Point:**	Not Applicable
Solubility:	Soluble in water	**Loss On Drying:**	Not Applicable
Proportion Of Non-propellant In The Spray	Not Applicable	**Fraction Reaching Alveoli:**	Not Applicable

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DOCUMENT CONTENT

THIS ASSESSMENT IS SOLELY BASED ON THE LIST OF INGREDIENTS AND PRODUCT SAFETY INFORMATION SUBMITTED FOR TOXICOLOGICAL RISK ASSESSMENT AND ASSUMES THAT THIS LIST IS ACCURATE AND THERE ARE NO ADDITIONAL INGREDIENTS OR DATA WHICH ARE NOT LISTED. IF THE INFORMATION IN THE REPORT IS INCORRECT, PLEASE CONTACT SAFETY ASSESSOR. THE CORRECT DATA MUST BE SENT WITHIN 30 DAYS FROM THE DATE OF RECEIVED DOCUMENT OTHERWISE UPDATES WILL BE CHARGEABLE.

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Manufacturer
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QUANTITATIVE AND QUALITATIVE (QQ)
COMPOSITION OF THE COSMETIC PRODUCT
BILL OF MATERIALS (BOM)

INCI / CHEMICAL NAME	CAS NUMBER	% BY WEIGHT	RESTRICTIONS AS PER Regulation (EC) 1223/2009 and UK
Aqua	7732-18-5	81.3696	None
Cocamidopropyl Betaine	61789-40-0	17.27232	None
Coco-Glucoside	110615-47-9	9.18528	None
Decyl Glucoside	54549-25-6(58846-77-8)141464-42-8(68515-73-1)	5.79072	None
Glycerin	56-81-5	3.4944	None
Glyceryl Oleate	25496-72-4(111-03-5)	2.29632	None
Phenoxyethanol	122-99-6	0.9984	1%
Propylene Glycol Dicaprylate/Dicaprate	68583-51-7(58748-27-9)68988-72-7	0.9984	None
Citrus Nobilis Peel Oil (naturallythinking)	8008-31-9(84929-38-4)	0.9984	Allergens declaration as required. Prohibited Furocoumarines (e. g. trioxysalen (INN), 8-methoxypsoralen, 5-methoxypsoralen) except for normal contentin natural essences used.In sun protection and in bronzing products, furocoumarines shall be below 1 mg/kg
Xanthan Gum	11138-66-2	0.89856	None
Eugenia Caroyphyllus Bud Oil (naturallythinking)	84961-50-2	0.69888	Allergens declaration as required Proposed from 2023: The presence of the substance shall be indicated as ‘Eugenia Caryophyllus Oil’ in the list of ingredients referred to in Article 19(1), point (g), when the concentration of the substance or substances exceeds:- 0,001 % in leave-on products- 0,01 % in rinse-off products.

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QUANTITATIVE AND QUALITATIVE (QQ)
COMPOSITION OF THE COSMETIC PRODUCT
BILL OF MATERIALS (BOM)

INCI / CHEMICAL NAME	CAS NUMBER	% BY WEIGHT	RESTRICTIONS AS PER Regulation (EC) 1223/2009 and UK
Aloe Barbadensis Leaf Juice Powder	85507-69-3(94349-62-9)	0.4992	None
Sodium Benzoate	532-32-1	0.4992	a) Rinse-off products, except oral care products: 2.5% (acid) b) Oral care products: 1.7% (acid) c) Leave-on products 0.5% (acid)
Potassium Sorbate	24634-61-5(590-00-1)	0.4992	0.6 % (acid)
Citric Acid	77-92-9(5949-29-1)	0.29952	None
Tocopheryl Acetate	7695-91-2(58-95-7)	0.29952	None
Cannabidiol (CBD)	13956-29-1	0.160	Permitted if derived from parts of the Cannabis like leaves and stems. Prohibited if contains narcotics, natural and synthetic (e.g. delta-9-tetrahydrocannabinol)). Prohibited if derived from hemp flower (France).

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PERFUME OR AROMATIC COMPOSITIONS

SED Product = 2.45454545 mg / cm2

Perfume	Name / Code : Citrus Nobilis Peel Oil (naturallythinking) (Supplier : Naturallythinking)					
Allergens Material	**Cas. No**	**Concentration in Perfume[%]**	***Safe Concentration[%]**	***SED Concentration [µg / cm2] for surface area**	**Final Product[%]**	**Mos**
d-Limonene ((R)-p-Mentha-1,8-diene; (4R)-1-Methyl-4-(1-methylethenyl) cyclohexene)	5989-27-5 (68606-81-5)138-86-3	75.000000	0.800	18.379636	0.748800	54.408041
Linalool (1,6-Octadien-3-ol, 3,7-dimethyl-)	78-70-6	0.300000	0.800	0.073519	0.002995	7504.228989

Perfume	Name / Code : Eugenia Caryophyllus Bud Oil (naturallythinking) (Supplier : Naturallythinking)					
Allergens Material	**Cas. No**	**Concentration in Perfume[%]**	***Safe Concentration[%]**	***SED Concentration [µg / cm2] for surface area**	**Final Product[%]**	**Mos**
Eugenol	97-53-0	92.000000	0.800	15.781981	0.642970	37.422425
Isoeugenol	97-54-1 (5932-68-3)	0.500000	0.020	0.085772	0.003494	80.446174

Labelling Requirements, any of the 26 allergens listed in Annex III / EC No 1223/2009 must be declared on the packaging when present at the specified concentration and product type as below:

Leave – on >0.001% (10 ppm)
Rinse – off >0.01% (100 ppm)

*RIFM NEL for sensitisation (Monographs on fragrance raw materials. D.L.J. Opdyke. Research Institute for Fragrance Materials, 1976.)

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STABILITY OF THE COSMETIC PRODUCT

PRODUCT STABILITY:

The product underwent a 6-months accelerated and 24-months real-time stability testing and was monitored for changes in appearance, colour, CBD content, cannabinoid profile and preservative content at the temperature conditions of 40°C/ 75% R.H. and 25°C/60% R.H. respectively. The test report showed slight changes to the cannabidiol and preservative content during both tests. The product passed the manufacturer 's specification.

PACKAGING SPECIFICATION:

Specifications of the substances in the package are available in the product documentation at the address of the person responsible for placing the product on the market. The packaging characteristics show no potential problems with regards to product safety during use and storage.

GENERAL RECOMMENDATION:

Relevant stability and packaging compatibility tests adapted to the type of cosmetic product and its intended use should be carried out. This is to ensure that no stability problems are induced by the type of container and packaging used. Physical stability tests are usually carried out either with inert containers or those intended to be used on the market (*).

* Ref. The SCCS's Notes of Guidance for the Testing of Cosmetic Substances and their Safety Evaluation

PRODUCT DURABILITY:

Shelf life: 24 months from manufacturing

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MICROBIOLOGICAL QUALITY

MESOPHILIC AEROBIC BACTERIA COUNT: < 100 cfu/g

YEAST AND MOULDS: < 100 cfu/g

PATHOGENS: Listeria species: not detected in 25g; Salmonella: not detected in 10g

CHALLENGE TEST:

The samples of the hand wash base were inoculated with cultures of bacteria such as Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans and Aspergillus brasiliensis. After 7, 14 and 28 days, the tested samples were 'free from microbial load'. These results indicate that the preservative system is functional and that the growth of micro-organisms is not likely to occur.

Challenge test result for the final product was not provided by the time of assessing the product. The efficacy of the preservative system and microbiological stability (TVC, mould, fungi, absence of pathogens) must meet the acceptance criteria based on the positive evaluation prior to marketing.

MICROBIOLOGICAL LIMITS FOR COSMETICS. EUROPEAN STANDARD EN ISO 17516:2014 COSMETICS – MICROBIOLOGY – MICROBIOLOGICAL LIMITS:

Products specifically intended for children under three years of age, the eye area or the mucous membranes:
Total Aerobic Mesophilic Microorganisms (Bacteria plus yeast and mould) ≤ 1 x 10^2 CFU per g or ml^a.
Pathogens (Escherichia coli, Pseudomonas aeruginosa, Staphyloccocus aureus, Candida albicans) must be absent in 1 g or 1 ml.

Other products:
Total Aerobic Mesophilic Microorganisms (Bacteria plus yeast and mould) ≤ 1 x 10^3 CFU per g or ml^b
Pathogens (Escherichia coli, Pseudomonas aeruginosa, Staphyloccocus aureus, Candida albicans) must be absent in 1 g or 1 ml.

Additionally: Due to inherent variability of the plate count method, according to USP Chapter 61 or EP Chapter 2.6.12, Interpretation of results, results considered out of limit if a>200 CFU/g or ml, b>2 000 CFU/g or ml. NOTE When colonies of bacteria are detected on Sabouraud Dextrose agar, Sabouraud Dextrose agar containing antibiotics may be used (ref. SCCS/1564/15, Table 5)

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IMPURITIES, TRACES, INFORMATION ABOUT THE PACKAGING MATERIAL

A complete set of technical specifications of the product, raw materials and the packaging were not provided at the time of the assessment. Impurities in the form of controlled or prohibited chemical or biological materials should be solely present (if any) at levels within recommended standards. Prohibited ingredients are permissible only at trace levels as defined by best industrial practices. The content of heavy metals as impurities shall occur in quantities within the safety levels recommended by The Federal Institute for Risk Assessment (BfR) for cosmetic products.

NORMAL AND REASONABLY FORESEEABLE USE

Hand wash intended for use by adults.

EXPOSURE TO THE Cosmetic PRODUCT

The site(s) of application:	Hands
The surface area(s) of application:	880 cm^2
The amount of product applied:	2.16 g
Exposure time:	Rinse Off
The duration and frequency of use:	Five times per day
The normal and reasonably foreseeable exposure route(s):	Skin.
The targeted (or exposed) population(s):	16+

The SCCS's Notes of Guidance for the Testing of Cosmetic Substances and their Safety Evaluation

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EXPOSURE TO THE SUBSTANCES (DERMAL)

SED Product = 36 mg / kg bw / day

INCI / Chemical Name	Concentration in finished product [C %]	* Daily exposure of product (a g/day)	**Dermal Absorption (Dap %)	***Systemic Exposure Dose (SED mg/kg bw/ day)	NOAELs (mg/kg bw/day)	MoS
Aqua	81.369600	2.16	100.000	0.29293056	Not available	No MoS calculated as no NOAEL available
Cocamidopropyl Betaine	17.272320	2.16	10.000	0.00621804	Not available	No MoS calculated as no NOAEL available
Coco-Glucoside	9.185280	2.16	100.000	0.03306701	Not available	No MoS calculated as no NOAEL available
Decyl Glucoside	5.790720	2.16	100.000	0.02084659	Not available	No MoS calculated as no NOAEL available
Glycerin	3.494400	2.16	100.000	0.01257984	5040	400641.025641
Glyceryl Oleate	2.296320	2.16	100.000	0.00826675	Not available	No MoS calculated as no NOAEL available
Propylene Glycol Dicaprylate/Dicaprate	0.998400	2.16	100.000	0.00359424	Not available	No MoS calculated as no NOAEL available
Phenoxyethanol	0.998400	2.16	90.000	0.00323482	500	154568.296929
Citrus Nobilis Peel Oil (naturallythinking)	0.998400	2.16	100.000	0.00359424	Not available	No MoS calculated as no NOAEL available
Xanthan Gum	0.898560	2.16	100.000	0.00323482	Not available	No MoS calculated as no NOAEL available
d-Limonene ((R)-p-Mentha-1,8-diene; (4R)-1-Methyl-4-(1-methylethenyl)cyclohexene)	0.748800	2.16	100.000	0.00269568	Not available	No MoS calculated as no NOAEL available
Eugenia Caroyphyllus Bud Oil (naturallythinking)	0.698880	2.16	100.000	0.00251597	Not available	No MoS calculated as no NOAEL available
Eugenol	0.642970	2.16	100.000	0.00231469	Not available	No MoS calculated as no NOAEL available
Sodium Benzoate	0.499200	2.16	100.000	0.00179712	2500	1391114.672365

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INCI / Chemical Name	Concentration in finished product [C %]	* Daily exposure of product (a g/day)	**Dermal Absorption (Dap %)	***Systemic Exposure Dose (SED mg/kg bw/ day)	NOAELs (mg/kg bw/day)	MoS
Potassium Sorbate	0.499200	2.16	25.000	0.00044928	Not available	No MoS calculated as no NOAEL available
Aloe Barbadensis Leaf Juice Powder	0.499200	2.16	100.000	0.00179712	Not available	No MoS calculated as no NOAEL available
Tocopheryl Acetate	0.299520	2.16	100.000	0.00107827	Not available	No MoS calculated as no NOAEL available
Citric Acid	0.299520	2.16	100.000	0.00107827	Not available	No MoS calculated as no NOAEL available
Cannabidiol (CBD)	0.160000	2.16	100.000	0.00057600	Not available	No MoS calculated as no NOAEL available
Isoeugenol	0.003494	2.16	100.000	0.00001258	Not available	No MoS calculated as no NOAEL available
Linalool (1,6-Octadien-3-ol, 3,7-dimethyl-)	0.002995	2.16	100.000	0.00001078	250	23185244.539411

*Daily exposure of product (A) estimated daily exposure as referenced by SCCS Notes of Guidance
** Dermal absorption (DAp): a worst case scenario 100%
** Systemic Exposure Dose (SED) =(A mg/g x C/100) / 60 mg/kg/day

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EXPOSURE TO THE SUBSTANCES (DERMAL) - ALLERGEN SUMMARY

SED Product = 36 mg / kg bw / day

INCI / Chemical Name	Concentration in finished product [C %]	* Daily exposure of product (a g/day)	**Dermal Absorption (Dap %)	***Systemic Exposure Dose (SED mg/kg bw/ day)	NOAELs (mg/kg bw/day)	MoS
d-Limonene ((R)-p-Mentha-1,8-diene; (4R)-1-Methyl-4-(1-methylethenyl)cyclohexene)	0.748800	2.16	100.000	0.00269568	Not available	No MoS calculated as no NOAEL available
Eugenol	0.642970	2.16	100.000	0.00231469	Not available	No MoS calculated as no NOAEL available
Isoeugenol	0.003494	2.16	100.000	0.00001258	Not available	No MoS calculated as no NOAEL available
Linalool (1,6-Octadien-3-ol, 3,7-dimethyl-)	0.002995	2.16	100.000	0.00001078	250	23185244.539411

*Daily exposure of product (A) estimated daily exposure as referenced by SCCS Notes of Guidance
** Dermal absorption (DAp): a worst case scenario 100%
** Systemic Exposure Dose (SED) =(A mg/g x C/100) / 60 mg/kg/day

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EXPOSURE TO THE SUBSTANCES (ORAL)

SED Product = 36 mg / kg bw / day

INCI / Chemical Name	Concentration in finished product [C %]	* Daily exposure of product (a g/day)	***Systemic Exposure Dose (SED mg/kg bw/ day)	NOAELs (mg/kg bw/day)	MoS
Aqua	81.369600	2.16	29.29305600	Not Available	No MoS calculated as no NOAEL available
Cocamidopropyl Betaine	17.272320	2.16	6.21803520	750	60.30844
Coco-Glucoside	9.185280	2.16	3.30670080	1000	151.208117
Decyl Glucoside	5.790720	2.16	2.08465920	100	23.984736
Glycerin	3.494400	2.16	1.25798400	8000	3179.69068
Glyceryl Oleate	2.296320	2.16	0.82667520	Not Available	No MoS calculated as no NOAEL available
Propylene Glycol Dicaprylate/Dicaprate	0.998400	2.16	0.35942400	1000	1391.114672
Phenoxyethanol	0.998400	2.16	0.35942400	369	513.321314
Citrus Nobilis Peel Oil (naturallythinking)	0.998400	2.16	0.35942400	1000	1391.114672
Xanthan Gum	0.898560	2.16	0.32348160	750	1159.262227
d-Limonene ((R)-p-Mentha-1,8-diene; (4R)-1-Methyl-4-(1-methylethenyl)cyclohexene)	0.748800	2.16	0.26956800	825	1530.22614
Eugenia Caroyphyllus Bud Oil (naturallythinking)	0.698880	2.16	0.25159680	Not Available	No MoS calculated as no NOAEL available
Eugenol	0.642970	2.16	0.23146906	79.3	171.297195
Sodium Benzoate	0.499200	2.16	0.17971200	1000	2782.229345
Potassium Sorbate	0.499200	2.16	0.17971200	750	2086.672009
Aloe Barbadensis Leaf Juice Powder	0.499200	2.16	0.17971200	Not Available	No MoS calculated as no NOAEL available
Tocopheryl Acetate	0.299520	2.16	0.10782720	800	3709.639126
Citric Acid	0.299520	2.16	0.10782720	4000	18548.195632
Cannabidiol (CBD)	0.160000	2.16	0.05760000	Not Available	No MoS calculated as no NOAEL available
Isoeugenol	0.003494	2.16	0.00125798	300	119238.400488
Linalool (1,6-Octadien-3-ol, 3,7-dimethyl-)	0.002995	2.16	0.00107827	160	74192.782526

*Daily exposure of product (A) estimated daily exposure as referenced by SCCS Notes of Guidance
** Dermal absorption (DAp): a worst case scenario 100%
*** Systemic Exposure Dose (SED) =A mg/g x C/100 x DAp/100/60 mg/kg/day

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EXPOSURE TO THE SUBSTANCES (ORAL) - ALLERGEN SUMMARY

SED Product = 36 mg / kg bw / day

INCI / Chemical Name	Concentration in finished product [C %]	* Daily exposure of product (a g/day)	***Systemic Exposure Dose (SED mg/kg bw/ day)	NOAELs (mg/kg bw/day)	MoS
d-Limonene ((R)-p-Mentha-1,8-diene; (4R)-1-Methyl-4-(1-methylethenyl)cyclohexene)	0.748800	2.16	0.26956800	825	1530.22614
Eugenol	0.642970	2.16	0.23146906	79.3	171.297195
Isoeugenol	0.003494	2.16	0.00125798	300	119238.400488
Linalool (1,6-Octadien-3-ol, 3,7-dimethyl-)	0.002995	2.16	0.00107827	160	74192.782526

*Daily exposure of product (A) estimated daily exposure as referenced by SCCS Notes of Guidance
** Dermal absorption (DAp): a worst case scenario 100%
*** Systemic Exposure Dose (SED) =A mg/g x C/100 x DAp/100/60 mg/kg/day

Product Name

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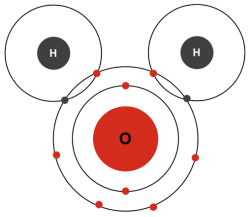
TOXICOLOGICAL PROFILE OF THE SUBSTANCES



IDENTIFICATION
Aqua (Antiplaque, skin conditioning, solvent)
EU INCI: Aqua.
CTFA INCI: Water.
CNDA INCI: Eau.
Chinese: 水.
CAS Number: 7732-18-5.
EINECS Number: 231-791-2.
Symbol: H2O.
Molecular Weight: 18.015 g/mol.
Description: Aqua is a clear, colorless, odorless, tasteless liquid that freezes into ice below 0 degrees centigrade and boils above 100 degrees centigrade.
Synonyms: Distilled water; Deionized Water,Purified Water

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Odourless
pH: 6.0 - 8.0 at 25 °C
Viscosity: 0.8949 cP
Water Solubility: Miscible
Partial Coefficient logPow: -1.38
Boiling Point: 100°C at 760 mm Hg
Density: 1.000 g/cm3
Flammability: Not flammable.
Melting Point: 0°C
Microbiological stability: Susceptible to microbiological contamination
Physical State: Liquid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI.
REACH Annex XVII: Not listed in the Annex XVII (Mentioned as exemption from the obligation to register).
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: Not classified as per GHS.
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: Water is non-toxic liquid essential for life. It is composed of hydrogen and oxygen. Water is commonly used as solvent in cosmetic products. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is not considered to be of toxicological concern when used as intended.

TOXICOLOGICAL PROFILE
Endocrine Effects: Does not have Endocrine disruptors (ED) properties.
Eye Irritation: Not irritating to the eyes.
Genotoxicity: Water is not-genotoxic
Hypoallergenic: Unlikely to cause an allergic reaction.
LD50: No studies recorded.
Mutagenicity: Not mutagenic
NOAEL Oral: The NOAELs were not available in order to review however based on a history of safe use in consumer products this material is considered safe when used as intended. In conclusion, at the given concentration in the final product, the ingredient is not considered to be of toxicological concern when used as intended.
Phototoxicity: Not a phototoxic chemical.
Repeated Dose Toxicity: No studies recorded.
Reproductive Toxicology: No studies recorded.
Skin Irritation: Not irritating to skin.
Skin Sensitisation: Water is an inorganic solvent which is very rare associated with allergenic reactions.
Carcinogenicity: Not a carcinogenic chemical material.

OTHER
Detergent Class: Dilutant

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

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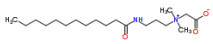
TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Cocamidopropyl Betaine (Antistatic,Cleansing,Foam Boosting,Hair Conditioning,Surfactant,Viscosity Controlling)
EU INCI: Cocamidopropyl Betaine.
CTFA INCI: Cocamidopropyl Betaine.
CNDA INCI: Cocamidopropyl Betaine.
CAS Number: 61789-40-0.
EINECS Number: 263-058-8(931-296-8).
Symbol: C19H38N2O3.
Molecular Weight: 342.517 Da.
Description: Amphoteric surfactant which decreases the irritation level of the anionic surfactants on the skin.
Synonyms: 3-Amino-N-(carboxymethyl)-N,N-dimethyl-1-propanaminium N-coco acyl derivs. hydroxides inner salts. 1-Propanaminium, 3-amino-N-(carboxymethyl) derivs., hydroxides, inner salts.



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Odourless/Slight odor
Oxidising Properties: Non oxidising
pH: 4.5 - 5.5
Specific Gravity: 1.04 relative to water (CIR)
Water Solubility: Soluble in cold water, 35 000 mg/L at 20 °C
Boiling Point: >110°C (230°F)
Particle Size: The particle size distribution was determine to be in the range of 150 micron to 25 micron: 106 microns 51.34 %, 75 microns 39.28 %
Density: 1.05 g/cm3
Flammability: Not classified.
Flash Point: 230 °C at 101 325 Pa
Vapour Pressure: 3.3 kPa (@ 25°C)
LogP Log Kow: -1
Melting Point: 283 °C at 101 325 Pa
Physical State: Solid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI
REACH Annex XVII: Not listed in the Annex XVII
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: H315: Causes skin irritation. H319: Causes serious eye irritation. H317: May cause an allergic skin reaction. H412: Harmful to aquatic life with long lasting effects..
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: The in vivo studies resulted in scoring the substance as irritating to eyes, irritating to human skin and weakly sensitising. Cocamidopropyl betaine shows low acute toxicity with LD50 above 5 000 mg/kg bw and above 2 000 mg/kg bw in oral and dermal exposure respectively. NOAEL Oral was indicated at 750 mg/kg bw and 1 000 mg/kg bw in oral exposure for reproductive toxicity. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is not considered to be of toxicological concern when used as intended.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo on rabbits to examine ocular irritation after application. The studies resulted in scoring the substance is irritating to eyes. The chemical is classified as category 2 according to the GHS criteria (ECHA).
Genotoxicity: In vitro: negative (S. typhimurium, other: TA 1535, TA 1537, TA 98, TA 100, TA 1538 and E. coli WP2).(ECHA)
LD50: LD50 (oral, rat) > 5000 mg/kg (OECD Guideline 401 (Acute Oral Toxicity)), LD50 (dermal, rat) > 2000 mg/kg. Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity. Acute toxicity studies via dermal route of exposure showed that the substance has low skin toxicity. Source: ECHA.
NOAEL Oral: NOAEL 750 mg/kg bw. Study type: 28-day repeated dose toxicity. Endpoint: short-term repeated dose toxicity: oral. Route of administration: oral. Species: rat. Bibliographic source: U. S. Environmental Protection Agency (EPA) Office of Pollution Prevention and Toxics (OPPT) Risk Assessment Division (RAD), 2001. Report date: 2001. Source: ECHA. MoS was calculated based on this data.
Precutaneous Absorption: 10%
Safety evaluation: Mixtures of surfactants tend to reduce the degree of irritation when contact with the skin.
Skin Irritation: In vivo studies on humans, using open patch tests were conducted. The substance was found to be irritating to the human skin. (ECHA) Cocamidopropyl Betaine (CAPA), an amphoteric surfactant is less irritating to skin and eyes because when applied to skin induces less skin surface water loss comparing with SLS.
Skin Sensitisation: May cause skin sensitisation due to the presence of impurities Amidoamine (AA) < 0.3 Dimethylaminopropylamine (DMAPA) < 15 ppm. Non-LLNA in vivo examinations, using human patch tests, were conducted. The test results showed that the substance should be considered a potentially weak skin sensitizer (ECHA).
Allergens HRIPT: The substance was tested in several HRIPT studies on 478 subjects in total in concentrations varying from 0.018% to 1.5%. No sensitisation was observed. The formulations caused slight response which was attributed to primary irritation rather than sensitization. Source: CIR
Allergens Patch Test: The substance was tested in several Patch Test studies on over 11,500 subjects in total in concentrations varying from 0.3% to 1%. No sensitisation was observed. The formulations caused response in small fraction of subjects (0.27% in the largest probe) Source: CIR In several patch tests results from case reports, the substance was found positive at concentrations 0.5%. (CIR)
Carcinogenicity: Not associated with carcinogenic, mutagenic and reprotoxic (CMR) chemicals.

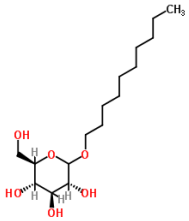
OTHER
Biodegradability (Environmental): Biodegradation in water. Results: > 90 % degradation (test mat. analysis) after 5 days. Conclusion: readily biodegradable. (ECHA)
LC50 (Environmental): LC50 Danio rerio, 2 mg/L, 96h; L0 Danio rerio, 1.7 mg/l , 96h; EC50 Ulva lactuca, 30 mg/L, 48h (ECHA)

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



IDENTIFICATION
Coco-Glucoside (Cleansing,Emulsion Stabilising,Surfactant)
EU INCI: Coco-Glucoside.
CTFA INCI: Coco-Glucoside.
CAS Number: 110615-47-9.
EINECS Number: 600-975-8.
Symbol: CH16H32O6.
Molecular Weight: 320.426 g/mol.
Description: Coco-Glucoside is a surfactant produced by chemical reaction between glucose and coconut oil derived ingredient
Synonyms: D-Glucoside, Decyl, Decyl D-glucopyranoside [ACD/IUPAC Name]Decyl-D-glucopyranosid [German] [ACD/IUPAC Name]D-Glucopyranoside de décyle [Fr
Glucopyranoside, decyl [ACD/Index Name](3R,4S,5S,6R)-2-(DECYLOXY)-6-(HYDROXYMETHYL)OXANE-3,4,5-TRIOL(3R,4S,5S,6R)-2-(Decyloxy)-6-(hydroxymethy
triol(3R,4S,5S,6R)-2-(Decyloxy)-6-(hydroxymethyl)-tetrahydro-2H-Pyran-3,4,5-triol(3R,4S,5S,6R)-2-decoxy-6-(hydroxymethyl)oxane-3,4,5-triol[68515-73-1]

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Oxidising Properties: Non oxidising
Water Solubility: > 200 g/L at 20 °C, solubility in organic solvents: 170 g/L at 20 °C in n-octanol
Boiling Point: 476.5±45.0 °C at 760 mmHg
Density: 1.161 g/cm³ at 20 °C
Flammability: Non flammable upon ignition.
Flash Point: 242.0±28.7 °C
Vapour Pressure: ≤ 0.0077 Pa at 20 °C
LogP Log Kow: log Kow ≤ -0.07 (calculated)
Melting Point: The test item shows no area of melting temperature up to 150 °C.
Physical State: Liquid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI.
REACH Annex XVII: Not listed in the Annex XVII
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: H315: Causes skin irritation. H318: Causes serious eye damage..
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: The substance is commonly used as cleansing, emulsion stabilising and surfactant. Data derived in vivo (animal studies) indicated that the substance is irritating to eyes, irritating to skin and non-sensitising. The substance shows low acute toxicity with LD50 above 5 000 mg/kg in oral exposure and LD50 above 2000 mg/kg bw in dermal exposure. The available NOAEL (repeated dose toxicity and reproduction toxicity) were determined to be around 1000 mg/kg/bw/day and therefore the substance is considered to have low systemic toxicity potential. Overall, the ingredient is not considered to be of toxicological concern when used as intended.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo on rabbits to examine ocular irritation after application. The studies resulted in scoring the chemical as corrosive. The substance is classified as category 1 according to the GHS criteria (ECHA).
Genotoxicity: In vitro: negative (S. typhimurium TA 1535, TA 1537, TA 98 and TA 100 and E. coli WP2 uvr A); Method: according to guideline 471; Report date: 2005; Source: ECHA. In vitro: negative (mouse lymphoma L5178Y cells); In vivo: negative (mouse) (ECHA)
LD50: LD50 (oral rat) > 5 000 mg/kg bw; LD50 (dermal, rabbit) > 2 000 mg/kg bw. Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity. Acute toxicity studies via dermal route of exposure in rabbits showed that the substance has low skin toxicity. (ECHA)
NOAEL Oral: NOAEL 1000 mg/kg bw. Study type: Repeated dose toxicity. Endpoint sub-chronic toxicity. Route of administration: oral. Species: rat. Methods: EU Method B.26 (Sub-Chronic Oral Toxicity Test: Repeated Dose 90-Day Oral Toxicity Study in Rodents). Report date: 1989. Source: ECHA. MoS was calculated based on this data.
Skin Irritation: In vivo studies on rabbits with occlusive coverage were conducted. The substance was found to be irritating to the skin and classified as category Skin Irrit. 2 according to the GHS criteria. (ECHA)
Skin Sensitisation: LLNA in vivo examinations were conducted to find evidence for skin sensitisation. The substance was found to be non-sensitising (ECHA).
Allergens HRIPT: 1% solution of coco-glucoside was used in a HRIPT. The substance was scored as not irritating and not sensitising. (CIR)
Allergens Patch Test: Epicutaneous patch test was conducted on 20 volunteers. The formulation containing 2% of the coco-glucoside at pH 6.5 was used. The substance under occlusion was applied to the skin for 24h. The substance was found to be slightly irritating. (International Journal of Toxicology 2018)

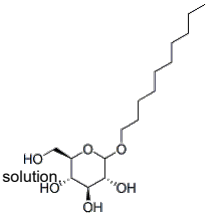
OTHER
Biodegradability (Environmental): Biodegradation in water. Results: 88% degradation based on the O2-consumption. Conclusion: readily biodegradable. (Stelter, 1994b, c, d; Mitsubishi chemical safety science institute, 1991 and Garcia et al., 1997) (ECHA)
LC50 (Environmental): LC50 Brachydanio rerio 2.95 mg a. i./L, 96h (OECD guideline 203 “Fish, Acute Toxicity Test, Stelter, 1995a). LC50 Scophthalmus maximus 4.4 mg/L, 4.88 mg/L and 20.27 mg/L, 96h (OECD Guideline 203 (Fish, Acute Toxicity Test, (Hudson, 2003a, b, c).); EC50 Scenedesmus subspicatus, 12.5 mg a.i./L , 72h (Stelter, 1995) (ECHA)

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



IDENTIFICATION
Decyl Glucoside (Cleansing,Emulsion Stabilising,Surfactant)
EU INCI: Decyl Glucoside.
CTFA INCI: Decyl Glucoside.
CNDA INCI: Decyl Glucoside.
Trade Name: iSURF DG816.
CAS Number: 54549-25-6(58846-77-8)141464-42-8(68515-73-1).
EINECS Number: 259-218-1.
Symbol: C16H32O6.
Molecular Weight: 320.42 g/mol.
Description: Decyl Glucoside is the product obtained from the condensation of decyl alcohol with glucose. The substance is a solid but is usually marketed as 50% liquid solution.

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Slight odor
pH: 11.5 - 12.5 (25℃, 1% aq. soln.)
Water Solubility: > 200 g/L at 20 °C
Oxidising Properties: Non oxidising
Boiling Point: 476.538°C at 760 mmHg
Colour: Pale yellow
Density: 1160 - 1176 kg/m³ at 20 °C
Flash Point: 242.002°C (aq. solution)
Physical State: Solid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI.
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: H318: Causes serious eye damage..
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: Decyl Glucoside is the product obtained from the condensation of decyl alcohol with glucose. The substance is not associated with the skin sensitisation and skin irritation. However, the available toxicological data demonstrate that the substance is highly irritating to eyes. It shows low acute toxicity with LD50 above 2000 mg/kg bw in both oral and dermal route of exposure. Repeated dose toxicity study was conducted and the NOAEL was determined to be around 100 mg/kg bw/day for rats and therefore it is considered as high toxicological concern via oral route of administration. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is considered to be safe when used as intended.

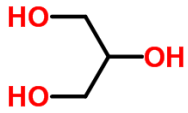
TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as highly irritating. (ECHA)
Genotoxicity: In vitro: negative. (Chinese hamster lung fibroblasts (V79)). In vivo: negative (mouse) (ECHA)
LD50: LD50 (oral, rat) >2000 mg/kg bw; OECD Guideline 423 (Acute Oral toxicity - Acute Toxic Class Method); Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity of the substance. LD50 (dermal, rabbit) > 2 000 mg/kg bw; OECD Guideline 402 (Acute Dermal Toxicity); Description: Acute toxicity studies via dermal route of exposure in rabbits (semiocclusive type of coverage) showed that the substance has low skin toxicity. (ECHA)
Mutagenicity: Non-mutagenic
NOAEL Oral: NOAEL 100 mg/kg bw/day. Study type: repeated dose toxicity. Endpoint:sub-chronic toxicity: oral. Species: rat. Guideline:EU Method B.26 (Sub-Chronic Oral Toxicity Test: Repeated Dose 90-Day Oral Toxicity Study in Rodents). Report date:1989. Source: ECHA. MoS was calculated based on this data
Skin Irritation: In the in vivo studies on rabbits with semiocclusive coverage the substance was found to be not irritating and not corrosive. (ECHA)
Skin Sensitisation: Non-LLNA in vivo examinations were conducted, using guinea pig Buehler test, to find evidence for skin sensitisation. The test results showed that the chemical is non-sensitising. (ECHA)

OTHER
Biodegradability (Environmental): Biodegradation in water. Results: 70% degradation in 28 days. Conclusion: readily biodegradable. (Garcia et al., 1997) (ECHA)
LC50 (Environmental): LC50 100.81 mg/L, Danio rerio, 96h (nominal, active ingredient) (ISO 7346/1-3); LC50 96.64 mg/L, Scophthalmus maximus , 96h (OSPARCOM 1995); EC50 27.22 mg/L, Scenedesmus subspicatus, 72h; EC10 6.25 mg/L, Scenedesmus subspicatus, 72h, (nominal, active ingredient, growth rate) (DIN 38412, part 9) (ECHA)

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Glycerin (Humectant,Denaturant,Hair Conditioning,Oral Care,Perfuming,Skin Protecting,Viscosity Controlling)
EU INCI: Glycerin.
CTFA INCI: Glycerin.
CNDA INCI: Glycerin.
Chinese: 甘油.
CAS Number: 56-81-5.
EINECS Number: 200-289-5.
Symbol: C3H8O3.
Molecular Weight: 92.09.
Description: Glycerin (also called glycerol) is a naturally occurring alcohol compound and a component of many lipids. Glycerin may be of animal or vegetable origin
EINECS No.: 200-289-5
Synonyms: Propane-1,2,3-triol; Glycerin; Glycerine; Propanetriol; 1,2,3-Trihydroxypropane; 1,2,3-Propanetriol



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Odourless
Oxidising Properties: No oxidising properties.
pH: 5,5 - 8
Viscosity: 1412 mPa*s at 20 °C
Water Solubility: Soluble
Partial Coefficient logPow: -1.75 at 25 °C
Boiling Point: 182 °C at 27 hPa - lit., 290 °C at 101 325 Pa
Particle Size: The non-solid or granular form does not require the particle size distribution study.
Colour: Clear
Density: 1.2611 g/cm3 at 20 °C
Flash Point: 160 °C - closed cup
Vapour Pressure: 0,0033 hPa at 50 °C, 0.01 Pa (0.001 mmHg) at 20 °C and below 26 Pa (0.2 mmHg) at 100 °C
LogP Log Kow: -1.75 at 25 °C
Melting Point: 18.17 °C
Microbiological stability: Not susceptible to microbiological contamination. The humectant has a low water activity when interact with water (≈0.7 < Aw < ≈0.8).
Physical State: Liquid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI.
REACH Annex XVII: Not listed in Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
Regulatory Controls: USA: Purified grade of glycerine free from diethylene glycol (DEG) in order to prevent from poison.
GHS Classification: Not classified as per GHS.
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: The chemical material, also known as glycerol, is commonly used as a humectant. Its intrinsic properties allow inhibiting the growth of microorganisms by reducing water activities in various products depending on glycerin concentration and formula type. When it comes to local toxicity the chemical does not induce or elicit skin allergy. Data derived from animal studies demonstrate that the substance is not irritating to the skin and eyes. It shows low acute toxicity and also low chronic toxicity where all three routes of exposure are considered (oral, dermal and inhalation). When used as cosmetic, food or pharmaceutical grade the risk associated with possible contamination of Diethylene glycol (DEG), the toxic chemical and its metabolites especially when accidentally ingested, is reduced. Other grades, such as industrial grades of this chemical, must not be used in consumer products particularly in these intended for use by children.

TOXICOLOGICAL PROFILE
Endocrine Effects: No endocrine effects are known from using this material in cosmetics.
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as not irritating (ECHA). Anhydrous glycerin was applied to the eyes of human patients. There was a strong burning and stinging sensation, with tear production, but no injury was observed. Based on the results, glycerin is not classified as eye irritating to eyes (CIR).
Genotoxicity: In vitro: negative. (S. typhimurium, other: TA 98, TA 100, TA 1535, TA 1537, TA 1538). (ECHA)
LD50: LD50 (oral, rat) 27 200 mg/kg bw; LD50 (dermal, guinea pig) 56,750 mg/kg; Description: Acute toxicity studies via oral route of administration in rat demonstrated low toxicity. Acute toxicity studies via dermal route of exposure in guinea pig showed that the substance has low skin toxicity. (ECHA)
Mutagenicity: No evidence of mutagenicity in Ames test.
NOAEL Dermal: NOEL 5040 mg/kg bw. Study type Repeated dose toxicity. Duration 90 day study. Method Draize method (Study report 1953)
NOAEL Inhalation: NOAEL167 mg/m3. Study type Repeated dose toxicity. Duration 2-week and 13-week of aerosolized material. Method OECD 413 (Publication data 1992).
NOAEL Oral: NOAEL was established at the range of 8000-10000 mg/kg bw. Study type Repeated dose toxicity. Duration Chronic toxicity. Method OECD 452 (Published data 1953).
Skin Irritation: In vivo studies on rabbits with occlusive type of coverage, the substance was found to be not irritating (ECHA). Glycerin solution in water (50%) was applied on 420 patients' skin for 20-24h. Only one patient has a positive reaction. Based on the results of the test, glycerin is not irritating to human skin (CIR).
Skin Sensitisation: LLNA in vivo examinations were conducted, using mouse local lymph node assay (LLNA) test, to find evidence for skin sensitisation. The test results showed that the chemical is not sensitising. (ECHA) Based on the modified Draize test glycerin is not considered to be skin sensitiser. (CIR)
Allergens HRIPT: A modified Draize test (n=48) was conducted using moisturiser (65.9% of glycerin). The substance was applied 10 times to the skin for 48 or 72h. Then the challenge phase was applied. No reactions were reported after induction or challenge phase. (CIR)
Allergens Patch Test: Patients with eczema showed no irritation and sensitization (CIR).
Carcinogenicity: Not a CMR material.

OTHER
Biodegradability (Environmental): Readily biodegradable in water. The study was conducted using industrial activated sludge. The substance was almost completely degraded within 24h. (ECHA)
LC50 (Environmental): Fish: LC50 fathead minnow >885 mg/L – 96h (Polyol 80 contained 86% glycerol); LC50 Cyprinodon variegatus >11,000 ug/L – 96h; Daphnia: LC50 Daphnia magna 1955 (1851 to 2068) mg/L – 48h; EC50 Daphnia magna >10,000 mg/L – 24h; Algae: EC3 S. quadricauda >10,000 mg/L and EC3 M. aeruginosa 2900 mg/L - 8 days; In a 28 days study Glycerol was evaluated as relatively nontoxic. Microorganisms: NOEC Pseudomonas putida >10,000 mg/L – 16h; the substance was considered as non-toxic to bacteria. (ECHA)

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Glyceryl Oleate (Emollient,Emulsifying,Perfuming)
EU INCI: Glyceryl Oleate.
CTFA INCI: Glyceryl Oleate.
CAS Number: 25496-72-4(111-03-5).
EINECS Number: 247-038-6.
Symbol: C21H40O4.
Molecular Weight: 356.55 g/mole.
Synonyms: (9Z)-9-Octadécénoate de 1,3-dihydroxy-2-propanyle [French] [ACD/IUPAC Name]1,3-Dihydroxy-2-propanyl (9Z)-9-octadecenoate [ACD/IUPAC Name]1,3-I
octadecenoat [German] [ACD/IUPAC Name]1,3-Dihydroxypropan-2-yl (9Z)-octadec-9-enoate247-038-6 [EINECS]253-407-2 [EINECS]25496-72-4 [RN]2-hydroxy-
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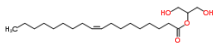


PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Sweet
Water Solubility: Insoluble in cold water.
Boiling Point: 239°C (462.2°F)
Density: 0.9420 at 20C
Melting Point: 35.0°C
Physical State: Solid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI
REACH Annex XVII: Not listed in the Annex XVII
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: Not classified as per GHS.
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: In vivo studies (animal and human) have shown that Glyceryl Oleate is slightly irritating to eyes and skin. No adverse reactions such as irritation or sensitisation were reported during human repeat insult patch test when the substance was applied in the concentration of 15%. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is not considered to be of toxicological concern when used as intended.

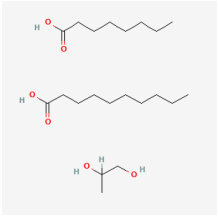
TOXICOLOGICAL PROFILE
Eye Irritation: The undiluted substance was tested for ocular irritation on rabbits. Only minimal eye irritation was observed. (CIR)
NOAEL Oral: The NOAEL value was not found, however, based on a history of safe use, this chemical material is considered safe for use in cosmetics. The chemical is unlikely to produce systemic toxicity following skin contact.
Skin Irritation: The substance underwent 5 studies - single insult occlusive patch tests to determine its irritating properties. The substance was applied to the clipped skin of rabbits. The undiluted substance cause only minimal skin irritation. (CIR)
Skin Sensitisation: The substance in a concentration 15% underwent HRIPT on 200 volunteers. The substance was applied 16 times on arm (3 times per week). After non treatment period the challenge phase was applied. No adverse reactions such as irritation or sensitisation were reported during the study. (CIR)
Allergens HRIPT: HRIPT of a substance concentration of 50% in paraffin was conducted on 107 subjects. There was no skin irritation or sensitisation effect observed. (CIR)
Allergens Patch Test: Human skin single insult occlusive patch tests of substance in 15% and 30% concentration and a fragrance preparation containing 19.0% was conducted. There was no evidence of skin irritation. In another studies, two sunscreen formulations containing 5% of the substance was tested in cumulative occlusive patch test. There was no skin irritation observed. (CIR)
Carcinogenicity: The substance was associated with few brain tumors in mice. (CIR)

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



IDENTIFICATION
Propylene Glycol Dicaprylate/Dicaprate (Emollient)
EU INCI: Propylene Glycol Dicaprylate/Dicaprate.
CTFA INCI: Propylene Glycol Dicaprylate/Dicaprate.
CAS Number: 68583-51-7(58748-27-9)68988-72-7.
EINECS Number: 271-516-3.
Symbol: C21H44O6.
Molecular Weight: 392.6.
Description: Decanoic acid, mixed diesters with octanoic acid and propylene glycol

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Odourless
Viscosity: 11.2 mm²/s at 20 °C and 6.2 mm²/s at 40 °C
Water Solubility: < 0.05 mg/L at 20 °C, pH 5.6-7.4
Boiling Point: 342 °C at ca. 1010 hPa
Colour: Light yellow
Flash Point: 185 °C at ca. 1013 hPa
Vapour Pressure: < 0.001 Pa at 20 °C
LogP Log Kow: 5.21
Melting Point: <-40 °C at ca. 1013 hPa
Physical State: Liquid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV)
GHS Classification: Not classified as per GHS.
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

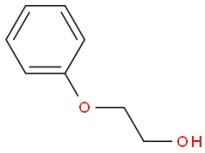
TOXICITY REVIEW
General Toxicity Review: Propylene Glycol Dicaprylate/Dicaprate is well known as emollient. When it comes to local toxicity the chemical does not induce or elicit skin allergy. Data derived from animal studies demonstrate that the substance is not irritating to the skin and eyes. It shows low acute toxicity with LD50 well above 2000 mg/kg bw in both dermal and oral exposure. It also has low chronic toxicity where oral systematic exposure is considered. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is not considered to be of toxicological concern when used in consumer products.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as not irritating. (ECHA)
LD50: LD50 (oral, rat) > 2 000 mg/kg bw; EU Method B.1 (Acute Toxicity (Oral)); Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity of the substance. LD50 (dermal, rat) > 2 000 mg/kg bw; EU Method B.3 (Acute Toxicity (Dermal)); Description: Acute toxicity studies via dermal route of exposure in rats (occlusive type of coverage) showed that the substance has low skin toxicity. (ECHA)
NOAEL Oral: NOAEL 1 000 mg/kg bw/day Study type: repeated dose toxicity; Endpoint:sub-chronic toxicity: oral; Guideline:OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity Study in Rodents); Species:rat; Report date:1993; SOurce: ECHA, MoS was calculated based on this data
Skin Irritation: In the in vivo studies on rabbits with semiocclusive coverage the substance was found to be not irritating and not corrosive. (ECHA)
Skin Sensitisation: Non-LLNA in vivo examinations were conducted, using guinea pig maximisation test, to find evidence for skin sensitisation. The test results showed that the chemical is non-sensitising. (ECHA)
Carcinogenicity: Not associated with carcinogenic, mutagenic and reprotoxic (CMR) chemicals.

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Phenoxyethanol (Preservative,Antimicrobial)
EU INCI: Phenoxyethanol.
CTFA INCI: Phenoxyethanol.
CNDA INCI: Phenoxyethanol.
Chinese: 苯氧乙醇.
CAS Number: 122-99-6.
EINECS Number: 204-589-7.
Symbol: C8H10O2.
Molecular Weight: 138.169.
Description: Phenoxyethanol is a germicidal and germistatic glycol ether, phenol ether, and aromatic alcohol.
IUPAC Name: 2-Phenoxyethanol
Ph. Eur. Name: 2-Phenoxyethanol
Synonyms: 2-Phenoxyethanol, Phenoxyethanol,Ethylene glycol monophenyl ether



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Faint aromatic odour
pH: 5.5-7.0 (1% aqueous solution)
Specific Gravity: 1.1050g/cm3
Viscosity: < 100 cps @ 25oC
Water Solubility: 30 g/L (20 ºC)
Partial Coefficient logPow: 1.2 @ 23oC.
Boiling Point: 245.2 deg C @ 760.00mm Hg
Density: 4.8
Flammability: Flammable
Flash Point: 126°C at 1013 hPa
Vapour Pressure: 0.01 hPa at 20°C,0.18 hPa at 50°C
LogP Log Kow: 1.2 at 23°C
Melting Point: 9.1°C at 1013 hPa
Microbiological stability: Not susceptible to microbiological contamination
Physical State: Colorless, oily liquid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as: AcuteTox. 4 H302; STOT SE 3 H335; Eye Dam. 1 H318; ATE: oral: ATE = 1 394 mg/kg bw'
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
Regulatory Controls: Maximum concentration in ready for use preparation is 1.0%
GHS Classification: H302: Harmful if swallowed. H319: Causes serious eye irritation..
Region : Europe Type : Cosmetic Restriction : 1%
Region : UK Type : Cosmetic Restriction : 1%

TOXICITY REVIEW
General Toxicity Review: The chemical is a well-known preservative. The intrinsic properties of the chemical cause that the product is quite toxic when it comes to acute toxicity, also systematic toxicity is relatively high. Some grades of the chemical may be contaminated with carcinogenic materials such as 1,4-Dioxane and Ethylene oxide. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is not considered to be of toxicological concern when used at below the restricted level of 1% in ready for use preparations.

TOXICOLOGICAL PROFILE
AcuteToxicology: LD50 > 2000 mg/kg bw
Endocrine Effects: Not associated with endocrine effects.
Eye Irritation: Causes serious eye irritation it was from experimental study conducted according to OECD Guideline 405 (Acute Eye Irritation / Corrosion). The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies results in scoring the chemical as irritating to eyes (ECHA).0.1 ml of undiluted phenoxyethanol was applied to the one eye of 12 rabbits. Many adverse effects like erythema, edema, injected irides, and slight cornea opacities were noticed. The substance was classified as strong eye irritant under the conditions of the study (CIR).
Genotoxicity: In vitro: negative (S. typhimurium TA 1535, TA 1537, TA 98 and TA 100) In vivo: negative (mouse) ref. ECHA
Inhalation: May cause respiratory tract irritation.
LD50: LD50 (Oral, rats) 1840 mg/kg bw this was from a experimental study conducted according to OECD Guideline 401, Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity of the substance. (ECHA) LD50 (dermal, rabbit) > 2 214 mg/kg bw Description: Acute toxicity studies via dermal route of exposure in rabbits (occlusive type of coverage) showed that the substance has low skin toxicity. (ECHA) LD50 (dermal, rats male/female) 14391 mg/kg bw based on a publication Final report on safety assessment of phenoxyethanol. J. Am. Coll. Toxicol. 9(2): 259 -277 (1990)
Local Toxicity: Low local toxicity.
Mutagenicity: Not associated with mutagenic.
NOAEL Dermal: NOAEL 500 mg/kg/day. Study type Repeated dose toxicity. Endpoints: sub-chronic toxicity. Route of administration: dermal. Species: rabbit. Result: Remarks no effects were found in all tested doses apart from an observation of erythema and scaling of the skin (local effects). Methods: OECD Guideline 411 (Subchronic Dermal Toxicity: 90-Day Study). Report date: 1986. Source: ECHA. MoS was calculated based on this data.
NOAEL Inhalation: NOAEC 48.2 mg/m3. Study type: Repeated dose toxicity. Endpoints;short-term repeated dose toxicity. Route of administration: inhalation. Method: OECD Guideline 412 (Subacute Inhalation Toxicity: 28-Day Study). Species: Rats. Report date 2007. MoS was calculated based on this data.
NOAEL Oral: NOAEL 369 mg/kg bw/day (actual dose received) . Study type: Endpoints: sub-chronic toxicity. Route of administration: oral. Species: rat. Method OECD and GLP. Remark Decreased red blood cells and haemoglobin with increase of hyperplasia in kidney and urinary bladder. Report date: 2003 Source: ECHA. NOAEL 249 mg/kg bw (oral, rats) and 468 mg/kg bw (oral, mouse) . Study type Carcinogenicity. Method OECD 451 (Galaxy Surfactants Limited 2016). MoS was calculated based on this data.
Phototoxicity: Not associated with phototoxicity.
Precutaneous Absorption: 90%
Safety evaluation: SCCS (2016) concluded that the preservative is safe for all population including sensitive subpopulations such as pregnant women.
Skin Irritation: The substance was tested in vivo on rabbits to examine skin irritation with occlusive coverage. The substance was applied to dorsal area of the trunk. After 4h exposure, the substance was found to be not irritating (ECHA). Of 2736 patients patch-tested with 1% phenoxyethanol in petrolatum, none had signs of irritant or allergic reactions 2 and 4 days after application. Based on the results, the substance is not skin irritant (CIR).
Skin Sensitisation: Reported to cause contact eczema in a single test study (http://www.medscape.com/viewarticle/516045_4). Allergenic contact dermatitis could be a rare adverse effect in patients with a history of flexural eczema to an aqueous cream which contains 1% of the preservative. No allergic sensitisation was observed in patients without history of an adverse reaction to 2-phenoxyethanol (Journal of the American Collage of Toxicology, 1990). When tested using Guinea pig maximisation test (vehicle olive oil) and LLNA method was found to be not sensitising (ECHA). Phenoxyethanol was evaluated for sensitization potential in a modified repeated insult patch test using a panel of 138 male and female subjects. A 10% solution of phenoxyethanol in petrolatum was applied under an occlusive patch to the backs of the test subjects. No skin reaction were observed. In was concluded that the substance is not a skin sensitiser (CIR).
Allergens HRIPT: Repeated Insult Patch Test was conducted on 51 subjects aged 16-60. The substance in the concentration of 10% (in mineral oil) was applied to skin. The patches were applied 3 times per week for 3 weeks. After the rest time the challenge phase was applied to the induction site and previously untreated. 2 participants reported mild irritation after induction 3 and 5 respectively. The substance is considered to be non primary irritant. (CIR)
Allergens LLNAEC3: When tested using Guinea pig maximisation test (vehicle olive oil) and LLNA method was found to be not sensitising. (ECHA)
Allergens Patch Test: Patch test was conducted on 2736 participants using 1% solution of Phenoxyethanol in petrolatum. No irritations or allergic reaction were observed after 2 and 4 days after application. In a different study 1, 5 and 10% solutions of Phenoxyethanol in Petrolatum were used. The study involved 130 participants. No irritations and allergic reactions were observed. Allergic contact dermatitis can be only a rare event in sensitive patients. (CIR)
Carcinogenicity: Not associated with carcinogenic, mutagenic and reprotoxic (CMR) chemicals.

OTHER
Detergent Class: Preservative
LC50 (Environmental): Fish: LC50 fathead minnows (Pimephales promelas) 344 mg/L -96h; LC50 Danio rerio 154 mg/L - 96h; NOEC Pimephales promelas 23 mg/L - 34 days; Daphnia/aquatic invertebrates: LC50 Daphnia magna 488 mg/L – 48h; LC50 Chaetogammarus marinus 941 mg/L – 48h and 357 mg/L -96h; NOEC Daphnia magna 9.43 mg/L - 21 days; Algae: EC50 Desmodesmus subspicatus 100 mg/L -72h; EC10 or NOEC Desmodesmus subspicatus 46 mg/L – 72h (OECD 201 (BASF and DOW 2012); Microorganisms: EC10 or NOEC oxygen consumption of activated sludge 360 mg/L; EC10 of 410 mg/L and an EC50 of 1494 mg/L - Pseudomonas putida (ECHA)

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Citrus Nobilis Peel Oil (naturallythinking) (Masking,Skin Conditioning,Tonic,Perfuming)
EU INCI: Citrus Nobilis Peel Oil.
CTFA INCI: Citrus Nobilis Peel Oil.
Trade Name: Mandarin Oil Cold Pressed.
CAS Number: 8008-31-9(84929-38-4).
EINECS Number: - / 284-521-0.
Description: Citrus Nobilis Peel Oil is the oil expressed from the peel of the Mandarin, Citrus nobilis, Rutaceae

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Sweet, pleasant citrus, reminiscent of mandarin
Water Solubility: 2.6 - 93.066 mg/L at 25ºC
Boiling Point: 160 °C
Density: 0.851 g/cm3 at 20ºC
Flammability: Flammable liquid and vapour
Flash Point: 51 °C
Vapour Pressure: 208.7 Pa at 25 °C
LogP Log Kow: 4.38
Physical State: Liquid.

REGULATORY REQUIREMENTS
IFRA Standard: IFRA Categories 1, 2, 3, 4, 5A, 5B, 5C, 5D, 6, 7B, 8, 10B, 11B with maximum concentration 25.000%. IFRA Categories 7A, 9, 10A, 11A with maximum concentration 100.00%. IFRA Category 12 without restriction. (IFRA 49th Amendment).
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC (Annex XIV).
GHS Classification: H226: Flammable liquid and vapour. H304: May be fatal if swallowed and enters airways. H315: Causes skin irritation. H317: May cause an allergic skin reaction. H411: Toxic to aquatic life with long lasting effects. Self classified: H410 Very toxic to aquatic life with long lasting effects..
Region : Europe Type : Cosmetic Restriction : Allergens declaration as required. Prohibited Furocoumarines (e. g. trioxysalen (INN), 8-methoxypsoralen, 5-methoxypsoralen) except for normal contentin natural essences used.In sun protection and in bronzing products, furocoumarines shall be below 1 mg/kg
Region : UK Type : Cosmetic Restriction : Allergens declaration as required. Prohibited Furocoumarines (e. g. trioxysalen (INN), 8-methoxypsoralen, 5-methoxypsoralen) except for normal contentin natural essences used.In sun protection and in bronzing products, furocoumarines shall be below 1 mg/kg

TOXICITY REVIEW
General Toxicity Review: Citrus Nobilis Peel Oil is commonly used as cosmetic substance. When it comes to local toxicity the chemical is sensitising to the skin. Data derived from animal studies demonstrate that the substance is moderately irritating to the skin and not irritating to eyes. It shows low acute toxicity with LD50 above 5000 mg/kg bw in both oral and dermal exposure. It has low chronic toxicity where oral systematic exposure is considered. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is not considered to be of toxicological concern when used in consumer products.

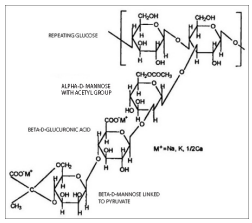
TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo to examine ocular irritation potential. Endpoint: The studies resulted in scoring the substance as non-irritating. Method: according to OECD Guideline 405 (Acute Eye Irritation / Corrosion) and EU Method B.5; Species: rabbits; Report date: 2003; Source: ECHA.
LD50: LD50 (oral, rat) > 5 000 mg/kg bw; Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity. Methods: OECD Guideline 401 (Acute Oral Toxicity), 1974 (ECHA). LD50 (dermal, rabbit) > 5 000 mg/kg bw; Description: Acute toxicity studies via dermal route of exposure in rabbits (occlusive type of coverage) showed that the substance has low skin toxicity. Methods: OECD Guideline 402 (Acute Dermal Toxicity), 1974 (ECHA).
NOAEL Oral: NOAEL 1 000 mg/kg bw/day Study type: Repeated dose toxicity. Endpoint: sub-chronic toxicity. Route of administration: oral. Species: dog. Methods: combination of rules from OECD Guidelines 409 and 452. Reference date 1975 (ECHA). MoS was calculated based on this data.
Skin Irritation: The substance was tested in vivo to examine skin irritation potential. Results: slight redness and edema was observed.. Endpoint: The substance was found to be moderately irritating to the skin. Method: test was conducted according to methods similar to OECD 402 (limit test) and was performed pre-GLP; Species: rabbits; Report date: 1973; Source: ECHA.
Skin Sensitisation: The substance was tested in vivo (LLNA) to examine skin sensitising potential. Endpoint: The substance was found to be sensitising. Method: Species: mouse; Report date: 2004; Source: ECHA.

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



IDENTIFICATION
Xanthan Gum (Binding,Emulsifying,Gel Forming,Skin Conditioning,Surfactant,Viscosity Controlling,Emulsion Stabilising)
EU INCI: Xanthan Gum.
CTFA INCI: Xanthan Gum.
CAS Number: 11138-66-2.
EINECS Number: 234-394-2.
Symbol: (C35H49O29)n.
Description: Xanthan gum is a polysaccharide, a sugar-based polymer produced by bacteria; it is used as a viscosity agent in personal care products and foods.
EINECS No.: 234-394-2
Ph. Eur. Name: gummi xanthanum
Synonyms: Corn Sugar Gum; Polysaccharide B 1459; Xanthan

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Characteristic
pH: 5.5-8.5 (1% solution at 25°C) (CIR)
Water Solubility: Soluble in water. Dissolves readily in water with stirring to give highly viscous solutions at low concentrations; completely solublein water, forming colloidal solution; readily soluble in hot or cold water to form neutral, viscous, and nonthixotropic solutions that have relatively high viscosity (CIR)
Particle Size: < 0,18 mm (95 %) and < 0,25 mm (99,5 %)
Colour: Creamy
Density: 650 - 850 kg/m3
Flammability: Non flammable
Melting Point: Decomposes without melting.
Microbiological stability: Total Plate Count max. 100/g ; E. coli negative/25 g ; Coliforms negative/25 g ; Salmonella negative/25 g ; Pseudomonas aeruginosa negative/g ; Staphylococcus aureus negative/g ; Enterococcus faecalis negative/g ; Molds max. 50/g ; Yeasts max. 50/g ;
Physical State: Solid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI.
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: Not classified as per GHS.
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: Xanthan gum is a sugar-based polymer produced by bacteria. It is well-known substance used as a viscosity agent in personal care products and foods. Data derived from animal studies demonstrate that the substance is not irritating to eyes and skin up to 1%. It is also non-sensitising. The substance shows low acute toxicity with LD50 above 5000 mg/kg (rats) and above 20 000 mg/kg (dogs) in oral route of exposure. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is not considered to be of toxicological concern when used in consumer products.

TOXICOLOGICAL PROFILE
Eye Irritation: Studies on rabbits were conducted to examine ocular irritation after application. The substance was found to be not irritating to eyes, up to 1%. (CIR)
Genotoxicity: In vitro: Xanthan gum did not show DNA-damaging activity when tested at 0.5 mg/disc in Bacillus subtilis (EFSA).
Inhalation: Prolonged dusts exposures may cause slight and temporary irritation to respiratory system.
LD50: LD50 (oral, rats) > 5000 mg/kg; LD50 (oral, dogs) > 20 000 mg/kg (International Journal of Toxicology, 2016). Description: Acute toxicity studies via oral route of administration in rats and dogs demonstrated low toxicity. LC50 >21 mg/L (inhalation, rabbits) (CIR)
ADI (Acceptable Daily Intake): 3 portions of the substance (150 mg/kg BW/d) was consumed by 5 participants in 23 days study. There was no hematology, clinical chemistry, or urinalysis parameters effects observed. (CIR)
NOAEL Oral: NOAEL 750 mg/kg bw. Study type Special studies in neonatal piglets. Source date 2017 (EFSA) NOEL 0.25 g/kg BW/d; Species: Beagle dogs (In diet, 12 weeks) (CIR)
Precutaneous Absorption: Based on the large molecular weight is not absorbed through the skin (CosmeticsInfo)
Reproductive Toxicology: Effects on fertility was measured using 0.5 g/kg/d of the test substance on rats. Fertility and developmental toxicity tests did not reveal any effect on reproduction (SDS).
Sensitisation via inhalation: Flu-like symptoms and/or hypersensitivity pneumonitis and chronic pulmonary effects were recorded in workplace.
Skin Irritation: The substance was tested on rabbits, using the occlusive patch test on intact and abraded skin. The substance was found to be not irritating the skin, up to concentration of 1%. One study was conducted on shaved rabbit skin with the use of 5% aqueous solution of the substance with daily application. The test results showed that the localised irritation was observed (CIR, 2012).
Skin Sensitisation: The studies on guinea pig were conducted, using injection intracutaneously of the 0.1% solution of the substance. The test results showed that the substance is non-sensitising. (CIR)
Carcinogenicity: Not associated with carcinogenic, mutagenic and reprotoxic (CMR) chemicals.

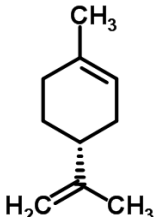
OTHER
Bioaccumulation (Environmental): Accumulation is not expected.
Biodegradability (Environmental): Readily biodegradable - Test: OECD 301
Ecological toxicity: The product has no known ecotoxicological effects.
LC50 (Environmental): LC50 (Oncorhynchus mykiss, 95h) = 420 mg/l, EC50/LC50 > 100 mg/l - aquatic species (calculated data).

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



IDENTIFICATION
d-Limonene ((R)-p-Mentha-1,8-diene; (4R)-1-Methyl-4-(1-methylethenyl)cyclohexene) (Perfuming,Masking)
EU INCI: Limonene.
CTFA INCI: Limonene.
CNDA INCI: Limonene.
CAS Number: 5989-27-5(68606-81-5)138-86-3.
EINECS Number: 227-813-5.
Symbol: C10H16.
Molecular Weight: 136.23 g/mol.
IUPAC Name: (4R)-1-methyl-4-(prop-1-en-2-yl)cyclohex-1-ene
Synonyms: (+)-Carvene / (+)-p-Mentha-1,8-diene / (R)-4-Isopropenyl-1-methyl-1-cyclohexene; p-Mentha-1,8-diene1-methyl-4-prop-1-en-2-ylcyclohexene; 1-Methyl-4-(1 1-Methyl-4-isopropenyl-1-cyclohexene; 4-Isopropenyl-1-methylcyclohexene; Cyclohexene, 1-methyl-4-(1-methylethenyl)-; Dipentene, (R)-(+)-Limonene.

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Viscosity: 0.846 mPa · s (dynamic) at 25 °C
Water Solubility: 5.69 mg/L at 25 °C
Boiling Point: 176 - 177 °C - lit.
Density: 0.844 at 20 °C
Flammability: Flammable liquid and vapour.
Flash Point: 50 °C
Vapour Pressure: 200 Pa at 25 °C
LogP Log Kow: 4.38 at 25 °C
Melting Point: -74 °C at 101325 Pa
Physical State: Liquid.

REGULATORY REQUIREMENTS
Labelling Requirements: The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products.
IFRA Standard: Fragrance ingredient specification: Oxidation products of Limonene, especially hydroperoxides, have been demonstrated tobe potent sensitizers.d-, l- and dl-Limonene and natural products containing substantial amounts of it, shouldonly be used when the level of (hydro)peroxides is kept to the lowest practical level, for instance by adding antioxidants at the time of production. The addition of 0.1%BHT or α-Tocopherol for example has shown great efficiency. Such products should have a peroxide value of less than 20 millimoles per liter, determined according to the IFRA analytical method for the determination of the peroxide value, which can be downloaded from the IFRA website (www.ifrafragrance.org). Flavour requirements: Due to the possible ingestion of small amounts of fragrance ingredients from their use in products in Categories 1 and 6, materials must not only comply with IFRA Standards but must also be recognized as safe as a flavoring ingredient as defined by the IOFI Code of Practice (www.iofi.org). For more details see chapter 1 of the Guidance for the use of IFRA Standards. Implementation date: Not applicable Publication date: 1995 (Amendment 29)
CLP Regulation (EC) No 1272/2008: Classified as: (cas 138-86-3) Flam. Liq. 3, H226; Skin Irrit. 2, H315; Skin Sens. 1, H317; Aquatic Acute 1, H400; Aquatic Chronic 1, H410. (cas 5989-27-5) Flam. Liq. 3 H226; Skin Irrit. 2 H315; Skin Sens. 1B H317; Asp. Tox. 1 H304; Aquatic Acute 1 H400; Aquatic Chronic 3 H412; M-factor: M = 1'
REACH Annex XVII: Not listed in the Annex XVII
REACH SVHC: Not included in SVHC list (Annex XIV).
Regulatory Controls: The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)g when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products. Proposed restrictions as per the EC public consultation published on 18th March 2019; When its concentration exceeds: 0,001 % in leave-on products and 0,01 % in rinse-off products the presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g).
GHS Classification: H226: Flammable liquid and vapour. H304: May be fatal if swallowed and enters airways. H315: Causes skin irritation. H317: May cause an allergic skin reaction. H400: Very toxic to aquatic life. H412: Harmful to aquatic life with long lasting effects..
Region : Europe Type : Cosmetic Restriction : Peroxide value less than 20 mmoles/L This limit applies to the substance and not to the finished cosmetic product. Label Review : The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products
Region : UK Type : Cosmetic Restriction : Peroxide value less than 20 mmoles/L This limit applies to the substance and not to the finished cosmetic product. Label Review : The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products

TOXICITY REVIEW
General Toxicity Review: Limonene is well known cosmetic allergen. The substance occurs in many fragrance compositions and Essential oils. It is known to be sensitising and irritating to the skin. Based on the animal testing results the substance may cause slight eye irritation. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is not considered to be of toxicological concern when used in consumer products under the condition that the concentration of the fragrance material does not exceed the considered safe level in finished products.

TOXICOLOGICAL PROFILE
AcuteToxicology: LD50 Oral - Rat - 4,400 mg/kg Remarks: Behavioral:Change in motor activity (specific assay). Respiratory disorder Skin and Appendages:Other: Hair LD50 Dermal - Rabbit - > 5,000 mg/kg
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as not irritating. However, Slight to moderate redness of conjunctivae was observed. Therefore the substance may cause slight eye irritation. (ECHA)
Genotoxicity: Negative in vitro gene mutation study in mammalian cells. (mouse lymphoma L5178Y cells) Negative in vivo mammalian cell study: DNA damage and/or repair. (rat) (ECHA)
LD50: LD50 (oral, rat) > 2 000 mg/kg bw; OECD Guideline 423 (Acute Oral toxicity - Acute Toxic Class Method); Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity of the substance. LD50 (dermal, rabbit) > 5 000 mg/kg bw; Description: Acute toxicity studies via dermal route of exposure in rabbits showed that the substance has low skin toxicity. (ECHA)
Mutagenicity: Non-mutagenic
NOAEL Oral: NOAEL 825 (male) and 1650 (female) mg/kg bw/day; Study type: Repeated dose toxicity; Endpoint:short-term repeated dose toxicity: oral; Guideline:OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity Study in Rodents); Species:rat; Source: ECHA, MoS was calculated based on this data
Reproductive Toxicology: NOAEL 500 mg/kg bw/day Study type: Toxicity to reproduction; Endpoint:reproductive toxicity, other; Guideline: OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents); Species:mouse; Source: ECHA
Skin Irritation: In the in vivo studies on rabbits with semiocclusive coverage the substance was found to be irritating. Erythema and oedema were observed in all animals. (ECHA)
Skin Sensitisation: LLNA in vivo examinations were conducted, using mouse local lymph node assay (LLNA) test, to find evidence for skin sensitisation. The test results showed that the chemical is sensitising. (ECHA)
Skin Sensitisation: Skin sensitiser. Various studies showed that not limonene itself but the common oxidation product of limonene called limonene hydroperoxide is the major cause of skin allergy.
Carcinogenicity: IARC Group 3 : The agent is not classifiable as to its carcinogenicity to humans.

OTHER
Hazard Class and Category Code(s): Skin Sens. 1
Hazard statement Code(s): H317
Biodegradability (Environmental): Biodegradation in water: screening test. Result: 71.4 % degradation (CO2 evolution) after 28 d. Conclusion: readily biodegradable (OECD Guideline 301 B) (ECHA)
LC50 (Environmental): Fish: LC50 Pimephales promelas (fathead minnow)720 µg/L - 96h (OECD Guideline 203); NOEC Pimephales promelas 0.37 mg/L - 8 days (OECD Guideline 212); Algae: Pseudokirchneriella subcapitata EC50 0.32 mg/L; NOEC 0.174 mg/L - 72h (OECD Guideline 201) (ECHA)

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Eugenia Caroyphyllus Bud Oil (naturallythinking) (Perfuming,Masking)
EU INCI: Eugenia Caroyphyllus Bud Oil.
CTFA INCI: Eugenia Caryophyllus (Clove) Bud Oil.
Trade Name: Clove Bud Oil.
CAS Number: 84961-50-2.
EINECS Number: 284-638-7.
Description: "Clove Oil". Eugenia Caryophyllus Bud Oil is an essential oil steam-distilled from the dried flower buds of the Clove, Syzygium aromaticum, syn. Eugenia caryophyllus, Myrtaceae. It contains eugenol (82-87% including about 10% acetyleugenol), caryophyllene

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Characteristic- spicy, eugenolic.
Colour: Yellow to light brown
Density: 1.027-1.065 at 20°C
Flammability: Non-flammable
Flash Point: >100°C
Physical State: Oil.

REGULATORY REQUIREMENTS
Labelling Requirements: Proposed from 2023: The presence of the substance shall be indicated as 'Eugenia Caryophyllus Oil' in the list of ingredients referred to in Article 19(1), point (g), when the concentration of the substance or substances exceeds:- 0,001 % in leave-on products- 0,01 % in rinse-off products..
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI. Fragrance composition contains hazardous substances classified as H317 - May cause an allergic skin reaction. Concerning the requirements of the CLP Regulation (Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures), the label on the packaging of mixtures that are not classified as sensitising but containing at least one substance classified as sensitising and present in a concentration equal to or greater than that specified in Annex I of the CLP shall bear the statement: 'Contains (name of sensitising substance). May produce an allergic reaction'.
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: Not classified as per GHS. Self classified: H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H304 May be fatal if swallowed and enters airways..
Region : Europe Type : Cosmetic Restriction : Allergens declaration as required Label Review : Proposed from 2023: The presence of the substance shall be indicated as 'Eugenia Caryophyllus Oil' in the list of ingredients referred to in Article 19(1), point (g), when the concentration of the substance or substances exceeds:- 0,001 % in leave-on products- 0,01 % in rinse-off products.
Region : UK Type : Cosmetic Restriction : Allergens declaration as required.

TOXICITY REVIEW
General Toxicity Review: Eugenia Caryophyllus (Clove) Bud Oil is an masking and perfuming ingredient. It may cause an allergic skin reaction, causes serious eye irritation. The substance is not associated with skin irritation. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is considered to be safe when used as intended.

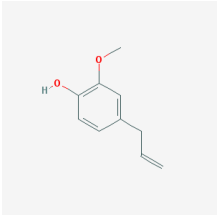
TOXICOLOGICAL PROFILE
Eye Irritation: May have reversible effects on the eyes.
NOAEL Oral: The NOAELs were not available in order to review however based on a history of safe use in consumer products this material is considered safe when used as intended. In conclusion, at the given concentration in the final product, the ingredient is not considered to be of toxicological concern when used as intended.
Skin Irritation: Based on the available toxicological data there is no evidence of skin irritation potential.
Skin Sensitisation: May cause an allergic reaction by skin contact.
Carcinogenicity: Not classifiable as to its carcinogenicity to humans.

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



IDENTIFICATION
Eugenol (Denaturant,Perfuming,Tonic)
EU INCI: Eugenol.
CTFA INCI: Eugenol.
CAS Number: 97-53-0.
EINECS Number: 202-589-1.
Symbol: C10H12O2.
Molecular Weight: 164.204 .
IUPAC Name: 2-methoxy-4-(prop-2-en-1-yl)phenol

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Strong odour of clove
Oxidising Properties: No oxidising properties
Viscosity: 8.39 mPa s at 25°C
Water Solubility: 1 154 mg/L at 20 °C
Partial Coefficient logPow: 1.83 at 30 °C
Boiling Point: 248 °C at 101325 Pa
Colour: Colourless or pale yellow
Density: 1.068 at 20°C
Flash Point: 124 °C at 101325 Pa
Vapour Pressure: 0.04 hPa at 25 °C
LogP Log Kow: 1.83 at 30 °C
Melting Point: -7.5°C at 101325 Pa
Physical State: Liquid.

REGULATORY REQUIREMENTS
Labelling Requirements: The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)g when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products.
IFRA Standard: INTRINSIC PROPERTY DRIVING RISK MANAGEMENT: DERMAL SENSITIZATION AND SYSTEMIC TOXICITY. FLAVOR REQUIREMENTS: Due to the possible ingestion of small amounts of fragrance ingredients from their use in products in Categories 1 and 6, materials must not only comply with IFRA Standards but must also be recognized as safe as a flavoring ingredient as defined by the IOFI Code of Practice (www.iofi.org). For more details see chapter 1 of the Guidance for the use of IFRA Standards. RESTRICTION LIMITS IN THE FINISHED PRODUCT (%): Category 1 0.45 %; Category 2 0.14 %; Category 3 1.4 %; Category 4 2.5 %; Category 5A 0.64 %; Category 5B 0.64 %; Category 5C 0.64 %; Category 5D 0.21 %; Category 6 0.64 %; Category 7A 1.4 %; Category 7B 1.4 %; Category 8 0.21 %; Category 9 4.9 %; Category 10A 4.9 %; Category 10B 18 %; Category 11A 0.21 %; Category 11B 0.21 %; Category 12 No Restriction. Implementation dates: For new submissions February 10, 2021; For existing fragrance compounds February 10, 2022. Publication date 2020 (Amendment 49)
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI. Proposed harmonised classification (ECHA CLH): Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1A, H317; STOT SE 3, H336; Aquatic Chronic 2, H411
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
Regulatory Controls: The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)g when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products. Proposed restrictions as per the EC public consultation published on 18th March 2019; When its concentration exceeds: 0,001 % in leave-on products and 0,01 % in rinse-off products the presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g).
GHS Classification: H319: Causes serious eye irritation. H317: May cause an allergic skin reaction. Self classified: H304: May be fatal if swallowed and enters airways..
Region : Europe Type : Cosmetic Restriction : Allergen declaration as required Label Review : The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)g when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products
Region : UK Type : Cosmetic Restriction : Allergen declaration as required Label Review : The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)g when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products

TOXICITY REVIEW
General Toxicity Review: The in vivo studies indicated that the substance is irritating to eyes and causes serious adverse, irreversible reactions. It has potential to cause skin irritation and sensitisation. Eugenol shows moderate acute toxicity with LD50 above 1 500 mg/kg bw via oral route of administration. Repeated dose toxicity was evaluated and NOAEL oral was determined at 600 mg/kg bw/day. Reproductive toxicology study indicated NOAEL at 230 mg/kg bw/day. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is not considered to be of toxicological concern when used in consumer products under the condition that the concentration of the fragrance material does not exceed the considered safe level in finished products.

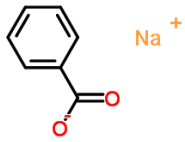
TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as irritating and causing serious adverse reactions, no reversibility was observed 7 days after exposure. (ECHA)
Genotoxicity: Negative in vitro DNA damage and/or repair study and in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus (ECHA); In vitro: negative (Salmonella typhimurium strains TA98, TA100, TA1535, TA1537, TA1538 and Escherichia coli WP2). In vivo: negative (rat). (ECHA)
LD50: LD50 (oral, mouse) > 1 500 - < 3 000 mg/kg bw; OECD Guideline 423 (Acute Oral toxicity - Acute Toxic Class Method); Description: Acute toxicity studies via oral route of administration in mice demonstrated slight toxicity of the substance. (ECHA)
Mutagenicity: Non-mutagenic
NOAEL Dermal: NOEL 5906 µg/cm2. Study type Human date. Source and date RIFM 2007; Mos was calculated based on this data
NOAEL Oral: NOAEL 600 mg/kg bw. Study type Repeated dose toxicity. Endpoint sub-chronic toxicity. Method OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents). Species:rat; Report date 1983; Source: ECHA; MoS was calculated based on this data
Reproductive Toxicology: NOAEL 230 mg/kg bw/day; Study type: Toxicity to reproduction; Endpoint: two-generation reproductive toxicity; Species:rat; OECD Guideline 416 (Two-Generation Reproduction Toxicity Study); Source: ECHA
Skin Irritation: In the in vivo studies on rabbits with semiocclusive coverage the substance was found to have potential to skin irritation, erythema and oedema were observed during the study (ECHA)
Skin Sensitisation: LLNA in vivo examinations were conducted, using mouse local lymph node assay (LLNA), to find evidence for skin sensitisation. The test results showed that the chemical is sensitising. (ECHA)
Carcinogenicity: No evidence of carcinogenic potential

OTHER
Biodegradability (Environmental): Biodegradation in water: 50% degradation after 7 days; 82% by the end of the study. Conclusion: readily biodegradable (EU Method C.4-E) (ECHA)
LC50 (Environmental): Fish: LC50 Danio rerio 13 mg/L - 96h (OECD Guideline 203); Algae: EC50 Desmodesmus subspicatus 24 mg/L - 72h; EC10 or NOEC 23 mg/L - Desmodesmus subspicatus (OECD Guideline 201) (ECHA)

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Sodium Benzoate (Anticorrosive,Masking,Preservative)
EU INCI: Sodium Benzoate.
CTFA INCI: Sodium Benzoate.
CNDA INCI: Sodium Benzoate.
CAS Number: 532-32-1.
EINECS Number: 208-534-8.
Symbol: C7H5NaO2.
Molecular Weight: 144.1 g/mol.
Description: Sodium Benzoate is a salt of Benzoic Acid (MW 122.12 g/mol).
Synonyms: Benzoic acid and its sodium salt



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Odourless
Oxidising Properties: No oxidizing properties.
pH: 7.0 - 8.5 at 144.1 g/l at 25 °C (77 °F)
Water Solubility: ca.144.1 g/l at 20 °C (68 °F)
Partial Coefficient logPow: -2.27
Oxidising Properties: No oxidising properties
Boiling Point: Substance decomposes between 450-475℃, has no boiling temperature
Particle Size: Particles size>or=100 micrometers
Colour: White
Density: 1.5 at 20℃
Flammability: Non flammable.
Flash Point: > 100 °C (> 212 °F)
Vapour Pressure: < 0.01 hPa (< 0.01 mmHg) at 20 °C (68 °F)
LogP Log Kow: 1.88
Melting Point: 436 °C
Microbiological stability: Not susceptible to microbiological contamination.
Physical State: Powder.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI.
REACH Annex XVII: Not listed in Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: H319: Causes serious eye irritation..
Region : Europe Type : Cosmetic Restriction : a) Rinse-off products, except oral care products: 2.5% (acid) b) Oral care products: 1.7% (acid) c) Leave-on products 0.5% (acid)
Region : UK Type : Cosmetic Restriction : a) Rinse-off products, except oral care products: 2.5% (acid) b) Oral care products: 1.7% (acid) c) Leave-on products 0.5% (acid)

TOXICITY REVIEW
General Toxicity Review: The chemical is a well-known preservative. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Following the restrictions in rinse-off products, except oral care products the maximum concentration should be equal 2.5% (acid), in oral care products: 1.7% (acid) and in leave-on products 0.5% (acid). It shows low acute toxicity with LD50 equal 3 140 mg/kg bw in oral route of exposure. The substance is not a skin irritant but may cause serious eye irritation. Studies on humans showed positive reactions in some of the participants. However, the substance is not classified as skin sensitiser or skin irritant. It shows low chronic toxicity where oral exposure is considered. Overall, the ingredient is not considered to be of toxicological concern when used at below the restricted level.

TOXICOLOGICAL PROFILE
Endocrine Effects: No endocrine effects are known from using this material in cosmetics.
Eye Irritation: According to the GHS classification the substance causes serious eye irritation.(ECHA) The substance was tested in vivo (rabbits) to examine ocular irritation after application according to OECD Guideline 405. The study resulted in scoring the chemical as slightly irritating to eyes (ECHA) According to the OECD SIDS initial assessment report, sodium benzoate (concentration not stated) was only slightly irritating to eyes (CIR).
Genotoxicity: In vitro: negative (S. typhimurium TA 1535, TA 1537, TA 98 and TA 100), In vivo: negative (rat) (ECHA).
Inhalation: Unlikely to be absorbed via respiratory epithelium due to its hydrophilic character (logPow 1.88).
LD50: Acute oral toxicity of the substance was tested according to guideline 84/449/EEC on rats. The median lethal dose was found to be LD50 = 3 140 mg/kg bw. Acute toxicity studies via oral route of administration in rats demonstrated low toxicity. (SCCS) LD50 (Dermal, rabbit) > 2 000 mg/kg bw (ECHA) Acute toxicity via inhalation was evaluated in fixed concentration procedure type of study, on rats with exposure duration of 4h. LC50 was found to be > 12 200 mg/m3 air. (rats, 1974) ref. ECHA
NOAEL Dermal: NOAEL 2500 mg/kg bw. Study type Repeated dose toxicity. Duration short a 28-day study. Species Rabbits. Method EPA OPP 82-2 (Repeated Dose Dermal Toxicity -21/28 Days). Remark slight dermal irritation (Report date 1981).
NOAEL Inhalation: NOAEL 250 mg/m3 for systemic effect (remark decreased body weight, kidney and lung reported). NOAEC 25 mg/cm3 for local effects (remark nasal redness and irritation). Study type Repeated dose toxicity. Duration short 28-day. Method OECD Guideline 412. Species Rats (Study date 1980).
NOAEL Oral: NOAEL 1000 mg/kg bw. Study type: repeated dose toxicity; Endpoint:chronic toxicity: oral; Species:rat; Report date:1979; Source: ECHA; MoS was calculated based on this data. NOAEL 1,400 mg/kg/day Species: rats (CIR)
Reproductive Toxicology: NOEL > 50 000 ppm Study type; Toxicity to reproduction. Endpoints; reproductive toxicity, other. Route of administration: oral. Species; rat. Methods; GLP Compliance confirmed in NTP TR 431. Report date; 1993. Source; ECHA. (read across). Sodium benzoate was tested for reproductive toxicity on mice, rats, hamsters and rabbits. The highest NOEL values: 175 - 300 mg/kg bw, (SCCP)
Skin Irritation: This substance was tested according to OECD test Guideline 404 on rabbits in semi-occlusie in vivo test (ECHA). Studies on rabbits were conducted to find evidence of skin irritation potential of the substance. The substance was found slightly skin irritating and not irritating (CIR). Studies of 0.5 g sodium benzoate moistened with 0.25 ml Milli-RO water were conducted on New Zealand albino rabbit. The substance was found not irritating and not corrosive. (CIR) Sodium benzoate in a concentration 2.35% (part of the formulation of dish washing and hand celaning product) was used in a 28-days use test. The study involved 24 healthy volunteers and 25 volunteers with dry skin. The study involved 49 participants, 4 of them had skin irritation after the 28 days application. (SCCNFP)
Skin Sensitisation: The substance was tested in order to evaluate its sensitising potential in an in vivo LLNA test. The substance was found to be non-sensitising by skin contact in LLNa test - equivalent or similar to OECD test guideline 429 carried on mice (ECHA). Occupational exposure to sodium benzoate has not resulted in skin sensitisation over a period of decades (CIR).
Allergens LLNAEC3: In vivo examinations using mouse LLNA test, to assess skin sensitisation potential. Endpoint: not sensitising; Method: according to OECD Guideline 429; Species: mouse; Report date: 1991; Source: ECHA.
Allergens Patch Test: Sodium benzoate showed positive reactions in 1.9% of the participants of the dermatological studies including 465 volunteers. (CIR) Case reports: Positive patch test reaction to 5% sodium benzoate on days 2 and 4; negative patch test results at inter digital area at 2 months on 64-year-old female with erythema and edema of finger. (CIR) There were two patch test conducted. The first one resulted in 5 positive skin reactions form 2045 subjects. The second showed positive non immunologic contact urticaria. (SCCS)
Carcinogenicity: Not associated with carcinogenic, mutagenic, or toxic for reproduction (CMR) materials. The substance in a 2% concentration was used in a carcinogenicity study on mice. The daily intake was approx. 5.95 - 6.2 g/kg bw/d. According to the testing results there was no indication of carcinogenic potential of teh substance. (SCCP)

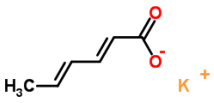
OTHER
Biodegradability (Environmental): Biodegradation in water. Results: 75% degradation of ThOD after 30 days. (Richterich, 1989); 85-92% degradation (CO_2-evolution) after 10 days (Kravetz, 1991). Conclusion: readily biodegradable. (ECHA)
LC50 (Environmental): LC50 Pimephales promelas - 484 mg/L- 96h (EPA OPP 72-1); LC50 Pimephales promelas, >100 mg/L, 96h (similar to OECD 203); EC50 Pseudokirchnerella subcapitata, >30.5 mg/l, 72h; EC10 Pseudokirchnerella subcapitata, 6.5 mg/l , 72h, NOEC 0.09 mg/L (OECD 201) (ECHA)

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Potassium Sorbate (Preservative)
EU INCI: Potassium Sorbate.
CTFA INCI: Potassium Sorbate.
CNDA INCI: Potassium Sorbate.
CAS Number: 24634-61-5(590-00-1).
EINECS Number: 246-376-1.
Symbol: C6H7KO2.
Molecular Weight: 150.22 g/mol.
Description: Potassium sorbate is a potassium salt of sorbic acid, a naturally occuring antimicrobial compound.
EINECS No.: 246-376-1
Synonyms: Potassium (2E,4E)-hexa-2,4-dienoate, E202Sorbistat-KSorbistat potassium



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
pH: 8.0 - 11.0 at 580 g/l at 20 °C (68 °F)
Viscosity: >= 17.4 - <= 19.3 at 20°C
Water Solubility: pH 4: 1,96 g/l at 20°C
Partial Coefficient logPow: 4.7
Density: Relative density at 20°C: 1.36
Flammability: The flammability test was conducted according to the provisions of Method A.10 (Council Directive 92/69/EEC). According to this test, the substance is not flammable (ECHA).
Vapour Pressure: <10-5 Pa at 25°C
Melting Point: 250 °C at 101 325 Pa
Microbiological stability: Not susceptible to microbiological contamination.
Physical State: Crystalline powder.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as: Eye Irrit. 2, H319.
REACH Annex XVII: Not listed in Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: H319: Causes serious eye irritation..
Region : Europe Type : Cosmetic Restriction : 0.6 % (acid)
Region : UK Type : Cosmetic Restriction : 0.6 % (acid)

TOXICITY REVIEW
General Toxicity Review: Potassium sorbate is a potassium salt of sorbic acid, a naturally occuring antimicrobial compound. It is well absorbed after oral administration and well distributed in the body. The substance is not associated with the skin sensitisation and skin irritation. However, it may cause serious eye irritation. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is not considered to be of toxicological concern when used at below the restricted level: 0.6 % (acid)

TOXICOLOGICAL PROFILE
Endocrine Effects: The chemical material does not have Endocrine disruptors (ED) properties.
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The test results showed that the substance cause serious eye irritation (ECHA). Potassium sorbate in concentrations 1, 5, and 10% (aqueus solutions), was tested on rabbits. The substance was not irritating to eyes. Formulations with 0.015% of the substance were not irritating to eyes (CIR).
Genotoxicity: In vitro: negative (S. typhimurium TA 1535, TA 1537, TA 98 and TA 100), In vivo: negative (mouse) (ECHA)
LD50: LD50 (oral, rat) 10 500 mg/kg bw; Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity of the substance. LD50 (dermal, rat) > 2 000 mg/kg bw; OECD Guideline 402 (Acute Dermal Toxicity); Description: Acute toxicity studies via dermal route of exposure in rats (semiocclusive type of coverage) showed that the substance has low skin toxicity. (ECHA)
NOAEL Oral: NOAEL 750 mg/kg bw. Repeated dose toxicity study (2 years) performed on male and female rats (Report date 2011).
Phototoxicity: Not a photo-toxic.
Precutaneous Absorption: 25%
Skin Irritation: In vivo studies on rabbits with semiocclusive coverage were conducted. The substance was found to be not irritating. However, slightly erythema and oedema were observed but the skin response disappeared 72 hours after patch removal (ECHA). Potassium sorbate irritating potential (in aqueous solution) was evaluated at concentrations of 1, 5, and 10% (pH not specified) on three rabbits under the semi-occlusive type of coverage. The test substance cause practically no dermal irritation and were well tolerated under these conditions (CIR). Draize test according to OECD guidelines 404 of 3333 mg/ml potassium sorbate in 0,9% aqueous NaCl was conducted on 3 albino New Zealand rabbits. There was no evidence of skin irritation. (CIR)
Skin Sensitisation: In vivo non- LLNA examinations were conducted, using guinea pig maximisation test to find evidence for skin sensitisation. The test results showed that the substance is not sensitising (ECHA).
Allergens HRIPT: Potassium sorbate used in a cosmetic formulations was used (0.15%) in a few HRIPT studies. The number of volunteers each study was about 200. The substance when used in a cosmetic formulation was scored as not irritating and not sensitising. (CIR)
Allergens MaximisationTest: In several cumulative irritation tests of cosmetic products containing 0.15% of the substance, there were very mild cumulative irritation effects observed. (CIR)
Carcinogenicity: Not associated with carcinogenic, mutagenic, or toxic for reproduction (CMR) materials.

OTHER
Bioaccumulation (Environmental): There is a low potential to bioaccumulate in aquatic and terrestrial ecosystems of the substance (ECHA).
Biodegradability (Environmental): Biodegradation in water. Results: reaching the pass-level of 60% after 10 days (the ten-day window). Conclusion: readily biodegradable. (ECHA).
Ecological toxicity: Short-term toxicity to aquatic invertebrates was evaluated in 48h tests on Daphnia magma as test organism. Effect concentration was determined: EC50 = 982 mg/L ref. ECHA
LC50 (Environmental): Short-term toxicity to fish was evaluated in 96h, static test conditions, on zebra fish. The median lethal dose was determined: LC50 > 500 mg/L ref. ECHA; LC50 Zebra fish, >500 mg/L, 96 hours; ECr50 Scenesdesmus subspicatu, 480 mg/l, 48 hours; NOEC Scenedesmus subspicatus, 97 mg/l, 48 hours (ECHA)

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Aloe Barbadensis Leaf Juice Powder (Skin Conditioning)
EU INCI: Aloe Barbadensis Leaf Juice Powder.
CTFA INCI: Aloe Barbadensis Leaf Juice Powder.
CNDA INCI: Aloe Barbadensis Leaf Juice Powder.
CAS Number: 85507-69-3(94349-62-9).
EINECS Number: 287-390-8 / 305-181-2.
Description: Aloe Barbadensis Leaf Juice Powder is the powder obtained from the dried juice leaves of the aloe, Aloe barbadensis, Liliaceae
Synonyms: Aloe Barbadensis Leaf Juice Powder; Aloe Vera Leaf Juice Powder; Aloe vera extracts; Aloe vera powder, Freeze Dried Aloe Vera Juice Powder 200X

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
pH: 3.5 - 5.0
Specific Gravity: 0.997 - 1.004
Water Solubility: Insoluble in cold water.
Boiling Point: 310°C (590°F)
Colour: White to beige
Flammability: May be combustible at high temperature.
Flash Point: Closed cup: Higher than 93.3°C (200°F).
Microbiological stability: Total plate count <10 cfu/g, Yeast and mould <10 cfu/g, No pathogens present
Physical State: Powder.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI.
REACH Annex XVII: Not listed in the Annex XVII
REACH SVHC: Not included in SVHC list (Annex XIV).
Regulatory Controls: According to the PubMed publication, Int J Toxicol, 2007 (quote) "The Cosmetic Ingredient Review (CIR) Expert Panel advised the industry that the total polychlorobiphenyl (PCB)/pesticide contamination of any plant-derived cosmetic ingredient should be limited to not more than 40 ppm, with not more than 10 ppm for any specific residue and that limits were appropriate for the following impurities: arsenic (3 mg/kg maximum), heavy metals (20 mg/kg maximum), and lead (5 mg/kg maximum)" It is noted that the full composition of the fragrance and technical data haven't been disclosed and therefore the manufacture (responsible person) must ensure that the fragrance does not contain any materials which are prohibited or restricted for the intended use.The presence of the fragrance substances (allergens) must be indicated in the list of ingredients referred to in Article 19(1)g when its concentration exceeds: 0.001% in leave-on products 0.01% in rinse-off products (EC No 1223/2009).
GHS Classification: Not classified as per GHS.
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

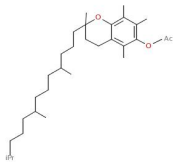
TOXICITY REVIEW
General Toxicity Review: The Aloe Barbadensis Leaf Juice Powder is commonly used as skin conditioning. There is no evidence of skin irritation or sensitisation potential. The material is in powder form and therefore may cause mechanical eye irritation. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is not considered to be of toxicological concern when used as intended.

TOXICOLOGICAL PROFILE
Eye Irritation: May cause a mechanical eye irritation - expert judgement.
Inhalation: May cause upper respiratory tract irritation - expert judgement.
NOAEL Oral: The NOAEL value was not found, however, based on a history of safe use, this chemical material is considered safe for use in cosmetics. The chemical is unlikely to produce systemic toxicity following skin contact. In conclusion, at the given concentration in the final product, the ingredient is not considered to be of toxicological concern when used as intended.
Skin Irritation: Based on the available toxicological data there is no evidence of skin irritation potential.
Skin Sensitisation: Based on the available toxicological data there is no evidence of skin allergy potential.

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Tocopheryl Acetate (Antioxidant,Skin Conditioning)
EU INCI: Tocopheryl Acetate.
CTFA INCI: Tocopheryl Acetate.
CNDA INCI: Tocopheryl Acetate.
CAS Number: 7695-91-2(58-95-7).
EINECS Number: 231-710-0 / 200-405-4 .
Symbol: C31H52O3.
Molecular Weight: 472.75.
Description: Vitamin E Acetate



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Almost odourless
Oxidising Properties: No oxidising.
Viscosity: 5706 mm²/s (5 458 mPa · s) at 20°C
Water Solubility: < 0,8mg/l at 20°C
Boiling Point: 184°C (Expl.)
Colour: Colourless to amber
Density: 0.9±0.1g/cm3 (Cal.)
Flammability: Non flammable upon ignition at 225.5°C.
Flash Point: 235.6±24.7°C (Cal.)
Vapour Pressure: 1.4 mbar at 240C
LogP Log Kow: 12.26 at 25C
Melting Point: -28°C (Expl.)
Microbiological stability: Not susceptible to microbiological contamination
Physical State: Liquid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI.
REACH Annex XVII: Listed in Annex XVII: Exemptions from the obligation to register in accordance with Article 2(7)(a).
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: Not classified as per GHS.
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: Tocopheryl Acetate is commonly used as antioxidant and skin conditioning agent. It is reported to cause contact dermatitis. Studies shown that it is not irritating to eyes and skin. It shows low acute toxicity with LD50 above 10 000 mg/kg bw in oral exposure and above 3 000 mg/kg bw in dermal exposure. Repeated dose toxicity study indicated the NOAEL for toxicity to reproduction via oral route of exposure at 800 mg/kg bw/day. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is not considered to be of toxicological concern when used as intended.

TOXICOLOGICAL PROFILE
Endocrine Effects: No endocrine effects are known from using this material in cosmetics.
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The undiluted test substance was instilled into the right eye of each of three rabbits. Slight irritation was noted at 1-48 h; the eyes were normal at 72 h. The studies resulted in scoring the substance as non-irritating (ECHA). Undiluted tocopheryl acetate was instilled into the conjunctival sac of 3 Vienna white rabbits. The eyes were not rinsed. Slight irritation were observed. The results shows that tocopheryl acetate was not irritating to rabbit eyes in 1 study, but it produced weak-to-moderate conjunctival irritation in another study (CIR).
Genotoxicity: In vitro: negative (Chinese hamster ovary AS52 cells), In vivo: negative (mouse) (ECHA).
Inhalation: Vitamin E acetate may be responsible for vaping - related death (FDA Preliminary Lab Analysis, Feb 2020)
LD50: LD50 (oral, rat) > 10 000 mg/kg bw; Guideline:OECD Guideline 401 (Acute Oral Toxicity); Acute toxicity studies via oral route of administration in rats demonstrated that the substance is practically non toxic. ; LD50 (dermal, rat) > 3 000 mg/kg bw ; Guideline:OECD Guideline 402 (Acute Dermal Toxicity); Acute toxicity via dermal route in rats showed slight toxicity of the substance (ECHA)
Mutagenicity: No evidence of mutagenic potential.
NOAEL Oral: NOAEL 800 mg/kg bw. Study type Toxicity to reproduction (one-generation reproductive toxicity). Method OECD Guideline 415 (Publication date 1977). (ECHA) MoS was calculated based on this data; NOAEL 2000 mg/kg bw. Study type Carcinogenicity (Published date 1978); Study type; Repeated dose toxicity. Endpoints; chronic toxicity. Route of administration: oral. Species; rat. Methods; OECD Guideline 453 (Combined Chronic Toxicity / Carcinogenicity Studies). Report date; 1978 Source; ECHA.
Skin Irritation: In vivo studies on rabbits with semiocclusive coverage was conducted. Three Vienna White rabbits were applied the undiluted test substance for 4 hours. The test results showed that the substance is not irritating (ECHA). 0.5 mL undiluted substance was applied to a shaved area of 3 Vienna white rabbits. No erythema or edema was observed. In conclusion, the substance is not classified as skin irritating (CIR).
Skin Sensitisation: When tested on guinea pig it did not exhibit photoallergenic potential under the study conditions. Reported to cause contact dermatitis (http://contactallergy.com/contact_allergy_009.htm) however the ester of acetic acid and tocopherol (vitamin E) is rather rarely associated with skin allergy or sensitisation in majority of population by comparison with Tocopherol. 0.5 mL undiluted substance was applied to a shaved area of 3 Vienna white rabbits. No erythema or edema was observed. In conclusion, the substance is not classified as skin sensitising (CIR).
Allergens HRIPT: Lotion containing 0.1% of Tocopheryl Acetate was used in a RIPT study which included 110 volunteers. The substance was applied on the back skin 3 times per weeks for 3 weeks. After rest time challenge patch was applied to the previously untreated area. No irritation or sensitisation were observed during the study. In a different study 100% of Tocopheryl acetate was used. After 10 applications in the induction phase and challenge phase all the sensitisation readings were negative (203 subjects). Mild irritation was observed in some of the participants. (CIR)
Allergens Patch Test: Occlusive patch test of 100% dl-a-Tocopheryl Acetate and 1%, 5%, 20%, and 50% Tocopheryl Acetate in petrolatum on 8 subjects was conducted. The mean irritation indices, on a scale of 0 to 4, was 0 for 100% Tocopheryl Acetate and 0.312 dor 50% Tocopheryl Acetate. (CIR)
Carcinogenicity: Not associated with carcinogenic, mutagenic and reprotoxic (CMR) chemicals.

OTHER
Biodegradability (Environmental): Biodegradation in water. Result 17% degradation after 28 days of testing. Conclusion: moderately/partly biodegradable (ECHA)
LC50 (Environmental): Fish: LC50 Rainbow trout (Oncorhynchus mykiss) > 11 mg/l - 96h (OECD Guideline 203); LC50 Leuciscus idusa >10000 mg/l -96h (BASF AG, 1988) ; Algae: EC50 Selenastrum capricornutum > 27.8 mg/l - 72h (OECD Guideline 201) (ECHA)

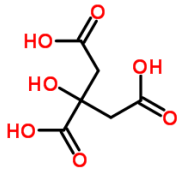
Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Citric Acid (Buffering, chelating, masking)
EU INCI: Citric Acid.
CTFA INCI: Citric Acid.
CNDA INCI: Citric Acid.
Chinese: 柠檬酸.
CAS Number: 77-92-9(5949-29-1).
EINECS Number: 201-069-1.
Symbol: C6H8O7.
Molecular Weight: 192.12 g/mol.
Description: Weak organic acid naturally occurring in citrus fruits.
EINECS No.: 201-069-1
IUPAC Name: Citric acid
Synonyms: Citric acid anhydrous; 2-Hydroxy-1,2,3-propanetricarboxylic acid; 2-Hydroxytricarballylic acid



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Odourless
Oxidising Properties: Not oxidising
pH: 1.6 @ 100g/l
Water Solubility: 750 g/L (20 ºC). Solubility in water increases with temperature (from 54%, w/w at 10C to 84%)□(CIR)
Partial Coefficient logPow: -1.72
Oxidising Properties: Non oxidising
Boiling Point: Decomposes before boiling. Decomposes above 175C□(CIR)
Particle Size: The fraction below 100 µm was 84.1%; the D50 of the fraction below 100 µm was at 31.99 µm.
Colour: White
Density: 1.542, 1.665 at 20°C
Flammability: Non flammable
Flash Point: 100 ºC
Vapour Pressure: 0 Pa, <0.001 mm Hg (20C)□(CIR)
LogP Log Kow: -0.2 to -1.8
Melting Point: 153-154.5 ºC
Microbiological stability: Not susceptible to microbiological contamination
Physical State: Solid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as: Eye Irrit.2 H319; STOT SE3 H335.
REACH Annex XVII: Not listed in Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
Regulatory Controls: Recommended warnings by SCCNFP: Avoiding contact with the eyes - avoiding or affording to protect from UV whilst using products containing AHA because of the suggestion of susceptibility to increased damage from UV whilst cosmetic products containing them are being used.
GHS Classification: H319: Causes serious eye irritation. H335: May cause respiratory irritation..
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: Citric acid is commonly used as buffering, chelating and masking agent. The in vivo studies resulted in scoring the substance as mildly irritating to eyes at concentrations of 30%, causing mild to severe skin erythema and mild to moderate edema, when used as undiluted substance and non-sensitising. It shows low acute toxicity with LD50 5 400 mg/kg bw in oral and above 2 000 mg/kg bw in dermal exposure. The substance has NOAEL 4000 mg/kg bw. Repeated dose toxicity study via oral route of exposure indicated low potential for inducing significant toxicological effects. It was found weak positive reaction in genotoxicity studies. Overall, the ingredient is not considered to be of toxicological concern when used as intended.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vitro (rabbits) to examine ocular irritation. The substance was found to be minimally irritating to eyes at concentration up to a 10% and mildly irritating at concentrations of 30%. (ref. International Journal of Toxicology 2014) Several studies were performed. It was found that at a concentration of 10% the substance is minimally irritating, at a concentrations 30% it is mildly irritating. (CIR)
Genotoxicity: In vivo: negative (rat). In vitro: negative (S. typhimurium, other: TA 1535, TA 100, TA 98, TA 1537, TA92 and TA 94) (ECHA) In vivo: weak positive (Saccharomyces D3 mice) (CIR)
LD50: LD50 (oral, mouse) 5 400 mg/kg bw; Description: Acute toxicity studies via oral route of administration in mouse demonstrated low toxicity of the substance. LD50 (dermal, rat) > 2 000 mg/kg bw (OECD Guideline 402 (Acute Dermal Toxicity)) Description: Acute toxicity studies via dermal route of exposure in rats (semiocclusive type of coverage) showed that the substance has low skin toxicity (ECHA). LD50 (dermal, rabbits) >5 g/kg (CIR)
NOAEL Oral: NOAEL 4000 mg/kg bw. Study type Repeated dose toxicity. Endpoint repeated dose toxicity. Route of administration: oral. Species: rat. Methods: `In a non-standard study, unspecified groups of rats were treated by gavage for 10 successive days with a further 10 days observation. ` Report date 1978. Source: ECHA. MoS was calculated based on this data.
ADME (Absorption, Distribution, Metabolism, Excretion): The substance after oral administration is well absorbed and largely metabolised. It can be used as a source of energy. In Krebs cycle the substance completes the breakdown of pyruvate, approx. 2 kg is formed and metabolized in human per day. (CIR)
Skin Irritation: The studies on rabbits showed that the substance is irritating to the skin. The chemical caused mild to severe erythema and mild to moderate edema, when used as undiluted substance. Tests on humans indicated that citric acid is not a skin irritant at concentration up to 5% aqueous solution. (ref. International Journal of Toxicology 2014). The substance in concentration 30% was found not to be a primary irritant. In concentration 60% erythema and edema that subsided with time occured. When undiluted substance was tested mild to severe erythema and mild to moderate edema were observed. (CIR)
Skin Sensitisation: Studies using skin prick test (at concentration of 2.5% aq) were conducted to find evidence for skin sensitisation. Some positive reactions were observed when patients also reacted to benzoic and propionic acids. Additionally products containing up to 4% of citric acid, was also tested using semiocclusive patch tests. The substance was found to be non-sensitising. (ref. International Journal of Toxicology 2014)
Allergens HRIPT: Available repeated insult patch testing at the highest leave-on concentration of 4% citric acid demonstrated an absence of both dermal irritation and sensitization (ref. Safety Assessment of Citric Acid, Inorganic Citrate Salts, and Alkyl Citrate Esters as Used in Cosmetics)
Allergens Patch Test: Patch test of 1% aq of the substance (48h, occlusive) was conducted on 133 oral disease patients. There was no skin irritation or sensitisation observed. (CIR) Available repeated insult patch testing at the highest leave-on concentration of 4% citric acid demonstrated an absence of both dermal irritation and sensitization (ref. Safety Assessment of Citric Acid, Inorganic Citrate Salts, and Alkyl Citrate Esters as Used in Cosmetics) Skin prick test was conducted on patients with chronic urticaria or angioedema. There was positive skin reactions in 3 of 91 patients. (CIR)
Carcinogenicity: Not associated with carcinogenic, mutagenic and reprotoxic (CMR) chemicals.

OTHER
Detergent Class: Buffer
Bioaccumulation (Environmental): Predicted log BCF of 0.5 = 3.2 L/kg wet weight
Biodegradability (Environmental): Biodegradation in water: screening tests. OECD 301B (CO2 evolution test): 97% in 28 days, OECD 301E(Modified OECD screening test): 100% in 19 days, OECD 302B (Inherent biodegradability: Zahn-Wellens test): 85% in 14 days. Considered as readily biodegradable. Biodegradation in soil test does not need to be conducted as the substance is readily biodegradable. (ECHA)
LC50 (Environmental): LC50 values for the fish (Leuciscus idus and Pimephales promelas) were between >100 and 1000 mg/L; LC50 Leuciscus idus melanotus- 440 mg/l - 48h (equivalent to OECD 203); EC10 or NOEC S. quadricauda- 425 mg/L - 8 days (equivalent to OECD 201) (ECHA)

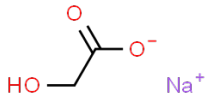
Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Sodium Glycolate (Buffering)
EU INCI: Sodium Glycolate.
CTFA INCI: Sodium Glycolate.
Trade Name: Sodium glycolate.
CAS Number: 2836-32-0.
EINECS Number: 220-624-9.
Symbol: C2H3NaO3.
Molecular Weight: 98.03.
Description: Glycolic acid, monosodium salt
Synonyms: Sodium hydroxyacetate; Sodium Hydroxyacetic Acid



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Characteristic
Water Solubility: Soluble in water
Partial Coefficient logPow: -5.19
Boiling Point: 265.6 °C
Colour: White
Density: 1.42 g/cm3
Flash Point: 128.7 °C
Melting Point: 210-218 °C
Physical State: Solid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI.
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: H315: Causes skin irritation. H319: Causes serious eye irritation. H335: May cause respiratory irritation..
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: The substance is not associated with skin sensitisation. Based on the available toxicological information, the substance causes skin irritation and serious eye irritation. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is not considered to be of toxicological concern when used in consumer products.

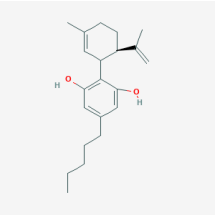
TOXICOLOGICAL PROFILE
Eye Irritation: Based on the CLP notifications provided by the companies to ECHA the substance is expected to cause serious eye irritation. May cause mechanical eye irritation as supplied.
Inhalation: May cause respiratory irritation. May cause upper respiratory track irritation when inhaled in the powder form - expert judgement.
LD50: LD50 (rat, oral) 7110 mg/kg
NOAEL Oral: The NOAEL value was not found, however, based on a history of safe use, this chemical material is considered safe for use in cosmetics. The chemical is unlikely to produce systemic toxicity following skin contact. In conclusion, at the given concentration in the final product, the ingredient is not considered to be of toxicological concern when used as intended.
Read-across: Not susceptible to microbiological contamination
Skin Irritation: Based on the CLP notifications provided by the companies to ECHA the substance is expected to cause skin irritation.
Skin Sensitisation: Based on the available toxicological data there is no evidence on skin sensitising potential. In a maximization study using guinea pigs topical application of 25% Sodium Glycolate showed no skin sensitisation effect. (CIR)
Carcinogenicity: Not associated with CMR materials.

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



IDENTIFICATION
Cannabidiol (CBD) (Antioxidant,Antiseborrhoeic,Skin Conditioning,Skin Protecting)
EU INCI: Cannabidiol - Derived from Extract of Tincture or Resin of Cannabis.
CAS Number: 13956-29-1.
Symbol: C21H30O2.
Molecular Weight: 314.469.
Description: Cannabidiol (CBD) derived from the hemp plant in its entirety
IUPAC Name: 2-[(1R,6R)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-5-pentylbenzene-1,3-diol
Synonyms: (-)-CBD; (-)-Cannabidiol; (-)-trans-Cannabidiol; CBD

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Negligible
Water Solubility: Insoluble in water
Colour: White, whitish to beige, slightly yellow
Flash Point: > 100°C
Melting Point: 69°C
Physical State: Solid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI.
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
Regulatory Controls: Cannabidiol (CBD) as such, irrespective of its source, is not listed in the Schedules of the 1961 Single Convention on Narcotic Drugs. However, it shall be prohibited from use in cosmetic products (II/306), if it is prepared as an extract or tincture or resin of Cannabis in accordance with the Single Convention. Please note that national legislations on controlled substances may also apply. As per European Court Cannabidiol (CBD) derived from the hemp plant in its entirety should not be prohibited by any of EU member state because it was not regarded as 'narcotic drug'. Cannabidiol (CBD) extracted from certain parts of the hemp plant like the leaves and stems had been permitted. CBD can be governed differently in each Member State. France prohibits CBD sourced from hemp flowers in cosmetics. Czech Republic permits CBD sourced from hemp flowers in cosmetics (February 2021). (THC) Prohibited if contains narcotics, natural and synthetic (e.g. delta-9-tetrahydrocannabinol)). According to Annex II of the European Regulation EC (No) 1223/2009 on cosmetic products narcotics, natural and synthetic cosmetic ingredients are prohibited. It is understood that Tetrahydrocannabinol (THC) is the psychoactive constituent of cannabis and therefore should not be present in raw materials for use in cosmetic products. Grades of hemp derivatives that contain more than 10 ppm of THC are considered not suitable for use in cosmetics. With regards to the CTPA (UK) position paper dated April 2019 THC is not allowed unless it is present as a trace element of the amount not more than 1mg in a product container'
GHS Classification: H302: Harmful if swallowed. H361: Suspected of damaging fertility or the unborn child. Self classified: H332 Harmful if inhaled. H336 May cause drowsiness or dizziness..
Region : Europe Type : Cosmetic Restriction : Permitted if derived from parts of the Cannabis like leaves and stems. Prohibited if contains narcotics, natural and synthetic (e.g. delta-9-tetrahydrocannabinol)). Prohibited if derived from hemp flower (France).
Region : UK Type : Cosmetic Restriction : Permitted if derived from parts of the Cannabis like leaves and stems. Prohibited if contains narcotics, natural and synthetic (e.g. delta-9-tetrahydrocannabinol)). Prohibited if derived from hemp flower (France).

TOXICITY REVIEW
General Toxicity Review: Cannabidiol is suspected of damaging fertility or the unborn child. Cannabidiol (CBD) as such, irrespective of its source, is not listed in the Schedules of the 1961 Single Convention on Narcotic Drugs. However, it shall be prohibited from use in cosmetic products (II/306), if it is prepared as an extract or tincture or resin of Cannabis in accordance with the Single Convention. It is also noted that national legislations on controlled substances may also apply. According to Annex II of the European Regulation EC (No) 1223/2009 on cosmetic products narcotics, natural and synthetic cosmetic ingredients are prohibited. It is understood that Tetrahydrocannabinol (THC) is the psychoactive constituent of cannabis and therefore should not be present either in raw materials for use in cosmetic products or finished products.Regarding various reference data, it is understood that grades of raw materials named Cannabidiol (CBD) or their derivatives that contain more than 10 ppm of THC are considered not suitable for use in cosmetics. With regards to the CTPA (UK) position paper dated April 2019, THC is not allowed unless it is present as a trace element of the amount not more than 1mg in a product container.

TOXICOLOGICAL PROFILE
Eye Irritation: May cause a mechanical eye irritation as supplied.
LD50: LD50 (Oral, rat) > 4400 mg/kg; LD50 (Dermal, rabbit) > 5000 mg/kg; (ref. SDS enecta)
NOAEL Oral: The NOAELs were not available in order to review however based on a history of safe use in consumer products this material is considered safe when used as intended. In conclusion, at the given concentration in the final product, the ingredient is not considered to be of toxicological concern when used as intended.
Safety evaluation: As per WHO paper Cannabidiol (CBD) is one of the naturally occurring cannabinoids found in cannabis plants, be converted to tetrahydrocannabinol (THC) under experimental conditions. There is no evidence of recreational use of CBD or any public health related problemsassociated with the use of pure CBD. Additionally , there is no substantive evidence as to whether (+)-CBD is likely to cause THC-like psychoactive effects (ref. 39th ECDD (2017) Agenda item 5.2)
Skin Irritation: Based on the available toxicological data there is no evidence of skin irritation potential.
Skin Sensitisation: Based on the available toxicological data there is no evidence of skin allergy potential.

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Nitrogen (Propellant)
EU INCI: Nitrogen.
CTFA INCI: Nitrogen.
CNDA INCI: Nitrogen.
CAS Number: 7727-37-9.
EINECS Number: 231-783-9.
Symbol: N2.
Molecular Weight: 28.014.
EINECS No.: 231-783-9
IUPAC Name: Nitrogen

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Odourless
Water Solubility: 18.1 mg/mL at 21 °C
Boiling Point: -195.79 °C
Particle Size: The non-solid or granular form does not require the particle size distribution study.
Colour: Colourless
Density: 1.251 g/L at 0 °C
Vapour Pressure: 1 Pa at -236 °C (solid); 10Pa at -232 °C (solid); 100Pa at -226.8 °C (solid); 1kPa at -220.2 °C (solid); 10kPa at -211.1 °C (solid); 100kPa at -195.9 °C (gas)
LogP Log Kow: 0.67
Melting Point: -210.01 °C
Physical State: Gas.

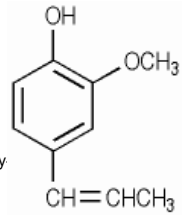
REGULATORY REQUIREMENTS
Labelling Requirements: Avoid direct inhalation. Do not use in confined spaces. (recommended).
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI.
REACH Annex XVII: Listed in Annex XVII as exemption from the obligation to register in accordance with Article 2(7)(a) (Annex IV).
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: H280: Contains gas under pressure; may explode if heated. H281: Contains refrigerated gas; may cause cryogenic burns or injury..
Region : Europe Type : Cosmetic Restriction : None Label Review : Avoid direct inhalation. Do not use in confined spaces. (recommended)
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: The Nitrogen is a colourless and odourless gas which is the main ingredient of the atmosphere. The substance is not considered to be toxic. Refrigerated Nitrogen may cause cryogenic burns or injury.

TOXICOLOGICAL PROFILE
Eye Irritation: Based on the available toxicological data there is no evidence of eye irritation potential.
Read-across: Not susceptible to microbiological contamination
Safety evaluation: Nitrogen, in its gas physical form, when released into an enclosed space can displace oxygen, and then lead to an asphyxiation hazard.Nitrogen, when inhaled at high partial pressures turn into an anaesthetic agent and causes nitrogen narcosis. This is a temporary state of mental impairment which is similar to nitrous oxide intoxication.
Skin Irritation: Based on the available toxicological data there is no evidence of skin irritation potential.
Skin Sensitisation: Based on the available toxicological data there is no evidence of skin allergy potential.
Carcinogenicity: Not associated with carcinogenic, mutagenic and reprotoxic (CMR) chemicals.

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



IDENTIFICATION
Isoeugenol (Flavouring,Perfuming)
EU INCI: Isoeugenol.
CTFA INCI: Isoeugenol.
CNDA INCI: Isoeugenol.
CAS Number: 97-54-1(5932-68-3).
EINECS Number: 202-590-7 / 227-678-2.
Symbol: C10H12O2.
Molecular Weight: 164.2 g/mol.
Synonyms: Phenol, 1-Methoxy-4-prop-1-enyl 4-Hydroxy-3-methoxy-1-propen-1-yl benzene 4-Propenylguaiacol 4-Hydroxy-3-methoxy-1-propenylbenzene, 3-Methoxy ylbenzene, 2-Methoxy-4-propenylphenol, 2-Methoxy-4-(1-propenyl)phenol, 1-Hydroxy-2-methoxy-4-propen-1-ylbenzene.

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Water Solubility: 700 - 810 mg/l
Boiling Point: 132 °C (270 °F) at 13 hPa (10 mmHg) - lit.
Colour: Yellow
Density: 1.081 - 1.087
Flash Point: 112 °C (234 °F) - closed cup
Vapour Pressure: 0.21 Pa at 25°C
LogP Log Kow: c. 2.1
Melting Point: 27.3°C
Physical State: Viscous liquid.

REGULATORY REQUIREMENTS
Labelling Requirements: The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products.
IFRA Standard: INTRINSIC PROPERTY DRIVING RISK MANAGEMENT: DERMAL SENSITIZATION AND SYSTEMIC TOXICITY. FLAVOR REQUIREMENTS: Due to the possible ingestion of small amounts of fragrance ingredients from their use in products in Categories 1 and 6, materials must not only comply with IFRA Standards but must also be recognized as safe as a flavoring ingredient as defined by the IOFI Code of Practice (www.iofi.org). For more details see chapter 1 of the Guidance for the use of IFRA Standards. RESTRICTION LIMITS IN THE FINISHED PRODUCT (%): Category 1 0.019 %; Category 2 0.0057 %; Category 3 0.12 %; Category 4 0.11 %; Category 5A 0.027 %; Category 5B 0.027 %; Category 5C 0.027 %; Category 5D 0.0090 %; Category 6 0.063 %; Category 7A 0.22 %; Category 7B 0.22 %; Category 8 0.0090 %; Category 9 0.21 %; Category 10A 0.21 %; Category 10B 0.75 %; Category 11A 0.0090 %; Category 11B 0.0090 %; Category 12 No Restriction. Implementation dates: For new submissions February 10, 2021; For existing fragrance compounds February 10, 2022. Publication date 2020 (Amendment 49)
CLP Regulation (EC) No 1272/2008: Classified as: Skin Sens. 1A H317.
REACH Annex XVII: Not listed in Annex XVII
REACH SVHC: Not included in SVHC list (Annex XIV)
Regulatory Controls: The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)g when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products. Proposed restrictions as per the EC public consultation published on 18th March 2019; When its concentration exceeds: 0,001 % in leave-on products and 0,01 % in rinse-off products the presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g).
GHS Classification: H317: May cause an allergic skin reaction. H302+H312+H332: Harmful if swallowed, in contact with skin or if inhaled. H315: Causes skin irritation. H319: Causes serious eye irritation. H335: May cause respiratory irritation..
Region : Europe Type : Cosmetic Restriction : 0.02% except oral products Label Review : The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products
Region : UK Type : Cosmetic Restriction : 0.02% except oral products Label Review : The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds: — 0,001 % in leave-on products — 0,01 % in rinse-off products

TOXICITY REVIEW
General Toxicity Review: Isoeugenol is commonly used as cosmetic substance. When it comes to local toxicity the substance is sensitising to the skin. Data derived from animal studies demonstrate that the chemical is irritating to eyes and skin. It shows moderate acute toxicity with LD50 of 1560 mg/kg bw and 1410 mg/kg bw in oral exposure and very high chronic toxicity in dermal exposure. It has high chronic toxicity where oral systematic exposure is considered. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is not considered to be of toxicological concern when used in consumer products under the condition that the concentration of the fragrance material does not exceed the considered safe level in finished products.

TOXICOLOGICAL PROFILE
AcuteToxicology: Isoeugenol is classified as hazardous with hazard category H304: May be fatal if swallowed and enters airways.
Eye Irritation: The substance was tested in vitro/ ex vivo (fresh bovine cornea) to examine ocular irritation after application. The studies resulted in scoring the chemical as irritating. (ECHA)
Genotoxicity: Negative: in vitro cytogenicity / chromosome aberration study in mammalian cells and in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus (ECHA)
LD50: LD50 (oral, mouse) 0.5 mL/kg bw; OECD Guideline 401 (Acute Oral Toxicity); Description: Acute toxicity studies via oral route of administration in mice demonstrated very high toxicity of the substance. LD50 (oral, rat)1560 mg/kg bw ; LD50 (oral, guinea pig) 1410 mg/kg bw, Rats and Guinea-pigs were given a single oral dose of test item and then observed for 14 days; Description: Acute toxicity studies in guinea pigs and rats showed moderate toxicity of the substance. LD50 (dermal, rabbit) 1.77 mL/kg bw; OECD Guideline 402 (Acute Dermal Toxicity); Description: Acute toxicity studies via dermal route of exposure in rabbits (occlusive type of coverage) showed that the substance has very high skin toxicity. (ECHA)
Mutagenicity: Non- mutagenic
NOAEL Dermal: NOEL 69 µg/cm2. Study type Human data. Source and date RIFM 2007
NOAEL Oral: NOAEL 600 mg/kg bw. Study type Repeated dose toxicity. Endpoint Sub-chronic toxicity. Method OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents). Species: mouse (female); Report date 1983 (ECHA); NOAEL 300 mg/kg bw/day; Study type: Repeated dose toxicity; Endpoint:sub-chronic toxicity: oral; Guideline: OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity Study in Rodents); Species:mouse (male/female); Source: ECHA. MoS was calculated based on this data
Sensitisation via inhalation: May cause respiratory irritation.
Skin Irritation: In the in vivo studies on rabbits with semiocclusive coverage the substance was found to be irritating. (ECHA) The chemical caused Severe skin irritations to rabbit skin after 24 h - Draize Test
Skin Sensitisation: LLNA in vivo examinations were conducted, using mouse local lymph node assay (LLNA) test, to find evidence for skin sensitisation. The test results showed that the chemical is sensitising. (ECHA)
Carcinogenicity: No evidence of carcinogenic potential.

OTHER
Biodegradability (Environmental): Biodegradation in water. Results: 79% degradation after 28 days (OECD Guideline 301F) Conclusion: readily biodegradable (ECHA)
Ecological toxicity: EC 50 Pseudokirchneriella subcapitata, Desmodesmus subspicatus, Scenedesmus quadricauda 5.6 mg/L -72h (OECD Guideline 201)
LC50 (Environmental): Fish: LC50 Danio rerio, Oncorhynchus mykiss, Lepomis macrochirus, Pimephales promelas, Oryzias latipes, Leuciscus idus 3.6 mg/L – 96h (EU Method C.1) ; Algae: EC50 13.9 mg/, 96h (QSAR prediction model, iSafeRat v1.5 and ECOSAR v1.11) .(ECHA)

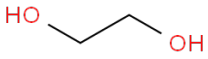
Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Glycol (Ethylene glycol) (Humectant,Solvent,Viscosity Controlling)
EU INCI: Glycol.
CTFA INCI: Glycol.
Chinese: 乙二醇(乙二醇).
CAS Number: 107-21-1.
EINECS Number: 203-473-3.
Symbol: C2H6O2.
Molecular Weight: 62.068 Da.
Description: Organic chemical synthesized from ethylene (ethene) where ethylene oxide reacts with water to produce ethylene glycol. Has poisoning properties if swallowed.
IUPAC Name: ethane-1,2-diol
Synonyms: ETHYLENE GLYCOL; 1,2-ethanediol; Ethane-1,2-diol



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Odourless
Oxidising Properties: Not oxidising
Viscosity: 16.1 mPas at 25 °C
Water Solubility: 1 000 g/L
Boiling Point: 197.4 °C at 1013 hPa
Colour: Colourless
Density: 1.11 g/cm3 at 20 °C
Flammability: Non flammable
Flash Point: 111 °C
Vapour Pressure: 0.123 hPa at 25 °C
LogP Log Kow: -1.36 at 25 °C
Melting Point: -13 °C
Physical State: Liquid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as: Acute Tox. 4 * H302
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: H302: Harmful if swallowed. H373: May cause damage to organs through prolonged or repeated exposure..
Region : Europe Type : Cosmetic Restriction : None. Not suitable for mouthwash and toothpaste products.
Region : UK Type : Cosmetic Restriction : None. Not suitable for mouthwash and toothpaste products.

TOXICITY REVIEW
General Toxicity Review: Based on the available information the substance is not associated with the skin sensitisation, skin and eye irritation. It shows low acute toxicity with LD50 >3500 mg/kg bw in both dermal and oral exposure. It also have low chronic toxicity where dermal exposure is considered. The ingredient characteristic suggest that after prolonged or repeated oral exposure to the substance it may cause damage to organs.

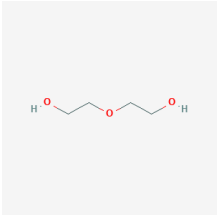
TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as not irritating. (ECHA)
Genotoxicity: Negative in vitro gene mutation study in bacteria and in vivo mammalian germ cell study: cytogenicity / chromosome aberration (ECHA)
LD50: LD50 (oral, rat) 7712 mg/kg bw; Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity of the substance. LD50 (dermal, mouse) >3500 mg/kg bw; Description: Acute toxicity studies via dermal route of exposure in mice (occlusive type of coverage) showed that the substance has low skin toxicity. (ECHA)
NOAEL Dermal: NOAEL 2200-4400 mg/kg bw. Study type: repeated dose toxicity. Species: dog. Endpoint: short-term repeated dose toxicity. Guideline:OECD Guideline 410 (Repeated Dose Dermal Toxicity: 21/28-Day Study); Report date:1991; Source: ECHA; MoS was calculated based on this data
NOAEL Oral: NOAEL 150 mg/kg bw/day. Study type: repeated dose toxicity. Endpoint: chronic toxicity. Guideline:OECD Guideline 452 (Chronic Toxicity Studies); Species:rat; Bibliographic source: Toxicol Appl Pharmacol 228: 165-178 (2008); Source: ECHA, MoS was calculated based n this data
Repeated Dose Toxicity: May cause damage to organs through prolonged or repeated exposure.
Reproductive Toxicology: NOAEL 1000 mg/kg bw/day Study type: Toxicity to reproduction; Endpoint:three-generation reproductive toxicity; Species:rat; Source: ECHA
Safety evaluation: The chemical is associated with poisoning caused by ingestion. Once swallowed it is broken down to toxic chemicals such as Glycolic acid and Oxalic acid.
ADME (Absorption, Distribution, Metabolism, Excretion): Glycolic acid is a relevant metabolite for developmental toxicity. (ECHA) Based on investigators research, Ethylene Glycol is poorly absorbed through the skin. (CIR)
Skin Irritation: In the in vivo studies on rabbits with occlusive coverage the substance was found to be not irritating. (ECHA)
Skin Sensitisation: Non-LLNA in vivo examinations were conducted, using guinea pig maximisation test, to find evidence for skin sensitisation. The test results showed that the chemical is non-sensitising. (ECHA)
Allergens HRIPT: Repeated patch test was conducted on 447 subjects. 3 of the subjects had reactions on challenge indicative of possible irritation and/or low level sensitization. The substance was considered to have low potential to induce dermal sensitization. (ECHA)

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



IDENTIFICATION
Diethylene glycol (Not Reported)
EU INCI: Diethylene glycol.
CTFA INCI: Diethylene glycol.
Chinese: 二甘醇.
CAS Number: 111-46-6.
EINECS Number: 203-872-2.
IUPAC Name: 2-(2-hydroxyethoxy)ethanol

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Characteristic
Viscosity: 30 mPas at 25 °C
Water Solubility: 1 000 g/L at 20 °C (miscible in any portion)
Boiling Point: 244.9 °C at 1013 hPa
Colour: Colourless
Density: 1.118 g/cm3 at 20 °C
Flammability: Non flammable
Flash Point: 138 °C
Vapour Pressure: 0.008 hPa at 25 °C
Physical State: Liquid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as: Acute Tox. 4 * H302
REACH Annex XVII: Not listed in Annex XVII.
REACH SVHC: Not listed in SVHC list (Annex XIV).
Regulatory Controls: SCCP is of the opinion that diethylene glycol (DEG) should not be used as an ingredient incosmetic products including oral care products. SCCP is of the opinion that a maximum concentration of up to 0.1% DEG from impurities in ingredients like glycerine and polyethylene glycols in the finished cosmetic products can be considered to be safe. (SCCP Opinion 2008)
GHS Classification: H302 Harmful if swallowed..
Region : Europe Type : Cosmetic Restriction : Prohibited or 0.1% as traces in ingredients
Region : UK Type : Cosmetic Restriction : Prohibited or 0.1% as traces in ingredients

TOXICITY REVIEW
General Toxicity Review: Data obtained in vivo and in vitro/ ex vivo (animal and human skin model studies) was found to be not irritating to eyes, and skin. The substance was found to be non-sensitising in guinea pig maximisation test. Overall, the ingredient is considered to be of toxicological concern when used in consumer products. It shows very low acute toxicity with LD50 at 16 500 mg/kg bw in oral and LD50 at 13 300 mg/kg bw in dermal route of exposure. Repeated dose toxicity study indicated the NOAEL at 2 220 mg/kg bw/day and 128 mg/kg bw/day via dermal and oral routes of exposure respectively. As per SCCS 2008 DEG is toxic primarily to the kidney and nervous system and can produce a wide variety of signs and symptoms after consumption. It was found that DEG is metabolized into ethylene glycol, which is poisonous due to the metabolic production of glycolic acid, glyoxylic acid, and finally oxalic acid. Accumulation of acid in the body is the main concern for human health which leads to acute kidney failure. The presence of a condition known as metabolic acidosis is associated with human poisoning, from the clinical observation is caused by neurologic symptoms, including encephalopathy, coma, and death.

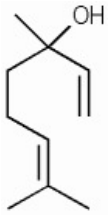
TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as not irritating. (ECHA)
LD50: LD50 (oral, rat) 16 500 mg/kg bw; Description: Acute toxicity studies via oral route of administration in rats demonstrated very low toxicity of the substance. LD50 (dermal, rabbit) 13 300 mg/kg bw; Description: Acute toxicity studies via dermal route of exposure in rabbits (occlusive type of coverage) showed that the substance has very low skin toxicity. (ECHA)
NOAEL Dermal: NOAEL 2 220 mg/kg bw/day Study type: Repeated dose toxicity; Endpoint:short-term repeated dose toxicity: dermal; Guideline:OECD Guideline 410 (Repeated Dose Dermal Toxicity: 21/28-Day Study); Species:dog; Report date:1991; Source: ECHA, MoS was calculated based on this data
NOAEL Oral: NOAEL 128 mg/kg bw/day Study type: Repeated dose toxicity; Endpoint:sub-chronic toxicity: oral; Species:rat; Duration: 225 days; Report date:1976; Source: ECHA; MoS was calculated based on this data
Reproductive Toxicology: NOAEL 3 060 mg/kg bw/day Study type: Toxicity to reproduction; Endpoint: two-generation reproductive toxicity: oral; Species: mouse; Guideline: New reproductive toxicology testing scheme which has been designated "Fertility Assessment by Continuous Breeding". Report date:1984; Source: ECHA;
Skin Irritation: In the in vitro / ex vivo studies on the human skin model the substance was found to be not irritating and not corrosive. (ECHA)
Skin Sensitisation: Non-LLNA in vivo examinations were conducted, using guinea pig maximisation test, to find evidence for skin sensitisation. The test results showed that the chemical is non-sensitising. (ECHA)
Allergens Patch Test: In patch test conducted on 40 human male volunteers, it was found that the substance is capable to eliciting visible skin changes deemed characteristic of a primary skin irritant. (ECHA) Patch test was performed on 10 volunteers. There was one slight erythema at 4 hours and marked erythema at 6 hours. Also one slight erythema at 6 hours, and one female subject had marked erythema at 6 hours. After 24h reaction disappeared. (ECHA)

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



IDENTIFICATION
Linalool (1,6-Octadien-3-ol, 3,7-dimethyl-) (Perfuming,Deodorant)
EU INCI: Linalool.
CTFA INCI: Linalool.
CNDA INCI: Linalool.
CAS Number: 78-70-6.
EINECS Number: 201-134-4.
Symbol: C10H18O.
Molecular Weight: 154.25.
IUPAC Name: 3,7-dimethylocta-1,6-dien-3-ol

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Viscosity: 4.465 mPa.s at 298.15 K
Water Solubility: 1 560 mg/L at 25 °C
Boiling Point: 196.3 °C at 101 325 Pa
Colour: Colourless
Density: 0.858 g/ml at 25 degrees Celsius.
Flash Point: 77.2 °C at 101.3 kPa
Vapour Pressure: 0.273 hPa at 25 °C
LogP Log Kow: 2.9 at 20 °C
Melting Point: -74 °C at 101325 Pa
Physical State: Liquid.

REGULATORY REQUIREMENTS
Labelling Requirements: The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds:— 0,001 % in leave-on products— 0,01 % in rinse-off products..
IFRA Standard: Fragrance ingredient specification: Oxidation products of Linalool, especially hydroperoxides, have been demonstrated to be potent sensitizers.d-, l- and dl-Linalool and natural products containing substantial amounts of it, should only be used when the level of (hydro)peroxides is kept to the lowest practical level, for instance by adding antioxidants at the time of production. The addition of 0.1% BHT or α-Tocopherol for example has shown great efficiency. Such products should have aperoxide value of less than 20 millimoles perliter, determined according to the IFRA analytical method for the determination of the peroxide value, which can be downloaded from the IFRA website (www.ifrafragrance.org). Flavor requirements: Due to the possible ingestion of small amounts of fragrance ingredients from their use in products in Categories 1 and 6, materials must not only comply with IFRA Standards but must also be recognized as safe as a flavoring ingredient as defined by the IOFI Code of Practice (www.iofi.org). For more details see chapter 1 of the Guidance for the use of IFRA Standards. Implementation dates: For new submissions*: May 6, 2004 For existing fragrance compounds*: May 6, 2005
CLP Regulation (EC) No 1272/2008: Classified as: Skin Sens. 1B , H317. Proposed classification: Skin Sens. 1A, H317 (ECHA accessed 23.04.21)
REACH Annex XVII: Not listed in the Annex XVII
REACH SVHC: Not included in SVHC list (Annex XIV).
Regulatory Controls: The presence of the fragrance substance must be indicated in the list of ingredients referred to in Article 19(1)g when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products. Proposed restrictions as per the EC public consultation published on 18th March 2019; When its concentration exceeds: 0,001 % in leave-on products and 0,01 % in rinse-off products the presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g).
GHS Classification: H315: Causes skin irritation. H319: Causes serious eye irritation. H317: May cause an allergic skin reaction..
Region : Europe Type : Cosmetic Restriction : Allergen declaration as required Label Review : The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds:— 0,001 % in leave-on products— 0,01 % in rinse-off products.
Region : UK Type : Cosmetic Restriction : Allergen declaration as required Label Review : The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g) when its concentration exceeds:— 0,001 % in leave-on products— 0,01 % in rinse-off products.

TOXICITY REVIEW
General Toxicity Review: The substance is well known cosmetic allergen. The substance is commonly used in fragrance compositions and occurs in the Essential oils. Based on the animal testing results the substance is irritating to the eyes and skin. The substance is a skin sensitiser. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is not considered to be of toxicological concern when used in consumer products under the condition that the concentration of the fragrance material does not exceed the considered safe level in finished products.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as irritating. (ECHA)
Genotoxicity: Negative in vitro gene mutation study in bacteria. (mouse lymphoma L5178Y cells) Negative in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus. (mouse) (ECHA)
LD50: LD50 (oral, rat) 2 790 mg/kg bw; OECD Guideline 401 (Acute Oral Toxicity); Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity of the substance. LD50 (dermal, rabbit) 5 610 mg/kg bw; OECD Guideline 402 (Acute Dermal Toxicity); Description: Acute toxicity studies via dermal route of exposure in rabbits (occlusive type of coverage) showed that the substance has low skin toxicity. (ECHA)
Mutagenicity: Non-mutagenic.
NOAEL Dermal: NOAEL 250 mg/kg bw/day Study type: Repeated dose toxicity. Endpoint: sub-chronic toxicity: dermal. Method OECD Guideline 411 (Subchronic Dermal Toxicity: 90-Day Study). Species Rats. Remark Effect: increase in squamous epithelial hyperplasia. Report date 1980 (ECHA) MoS was calculated based on this data
NOAEL Oral: NOAEL 160 mg/kg bw. Study type Repeated dose toxicity. Endpoint Short-term repeated dose toxicity. Duration, a 28-day study. Method OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity in Rodents). Report date 1990 (ECHA) MoS was calculated based on this data. NOAEL 200 mg/kg bw/day Study type: Repeated dose toxicity; Endpoint:short-term repeated dose toxicity: oral; Guideline:OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity Study in Rodents); Species:rat; Report date:1992; Source: ECHA
Reproductive Toxicology: NOAEL 200 mg/kg bw/day Study type: Toxicity to reproduction; Endpoint:screening for reproductive / developmental toxicity; Guideline:OECD Preliminary Reproduction Toxicity Screening Test (Precursor Protocol of GL 421); Species:rat; Report date:1992; Source: ECHA
Skin Irritation: In the in vivo studies on rabbits with semiocclusive coverage the substance was found to be irritating (ECHA)
Skin Sensitisation: May cause skin allergy. As per SCCS "Oxidized linalool and its hydroperoxide gave positive reactions in 1.8% of more that 1000 patients tested in a European multi-center study" (ref. SCCNFP/0760/03) LLNA in vivo examinations were conducted, using mouse local lymph node assay (LLNA) test, to find evidence for skin sensitisation. The test results showed that the chemical is sensitising. (ECHA)
Carcinogenicity: No evidence of carcinogenic potential.

OTHER
Biodegradability (Environmental): Biodegradation in water: screening test. Result: 64.2% biodegradation in 28 days. Conclusion: readily biodegradable (OECD TG 301 D). (ECHA)
LC50 (Environmental): Fish: LC50 Salmo gairdneri 27.8 mg/L - 96h (OECD guideline 203); Algae:Desmodesmus subspicatus EC50 156.7 mg/L; NOEC 54.3 mg/L - 96h (DIN guideline 38412 L9.) (ECHA)

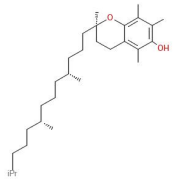
Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Tocopherol (Antioxidant, Masking, Skin Conditioning,Perfuming)
EU INCI: Tocopherol.
CTFA INCI: Tocopherol.
CNDA INCI: Tocopherol.
CAS Number: 59-02-9(10191-41-0)(1406-66-2)1406-18-4(54-28-4)(gamma).
EINECS Number: 200-412-2.
Symbol: C29H50O2.
Molecular Weight: 430.71 g/mole.
Description: Tocopherol consists of alpha-tocopherol, beta-tocopherol, delta-tocopherol and/or gamma-tocopherol and conforms to the formula.
IUPAC Name: (2R)-2,5,7,8-tetramethyl-2-[(4R,8R)-4,8,12-trimethyltridecyl]-3,4-dihydro-2H-1-benzopyran-6-ol
Synonyms: Vitamin E, D-alpha-Tocopherol; (2R)-3,4-Dihydro-2,5,7,8-tetramethyl-2-[(4R,8R)-4,8,12-trimethyltridecyl]-2H-1-benzopyran-6-ol



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Odorless
Oxidising Properties: No oxidising properties.
Specific Gravity: 0.95 (Water = 1)
Water Solubility: Soluble in diethyl ether, acetone. Insoluble in cold water. Soluble in alcohol.
Boiling Point: 200°C (392°F) - 220 C. @ 0.13 mm Hg
Colour: Light yellow
Density: 0.95
Flammability: Non flammable.
Flash Point: >110°C (230°F) closed cup
Vapour Pressure: Not applicable, calculated value: 1.80E-8 hPa at 25°C
LogP Log Kow: 12.2 at 25 °C
Melting Point: 2.5°C (36.5°F)
Microbiological stability: Not susceptible to microbiological contamination.
Physical State: Viscous liquid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI
REACH Annex XVII: Not listed in Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: Not classified as per GHS.
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: Tocopherol consists of alpha-tocopherol, beta-tocopherol, delta-tocopherol and/or gamma-tocopherol. Data derived from animal studies demonstrate that the substance is not irritating to eyes and slightly irritating to skin. The substance is classified as not sensitising to skin. It shows low acute toxicity with LD50 above 7500 mg/kg bw in oral route of exposure and LD50 above 5000 mg/kg bw in dermal route of exposure. Overall, the ingredient is not considered to be of toxicological concern when used in consumer products as intended.

TOXICOLOGICAL PROFILE
AcuteToxicology: Vitamin E toxicity is found to be rare, however high doses cause (or overdosing via supplementation) a risk of bleeding, along with muscle weakness, fatigue, nausea, or diarrhoea.
Endocrine Effects: The chemical material does not have Endocrine disruptors (ED) properties.
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as not irritating. (ECHA). Three rabbits were used to determine the ocular irritation potential of tocopherol. 0.1 ml of the undiluted test substance was applied to the rabbits' eyes. The eyes were observed up to 7 days. Tocopherol was a minimal eye irritant (CIR).
Genotoxicity: In vitro gene mutation study in bacteria: negative (S. typhimurium - TA1535, TA97, TA98, TA100, and TA102) (ECHA)
LD50: LD50 (oral, rat) > 7500 mg/kg bw; OECD Guideline 401 (Acute Oral Toxicity); No mortality occurred during the study. Description: Acute toxicity studies via oral route of administration in rats showed that the substance is practically non-toxic. Acute toxicity studies via dermal route of exposure in rabbits (occlusive type of coverage) showed that the substance has low skin toxicity. (ECHA). Overdose of vit. E is however toxic in humans.
NOAEL Oral: NOAEL 500 mg/kg bw/day; Study type: repeated dose toxicity. Endpoint:sub-chronic toxicity: oral; Species: rat; Guideline:OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity Study in Rodents); Bibliographic source:Fd Chem Toxic. 24 (10/11): 1043-1050. (1986) MoS was calculated based on this data (ECHA) ; NOAEL 167 mg/kg bw. Study type, LOAEL of 500 mg/kg bw/day based on potential for hemorrhagic effect. NOAEL = LOAEL /3 = 500/3 = 167 mg /kg bw/day. Report date 2012 (Mattilsynet)
Precutaneous Absorption: 2%
Reproductive Toxicology: NOAEL 800 mg/kg bw/day Study type: Toxicity to reproduction; Endpoint: one-generation reproductive toxicity; Guideline:OECD Guideline 415 [One-Generation Reproduction Toxicity Study (before 9 October 2017)]; Species: rat; Bibliographic source:J Agric Food Chem 25: 273-278 (1977) (ECHA). MoS was calculated based on this data.
Skin Irritation: In the in vivo studies on rabbits with semi-occlusive coverage the substance was found to be slightly irritating (ECHA). 0.3 ml of the test material was applied to the back of rabbits under an occlusive patch for 24h. Tocopherol, 1.0%, was a weak primary skin irritant (CIR).
Skin Sensitisation: Not classified as a skin sensitizer. It is known to have some sensitizing properties and therefore recommended to be used at below 0.1% in individuals with the confirmed skin allergy to vitamin E. Reported to cause allergic contact dermatitis (ACD) (http://contactallergy.com/contact_allergy_008.htm). When dermatologically tested at 1% in petrolatum showed positive allergic reactions (http://www.patchtesting.info). When Vitamin E is used in leave-on cosmetics the safety factor of 100 should be applied if products are intended for sensitive sub-populations. If Tocopherol and its derivatives are used in products intended for sensitive individuals dermatological patch test is recommended. Non-LLNA in vivo examinations were conducted, using guinea pig maximisation test in order to find evidence for skin sensitisation. The test results showed that the chemical is non-sensitising. (ECHA). Tocopherol was a moderate sensitiser in a guinea pig maximization test in 20 tests and 10 control female albino Dunkin Hartley guinea pigs. Tocopherol was classified as having moderate sensitisation potential in a local lymph node assay (LLNA) (CIR).
Allergens HRIPT: The mixture containing <0.1% of Tocopherol was used in a repeated patch test on guinea pigs. The test material was applied to the selected skin area for 10 days. After 24-days rest time the challenge phase was applied to the previously untreated area. No skin irritation or sensitisation was observed during the induction or challenge phase. (CIR)
Allergens MaximisationTest: The substance was tested in maximization test on guinea pigs (20 tests and 10 control female albino Dunkin Hartley guinea pigs). 62 Intradermal induction was conducted with 0.2% DL-alpha-tocopherol in light liquid paraffin or as an emulsion with Freund Complete Adjuvant. Reactions were evaluated 24 and 48 hours after patch removal. The substance was classified as having moderate sensitization potential. (CIR)
Carcinogenicity: Not associated with carcinogenic, mutagenic and reprotoxic (CMR) chemicals.

OTHER
Biodegradability (Environmental): Biodegradation in water: screening test. Result: 30-40% degradation after 39 days. Conclusion: inherently biodegradable. (ECHA)
LC50 (Environmental): Fish: LC50 Oncorhynchus mykiss (rainbow trout) 10 mg/L - 96h; OECD Guideline 203; Algae: EC10 or NOEC Selenastrum capricornutum 25.8 mg/L - 72h; OECD Guideline 201 (ECHA)

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Chloride (Not Reported)
EU INCI: Chloride.
CTFA INCI: Chloride.
Chinese: 氯化物.
CAS Number: 16887-00-6.
EINECS Number: 690-375-2.
Symbol: Cl-.
Molecular Weight: 35.45 g/mol.
IUPAC Name: chloride
Synonyms: Chloride anion ; Chloride ions; Chloride (ion); Chlorine anion; Chlorine, ion; Hydrochloric acid, ion(1-); Cl-; Chlorine ion; Chloride (Cl-); Chlorine(1-); Chlorine

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Water Solubility: 6.3 mg/mL at 25 °C
Particle Size: The non-solid or granular form does not require the particle size distribution study.
Melting Point: -101°C
Physical State: Liquid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI.
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: H317: May cause an allergic skin reaction..
Region : Europe Type : Cosmetic Restriction : Not controlled
Region : UK Type : Cosmetic Restriction : Not controlled

TOXICITY REVIEW
General Toxicity Review: Based on the available information, chlorides are not associated with the skin and eye irritation. However, they are considered to be skin sensitising. Read across to calcium chloride, sodium chloride, and potassium chloride, it shows low acute toxicity with LD50 around 1000, 3000, and 2430 mg/kg bw in oral route of exposure. Chloride toxicity has not been observed in humans apart from individuals with impaired sodium chloride metabolism, e.g. in congestive heart failure (WHO). Overall, the ingredient is not considered to be of toxicological concern when used in consumer products.

TOXICOLOGICAL PROFILE
Eye Irritation: Based on the available toxicological data there is no evidence of eye irritation potential.
LD50: LD50 (oral, rats) 1000, 3000, and 2430 mg/kg bw (read across to calcium chloride, sodium chloride, and potassium chloride)
NOAEL Oral: Chloride toxicity has not been observed in humans apart from individuals with impaired sodium chloride metabolism, e.g. in congestive heart failure (WHO).
ADME (Absorption, Distribution, Metabolism, Excretion): Based on WHO data 'In humans, 88% of chloride is extracellular and contributes to the osmotic activity of bodyfluids. The electrolyte balance in the body is maintained by adjusting total dietary intake andby excretion via the kidneys and gastrointestinal tract. Chloride is almost completely absorbedin normal individuals, mostly from the proximal half of the small intestine. Normal fluid lossamounts to about 1.5–2 litres/day, together with about 4 g of chloride per day. Most (90–95%) is excreted in the urine, with minor amounts in faeces (4–8%) and sweat (2%).'
Skin Irritation: Based on the available toxicological data there is no evidence of skin irritation potential.
Skin Sensitisation: May cause an allergic skin reaction (PubChem).
Carcinogenicity: Not associated with carcinogenic, mutagenic and reprotoxic (CMR) chemicals.

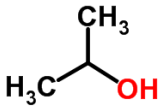
Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Isopropyl Alcohol (Antifoaming,Perfuming,Solvent,Viscosity Controlling)
EU INCI: Isopropyl Alcohol.
CTFA INCI: Isopropyl Alcohol.
CAS Number: 67-63-0.
EINECS Number: 200-661-7.
Symbol: C3H8O.
Molecular Weight: 60.095 Da.
Description: Isopropyl alcohol is a common solvent.
IUPAC Name: propan-2-ol
Synonyms: Propan-2-ol, 2-Propanol



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Characteristic, alcoholic
Oxidising Properties: No oxidising properties
Specific Gravity: 0.79 at 20C
Viscosity: 2.1 mPa.s at 25°C
Water Solubility: Miscible
Boiling Point: 82°C at 101325 Pa
Density: 0.7855 g/cm3 at 20°C
Flammability: Highly flammable
Flash Point: Substance could be sufficiently volatile at 12°C to create an ignitable mixture in air
Vapour Pressure: 4.4 kPa at 20°C
LogP Log Kow: 0.05 at 25°C
Melting Point: -89°C
Physical State: Liquid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as: Flam. Liq. 2 H225; Eye Irrit. 2 H319; STOT SE 3 H336
REACH Annex XVII: Not listed in Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: H319: Causes serious eye irritation. H336: May cause drowsiness or dizziness. H225: Highly flammable liquid and vapour..
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

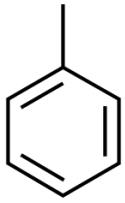
TOXICITY REVIEW
General Toxicity Review: The chemical Isopropyl alcohol is a well-known substance. When it comes to local toxicity the chemical does not induce or elicit skin allergy and skin irritation. However, the repeated exposure to the substance may cause skin dryness and cracking. Data derived form animal studies demonstrate that the substance is seriously irritating and may cause eye damage. The substance is not carcinogenic. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is not considered to be of toxicological concern when used as intended.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as seriously irritating. Possible corneal burns and eye damage. (ECHA) Studies of 0.1 mL Isopropyl alcohol in a 70% water solutionwas conducted on rabbits. It was found that the substance causes severe ocular irritant. (CIR)
Genotoxicity: Negative in vitro gene mutation study in mammalian cells (Chinese hamster Ovary (CHO)). Negative in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus. (mouse) (ECHA)
Inhalation: Inhalation of vapours irritates the respiratory tract. Exposure to high concentrations has a narcotic effect producing symptoms of dizziness, drowsiness, headache, staggering, unconsciousness and possibly death.
LD50: LD50 (oral, rat) 5.84 g/kg body weight; OECD Guideline 401 (Acute Oral Toxicity); Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity of the substance. ; LD50 (dermal, rabbit) 16.4 mL/kg bw (13 900 mg/kg bw); OECD Guideline 402 (Acute Dermal Toxicity); Description: Acute toxicity studies via dermal route of exposure in rabbits (rubber cuff type of coverage) showed that the substance has low skin toxicity. (ECHA)
Mutagenicity: Non-mutagenic
NOAEL Inhalation: NOAEC 12 500 mg/m³ Study type: Repeated dose toxicity: inhalation - systemic effects (inhalation, rat, 1994, OECd 451) (ref.echa) MoS was calculated based on this data
NOAEL Oral: NOAEL 500 mg/kg bw/day Study type: Toxicity to reproduction; Endpoint:two-generation reproductive toxicity; Guideline:OECD Guideline 416 (Two-Generation Reproduction Toxicity Study); Species:rat; Report date:1992; Source: ECHA, MoS was calculated based on this data
Read-across: Not susceptible to microbiological contamination.
Reproductive Toxicology: NOELs (maternal and developmental toxicity) 400 mg/kg in rats and 240 and 480 mg/kg in rabbits (CIR) NOAEL 100 mg/kg bw/day Study type; Toxicity to reproduction. Endpoints; two-generation reproductive toxicity. Route of administration: oral. Species; rat. Methods; OECD Guideline 416 (Two-Generation Reproduction Toxicity Study). Report date; 1992. Source; ECHA.
Safety evaluation: Only cosmetic or pharmaceutical grade shall be used.
ADME (Absorption, Distribution, Metabolism, Excretion): May be absorbed through the skin with possible systemic effects. Isopropyl alcohol is metabolized to acetone and then to acetate, formate, and ultimately carbon dioxide. The substance is absorbed by the dermal route. Significant toxicity is observed when exposure is prolonged.(CIR)
Skin Irritation: In the in vivo studies on rabbits with occlusive coverage the substance was found to be not irritating and not corrosive. (ECHA) However, the substance may cause skin irritation, redness, pain after repeated use.
Skin Sensitisation: Non-LLNA in vivo examinations were conducted, using guinea pigs, Buehler test, to find evidence for skin sensitisation. The test results showed that the chemical is non-sensitising. (ECHA) Isopropyl alcohol in a concentration: 80.74% (spray) didn't produce skin sensitisation in 9 volunteers. (CIR)
Allergens HRIPT: In a HRIPT study the isopropyl alcohol in a concentration of 2.85% was used. No sensitisation was observed during the study (109 participants). (CIR)
Allergens Patch Test: Spray concentrate with 80.74% of isopropyl alcohol showed no skin sensitization effect on 9 participants (CIR)
Carcinogenicity: NOAEC 12 290 mg/m³ Study type: 2-year carcinogenicity study in rats (Burleigh-Flayer and Benson, 1994). Conclusion: the substance is not classified as carcinogenic. (ECHA)

OTHER
Biodegradability (Environmental): The substance has a BOD5/ThOD ratio of 0.50, and is therefore considered to be readily degradable. (ECHA)
LC50 (Environmental): Fish: LC50 Pimephales promelas (Fathead minnow), 9 640 mg/L - 96h (US Environmental Protection Agency Committee on Methods for Toxicity Tests); Algae: EC10 or NOEC 1 800 mg/L, Scenedesmus quadricauda - 8 days (ECHA)

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



IDENTIFICATION
Toluene (Antioxidant,Solvent,Perfuming)
EU INCI: Toluene.
CTFA INCI: Toluene.
Trade Name: Toluene.
CAS Number: 108-88-3.
EINECS Number: 203-625-9.
Symbol: C7H8.
Molecular Weight: 92.138.
Synonyms: Tol; Toluol; Methylbenzene

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Benzene like
Viscosity: 0.56 mPa · s (dynamic) at 20 °C
Water Solubility: 587 mg/L at 25 °C
Boiling Point: 110.6°C
Colour: Colourless
Density: 0.866 g/cm3 at 20°C
Flammability: Highly flammable liquid and vapour
Flash Point: 4.4°C
Vapour Pressure: 3 089 Pa at 21.1 °C
LogP Log Kow: 2.73 at 20 °C
Melting Point: -95°C
Microbiological stability: Not susceptible to microbiological contamination
Physical State: Liquid.

REGULATORY REQUIREMENTS
Labelling Requirements: Keep out of reach of children. To be used by adults only.
IFRA Standard: Toluene should not be used as a fragrance ingredient. The level of Toluene has to be kept as low as practicable and should never exceed 100 ppm in the fragrance compound/mixture or fragrance oil. Implementation dates: For new submissions*: May 6, 2004For existing fragrance compounds*: May 6, 2005
CLP Regulation (EC) No 1272/2008: Classified as: Flam. Liq. 2 H225, Repr. 2 H361d ***, Asp. Tox. 1 H304, STOT RE 2 * H373 ** , Skin Irrit. 2 H315 , STOT SE 3 H336
REACH Annex XVII: Listed in the Annex XVII. Shall not be placed on the market, or used, as a substance or in mixtures in a concentration equal to or greater than 0,1 % by weight where the substance or mixture is used in adhesives or spray paints intended for supply to the general public.
REACH SVHC: Not included in SVHC list (Annex XIV)
Regulatory Controls: 25%, Keep out of reach of children, To be used by adults only. Shall not be placed on the market, or used, as a substance or in mixtures in a concentration equal to or greater than 0,1 % by weight where the substance or mixture is used in adhesives or spray paints intended for supply to the general public.
GHS Classification: H225: Highly flammable liquid and vapour. H304: May be fatal if swallowed and enters airways. H315: Causes skin irritation. H336: May cause drowsiness or dizziness. H361: Suspected of damaging fertility or the unborn child. H361d: Suspected of damaging the unborn child via inhalation. H373: May cause damage to organs <central nervous system via inhalation.> H412: Harmful to aquatic life with long lasting effects..
Region : Europe Type : Cosmetic Restriction : Nail products 25% Label Review : Keep out of reach of children. To be used by adults only
Region : UK Type : Cosmetic Restriction : Nail products 25% Label Review : Keep out of reach of children. To be used by adults only

TOXICITY REVIEW
General Toxicity Review: Toluene is suspected of damaging the unborn child via inhalation. It may cause damage to central nervous system via inhalation. In vivo studies indicated that toluene is slightly irritating to eyes and causes skin irritation. It was found to be not sensitising. It shows low acute toxicity with median lethal dose at 5 580 mg/kg bw via oral route of exposure and above 5 000 mg/kg bw via dermal route of exposure. Repeated dose toxicity studies have indicated NOAEL at 625 mg/kg bw/day which demonstrates moderate toxicity via oral route of exposure.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo to examine ocular irritation potential. Endpoint: Slightly irritating; Method: according to OECD Guideline 405; Species: rabbit; Report date: 1995; Source: ECHA.
Genotoxicity: In vitro: negative; Method: according to EU Method B.13/14; Species:S. typhimurium TA 1535, TA 1537, TA 98 and TA 100; Report date: 1983; Source: ECHA. In vivo: negative; Species: rat; Route of administration: intraperitoneal; Report date: 1978; Source: ECHA.
Inhalation: May cause drowsiness or dizziness
LD50: LD50 5 580 mg/kg bw; Route of exposure: oral, Species: rat, Method: according to EU Method B.1, Report date: 1975. Description: Acute toxicity studies via oral route of administration in rats demonstrated very low toxicity of the substance. LD50 > 5 000 mg/kg bw; Route of administration: dermal, Species: rabbit, Source: Range-finding toxicity data: List VII, Report date: 1969. Description: Acute toxicity studies via dermal route of exposure in rabbits (occlusive type of coverage) showed that the substance has very low skin toxicity. (ECHA)
Mutagenicity: May cause damage to organs
NOAEL Inhalation: NOAEC 1131 mg/m³ air (1.131 mg/L). Study type experimental study. Endpoint chronic toxicity: inhalation. Species rat. Duration 24 months. Methods OECD Guideline 453 . Reference date 1983 (ECHA)
NOAEL Oral: NOAEL 625 mg/kg bw/day Study type experimental study. Endpoint sub-chronic toxicity: oral. Species rat. Duration 13 weeks. Methods EU Method B.26. Reference date 1990 (ECHA)
Reproductive Toxicology: NOAEC: 600 ppm (2261 mg/m3); Endpoint: Suspected of damaging fertility or the unborn child. Species: rat; Route of administration: inhalation; Report date: 1996; Source: ECHA.
Skin Irritation: The substance was tested in vivo to examine skin irritation potential. Endpoint: Causes skin irritation; Method: according to EU Mathod B.4; Species: rabbit; Report date: 1988; Source: ECHA.
Skin Sensitisation: The substance was tested in vivo to examine skin sensitising potential. Endpoint: not sensitising; Method: according to EU Method B.6; Species: guinea pig; Report date: 1996; Source: ECHA.

OTHER
LC50 (Environmental): LC50: 25.7 mg/L air (male) and 30 mg/L air (female- analytical); Method: according to OECD Guideline 403; Species: rat; Route of administration: inhalation; Report date: 1980; Source: ECHA.

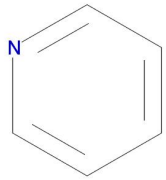
Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Pyridine (Not Reported)
EU INCI: Pyridine.
CTFA INCI: Pyridine.
CAS Number: 110-86-1.
EINECS Number: 203-809-9.
Symbol: C5H5N.
Molecular Weight: 79.10.
Synonyms: Azabenzene



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
pH: 8.81 at 20 °C
Viscosity: 0.879 mPa · s (dynamic) at 20 °C
Water Solubility: 1 000 g/L at 20 °C
Partial Coefficient logPow: 0.64 at 20 °C
Boiling Point: 115.2 °C at 101325 Pa
Colour: Colourless
Density: 0.982 g/cm3 at 20C
Flammability: Highly flammable liquid and vapour.
Flash Point: 20 °C
Vapour Pressure: 26.7 hPa at 20 °C
Melting Point: -46.1 °C
Physical State: Liquid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as: Flam. Liq. 2 H225; Acute Tox. 4 * H332; Acute Tox. 4 * H312; Acute Tox. 4 * H302
REACH Annex XVII: Pyridine, alkyl derivs. listed in the Annex XVII - Mutagens category 1B
REACH SVHC: Not included in SVHC.
GHS Classification: H225: Highly Flammable liquid and vapour. H332: Harmful if inhaled. H312: Harmful in contact with skin. H302: Harmful if swallowed. H315: Causes skin irritation. H319: Causes serious eye irritation..
Region : Europe Type : Cosmetic Restriction : Prohibited if it contains > 0.1% w/w benzene
Region : UK Type : Cosmetic Restriction : Prohibited if it contains > 0.1% w/w benzene
Region : Europe Type : Cosmetic Restriction : Prohibited

TOXICITY REVIEW
General Toxicity Review: In vivo studies resulted in scoring the chemical as serious eye irritant and skin irritant. The substance was found to be not sensitising. It shows moderate acute toxicity potential above 800 mg/kg bw via oral route and low acute toxicity potential above 1000 mg/kg bw via dermal route. Repeated dose toxicity study indicated NOAEL at 7 mg/kg bw/day for oral route. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is not considered to be of toxicological concern when used in consumer products.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo to examine ocular irritation potential. Endpoint: Causes serious eye irritation. Species: rabbit; Report date: 1978; Source: ECHA.
Genotoxicity: In vitro: negative; Method:according to OECD Guideline 471; Species/ strain: S. typhimurium TA 1535, TA 1537, TA 98 and TA 100; Report date: 1993; Source: ECHA. in vivo: Method: according to OECD Guideline 475; Species: mouse; Route of administration: intraperitoneal; Report date: 1997; Source: ECHA.
LD50: LD50 > 800 mg/kg bw; Route of administration: oral, Species: rat, Report date: 1978, Method: no guideline followed. Description: Acute toxicity studies via oral route of administration in rats demonstrated slight toxicity of the substance. LD50 >1000 mg/kg bw Route of administration: dermal, Species: rabbit, Report date: 1973, Method: according to OECD Guideline 402. Source: ECHA LD50 (dermal, rabbit) > 5 000 mg/kg bw Description: Acute toxicity studies via dermal route of exposure in rabbits (occlusive type of coverage) showed that the substance has slight skin toxicity. (ECHA)
NOAEL Inhalation: NOAEC 290 ppm (1105 mg/m3 / 1.105 mg/L) Study type: short-term repeated dose toxicity: inhalation; vapour, nose only, Report date:1984, Method: according to OECD Guideline 412; Source: ECHA.
NOAEL Oral: NOAEL 7 mg/kg bw/day Study type: chronic toxicity: oral; Species: rat, Report date: 2000, Method: EPA OTS 798.3260 (Chronic Toxicity) Source: ECHA. MoS was calculated based on this data.
Skin Irritation: The substance was tested in vivo to examine skin irritation potential. Endpoint: Causes skin irritation. Species: rabbit; Report date: 1977; Source: ECHA.
Skin Sensitisation: The substance was tested in vivo to examine skin sensitising potential. Endpoint: Not sensitising; Report date: 1981; Source: ECHA.
Carcinogenicity: NOAEL 7 mg/kg bw/day Study type: Carcinogenicity (chronic, rat) There is insufficient information to classify pyridine as human cacrcinogen according to IARC.

OTHER
LC50 (Environmental): LC50 4 900 ppm, Route of exposure: inhalation: vapour, nose only, Method: 4h, according to EPA OPPTS 870.1300, Report date: 1984; Source: ECHA.

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Calcium (Not Reported)
EU INCI: Calcium.
CTFA INCI: Calcium.
Chinese: 钙.
CAS Number: 7440-70-2.
EINECS Number: 231-179-5.
Symbol: Ca.
Molecular Weight: 40.08.
EINECS No.: 231-179-5
Synonyms: Aquacal; Atomic calcium; Blood-coagulation factor IV; Calcium atom; Calcium element; Praval; Vivinal MCA 26

Ca
(v0)

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Characteristic
Oxidising Properties: No oxidising properties
Boiling Point: 1 484 °C
Particle Size: Lumps: 10-100mm, 30-200mm, irregular lumps; Turnings: length 30-80mm, width 6-8mm, height 0.7-3.6mm; Granules/Crumbs: >(0.2)-0.4-2mm, 2-7mm; Strips: 2 inches x 2 inches, mixed cut
Colour: Silvery coloured
Density: 1.54 g/cm3 at 20°C
Flammability: Contact with water liberates highly flammable gases
Melting Point: 842 °C
Microbiological stability: Not susceptible to microbiological contamination
Physical State: Solid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Listed in CLP Regulation (EC) No 1272/2008: Water-react. 2 H261
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC.
GHS Classification: H261: In contact with water releases flammable gases..
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: There is limited toxicological information according to the toxicological safety of this substance, there is no evidence on eye and skin irritation potential as well as skin sensitisation potential. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is considered to be of toxicological concern when used in consumer products.

TOXICOLOGICAL PROFILE
Eye Irritation: Based on the available toxicological data there is no evidence of eye irritation potential.
Genotoxicity: Ubiquitous presence in the environment as various calcium compounds and essentiality for human nutrition, as well as for all living forms, withholds the necessity for further toxicity testing and risk analysis for genotoxicity. (ECHA)
LD50: LD50 (oral, rat) > 2 000 mg/kg bw. Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity. LD50 (dermal, rabbit) > 2000 mg/kg bw. Acute toxicity studies via dermal route of exposure in semi-occlusive type of coverage showed that the substance has low skin toxicity. (ECHA)
NOAEL Oral: The NOAEL value was not found, however, based on a history of safe use, this chemical material is considered safe for use in cosmetics. The chemical is unlikely to produce systemic toxicity following skin contact.
ADME (Absorption, Distribution, Metabolism, Excretion): For metallic calcium dermal absorption and absorption through respiratory system can be considered negligible. More than 99 % of the calcium stores in the body are located in the bones and teeth. Absorbed calcium is predominantly excreted via urine, but also via faeces and sweat. (ECHA)
Skin Irritation: Based on the available toxicological data there is no evidence of skin irritation potential.
Skin Sensitisation: Based on the available toxicological data there is no evidence of skin allergy potential.
Carcinogenicity: Calcium (in its ionic form) is an essential element, which is tightly regulated by the human body within its different compartments. Calcium does not exhibit any properties which would raise a concern for carcinogenic properties. Classification for carcinogenicity is not warranted for Ca (metal form). (ECHA)

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Ethylene oxide (Not Reported)
EU INCI: Ethylene oxide (Prohibited).
CTFA INCI: Ethylene oxide (Prohibited).
CNDA INCI: Ethylene oxide (Prohibited).
Chinese: 环氧乙烷.
CAS Number: 75-21-8.
EINECS Number: 200-849-9.
EINECS No.: 200-849-9
IUPAC Name: Oxirane
Synonyms: Oxirane

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Partial Coefficient logPow: -0.3 at 25 °C
Oxidising Properties: No oxidising properties
Boiling Point: 10.7 °C at 1013 hPa
Colour: Colorless gas of sweetish ethereal odour.
Flammability: Extremely flammable gas
Physical State: Gaseous.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as: Flam. Gas 1, H220; Press. Gas, H350; Carc. 1B, H340; Muta. 1B, H360Fd; Repr. 1B, H331; Acute Tox. 3, H301; Acute Tox. 3, H335; STOT SE 3, H336; STOT SE 3, STOT RE 1, H372 (nervous system); Skin Corr. 1, H314; Eye Dam. 1, H318
REACH Annex XVII: Listed in Annex XVII. Reason of inclusion: carcinogenic 1B, mutagenic category 1B, reproductive toxicants: category 1B.
REACH SVHC: Not included in SVHC list (Annex XIV)
GHS Classification: H220: Extremely flammable gas. H230: May react explosively even in the absence of air. H280: Contains gas under pressure; may explode if heated. H301: Toxic if swallowed. H314: Causes severe skin burns and eye damage. H318: Causes serious eye damage. H331: Toxic if inhaled. H335: May cause respiratory irritation. H336: May cause drowsiness or dizziness. H340: May cause genetic defects. H350: May cause cancer. H360: May damage fertility or the unborn child. H372: Causes damage to organs through prolonged or repeated exposure (nervous system)..
Region : Europe Type : Cosmetic Restriction : Prohibited
Region : UK Type : Cosmetic Restriction : Prohibited

TOXICITY REVIEW
General Toxicity Review: Ethylene oxide is a toxic chemical substance officially classified as carcinogenic and mutagenic. The substance causes skin irritation and serious eye irritation. It shows moderate acute toxicity with LD50 above 270 mg/kg bw and equal 330 mg/kg bw in oral route of exposure for guinea pigs and rats, respectively. It shows also moderate acute Toxicity with LD 50 equal 1189 mg/m3 air in inhalation route of exposure for mice. Repeated dose toxicity study was conducted and the NOAEL was determined to be around 30 mg/kg bw for rats and therefore it is considered as high toxicological concern via oral route of administration. Overall, the ingredient is considered to be of toxicological concern when used in consumer products.

TOXICOLOGICAL PROFILE
Eye Irritation: Based on the available toxicological data the substance causes serious eye damage. The substance was tested in vivo to examine ocular irritation potential. Endpoint: The substance was not irritating to eyes of rabbits under test conditions. Method: 0.05 ml of diluted ethylene oxide (0.1%) was installed to rabbit eyes, the reaction was evaluated after 6h, 24h and 48h; Species: rabbit; Report date: 1977; Source: ECHA.
Genotoxicity: May cause genetic defects. In vitro: positive (S. typhimurium TA 1535, TA 100); In vivo: ambiguous (Macaca fascicularis monkey) (ECHA)
Inhalation: May cause respiratory irritation. May cause drowsiness or dizziness.
LD50: LC50 (inhalation, mice) 1189 mg/m3 air. LD50 (oral, guinea pigs) > 270 mg/kg bw. LD50 (oral, rats) 330 mg/kg bw. Description: The substance when tested for acute toxicity via inhalation was found to be non toxic. Acute toxicity studies via oral route of administration in guinea pigs and rats demonstrated moderate toxicity. (ECHA)
NOAEL Inhalation: NOAEC < 50 ppm (nominal)Study type: repeated dose toxicity. Endpoint: sub-chronic toxicity: inhalation. Route of administration: inhalation. Species: rat and mouse. Method: OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study)Report date: 1982. Source: ECHA. MoS was calculated based on this data.
NOAEL Oral: NOAEL 30 mg/kg bw. Study type: repeated dose toxicity. Endpoint: short-term repeated dose toxicity. Route of administration: oral. Species: rat. Method: OECD Guideline 401 (Acute Oral Toxicity). Report date: 1956. Source: ECHA. MoS was calculated based on this data.
Repeated Dose Toxicity: Causes damage to organs through prolonged or repeated exposure (nervous system).
Reproductive Toxicology: May damage fertility. NOAEC 0.054 mg/L air (nominal). Study type: Toxicity to reproduction. Endpoint: one-generation reproductive toxicity. Route of administration: inhalation. Species: rat. Method: OECD Guideline 415 [One-Generation Reproduction Toxicity Study (before 9 October 2017)]. Report date: 1982. Source: ECHA.
ADME (Absorption, Distribution, Metabolism, Excretion): Due to high volatility of the substance dermal absorption is suggested to be the least crucial route. Absorption rate in dermal is considered to be 1.3%. (ECHA)
Skin Irritation: The substance was tested in vivo to examine skin irritation potential. Endpoint: The substance was found to cause severe skin burns; Method: occlusive application of diluted substance (10-50%) to shaved skin of rabbits for 1-60 minutes; Species: rabbit; Report date: 1956; Source: ECHA.
Skin Sensitisation: The substance was tested in vivo to examine skin sensitising potential. Endpoint: The substance was found to be sensitising; Method: according to OECD Guideline 429; Species: mouse; Report date: 2006 and 2011; Source: ECHA.
Allergens LLNAEC3: In vivo LLNA test was conducted in order to assess skin sensitising potential of the substance. Endpoint: The substance was found to be sensitising. Method: according to OECD 429; Species: mouse; Report date: 2006 and 2011; Source: ECHA.
Carcinogenicity: Carc. Cat 1B

OTHER
Biodegradability (Environmental): Ethylene oxide is readily biodegradable according to OECD criteria.

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Chlorine (Not Reported)
EU INCI: Chlorine (Prohibited).
CTFA INCI: Chlorine (Prohibited).
Chinese: 氯.
CAS Number: 7782-50-5.
EINECS Number: 231-959-5.
Symbol: Cl2.
Molecular Weight: 70.906.

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Characteristic, stringent
Oxidising Properties: May cause or intensify fire; oxidiser.
Viscosity: 13.3 mPa · s (dynamic) at 20 °C
Water Solubility: 7 410 mg/L at 20 °C
Partial Coefficient logPow: -0.85 at 20 °C
Boiling Point: -34.05 °C
Colour: Greenish-yellow
Density: 1411 kg/dm3 (pressure 10 kg/cm2; compressed liquid chlorine at 20 °C)
Flammability: Non flammable
Vapour Pressure: 6 780 hPa at 20 °C
Melting Point: -101.05 °C
Physical State: Gas.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as: Ox. Gas 1, H270; Press. Gas, H331; Acute Tox. 3 *, H319; Eye Irrit. 2, H335 STOT SE 3, H315 Skin Irrit. 2,Aquatic Acute 1, H400
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: H270: May cause or intensify fire; oxidiser. H331 Toxic if inhaled. H319 Causes serious eye irritation. H335: May cause respiratory irritation. H315 Causes skin irritation. H400: Very toxic to aquatic life..
Region : Europe Type : Cosmetic Restriction : Prohibited
Region : UK Type : Cosmetic Restriction : Prohibited

TOXICITY REVIEW
General Toxicity Review: Chlorine is considered as unsafe and is prohibited in cosmetic products. The available toxicological data demonstrate that Chlorine causes serious eye and skin irritation. It may also cause respiratory irritation. However, the substance is not sensitising to the skin. It shows low toxicity with LD50 1 100 mg/kg bw for oral exposure. It is practically non-toxic for dermal exposure (LD50 over 20 000 mg/kg bw) and moderate toxic for inhalation exposure (LC50 1 462 mg/m³ air). Overall, the ingredient is considered to be of toxicological concern when used in consumer products. Only unavoidable trace levels are acceptable.

TOXICOLOGICAL PROFILE
Eye Irritation: Causes serious eye irritation.
Genotoxicity: In vitro: positive with metabolic activation (S. typhimurium TA100, TA98); In vivo: negative (mouse) (ECHA).
LD50: LD50 (oral, rat) 1 100 mg/kg bw (1981, OECD 401); Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity of the substance. LD50 (dermal, rabbit) > 20 000 mg/kg bw (1978, OECD 402) Description: Acute toxicity studies via dermal route of exposure in rabbits (occlusive type of coverage) showed that the substance is non-toxic. LC50 (inhalation, mouse) 1 462 mg/m³ air. Description: The substance when tested for acute toxicity via inhalation and was found to be moderately toxic. (ref. ECHA)
NOAEL Inhalation: NOAEL 0.5 ppm (0.5 mg/kg) Study type; repeated dose toxicity. Endpoints; sub-chronic toxicity: inhalation. Route of administration: inhalation; whole body. Species; monkey. Methods; OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study). Report date; 1987. Source; ECHA. MoS was calculated based on this data.
NOAEL Oral: NOAEL 25 mg/kg bw/day Study type; repeated dose toxicity. Endpoints; sub-chronic toxicity: oral. Route of administration: oral. Species; rat. Methods; OECD Guideline 453 (Combined Chronic Toxicity / Carcinogenicity Studies); OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity Study in Rodents). Report date; 1986. Source; ECHA. MoS was calculated based on this data.
Sensitisation via inhalation: May cause respiratory irritation.
Skin Irritation: Causes skin irritation. In the in vivo studies on rabbits and guinea pig with semiocclusive coverage the substance was found to be slightly irritating. (ECHA)
Skin Sensitisation: Not sensitising. In vivo examinations were conducted, on guinea pig to find evidence for skin sensitisation. The test results showed that the chemical is non-sensitising (ECHA).

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Arsenic and its compounds (Not Reported)
EU INCI: Arsenic and its compounds (Prohibited).
CTFA INCI: Arsenic and its compounds (Prohibited).
Chinese: 砷及其化合物.
CAS Number: 7440-38-2.
EINECS Number: 231-148-6.
Symbol: As.
Molecular Weight: 74.92.
EINECS No.: 231-148-6

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Odourless
Oxidising Properties: Non oxidising
Water Solubility: Insoluble
Oxidising Properties: Non oxidising
Boiling Point: The study does not need to be conducted because the substance is a solid which melts above 300°C
Particle Size: The smallest particle size is 0.5 mm and the most common specification is 2-15 mm. Since the final product is deliberately prepared with these specifications, further experimental verification of the particle size distribution is not considered to be required (in accordance with section 1, Annex XI of Regulation (EC) 1907/2006).
Colour: Grey, metallic
Density: 5.6 g/cm3 at 22.4 °C
Flammability: Arsenic metal (powder) was not flammable in a study where an attempt was made to ignite a pile of the metal powder with a flame.
Flash Point: The study does not need to be conducted because the flash point is only relevant to liquids and low melting point solids
Vapour Pressure: 1 Pa at 280°C to 100 kPa at 601°C.
Melting Point: 616 °C
Physical State: Powder.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as: Acute Tox. 3 * H331; Acute Tox. 3 * H301; Aquatic Acute 1 H400; Aquatic Chronic 1 H410
REACH Annex XVII: Listed in the Annex XVII. Conditions of restriction: 1. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use to prevent the fouling by micro-organisms, plants or animals of:— the hulls of boats, — cages, floats, nets and any other appliances or equipment used for fish or shellfish farming,— any totally or partly submerged appliances or equipment. 2. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use in the treatment of industrial waters, irrespective of their use. 3. Shall not be used in the preservation of wood. Furthermore, wood so treated shall not be placed on the market.
REACH SVHC: Not included in SVHC.
GHS Classification: H301: Toxic if swallowed. H331: Toxic if inhaled. H350: May cause cancer. H360: May damage fertility or the unborn child. H372: Causes damage to organs through prolonged or repeated exposure. H410: Very toxic to aquatic life with long lasting effects..
Region : Europe Type : Cosmetic Restriction : Prohibited in cosmetic products.
Region : UK Type : Cosmetic Restriction : Prohibited in cosmetic products.

TOXICITY REVIEW
General Toxicity Review: Arsenic and its compounds are known to have carcinogenic activity. In vivo studies resulted in scoring the material as causing irreversible effects on eyes and corrosive to skin. Skin sensitising study was not necessary due to the corrosive activity of the compound. It shows high acute toxicity potential with median lethal dose at 144 mg/kg bw via oral route. Dermal route of exposure median lethal dose at > 2 400 mg/kg bw. Repeated dose toxicity study determined NOAEL oral at 0.0008 mg/kg bw/day.

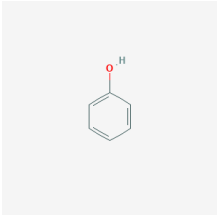
TOXICOLOGICAL PROFILE
Eye Irritation: The instillation of Arsenic Metal, Powder <0.2 mm, >99.99% into the eye of the male rabbit resulted in corneal opacity, congestion, swelling, moderate circumcorneal hyperemia, in diffuse beefy red conjunctivae and in chemosis. Based on the results, the substance causes serious eye damage and according to the EC Regulation No. 1272/2008 is classified Category 1. (ECHA)
Genotoxicity: In vitro: negative (E. coli, other: WP2 (trpE), WP2s (trpE, uvrA), WP6 (trpE, polA1), WP10 (trpE, recA1), WP44s-NF (trpE, uvrA, tif-1/sfi-), WP44s-NF amp^r and WP2s (λ)); In vivo: positive (mouse) (ECHA)
Inhalation: Toxic if inhaled
LD50: LD50 (oral, mouse) = 144 mg/kg bw. LD50 (dermal, rat)> 2 400 mg/kg bw. Description: Acute toxicity studies via oral route of administration in rats demonstrated moderate toxicity. Acute toxicity studies via dermal route of exposure showed that the substance has low skin toxicity (ECHA).
NOAEL Oral: LOEL 100 mg/L drinking water. NOAEL: 0.0008 mg/kg/day. Study type: repeated dose toxicity. Endpoint: chronic toxicity. Route of administration: oral. Species: rat. Reference type: publication 'Results of a long-term carcinogenicity bioassay on Sprague-Dawley rats exposed to sodium arsenite administered in drinking water'. Report date: 2006. Source: ECHA. MoS was calculated based on this data.
ADME (Absorption, Distribution, Metabolism, Excretion): Absorption of water soluble inorganic arsenic compounds through the G.I. tract is very high. In humans, absorption rates of 96.5% for trivalent sodium arsenite and 94% for soluble pentavalent arsenic have been reported (Bettley and O'Shea, 1975; Pomroy et al., 1980). In contrast, G.I. absorption of the less soluble arsenic trisulfide and lead arsenate was reported to be only 20-30% in hamsters (Marafante and Vahter, 1987). In tests on humans, absorption of the insoluble arsenic selenide appeared to be neglible as indicated by the absence of an increase in urinary arsenic excretion (Mappes, 1977). Following absorption of trivalent or pentavalent arsenic compounds, arsenic is initially accumulated in the liver, kidney, lung, spleen, aorta, and skin. With the exception of the skin, clearance from these organs is rapid. Arsenic is also extensively deposited in the hair and nails (U.S. EPA, 1984). Arsenic compounds are subject to metabolic transformation. In both humans and animals, pentavalent arsenic compounds are reduced to trivalent forms and then methylated in the liver to less toxic methylarsinic acids (ATSDR, 1989). Arsenic is cleared from the body relatively rapidly and primarily in the urine. Urinary excretion rates of 80% in 61 hr following oral doses and 30-80% in 4-5 days following parenteral doses have been measured in humans (Crecelius, 1977; Hunter et al., 1942).
Skin Irritation: After treatment with the test item arsenic metal, powder (particle size < 0.2 mm, purity > 99.99 %) the mean relative absorbance value decreased to 8.8 %. This value is below the treshold for irritancy of ≤ 50 %. Therefore, the test item is considered to causes skin irritation (category 2). (ECHA)
Skin Sensitisation: The sensitive predictive test method (GMPT) does not suggest that the studied arsenicals are skin allergens (ECHA). Skin contact with inorganic arsenic dusts in occupationally exposed workers has been associated with direct dermatitis, allergenic hypersensitivity, and conjunctivitis (U.S. EPA, 1984; Pinto and McGill, 1953; Holmqvist, 1951).
Carcinogenicity: Carcinogenic category 1A, 1B

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



IDENTIFICATION
Phenol (Not Reported)
EU INCI: Phenol (Prohibited).
CTFA INCI: Phenol (Prohibited).
CNDA INCI: Phenol (Prohibited).
Chinese: 苯酚.
CAS Number: 108-95-2.
EINECS Number: 203-632-7.
Symbol: C6H6O.
Molecular Weight: 94.11.
Synonyms: carbolic acid; Hydroxybenzene; Phenic acid; Oxybenzene; Phenylic acid; Benzenol; Monophenol; Phenyl hydrate; Phenylic alcohol; Phenyl hydroxide

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Characteristic, phenol
Oxidising Properties: Not oxidising
Viscosity: 3.437 mPa x s at 50°C
Water Solubility: 84 g/L at 20°C
Partial Coefficient logPow: 1.47 at 30°C
Boiling Point: 181.8-181.9 °C at 101 325 Pa
Colour: Colourless to light yellow or light pink
Density: 1.07 g/cm³ at 20°C; 1.13 g/cm³ at 25°C
Flammability: Non flammable
Flash Point: 81 °C at 101325 Pa
Vapour Pressure: 0.2 hPa at 20°C
Melting Point: 40.9 °C at 101325 Pa
Physical State: Solid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: CLassified as: Muta. 2 H341; Acute Tox. 3 * H331; Acute Tox. 3 * H311; Acute Tox. 3 * H301; STOT RE 2 * H373 **; Skin Corr. 1B H314. Specific concentration limits: *Skin Corr. 1B;H314: C ≥ 3 % Skin Irrit. 2; H315 1 % ≤ C<3 % Eye Irrit. 2; H319:1 % ≤C<3 %
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: H341 Suspected of causing genetic defects. H331 Toxic if inhaled. H311 Toxic in contact with skin. H301 Toxic if swallowed. H314 Causes severe skin burns and eye damage. H373 Causes damage to organs through prolonged or repeated exposure..
Region : Europe Type : Cosmetic Restriction : Prohibited
Region : UK Type : Cosmetic Restriction : Prohibited

TOXICITY REVIEW
General Toxicity Review: Phenol causes severe skin burns and eye damage. The substance is toxic after skin contact, inhalation and ingestion. May cause damage to organs and genetic defects. Overall, the ingredient is considered to be of toxicological concern when used in costumer products. Only unavoidable trace levels are allowed.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as corrosive (ECHA)
Genotoxicity: In vitro: positive (Chinese hamster Ovary (CHO)); In vivo: negative (mouse) (ECHA)
LD50: LD50 (oral, rat) 340 mg/kg bw; OECD Guideline 401 (Acute Oral Toxicity); Description: Acute toxicity studies via oral route of administration in rats demonstrated high toxicity of the substance. LD50 (dermal, rat) 660 mg/kg bw; OECD Guideline 402 (Acute Dermal Toxicity); Description: Acute toxicity studies via dermal route of exposure in rats showed that the substance has high skin toxicity. (ECHA)
Mutagenicity: Mutagenic category 2.
NOAEL Dermal: NOAEL 130 mg/kg bw/day Study type: repeated dose toxicity; Endpoint:short-term repeated dose toxicity: dermal; Species:rabbit; Bibliographic source:Arch Ind Hyg Occ Med 2: 454-461; ECHA, MoS was calculated based on this data
NOAEL Inhalation: NOAEC 100 mg/m³ air Study type: repeated dose toxicity; Endpoint:sub-chronic toxicity: inhalation; Species:rat; Bibliographic source:Amer J Clin Pathol 14: 273-277; ECHA, MoS was calculated based on this data
NOAEL Oral: NOAEL 450 mg/kg bw/day Study type: repeated dose toxicity; Endpoint:chronic toxicity: oral; Species:rat; Guideline: OECD 451 (carcinogenicity study); Bibliographic source:NIH Publication No. 80-1759; ECHA, MoS was calculated based on this data
Skin Irritation: In the in vivo studies on rabbits the substance was found to be corrosive. (ECHA)
Skin Sensitisation: Non-LLNA in vivo examinations were conducted, using guinea pig, modified Buehler test, to find evidence for skin sensitisation. The test results showed that the chemical is non-sensitising. (ECHA)

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Iron Powder (Opacifying,Reducing)
EU INCI: Iron Powder.
CTFA INCI: Iron Powder.
CNDA INCI: Iron Powder.
Chinese: 铁粉.
CAS Number: 7439-89-6.
EINECS Number: 231-096-4.
Symbol: Fe.
Molecular Weight: 55.845.
Description: Iron Powder is the element consisting of powdered metallic iron

Fe

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Oxidising Properties: No oxidising
Water Solubility: Iron powder is insoluble at 22°C
Oxidising Properties: No oxidising properties
Boiling Point: 2861 °C at 101 325 Pa
Colour: Grey to black, metallic
Density: 7.87 g/cm^3 at 20 °C
Flammability: Flammable solid
Melting Point: 1 538 °C at 101325 Pa
Microbiological stability: Not susceptible to microbiological contamination
Physical State: Solid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV)
GHS Classification: Not classified as per GHS. Self classified: H228: Flammable solid. H251: Self-heating; may catch fire.
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: The substance is not associated with skin irritation, skin sensitisation and is not expected to cause an eye irritation. It is practically non-toxic with LD50 98.6 g/kg bw / 98600 mg/kg bw for oral exposure and LC50 > 250 mg/m³ air for inhalation exposure. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is considered to be safe when used as intended.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as not irritating. (ECHA)
Genotoxicity: In vitro: negative (strains TA97a, TA98, TA 100, TA102, TA1535, TA1537 & TA1538 of Salmonella typhimurim) (ECHA)
LD50: LD50 (oral, rat) 98.6 g/kg bw / 98600 mg/kg bw; OECD Guideline 401 (Acute Oral Toxicity); Description: Acute toxicity studies via oral route of administration in rats demonstrated that the substance is practically non-toxic. (ECHA) LC50 (inhalation, rat) > 250 mg/m³ air. Description: The substance when tested for acute toxicity via inhalation for 6 hours (dust) was found to be practically non-toxic.(ECHA)
NOAEL Inhalation: NOAEC 5 mg/m3 (0.005 mg/L). Study type Repeated dose toxicity. Endpoint short-term repeated dose toxicity:. Study date 1997 (ECHA)
Skin Irritation: In the in vivo studies on rabbits with semiocclusive coverage the substance was found to be not irritating and not corrosive. (ECHA)
Skin Sensitisation: Non-LLNA in vivo examinations were conducted, using guinea pig Maurer optimisation test, to find evidence for skin sensitisation. The test results showed that the chemical is non-sensitising. (ECHA)

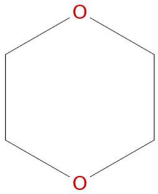
Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
1,4-Dioxane (Not Reported)
EU INCI: 1,4-Dioxane (Prohibited).
CTFA INCI: 1,4-Dioxane (Prohibited).
Chinese: 二噁烷.
CAS Number: 123-91-1.
EINECS Number: 204-661-8.
Symbol: C4H8O2.
Molecular Weight: 88.11.
Description: The chemical material is a heterocyclic organic compound and is classified as an ether, also know as Dioxane. It is a colorless liquid with a faint sweet odo
IUPAC Name: 1,4-Dioxane
Synonyms: Dioxane, p-Dioxane, 1,4-Diethylene dioxide, diethylene ether, Tetrahydro-p-dioxin, Tetrahydro-1,4-dioxin



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Ethereal
Water Solubility: 1000g/l at 20°C
Partial Coefficient logPow: -0.42 at 20°C
Boiling Point: 100.8 - 101.5°C at 1013 hPa
Colour: Colourless
Density: 1.03 at 20°C
Flammability: Highly Flammable liquid and vapour.
Flash Point: 11°C (closed cup)
Vapour Pressure: 42.8 hPa at 23°C
Melting Point: 11.8°C - 11.9°C
Physical State: Liquid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as: Flam. Liq. 2 H225; Carc. 2 H351; Eye Irrit. 2 H319; STOT SE 3 H335; Carc. 1B H350.
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Included in SVHC. Reason of inclusion: Carcinogenic (Article 57 (a)) Equivalent level of concern having probable serious effects to the environment (Article 57 (f) -environment) Equivalent level of concern having probable serious effects to human health (Article 57 (f) –human health)
Regulatory Controls: It is noted that the SCCS opinion has recently proposed the safe level of the carcinogen impurity named 1,4-dioxane (CAS No 123-91-1) at < 10 ppm (0.001%) in the finished cosmetic product.
GHS Classification: H225 Highly Flammable liquid and vapour. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H351: Suspected of causing cancer..
Region : Europe Type : Cosmetic Restriction : Prohibited
Region : UK Type : Cosmetic Restriction : Prohibited

TOXICITY REVIEW
General Toxicity Review: Dioxane is suspected of causing cancer. The substance causes serious eye irritation but is not irritating to the skin. It shows very high systemic toxicity after oral exposure. Overall, the ingredient is considered to be of toxicological concern when used in consumer products. Only unavoidable trace levels are allowed.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as seriously irritating. (ECHA)
Inhalation: May cause respiratory irritation
LD50: LD50 (oral, rat) 5150 mg/kg bw; OECD Guideline 401 (Acute Oral Toxicity); Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity of the substance. (ECHA)
NOAEL Inhalation: NOAEC > 400 mg/m³ air Study type: repeated dose toxicity; Endpoint:chronic toxicity: inhalation; Species:rat; Bibliographic source:Toxicol. Appl. Pharmacol. 30, 287-298; ECHA, MoS was calculated based on this data
NOAEL Oral: NOAEL 9.6 mg/kg bw/day Study type: repeated dose toxicity; Endpoint:chronic toxicity: oral; Species:rat; Bibliographic source:Regulatory Toxicology and Pharmacology 88; ECHA, MoS was calculated based on this data
ADME (Absorption, Distribution, Metabolism, Excretion): In vitro study showed that the substance can penetrate human skin when occluded even though to a small extend, but rapidly evaporates without occlusion (Bronaugh, 1982). As a worst case scenario 100% dermal absorption was chosen. The major metabolite in human urine: β-hydroxyethoxyacetic acid (HEAA; Young et al., 1977). The reactive metabolite: 2-Hydroxyethoxyacetaldehyde (ECHA)
Skin Irritation: In the in vivo studies on rabbits with occlusive coverage the substance was found to be not irritating. (ECHA)
Skin Sensitisation: Non-LLNA in vivo examinations were conducted, using guinea pig maximisation test, to find evidence for skin sensitisation. The test results showed that the chemical is non-sensitising. (ECHA)
Carcinogenicity: Carcinogenic cat. 2

OTHER
Biodegradability (Environmental): Based on the available experimental and estimated data, the substance is evaluated to be not readily biodegradable according to OECD criteria (freshwater) (ECHA)
Ecological toxicity: LC50 > 100 mg/L (Oryzias latipes, 21 d, 2020, OECD Guideline 204 (Fish, Prolonged Toxicity Test: 14-day Study)); NOEC = 145 mg/L (Pimephales promelas, 32 d, 2002, OECD Guideline 210 (Fish, Early-Life Stage Toxicity Test)); EC50> 1 000 mg/L (Daphnia magna, 48h, 2020, OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)); NOEC = 1 000 mg/L (Daphnia magna, 21 d, 2002, OECD Guideline 211 (Daphnia magna Reproduction Test)); EC5= 2 700 mg/L (Pseudomonas putida, 16h, 2002, DIN 38412-8 (Pseudomonas Zellvermehrungshemmtest)); EC50> 1 000 mg/L (Pseudokirchneriella subcapitata , 72h. 1996, OECD Guideline 201 (Alga, Growth Inhibition Test)) (ECHA)

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Lead and its compounds (Not Reported)
EU INCI: Lead and its compounds (Prohibited).
CTFA INCI: Lead and its compounds (Prohibited).
Chinese: 铅及其化合物.
CAS Number: 7439-92-1.
EINECS Number: 231-100-4.

Pb

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Characteristic
Oxidising Properties: Non oxidising
Water Solubility: 185 mg/L
Particle Size: Particle diameter < 1 mm: D50 = 12.7 µm.Mass median aerodynamic diameter of airborne fraction 33.7 µm.
Colour: Grey- blue
Melting Point: 326 °C at 101 325 Pa
Physical State: Powder.

REGULATORY REQUIREMENTS
Specific Conc. Limits, M-factors and ATEs: Repr. 1A; H360D: C≥ 0,03 %; M = 1 (H400) ; M = 10 (H410).
CLP Regulation (EC) No 1272/2008: Classified as: Repr. 1A, H360FD; Lact. H362; Acute Tox. 4 *, H332; Acute Tox. 4 *, H302; STOT RE 2 *, H373 **; Aquatic Acute 1,H400; Aquatic Chronic 1, H410
REACH Annex XVII: Listed. Toxic to reproduction category 1A,
REACH SVHC: Included in SVHC. Reason of inclusion: Toxicity to reproduction (Article 57c).
Regulatory Controls: An impurity. Prohibited as an ingredient.
GHS Classification: H360FD: May damage fertility. May damage the unborn child. H362: May cause harm to breast-fed children. H372: Causes damage to organs through prolonged or repeated exposure: Causes damage to central nervous system, blood and kidneys through prolonged or repeated exposure by inhalation or ingestion.
Region : Europe Type : Cosmetic Restriction : Prohibited
Region : UK Type : Cosmetic Restriction : Prohibited

TOXICITY REVIEW
General Toxicity Review: Lead is considered as unsafe and is prohibited in cosmetic products. The substance: may damage fertility or the unborn child and may cause harm to breast-fed children. Lead causes damage to organs through prolonged or repeated exposure: central nervous system, blood and kidneys through prolonged or repeated exposure by inhalation or ingestion. Overall, the ingredient is considered to be of toxicological concern when used in consumer products. Only unavoidable trace levels are acceptable.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo to examine ocular irritation potential. Endpoint: Not irritating;Method: according to OECD Guideline 405; Species: rabbit; Report date: 2003; Source: ECHA.
LD50: LD50 > 2 000 mg/kg bw; Route of exposure: oral, Species: rat, Report date: 2003, Method: according to OECD Guideline 423. Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity of the substance. LD50 > 2 000 mg/kg bw Route of exposure: dermal, Species: rat, Report date: 2003, Method: according to OECD Guideline 402. Description: Acute toxicity studies via dermal route of exposure in rabbits (occlusive type of coverage) showed that the substance has low skin toxicity. Source ECHA.
NOAEL Oral: NOEL 0.002 mg/kg bw/day Study type: repeated dose, chronic toxicity; Route of exposure: oral; Species: rat, Report date: 1979; Method: Followed guidelines of an EPA chronic feeding study.; Source: ECHA.
Reproductive Toxicology: Toxic to fertility oral and inhalation route.
Safety evaluation: Consequently, the environmental classification of lead should be reviewed by RAC, in accordance with recital 5 of the draft Commission Regulation updating the entry of lead listed in Annex VI of Regulation (EC) No 1272/2008. (5) With regard to the substance lead (CAS number 7439-92-1 and index numbers 082-013- 00-1 (lead powder; [particle diameter < 1mm];) and 082-014-00-7 (lead massive; [particle diameter ≥ 1mm];)), RAC proposed in its opinion of 30 November 2018 to apply the same environmental classification to the massive and the powder form. However, in view of the lower dissolution rate of the massive form, the malleable structure of lead, the specific intentional production of the powder and the different environmental classification between massive and powder forms for existing entries in Annex VI for other metals, further assessment needs to be done by RAC on whether to apply the same environmental classification to the massive as to the powder form of lead. In addition, new scientific data has been made available suggesting that the environmental classification for the massive form as recommended in the RAC opinion might not be appropriate Therefore, the environmental classification for the massive form will not be included in Annex VI to Regulation (EC) No 1272/2008 until RAC has had the opportunity to delive a revised opinion. European Chemicals Agency (ECHA) requested a review concerning environmental classification of lead from the Committee for Risk Assessment (RAC).
ADME (Absorption, Distribution, Metabolism, Excretion): In vitro / ex vivo studies showed that through unabraded human skin absorption is considered to be minimal (<0 .1%). (ECHA)
Skin Irritation: The substance was tested in vivo to examine skin irritation potential. Endpoint: Not irritating; Method: according to OECD Guideline 404; Species: rabbit; Report date: 2003; Source: ECHA.
Skin Sensitisation: The substance was tested in vivo to examine skin sensitising potential. Endpoint: Not associated with skin sensitisation; Method: according to OECD Guideline 406; Species: guinea pig; Report date: 2003; Source: ECHA.
Carcinogenicity: NOAEL 7.8 mg/kg bw/day (chronic toxicity, rat) (ECHA)

OTHER
Ecological toxicity: Very toxic to aquatic life with long lasting effects

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Nickel (Not Reported)
EU INCI: Nickel (Prohibited).
CTFA INCI: Nickel (Prohibited).
Chinese: 镍.
CAS Number: 7440-02-0.
EINECS Number: 231-111-4.

Ni

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Water Solubility: Insoluble
Particle Size: <100 um, 97.1%<10 um, 0.61%<5.5 um, 0.31%
Colour: Lustrous white to grey
Density: 8.9 g/cm3 at 25°C
Melting Point: 1455°C
Physical State: Solid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as: Carc. 2 H351; STOT RE 1 H372**; Skin Sens. 1 H317; Additionally nickel powder [particle diameter <1mm] : Aquatic Chronic 3 H412
REACH Annex XVII: Listed in Annex XVII. Reason of inclusion Carcinogenic 2B. substance with the specific concentration limit: 0,0005 %
REACH SVHC: Not included in SVHC
GHS Classification: H351: Suspected of causing cancer (inhalation); H372: Causes damage to organs through prolonged or repeated exposure (inhalation); H317: May cause an allergic skin reaction. H412: Harmful to aquatic life with long lasting effects..
Region : Europe Type : Cosmetic Restriction : Prohibited
Region : UK Type : Cosmetic Restriction : Prohibited

TOXICITY REVIEW
General Toxicity Review: Nickel is considered as unsafe and is prohibited in cosmetic products. The substance may cause an allergic skin reaction and is suspected of causing cancer (inhalation). Nickel causes damage to organs through prolonged or repeated exposure by inhalation. Overall, the ingredient is considered to be of toxicological concern when used in consumer products. Only unavoidable trace levels are acceptable.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as not irritating. (ECHA)
LD50: LD50 (oral, rat) > 9 000 mg/kg bw; OECD Guideline 401 (Acute Oral Toxicity); Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity of the substance. (ECHA)
NOAEL Inhalation: LOAEC 0.1 mg/m³ air Study type: Repeated dose toxicity; Endpoint:repeated dose toxicity: inhalation(aerosol, whole body); Species:rat; Guideline: OECD Guideline 451 (Carcinogenicity Studies); Source: ECHA
NOAEL Oral: NOAEL 2.2 mg Ni/kg bw/day Study type: repeated dose toxicity: oral; Species:rat; Guideline:OECD Guideline 451 (Carcinogenicity Studies); Source: ECHA, MoS was calculated based on this data
Reproductive Toxicology: NOAEL 10 mg/kg bw/day Study type: Toxicity to reproduction; Endpoint:two-generation reproductive toxicity; Species:rat; Guideline:OECD Guideline 416 (Two-Generation Reproduction Toxicity Study); Source; ECHA
Skin Irritation: In the in vivo studies on rabbits with semiocclusive coverage the substance was found to be not irritating and not corrosive. (ECHA)
Skin Sensitisation: May cause skin sensitisation. Officially classified as Skin. Sens 1 by the CLP regulation.
Carcinogenicity: It is classified as Category 2; H351 carcinogen under the EU CLP; and Group 2B carcinogen (possible human carcinogen) by IARC (1990)

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Cadmium (Not Reported)
EU INCI: Cadmium (Prohibited).
CTFA INCI: Cadmium (Prohibited).
Chinese: 镉.
CAS Number: 7440-43-9.
EINECS Number: 231-152-8.
Symbol: Cd.
Synonyms: Cadmium (non-pyrophoric)

Cd

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Odourless
Water Solubility: 2.3 mg/L at 20 °C
Particle Size: D50 of the cadmium powder is 16.27 µm, the D80 is <20 µm
Colour: Brownish
Density: 8.64 g/cm3
Melting Point: 321°C
Physical State: Powder.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as: Carc. 1B, H350; Muta. 2, H341; Repr. 2, H361fd; Acute Tox. 2 *, H330; STOT RE 1, H372 **; Aquatic Acute 1, H400; Aquatic Chronic 1, H410
REACH Annex XVII: Listed in Annex XVII. Reason of inclusion: Carcinogenic category 1B
REACH SVHC: Included in SVHC. Reason of inclusion: Carcinogenic (Article 57a), Specific target organ toxicity after repeated exposure (Article 57(f) - human health).
GHS Classification: H350: May cause cancer. H341: Suspected of causing genetic defects. H361 fd: Suspected of damaging fertility. H330: Fatal if inhaled. H372: Causes damage to organs through prolonged or repeated exposure. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects..
Region : Europe Type : Cosmetic Restriction : Prohibited
Region : UK Type : Cosmetic Restriction : Prohibited

TOXICITY REVIEW
General Toxicity Review: Cadmium is considered as unsafe and is prohibited in cosmetic products. It is known to be carcinogenic, mutagenic and reprotoxic. There is no evidence of potential irritating properties for skin and eyes. The substance is not expected to cause skin sensitisation. It is moderately toxic with LD50 63 mg/kg bw for oral exposure. The substance causes organs damage after prolonged and repeated use. Overall, the ingredient is considered to be concern of safe use.

TOXICOLOGICAL PROFILE
Eye Irritation: Based on the available toxicological data there is no evidence of eye irritation potential.
Developmental toxicity: NOAEL 0.5 mg/m³ air and LOAEL 2 mg/m³ air Study type: Developmental toxicity / teratogenicity (rat, inhalation-whole body, 1995, OECD 414). Maternal toxicity was observed in rats: lower body weight, dyspnea and hypoactivity. (ref.ECHA)
Genotoxicity: In vitro: negative (S. typhimurium TA 1535, TA 1537, TA 98 and TA 100); In vivo: negative (mouse) (ECHA)
LD50: LD50 (oral, mouse) 63 mg/kg bw (2007). Description: Acute toxicity studies via oral route of administration in mouse demonstrated moderate toxicity of the substance. LC50 (inhalation, mouse) > 9.02 mg/m³ air. (ref. ECHA)
NOAEL Inhalation: LOAEL 25 other: µg/m3 Study type: sub-chronic toxicity: inhalation (aerosol, rat, 1978) (ECHA)
NOAEL Oral: NOAEL 3 mg/kg bw/day (nominal). Endpoints; sub-chronic toxicity: oral. Methods; no guideline followed. Species; rat. Route of administration; oral: feed. Report date; 1997. Source; ECHA. (Toxicology 7: 215-224) MoS was calculated based on this data.
Reproductive Toxicology: NOAEL 0.1 mg/m³ air Study type: toxicity to reproduction (inhalation: aerosol, whole body, rat, 1995, OECD TG 413 and EC TM B26 Dir. 87/302/EEC 30/05/88). During the study reduced number of spermatids per testis and an increase in the length of the estrous cycle were observed. (ref.ECHA)
ADME (Absorption, Distribution, Metabolism, Excretion): In vitro human skin models suggest that, although cadmium may penetrate through skin, absorption of soluble and less soluble compounds is generally lower than 1% (Kimura and Otaki, 1972; Lansdown and Sampson, 1996; Wester et al., 1992; ECB, 2008). (ECHA)
Skin Irritation: In the in vitro / ex vivo studies on the human skin model the substance was found to be not irritating and not corrosive. (ECHA)
Skin Sensitisation: Based on the available toxicological data there is no evidence of skin allergy potential.
Carcinogenicity: Carcinogenic category 1B. LOAEL 3.5 mg/kg bw/day Study type: Carcinogenicity: via oral route (target organ): urogenital: prostate. LOAEC 0.03 mg/m³ Study type: Carcinogenicity: via inhalation route (target organ): respiratory: lung According to animal testing cadmium is carcinogen. (ECHA)

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Mercury and its compounds (Not Reported)
EU INCI: Mercury and its compounds (Prohibited).
CTFA INCI: Mercury and its compounds (Prohibited).
Chinese: 汞及其化合物.
CAS Number: 7439-97-6.
EINECS Number: 231-106-7.

Hg

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Oxidising Properties: Non oxidising
Viscosity: 1.55 mPa · s (dynamic) at 20 °C
Water Solubility: 0.057 mg/L at 25 °C
Boiling Point: 356.66 °C at 101 325 Pa
Colour: Silver
Density: 13.54 at 20C
Flammability: Non flammable
Vapour Pressure: 0.002 hPa at 20 °C
Melting Point: -38.67 °C at 101 325 Pa
Microbiological stability: Not susceptible to microbiological contamination
Physical State: Liquid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as: Repr. 1B, H360D***; Acute Tox. 2 *, H330; STOT RE 1, H372**; Aquatic Acute 1, H400; Aquatic Chronic 1, H410
REACH Annex XVII: Listed. Reason of inclusion: Toxic to reproduction: category 1B
REACH SVHC: Not included in SVHC list (Annex XIV)
GHS Classification: H330: Fatal if inhaled. H360: May damage fertility or the unborn child. H372: Causes damage to organs. H410: Very toxic to aquatic life with long lasting effects..
Region : Europe Type : Cosmetic Restriction : Prohibited in all products
Region : UK Type : Cosmetic Restriction : Prohibited in all products

TOXICITY REVIEW
General Toxicity Review: Mercury is considered as unsafe and is prohibited in cosmetic products. The substance may cause damage to organs and fertility or the unborn child. The substance is highly toxic with LD50 > 9.2 mg/kg bw for oral exposure and very toxic with LC50 > 26.6 mg/m³ air (analytical) for inhalation exposure. Overall, the ingredient is considered to be of toxicological concern when used in costumer products. Only unavoidable trace levels are acceptable.

TOXICOLOGICAL PROFILE
Eye Irritation: Based on the available toxicological data there is no evidence of eye irritation potential.
Genotoxicity: In vitro: positive (mouse lymphoma L5178Y cells); In vivo: positive (mouse) (ECHA).
LD50: LD50 (oral, rat) > 9.2 mg/kg bw; Description: Acute toxicity studies via oral route of administration in rats demonstrated high toxicity of the substance. (ECHA) LC50 (inhalation, rat) > 26.6 mg/m³ air (analytical). Description: The substance when tested for acute toxicity via inhalation and was found to be very toxic. (ECHA)
NOAEL Oral: LOAEL 0.312 mg/kg bw/day Study type: sub-chronic toxicity: oral (rat, 1993) (ref.echa); NOAEL 0.23 mg/kg body weight Study type: repeated dose toxicity (26-week, oral, mercuric chloride) (ref.WHO) NOAEL 0.005 mg Hg/kg/day Study type: repeated dose toxicity (2-years, oral, rat) (Fitzhugh et al. 1950)
Reproductive Toxicology: LOEL 7.5 mg/kg bw/day Study type: toxicity to reproduction (oral, rat, 1996) (ref.echa)
Skin Irritation: In the in vivo studies on rabbits with occlusive coverage the substance was found to be not irritating. (ECHA)
Skin Sensitisation: Non-LLNA in vivo examinations were conducted, using guinea pig Buehler test, to find evidence for skin sensitisation. The test results showed that the chemical is non-sensitising. (ECHA)

Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name
Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

Manufacturer
Eresos Health + Wellbeing LTD
14 A Commercial Road
London
N18 1TP

UNDESIRABLE EFFECTS AND SERIOUS UNDESIRABLE EFFECTS MONITORING POST MARKETING SURVEILLANCE

HOW LONG ON THE MARKET: New product – no data.

AMOUNT OF UNITS SOLD: New product – no data.

REMARKS: New product – no data.

INFORMATION ON THE COSMETIC PRODUCT DERMATOLOGICAL TESTS

Based on the information received for the assessment, the product has not undergone additional testing due to the absence of other declared functions, except for those that clearly result from the definition of the cosmetic product.

LABELLED WARNINGS

Manufacturer`s warnings:
Rinse immediately with clean, warm water if any contact is made with the eyes. This product is not intended to diagnose, treat, cure, or prevent any diseases. If pregnant or breastfeeding, consult your doctor before use. Keep out of reach of children.
We recommend that you store our products in a cool, dark place.

Product Name
Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

Manufacturer
Eresos Health + Wellbeing LTD
14 A Commercial Road
London
N18 1TP

INSTRUCTION OF USE

Apply a generous amount of hand wash under clean, running water. Lather your hands by rubbing them together with the hand wash for a minimum of 30 seconds to ensure full antibacterial cleanse. Dry thoroughly afterwards.

REASONING
TOXICOLOGICAL ASSESSMENT

OVERALL TOXICOLOGICAL REVIEW

The NOAELs were not available for all ingredients. For the substances where NOAELs (usually derived based on repeated dose toxicity (chronic toxicity), are not available, the safety of these substances is justified based on other available toxicological endpoints such as local toxicity (allergenicity, irritation, corrosivity), percutaneous absorption, acute toxicity (oral and dermal), toxicokinetics, carcinogenicity and genotoxicity.

It is noted that the NOAELs were not available for review for all of the ingredients, however, for the substances, where values were available, the margin of safety (MoS) is usually above the typical 100-fold recommendation as per reference to the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation. A number of other materials have recommended safe levels (as established by bodies such as the Cosmetics Ingredient Review (CIR) Expert Panel) or legal limits that are described in percentage terms. All such materials are present at/or below the recommended safe levels or legal maximums as per the regulatory requirements.

This assessment is based on the maximum percentages of each ingredient and as such does not equal 100%.

It is noted that for some chemical materials the MoS for oral exposure was calculated below 100. Bearing in mind that the product is intended for adults the risk of accidental ingestion is unlikely.

A complete set of technical specifications of the product, raw materials and the packaging were not provided at the time of the assessment. It is the responsibility of the RP to ensure that the product does not contain ingredients that are restricted or prohibited prior to marketing.

It is noticed that the MoS of Limonene, Eugenol, Isoeugenol are slightly below the value of 100 considered as a safe concentration by WHO. IFRA Certificates for Eugenia Caroyphyllus Bud Oil and Citrus Nobilis Peel Oil were not provided at the time of the assessment. The level of essential oils should be within the IFRA Category 9 (Rinse-off products) as per supplier IFRA certificate. However, the hand wash is the rinse-off product, therefore the risk of skin irritation or sensitisation is reduced.

This product is considered safe and in compliance with the Cosmetic Regulation (EC) No 1223/2009 requirements and with Schedule 34 of the Product Safety & Metrology etc (Amendment etc) (EU Exit) Regulations 2019 UK Cosmetics Regulation and subsequent amendments under the conditions that the efficacy of the preservative system and microbiological stability (TVC, mould, fungi, absence of pathogens) meet the acceptance criteria based on the positive evaluation prior to marketing. The product must be manufactured according to Good Manufacturing Practice.

Product Name
Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

Manufacturer
Eresos Health + Wellbeing LTD
14 A Commercial Road
London
N18 1TP

REASONING
TOXICOLOGICAL ASSESSMENT

EFFECT ON SKIN
May cause skin irritation.

The product contains perfume materials that are known to cause an allergic reaction, however, the risk of inducing allergy is low for the general population due to the dilution factor.

EFFECT ON EYES
May cause significant eye irritation and discomfort.

EFFECT ON INGESTION
This product is intended for external use only and should not be ingested.
The product is expected to cause some adverse health effect when it accidentally enters the GI tract in a large amount. If swallowed in a small amount, may cause some irritation to the mouth and upper GI tract.

EFFECT ON INHALATION
It is unlikely that inhalation will be a route of exposure.

Product Name
Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

Manufacturer
Eresos Health + Wellbeing LTD
14 A Commercial Road
London
N18 1TP

ASSESSMENT CONCLUSION

This safety assessment has been prepared in accordance with the Cosmetic Regulation (EC) No 1223/2009. This is the safety assessment of regulated products and their toxicology of which are assessed as follows:

Quantitative and qualitative composition of the cosmetic product
Physical/chemical characteristics and stability of the cosmetic product
Microbiological quality
Impurities, traces, information about the packaging material
Normal and reasonably foreseeable use
Exposure to the cosmetic product / Exposure to the substances
Toxicological profile of the substances
Information on the cosmetic product
The regulatory status of the ingredients for use in the cosmetic products
The safety data identified for each ingredient obtained during literature searches in medical and toxicology databases.

Taking into account the information and the present state of knowledge, this product complies with the annexes to the Cosmetic Regulation (EC) No 1223/2009 requirements.
Under normal and reasonably foreseeable conditions of use the product should not cause damage to human health when placed in the market.

The individual ingredients characteristic suggest that interaction of the materials would not lead to any synergistic or unpredictable adverse effects.

This safety assessment is relevant solely to the information and conditions described in this document. Any changes to ingredients and their concentrations of use, or change application use shall be subjected to a new assessment.

This product is considered safe and in compliance with the Cosmetic Regulation (EC) No 1223/2009 requirements and with Schedule 34 of the Product Safety & Metrology etc (Amendment etc) (EU Exit) Regulations 2019 UK Cosmetics Regulation and subsequent amendments under the conditions that the efficacy of the preservative system and microbiological stability (TVC, mould, fungi, absence of pathogens) meet the acceptance criteria based on the positive evaluation prior to marketing.

The product must be manufactured according to Good Manufacturing Practice.

TOXICOLOGICAL AND REGULATORY ASSESSOR

23 January 2023

A T Nnolim, MScTox, MScEng, CChem,CSci, EurChem, PostDipMicro, EUROTOX Registered Toxicologist
NOLICHEM Consultancy, 4 Lime Crescent, Willand, Cullompton, EX15 2SL, UK

SAFETY ASSESSOR

23 January 2023

D M Warcholek, BSc, MSc, Safety Assessor
NOLICHEM Consultancy, 4 Lime Crescent, Willand, Cullompton, EX15 2SL, UK

Product Name
Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

Manufacturer
Eresos Health + Wellbeing LTD
14 A Commercial Road
London
N18 1TP

IMPURITIES

CAS No	IMPURITY	SOURCE CHEMICAL	Concentration in finished product[C %]
2836-32-0	Sodium Glycolate	Cocamidopropyl Betaine	0.1727232000
7727-37-9	Nitrogen	Xanthan Gum	0.0134784000
111-46-6	Diethylene glycol	Glycerin	0.0034944000
107-21-1	Glycol (Ethylene glycol)	Glycerin	0.0034944000
59-02-9(10191-41-0)(1406-66-2)1406-18-4(54 -28-4)(gamma)	Tocopherol	Tocopheryl Acetate	0.0014976000
16887-00-6	Chloride	Glycerin	0.0012230400
67-63-0	Isopropyl Alcohol	Xanthan Gum	0.0006739200
108-88-3	Toluene	Tocopheryl Acetate	0.0000239616
110-86-1	Pyridine	Tocopheryl Acetate	0.0000239616
7440-70-2	Calcium	Citric Acid	0.0000224640
75-21-8	Ethylene oxide	Phenoxyethanol	0.0000199680
7439-92-1	Lead and its compounds	Glycerin	0.0000174720
7782-50-5	Chlorine	Citric Acid	0.0000149760
7440-38-2	Arsenic and its compounds	Glycerin	0.0000104832
108-95-2	Phenol	Phenoxyethanol	0.0000099840
7439-97-6	Mercury and its compounds	Glycerin	0.0000034944
7440-43-9	Cadmium	Glycerin	0.0000034944
7440-38-2	Arsenic and its compounds	Xanthan Gum	0.0000017971
7439-92-1	Lead and its compounds	Xanthan Gum	0.0000017971
7439-89-6	Iron Powder	Citric Acid	0.0000014976
123-91-1	1,4-Dioxane	Phenoxyethanol	0.0000009984
7439-97-6	Mercury and its compounds	Xanthan Gum	0.0000008986
7440-43-9	Cadmium	Xanthan Gum	0.0000008986
7439-92-1	Lead and its compounds	Tocopheryl Acetate	0.0000005990
7440-38-2	Arsenic and its compounds	Tocopheryl Acetate	0.0000002995
7440-02-0	Nickel	Tocopheryl Acetate	0.0000002995
7439-97-6	Mercury and its compounds	Citric Acid	0.0000002995
7440-43-9	Cadmium	Tocopheryl Acetate	0.0000001498
7439-92-1	Lead and its compounds	Citric Acid	0.0000001498
7440-38-2	Arsenic and its compounds	Citric Acid	0.0000001198
7439-97-6	Mercury and its compounds	Tocopheryl Acetate	0.0000000300

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EXPOSURE TO POTENTIAL IMPURITIES

SED Product = 36 mg / kg bw / day

INCI / Chemical Name	Concentration in finished product [C %]	* Daily exposure of product (a g/day)	***Systemic Exposure Dose (SED mg/kg bw/ day)	NOAELs (mg/kg bw/day)	MoS
Sodium Glycolate	0.1727232000	2.16	0.06218035	Not Available	No MoS calculated as no NOAEL available
Nitrogen	0.0134784000	2.16	0.00485222	Not Available	No MoS calculated as no NOAEL available
Glycol (Ethylene glycol)	0.0034944000	2.16	0.00125798	150	59619.200244
Diethylene glycol	0.0034944000	2.16	0.00125798	128	50875.050875
Tocopherol	0.0014976000	2.16	0.00053914	500	463704.890788
Chloride	0.0012230400	2.16	0.00044029	Not Available	No MoS calculated as no NOAEL available
Isopropyl Alcohol	0.0006739200	2.16	0.00024261	500	1030455.312863
Toluene	0.0000239616	2.16	0.00000863	625	36226944.59283
Pyridine	0.0000239616	2.16	0.00000863	7	405741.77944
Calcium	0.0000224640	2.16	0.00000809	Not Available	No MoS calculated as no NOAEL available
Lead and its compounds	0.0000200179	2.16	0.00000721	7.8	541181.767803
Ethylene oxide	0.0000199680	2.16	0.00000719	30	2086672.008547
Chlorine	0.0000149760	2.16	0.00000539	50	4637048.907882
Arsenic and its compounds	0.0000126996	2.16	0.00000457	0.0008	87.491489
Phenol	0.0000099840	2.16	0.00000359	450	62600160.25641
Mercury and its compounds	0.0000047224	2.16	0.00000170	0.005	1470.522909
Cadmium	0.0000045427	2.16	0.00000164	3	917218.465295
Iron Powder	0.0000014976	2.16	0.00000054	Not Available	No MoS calculated as no NOAEL available
1,4-Dioxane	0.0000009984	2.16	0.00000036	9.6	13354700.854701
Nickel	0.0000002995	2.16	0.00000011	2.2	10201507.597341

*Daily exposure of product (A) estimated daily exposure as referenced by SCCS Notes of Guidance
** Dermal absorption (DAp): a worst case scenario 100%
** Systemic Exposure Dose (SED) =(A mg/g x C/100) / 60 mg/kg/day

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Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

Manufacturer
Eresos Health + Wellbeing LTD
14 A Commercial Road
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Manufacturer
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Manufacturer
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Manufacturer
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Product Name
Mandarin & Clove Hand Wash 500mg (2022-753-5058) CPSR EU/UK passed under condition

Manufacturer
Eresos Health + Wellbeing LTD
14 A Commercial Road
London
N18 1TP

LITERATURE SOURCES

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LITERATURE SOURCES

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Toy Directive	**Accessed Date:**	23/12/2022
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Water Activity in Glycerol–Water Mixtures	**Accessed Date:**	23/12/2022
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Annex 1: Assessor Credentials

Curriculum Vitae

Agnieszka Teresa Nnolim

MScTox, MScEng, MRSC, CChem, CSci, EurChem, PostDip(Ind.Microb.),
EUROTOX Registered Toxicologist

Employment

- **Toxicologist and Head of Safety** (26th February 2019 – present) – Nolichem Sp. z o.o. (Poland – EU)
- **Toxicologist, Regulatory and Safety Assessor** (2nd June 2014 – present) - Nolichem Consultancy Ltd (United Kingdom)
- **Toxicology Consultant** (September 2011 – May 2014) – Delphic HSE Solutions Limited (England-Europe)
- **Toxicologist** (August 2010 – August 2011) - Intertek Toxicology Assessment (England-Europe)
- **Product Safety Assessor** (June 2004 – July 2010) - Intertek Toxicology Assessment (England-Europe)
- **Formulation Chemist and Microbiology Quality Assurance** (October 2002 – May 2003) - Quiz Cosmetics
- **Coordinator of Production and Microbiology** (March 2001 – September 2002) - Bell Cosmetics Manufacturer
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Qualification and Education

- **EUROTOX Registered Toxicologist** (EUROTOX / ERT)
- **European Chemist** (EurChem)
- **Chartered Scientist** (CSci)
- **Chartered Chemist** (CChem)
- **MSc Degree in Applied Toxicology** , Faculty of Health and Medical Sciences, University of Surrey, UK (January 2016)
- **Advisory Board Member** (World of the Cosmetic Industry, FARMACOM, Poland, since 2014)
- IELTS English Exam (Academic), University of Exeter, UK (2004)
- **Postgraduate Diploma in Industrial Microbiology**: Microbiology, Hygiene and Quality in Industry –Lodz University of Technology (Poland), Department of Biotechnology and Consumer Chemistry. Thesis: *Cosmetic Products as a Source of Beauty and Aesthetics' in the Aspect of Microbiological Quality* (2002)
- **Diploma in Science Education of Chemistry, Mathematics and Physics** –Cracow University of Technology (Poland) (2000)
- **MSc(Eng) Degree in Chemical Engineering and Technology***: Chemical Technology majoring in Inorganic Technology – Cracow University of Technology (Poland). Thesis: Investigating the Physical and Chemical Properties of Brines from Post-Electroplating Treatment Plants and the Possibility of their Utilization (1999)*
- ***Academic Internship*** *- Chemical Plant ALWERNIA the major producer of phosphorus and chromium compounds, nitrates and sulphates including food additives, fodders and fertilizers, Cracow (August 1998)*

Skills and Expertise

- *Animal studies and in vitro replacements in assessing the possible **irritancy and sensitisation of chemicals** to which man may be exposed.*

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- *Tests for **contact hypersensitivity** using traditional animal models. Alternatives and progress that has been made toward each objective of (a) Refinement, (b) Reduction and (c) Replacement (Alternative Methodologists to Animas Studies)*
- *The relevance of in vitro studies for predicting **in vivo skin absorption**. Species differences – animal models currently used for in vitro and in vivo OECD-compliant studies (Dermal Toxicology).*
- ***REACH** and its impact on the **3Rs** and the standard approach to risk assessment (Experimental Toxicology and Risk Assessment)*
- ***Drug metabolism** studies in experimental animals in the **safety assessment** of drugs in man (Toxicokinetics and Metabolism).*
- *Critical evaluation of the purpose of **genotoxicity testing** in drug development (Carcinogenicity and Mutagenicity).*
- *Process of **atherogenesis** in man and its model (Cardiorespiratory and Haematopoietic Systems).*
- ***Apoptosis** and the development of tissue damage following chemical injury (Toxicological Pathology).*
- ***Risk assessment** in the **workplace** and risk assessment in the **wider environment** (Occupational Toxicology)*
- ***Endocrine disruptors** - reproduction and development (Reproductive Toxicology)*
- ***Endocrine tissues** - mechanisms which control hyperplasia in glands such as thyroid (Endocrine System)*
- *Exposure to **mercury and organic mercury** and effects on **neurological development** during infancy (Central* - Peripheral *Nervous, Endocrine and Musculoskeletal Systems)*
- *Pre-clinical **paediatric** programme for treatment of epilepsy of children less than 3 months of age (Paediatric Toxicology)*

University Courses and Trainings (Selection)

- Target Organ Toxicology - System I : Liver, Kidney, Gastrointestinal Tract & Skin, UK (July 2015)
- Target Organ Toxicology - System II: CNS, PNS, Endocrine and Musculoskeletal Systems, University of Surrey, UK (January 2014)
- Occupational Toxicology, University of Surrey, UK (November 2013)
- Reproductive Toxicology, University of Surrey, UK (October 2013)
- Alternative methodologies to the use of animals in toxicology, University of Surrey, UK (September 2013)
- Target Organ Toxicology - System III: Cardiorespiratory and Haematopoietic Systems, University of Surrey, UK (January 2013)
- The requirements of the EN ISO 22716:2009 Good Manufacturing Practice Guide (GMP), Poland (November 2012)
- Dermal Toxicology, University of Surrey, UK (September 2012)
- Toxicokinetics and Metabolism, University of Surrey, UK (May 2012)
- Carcinogenicity and Mutagenicity, University of Surrey, UK (March 2012)
- New Toy Directive, Intertek Leicester, UK (May 2011)
- Paediatric Toxicology, University of Surrey, UK (April 2011)
- Principles of Experimental Toxicology and Risk Assessment,University of Surrey, UK (Nov 2010)
- Human Repeat Patch Test (HRPT) study – application, reading and scoring training to investigative skin irritancy potential, Intertek - 4Front, Maldon, UK (April 2009)
- Committee on Toxicity 21st Century Toxicology, Meriden, UK (Feb 2009)
- Implementing the Globally Harmonized System (GHS), Macclesfield, UK (April 2008)

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- Principles of Toxicological Pathology, University of Surrey, UK (June 2008)
- Professional Development Programme, Royal Society of Chemistry, UK (June 2007- Sep 2009)
- Advanced Toxicology Pharmaceutical Training International Course, AstraZeneca, London, UK (May 2007)
- Methodology and Principles of Toxicology, University of Surrey, UK (June 2006)

Professional Membership

- Member of the UK Register of Toxicologists (**EUROTOX**)
- Member of the German Society for Toxicology **(GT)**
- Member of the Royal Society of Chemistry (**RSC**)
- Member of the Society of Cosmetic Scientists (**SCS**)
- Member of the US Society of Toxicology (**SOT**) – application in progress
- Member of the British Toxicology Society (**BTS**) - application to renew
- Member of the Chemical Hazards Communication Society (**CHCS**) – application to renew
- British Society for Investigative Dermatology (**BSID**) – application in progress

Languages

- English Full professional proficiency
- Polish Native or bilingual proficiency
- French Limited working proficiency
- Russian Limited working proficiency

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Curriculum Vitae

Dominika Maria Warchołek, MSc, BSc

Professional Employment

Safety assessor of cosmetic products – 1st January 2022 – present - NOLICHEM Sp. z o.o., Cracow

Responsibilities:

- Checking regulatory and safety data and assessing consumer products
- Working closely with regulatory manager
- Communicating actively with the members of the team to ensure swift workflow

Chemical Substances Technical Data Specialist, Trainee Safety Assessor – 1st March 2021 –31 December 2021 - NOLICHEM Sp. z o.o., Cracow

Responsibilities:

- Supporting the senior toxicologist and regulatory manager with the preparation and completion of safety assessments
- Preparing safety data sheets for cosmetic mixtures

Technical and Regulatory Data Entry Specialist – 1st October 2020- 28th February 2020 – NOLICHEM Sp. z o.o., Cracow

Responsibilities:

- Technical Data Entry
- Toxicological entry of chemical materials
- Carry out research and reports to help support the Senior Toxicologist
- Managing allocated workload to ensure tasks are completed on time and to a suitable quality
- Liaising with customers and other members of the team in order to ensure tasks are completed
- Customer service by phone or email

Student Internship – (1st August 2018- 11th September 2018)- EKO-LABOR Laboratorium Ochrony Środowiska i Higieny Pracy Spółdzielnia Pracy, Cracow

Responsibilities:

- Air sampling at workstations in industry for chemical analysis
- Measurements of the noise level and light intensity at the place of work in companies
- Determination of the dust concentration using the weight method
- Application of testing procedures
- Creation and interpretation of measurements results

Qualification and Education

25th February 2019- 7th July 2020 - Cracow University of Technology, Faculty of Chemical Engineering and Technology

- **MSc** in Chemical Technology, Industrial and Environmental Analysis
  Thesis title: Development of method for the determination of vitamin C using UV-Vis Derivative Spectrophotometry

1st October 2015- 30th January 2019 - Cracow University of Technology, Faculty of Chemical Engineering and Technology

- **BSc** in Chemical Technology, Industrial and Environmental Analysis
  Thesis title: Determination of nitrite content in cold cuts and smoked meat

Skills and Expertise

- Safety assessment of cosmetics
- Regulatory and safety data check and interpretation
- Material safety data preparation
- Familiarity with GC, HPLC, MS, UV-Vis spectroscopy
- Solid knowledge of NMR, IR, AAS
- Hands-on experience with spectrophotometric analysis
- Ability to use the MS Office Software
- Open to new interesting ideas and broaden knowledge
- Excellent communications and interpersonal skills
- Ability to multitask and work under pressure
- Ready to take challenges

University Courses

- Physics and physicochemical bases of the methods of the chemical analysis
- Environmental protection in chemical technology
- Control of the quality of products
- Polish legislation in environmental protection
- Measurements of organized emission to the atmosphere
- The basis of the environmental analytics
- Selected field of analytical, physical, organic and inorganic chemistry
- Chemical speciation
- The analysis vestigial in investigations of environment
- Modelling of technological processes

Additionally:

- PN-EN ISO/IEC 17025 Internal Auditor Certificate - 3rd July 2020 - TÜV Rheinland Poland

Workshops and training in-house

- Testing of cosmetics preparation according to the EU and UK regulatory requirements - 20th April 2021
- Toxicological profile of the substances - 13th April 2021
- CPNP Notification Portal – 26th January 2021
- Packaging for cosmetic products EU - 19th January 2021
- Cosmetics Regulation in China - 12th January 2021
- Safety Assessment and EU Requirements - 24th November 2020
- UK Cosmetics Regulation (UKCR) - 18th November 2020

Languages

- English – professional working proficiency
- Polish – native and bilingual proficiency
- German – elementary proficiency

Presentations in-house

- Cruelty-Free Certification – 14th January 2021

Publications in-house

- Dermatological tests of cosmetics – 13th April 2021

Conferences

- Online seminar organized by the Polish Chamber of Chemical Industry (PIPC) – Sustainable Chemistry– 19th October 2021
- Home and Personal Care Ingredients (HPCI) Exhibition and Conference Warsaw 2021 Conference – 22-23rd September 2021