

Laboratory Test Report

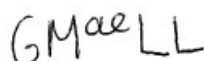
Report Number: 2022-753-5055

Page 1 of 1

Prepared for: Eresos Health + Wellbeing LTD
Address: 14 A Commercial Road
London
N18 1TP
Customer Sample Description: Sweet Almond Hand & Body Oil 4000mg
Eurofins Registration Number: 2022-753-5055
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)



Georgia Lees-Lowe
Technical Account Executive

Date: 06/02/2023

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

Product Name

**Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR
UE/UK passed**

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: 2022-753-5055
Client Name: Eurofins Consumer Product Testing Services
Contact Name: Georgia Lees-Lowe

PRODUCT CHARACTERISTICS

Product Group: Body Oil
Type Of Product: Leave On
Physical State: Oil
Nominal Size: 190g
Type Of Package: PET glass-polymer bottle with PET cap

PHYSICAL/CHEMICAL CHARACTERISTICS

Appearance:	Light yellow transparent oily liquid	Specific Gravity [20°C]:	Not Available
Odour:	Characteristic	Particles Size:	Not Applicable
pH:	7	Density:	Not Available
Viscosity[cp]:	Not Available	Flash Point:	Not Applicable
Solubility:	Insoluble 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

No.	Name	Page
PART A - Cosmetic product safety information		
1.	Quantitative and qualitative composition of the Cosmetic product	3
	- perfume or aromatic compositions	5
2.	Physical/chemical characteristics and - stability of the Cosmetic product	1
		6
3.	Microbiological quality	7
4.	Impurities, traces, information about the packaging material	8
5.	Normal and reasonably foreseeable use	8
6.	Exposure to the product	8
7.	Exposure to the substances	9
8.	Toxicological profile of the substances	14
9.	Undesirable effects and serious undesirable effects	38
10.	Information on the Cosmetic product	38
PART B - Cosmetic product safety assessment		
1.	Assessment conclusion	41
2.	Labelled warnings and - instructions of use	38
		39
3.	Reasoning	40
4.	Literature source (reference books, scientific opinions and articles)	43
ANNEX		

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

**Eresos Health + Wellbeing LTD
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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
Prunus Amygdalus Dulcis (Sweet Almond) Oil	8007-69-0(90320-37 -9)	44.44206	None
Vitis Vinifera (Grape) Seed Oil	85594-37-2(84929 -27-1)8024-22-4	44.44206	None
Caprylic/Capric Triglyceride	73398-61-5(65381 -09-1)	22.22103	None
Cannabidiol (CBD)	13956-29-1	2.110	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).
Pogostemon Cablin Leaf Oil (naturallythinking)	8014-09-3(84238-39 -1)	0.48945	Allergens declaration as required Proposed from 2023: The presence of the substance shall be indicated in the list of ingredients referred to in Article 19(1), point (g), when its concentration exceeds: - 0,001 % in leave-on products - 0,01 % in rinse-off products.
Citrus Aurantium Dulcis Peel Oil (naturallythinking)	8008-57-9	0.48945	Allergens declaration as required Proposed from 2023: The presence of the substance or substances shall be indicated as 'Citrus Aurantium Peel 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.

Product Name

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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
Citrus Grandis (Grapefruit) Peel Oil (naturallythinking)	90045-43-5(8016-20 -4)	0.48945	Prohibited Furocoumarines (e.g. trioxysalen (INN), 8- methoxypsoralen, 5- methoxypsoralen) except for normal content in natural essences used. In sun protection and in bronzingproducts, furocoumarines shall be below 1 mg/kg
Juniperus Communis (Juniper Berry) Fruit Oil (naturallythinking)	8002-68-4(73049-62 -4)84603-69-0	0.29367	Allergens declaration as required.
Tocopheryl Acetate	7695-91-2(58-95-7)	0.29367	None

Product Name

Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

Manufacturer

**Eresos Health + Wellbeing LTD
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PERFUME OR AROMATIC COMPOSITIONS

SED Product = 1.19144863 mg / cm²

Perfume	Name / Code : Citrus Aurantium Dulcis Peel Oil (naturallythinking) (Supplier : Naturallythinking)					
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Allergens Material	Cas. No	Concentration in Perfume[%]	*Safe Concentration[%]	*SED Concentration [µg / cm ²] 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	96.000000	0.800	5.598283	0.469872	178.626181
Linalool (1,6-Octadien-3-ol, 3,7-dimethyl-)	78-70-6	0.700000	0.800	0.040821	0.003426	13515.163054
Citral (3,7-Dimethyl-2,6-octadienal)	5392-40-5	0.300000	0.010	0.017495	0.001468	8002.452899
Citronellol	106-22-9 (26489-01-0)(7540-51-4) (1117-61-9)	0.050000	0.600	0.002916	0.000245	102888.680128

Perfume	Name / Code : Juniperus Communis (Juniper Berry) Fruit Oil (naturallythinking) (Supplier : Naturallythinking)					
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Allergens Material	Cas. No	Concentration in Perfume[%]	*Safe Concentration[%]	*SED Concentration [µg / cm ²] 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	20.000000	0.800	0.699785	0.058734	1429.009446
Linalool (1,6-Octadien-3-ol, 3,7-dimethyl-)	78-70-6	0.200000	0.800	0.006998	0.000587	78838.451148

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 and cannabinoid profile 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 product colour and appearance 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

Product Name

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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 product is water free and is therefore considered as microbiologically low - risk product. This type of product does not require a preservative challenge test.

**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) $\leq 1 \times 10^2$ CFU per g or ml^a.

Pathogens (Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans) must be absent in 1 g or 1 ml.

Other products:

Total Aerobic Mesophilic Microorganisms (Bacteria plus yeast and mould) $\leq 1 \times 10^3$ CFU per g or ml^b

Pathogens (Escherichia coli, Pseudomonas aeruginosa, Staphylococcus 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 and body oil intended for use by adults.

EXPOSURE TO THE Cosmetic PRODUCT

The site(s) of application:	Body
The surface area(s) of application:	15670 cm ²
The amount of product applied:	18.67 g
Exposure time:	Leave On
The duration and frequency of use:	Twice 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

Product Name

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Manufacturer

**Eresos Health + Wellbeing LTD
14 A Commercial Road
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N18 1TP**
EXPOSURE TO THE SUBSTANCES (DERMAL)

SED Product = 311.166667 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
Vitis Vinifera (Grape) Seed Oil	44.442060	18.67	100.000	138.28887670	Not available	No MoS calculated as no NOAEL available
Prunus Amygdalus Dulcis (Sweet Almond) Oil	44.442060	18.67	100.000	138.28887670	Not available	No MoS calculated as no NOAEL available
Caprylic/Capric Triglyceride	22.221030	18.67	100.000	69.14443835	1875	27.117148
Cannabidiol (CBD)	2.110000	18.67	100.000	6.56561667	Not available	No MoS calculated as no NOAEL available
d-Limonene ((R)-p-Mentha-1,8-diene; (4R)-1-Methyl-4-(1-methylethenyl)cyclohexene)	0.528606	18.67	100.000	1.64484567	Not available	No MoS calculated as no NOAEL available
Pogostemon Cablin Leaf Oil (naturallythinking)	0.489450	18.67	100.000	1.52300525	Not available	No MoS calculated as no NOAEL available
Citrus Grandis (Grapefruit) Peel Oil (naturallythinking)	0.489450	18.67	100.000	1.52300525	Not available	No MoS calculated as no NOAEL available
Citrus Aurantium Dulcis Peel Oil (naturallythinking)	0.489450	18.67	100.000	1.52300525	Not available	No MoS calculated as no NOAEL available
Tocopheryl Acetate	0.293670	18.67	100.000	0.91380315	Not available	No MoS calculated as no NOAEL available
Juniperus Communis (Juniper Berry) Fruit Oil (naturallythinking)	0.293670	18.67	100.000	0.91380315	Not available	No MoS calculated as no NOAEL available
Linalool (1,6-Octadien-3-ol, 3,7-dimethyl-)	0.004013	18.67	100.000	0.01248864	250	20018.187644
Citral (3,7-Dimethyl-2,6-octadienal)	0.001468	18.67	100.000	0.00456902	Not available	No MoS calculated as no NOAEL available
Citronellol	0.000245	18.67	100.000	0.00076150	Not available	No MoS calculated as no NOAEL available

Product Name

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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
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*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

Product Name

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UE/UK passed**

Manufacturer

**Eresos Health + Wellbeing LTD
14 A Commercial Road
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EXPOSURE TO THE SUBSTANCES (DERMAL) - ALLERGEN SUMMARY

SED Product = 311.166667 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)	0.528606	18.67	100.000	1.64484567	Not available	No MoS calculated as no NOAEL available
Linalool (1,6-Octadien-3-ol, 3,7-dimethyl-)	0.004013	18.67	100.000	0.01248864	250	20018.187644
Citral (3,7-Dimethyl-2,6-octadienal)	0.001468	18.67	100.000	0.00456902	Not available	No MoS calculated as no NOAEL available
Citronellol	0.000245	18.67	100.000	0.00076150	Not available	No MoS calculated as no NOAEL available

*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

Product Name

**Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR
UE/UK passed**

Manufacturer

**Eresos Health + Wellbeing LTD
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N18 1TP**
EXPOSURE TO THE SUBSTANCES (ORAL)

SED Product = 311.166667 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
Vitis Vinifera (Grape) Seed Oil	44.442060	18.67	138.28887670	Not Available	No MoS calculated as no NOAEL available
Prunus Amygdalus Dulcis (Sweet Almond) Oil	44.442060	18.67	138.28887670	Not Available	No MoS calculated as no NOAEL available
Caprylic/Capric Triglyceride	22.221030	18.67	69.14443835	5000	36.156198
Cannabidiol (CBD)	2.110000	18.67	6.56561667	Not Available	No MoS calculated as no NOAEL available
d-Limonene ((R)-p-Mentha-1,8-diene; (4R)-1-Methyl-4-(1-methylethenyl)cyclohexene)	0.528606	18.67	1.64484567	825	250.783406
Pogostemon Cablin Leaf Oil (naturallythinking)	0.489450	18.67	1.52300525	Not Available	No MoS calculated as no NOAEL available
Citrus Grandis (Grapefruit) Peel Oil (naturallythinking)	0.489450	18.67	1.52300525	Not Available	No MoS calculated as no NOAEL available
Citrus Aurantium Dulcis Peel Oil (naturallythinking)	0.489450	18.67	1.52300525	Not Available	No MoS calculated as no NOAEL available
Tocopheryl Acetate	0.293670	18.67	0.91380315	800	437.731036
Juniperus Communis (Juniper Berry) Fruit Oil (naturallythinking)	0.293670	18.67	0.91380315	Not Available	No MoS calculated as no NOAEL available
Linalool (1,6-Octadien-3-ol, 3,7-dimethyl-)	0.004013	18.67	0.01248864	160	6405.820046
Citral (3,7-Dimethyl-2,6-octadienal)	0.001468	18.67	0.00456902	887	97066.857342
Citronellol	0.000245	18.67	0.00076150	1000	656596.554739

*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

**Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR
UE/UK passed**

Manufacturer

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EXPOSURE TO THE SUBSTANCES (ORAL) - ALLERGEN SUMMARY

SED Product = 311.166667 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)	0.528606	18.67	1.64484567	825	250.783406
Linalool (1,6-Octadien-3-ol, 3,7-dimethyl-)	0.004013	18.67	0.01248864	160	6405.820046
Citral (3,7-Dimethyl-2,6-octadienal)	0.001468	18.67	0.00456902	887	97066.857342
Citronellol	0.000245	18.67	0.00076150	1000	656596.554739

*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

Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION

Vitis Vinifera (Grape) Seed Oil (Emollient, Skin Conditioning)

EU INCI: Vitis Vinifera Seed Oil.

CTFA INCI: Vitis Vinifera (Grape) Seed Oil.

CNDA INCI: Vitis Vinifera (Grape) Seed Oil.

Chinese: 葡萄(VITIS VINIFERA) 籽油.

Trade Name: Grape Seed Oil.

CAS Number: 85594-37-2(84929-27-1)8024-22-4.

EINECS Number: 287-896-9 / 284-511-6 /

Description: Vitis Vinifera Seed Oil is the fixed oil, consisting primarily of the glycerides of the fatty acids, obtained by pressing the seeds of the Grape, Vitis Vinifera L., Vitaceae

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY

Odour: Mild odor

Specific Gravity: 0.913-0.930 g/cm3

Water Solubility: Insoluble

Boiling Point: 230 °C

Particle Size: The non-solid or granular form does not require the particle size distribution study.

Colour: Pale yellowish green to green

Density: 0.915 - 0.925 @ 20 °C

Flash Point: 310 °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: Not classified as per GHS.

Region : Europe Type : Cosmetic Restriction : None

Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW

General Toxicity Review: Grape seed oil is a well-known substance used also in food industry. The substance is not associated with the skin sensitisation, skin and 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 considered to be safe when used as intended.

TOXICOLOGICAL PROFILE

Eye Irritation: Based on the available toxicological data there is no evidence of eye irritation or corrosivity potential.

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.

Allergens Patch Test: Human Patch tests show no signs of irritation or sensitivity. HRIPTs of several products containing: 39% of the substance in a preshave lotion; 90% of the substance in a fragranced oil were conducted. There was no skin irritation or sensitisation observed. (CIR)

Carcinogenicity: Not associated with carcinogenic, mutagenic and reprotoxic (CMR) chemicals.

Product Name

Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION

Prunus Amygdalus Dulcis (Sweet Almond) Oil (Skin Conditioning)

EU INCI: Prunus Amygdalus Dulcis Oil.

CTFA INCI: Prunus Amygdalus Dulcis (Sweet Almond) Oil.

CNSA INCI: Prunus Amygdalus Dulcis (Sweet Almond) Oil.

CAS Number: 8007-69-0(90320-37-9).

EINECS Number: 291-063-5.

Description: Prunus Amygdalus Dulcis Oil is the fixed oil obtained from the ripe seed kernel of the Sweet Almond Tree, Prunus amygdalus var. dulcis, Rosaceae

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY

Odour: Characteristic, faint.

Viscosity: 66-76 cP

Water Solubility: Insoluble

Colour: Pale, straw- colored or colourless

Density: 0.910 - 0.918 g/ml

Flash Point: >240 °C

Microbiological stability: Total Plate Count < 1,000cfu/g; Mold and Yeast < 100cfu/g

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: Sweet almond oil is commonly used as cosmetic ingredient. In vivo studies resulted in scoring the chemical as not irritating to minimally irritating to eyes and not irritating to skin. Non-LLNA in vivo study indicated that the substance is not sensitising. It shows very low acute toxicity potential above 5 000 mg/kg bw via 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 as intended.

TOXICOLOGICAL PROFILE

Eye Irritation: The substance when used up to concentration of 25 %, was found to be not irritating to minimally irritating to eyes. During the studies in rabbits, the conjunctival irritation was observed, however the reaction disappeared after 3 days. (CIR)

LD50: LD50 (Oral, rat) > 5 000 mg/kg bw. The substance was tested in rats for acute oral toxicity. The substance was found to be practically non-toxic. (ref. 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. 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: It is known that tree nuts may cause severe allergic reaction (anaphylaxis) especially when ingested. Grades of almond oil for skincare products should be checked for protein content in order to avoid of risk of allergic reactions.

Skin Irritation: Undiluted oil when tested for skin irritancy in albino rabbits at 25% using patch test under occlusion demonstrated that almond oil was minimally irritating to skin. The substance was also tested clinically with using the single insult patch test (SIPT) for 3 weeks. The test results showed that the substance is non- irritating. (CIR)

Skin Sensitisation: The substance was tested on guinea pigs, with the use of patch test method (occlusive coverage for 48 hours) to find evidence for skin sensitisation. The test results indicated that the substance is non- sensitising. The substance also underwent tests using repeated insult patch testing (RIPT) and was considered to be not sensitising. (CIR)

Allergens HRIPT: The HRIPT was conducted on 52 subjects, using the 100% almond oil. The substance was applied 3 times per week for 3 weeks. After 2-weeks rest period the challenge phase was applied to the previously untreated area. The substance was scored as not-irritating and not-sensitising. (CIR)

Allergens MaximisationTest: The Magnusson-Kligman Maximization test was conducted on guinea pigs using Sweet almond oil. The concentrations: 5%, 10% and 100% were used. The study included 50 animals, after single application slight irritation was observed in some of the animals. No reactions were observed after applying the challenge phase. (CIR)

Allergens Patch Test: The patch test was conducted on 101 participants. The test material was applied on the back skin under the occlusion. No adverse reactions were reported during the study. (CIR)

Carcinogenicity: Not associated with CMR materials.

Product Name

Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION

Caprylic/Capric Triglyceride (Masking, Perfuming, Skin Conditioning)

EU INCI: Caprylic/Capric Triglyceride.

CTFA INCI: Caprylic/Capric Triglyceride.

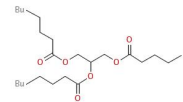
CNSA INCI: Caprylic/Capric Triglyceride.

CAS Number: 73398-61-5(65381-09-1).

EINECS Number: 277-452-2 / 265-724-3.

Symbol: C27H50O6 to C33H62O6.

Description: Caprylic/capric triglyceride belongs to chemical group known as medium chain triglyceride (MCT). IT is a mix of tri-esters with carbon chains of C8 and C



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY

Odour: Odourless

Oxidising Properties: Non oxidising

Viscosity: 27-33mPas@20°C

Water Solubility: Immiscible with water. Miscible with most organic solvents.; < 1 mg/L (ECHA)

Partial Coefficient logPow: log Pow = 8.2 - 10.9

Boiling Point: > 300 °C, decomposition probable

Colour: Slightly yellowish

Density: 945 - 949 kg/m³ at 20 °C

Flammability: Non flammable

Flash Point: >260°C (closed cup)

Vapour Pressure: < 5.4E-9 Pa at 20 °C (ECHA); Old: >240 (COC)

Melting Point: < -5 °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 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: The available toxicological data demonstrate that the Caprylic/Capric Triglyceride is not irritating to eyes. Moreover, the substance is also not irritating and non-sensitising to skin. It shows low acute toxicity with LD50 above 5000 mg/kg in oral, LD50 above 2 000 mg/kg bw in dermal and above 1.86 mg/l air in inhalation 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

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 substance is not irritating. (ECHA)

Genotoxicity: In vitro: negative (Chinese hamster Ovary (CHO)). In vivo: negative (mouse) (ECHA).

LD50: LD50 (oral, mouse) > 5000 mg/kg; OECD Guideline 401 (Acute Oral Toxicity) Acute toxicity studies via oral route of administration in mice demonstrated slight toxicity. LD50 (dermal, rat) > 2 000 mg/kg bw; 79/831/EWG, Annex V, Part B, Acute toxicity studies via dermal route of exposure in rats showed that the substance has low skin toxicity. LC50 (inhalation, rat) > 1.86 mg/l air. The substance was tested for an acute toxicity via inhalation for 6 hours (aerosol) was found to be moderately toxic (no deaths occurred). (ECHA)

Mutagenicity: Non-mutagenic.

NOAEL Dermal: NOAEL 1875 mg/kg bw. Study type: experimental study. Endpoints: sub-chronic toxicity Route of administration: dermal. Species: rat. Methods: weight of evidence. Report date: 1980. Source: ECHA. MoS was calculated based on this data.

NOAEL Oral: NOAEL 5000 mg/kg bw. Study type: repeated dose toxicity. Endpoints: sub-chronic toxicity Route of administration: oral. Species: rat. Methods: OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents). Report date: 1992. Source: ECHA. MoS was calculated based on this data.

Reproductive Toxicology: For Glycerides, C8-18 and C18-unsatd. mono- and di-, acetates (CAS No. 91052 -13 -0) a NOAEL for parental fertility of 1000 mg/kg bw in rats could be identified. (ECHA)

Skin Irritation: In vivo studies on rabbits with semiocclusive coverage were conducted. The substance was found to be not irritating. (ECHA)

Skin Sensitisation: Non-LLNA in vivo examinations were conducted, using guinea pig testing, to examine ocular irritation after application. The substance was found to be non-sensitising. (ECHA)

Allergens HRIPT: Undiluted Caprylic/Capric Triglyceride was not irritating or sensitising in 128 subjects (Draize repeated insult patch test) (CIR)

Allergens Maximisation Test: The substance was classified as non-sensitising in a human modified maximization patch test with 26 subjects. (CIR)

Allergens Patch Test: Facial oil containing 95.51% of the substance was used in a 24-h single insult occlusive patch test. The study involved 17 participants. The substance was classified as not irritating. (CIR)

Carcinogenicity: Not associated with carcinogenic, mutagenic, or toxic for reproduction (CMR) materials.

OTHER

Biodegradability (Environmental): Biodegradation in water. Result: 60- 93% degradation after 28 days. Conclusion: readily biodegradable (ECHA)

Ecological toxicity: No effect on fish and aquatic algae up to the limit of water solubility is expected. (ECHA)

LC50 (Environmental): Fish: No effect up to the limit of the water solubility after 5 short-term studies with Danio rerio - 96h; Algae: No effect up to the limit of the water solubility after 4 studies with the freshwater algae Scenedesmus subspicatus - 72h (ECHA)

Product Name

Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION

Cannabidiol (CBD) (Antioxidant,Antiseborrheic,Skin Conditioning,Skin Protecting)

EU INCI: Cannabidiol - Derived from Extract of Tincture or Resin of Cannabis.

CAS Number: 13956-29-1.

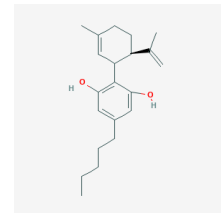
Symbol: C21H30O2.

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 problems associated 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.

Product Name

Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION

Pogostemon Cablin Leaf Oil (naturallythinking) (Perfuming)

EU INCI: Pogostemon Cablin Leaf Oil.

CTFA INCI: Pogostemon Cablin Leaf Oil.

CAS Number: 8014-09-3(84238-39-1).

EINECS Number: - / 282-493-4.

Description: Pogostemon Cablin Leaf Oil is the volatile oil obtained from the leaves of the Patchouli, Pogostemon cablin, Labiatae

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY

Physical State: Oil.

REGULATORY REQUIREMENTS

Labelling Requirements: Proposed from 2023: The presence of the substance shall be indicated in the list of ingredients referred to in Article 19(1), point (g), when its concentration 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.

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 : Allergens declaration as required Label Review : Proposed from 2023: The presence of the substance shall be indicated in the list of ingredients referred to in Article 19(1), point (g), when its concentration 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: There is limited toxicological information for Pogostemon Cablin Leaf Oil. According to the toxicological safety of the substance there is no evidence on eye, skin irritation or 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 safe when used as intended.

TOXICOLOGICAL PROFILE

Eye Irritation: Based on the available toxicological data there is no evidence of eye irritation or corrosivity potential.

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: Based on the available toxicological data there is no evidence of skin allergy potential.

Carcinogenicity: Not associated with carcinogenic, mutagenic and reprotoxic (CMR) chemicals.

Product Name

Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION

Citrus Grandis (Grapefruit) Peel Oil (naturallythinking) (Masking,Perfuming,Skin Conditioning)

EU INCI: Citrus Grandis Peel Oil.

CTFA INCI: Citrus Grandis (Grapefruit) Peel Oil.

Trade Name: GRAPEFRUIT OIL, COLD PRESSED.

CAS Number: 90045-43-5(8016-20-4).

EINECS Number: 289-904-6 / -.

Description: Citrus Grandis Peel Oil is the volatile oil obtained from the peel of the Grapefruit, Citrus grandis, Rutaceae

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY

Odour: Characteristic, Grapefruit. Citrus-like

Specific Gravity: 0.848-0.856

Water Solubility: Insoluble

Colour: Yellow. Reddish-orange.

Flammability: Flammable

Flash Point: 44°C/111°F (Closed cup)

Physical State: Oil.

REGULATORY REQUIREMENTS

IFRA Standard: Restriction limits in the finished product: Category 1, 2, 3, 4, 5A, 5B, 5C, 5D, 6, 7B, 8, 10B, 11B: 0.0015 % (5-MOP); Category 7A, 9, 10A, 12: No restriction. Where the Bergapten (5-Methoxypsoralen, (5-MOP)) content of all relevant oils present in a compound has been determined, it is recommended that for applications on areas of skin exposed to UV-light, the total level of Bergapten in the consumer products should not exceed 0.0015% (15 ppm). This upper concentration level only applies to applications on skin exposed to UV-light, excluding rinse-off products and incidental skin contact products as detailed in the Guidance for the use of IFRA Standards. Where the level of Bergapten has not been determined by appropriate methods, the limits specified in the guidelines on individual oils should apply. In those cases, where such oils are used in combination with other furocoumarin-containing phototoxic fragrance ingredients (extracts), the additive effect has to be taken into consideration and the concentration levels have to be reduced accordingly. The sum of the concentrations of all furocoumarin-containing phototoxic fragrance ingredients (extracts), expressed in % of their recommended upper concentration level in the finished consumer product, shall not exceed 100. 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 flavouring 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*: February 10, 2021; For existing fragrance compounds*: February 10, 2022

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: Prohibited Furocoumarines (e.g. trioxysalen (INN), 8-methoxypsoralen, 5-methoxypsoralen) except for normal content in natural essences used. In sun protection and in bronzing products, furocoumarines shall be below 1 mg/kg

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..

Region : Europe Type : Cosmetic Restriction : Prohibited Furocoumarines (e.g. trioxysalen (INN), 8-methoxypsoralen, 5-methoxypsoralen) except for normal content in natural essences used. In sun protection and in bronzing products, furocoumarines shall be below 1 mg/kg

Region : UK Type : Cosmetic Restriction : Prohibited Furocoumarines (e.g. trioxysalen (INN), 8-methoxypsoralen, 5-methoxypsoralen) except for normal content in natural essences used. In sun protection and in bronzing products, furocoumarines shall be below 1 mg/kg

TOXICITY REVIEW

General Toxicity Review: Citrus Grandis (Grapefruit) Peel Oil is commonly used as cosmetic substance. When it comes to local toxicity the substance is a skin sensitiser. Data derived from animal studies demonstrate that the chemical is not irritating to eyes but moderately irritating to the skin. It shows low acute toxicity with LD50 above 5000 mg/kg bw in both oral and dermal 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 on rabbits to examine ocular irritation after application. The studies resulted in scoring the substance as not irritating to eyes. (ECHA)

Genotoxicity: In vitro: negative. (S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and E. coli WP2 uvr A). (ECHA)

Inhalation: May cause irritation of respiratory tract.

LD50: LD50 (Oral, rat) > 5 000 mg/kg bw (OECD Guideline 401 (Acute Oral Toxicity)); LD50 (dermal, rabbit) > 5000 mg/kg (OECD Guideline 402 (Acute Dermal Toxicity)) (ECHA)

NOAEL Oral: NOAEL 1 000 mg/kg bw/day (actual dose received). Study type: Repeated dose toxicity. Endpoints: sub-chronic toxicity. Route of administration: oral. Species: dog- Japanese beagle. Methods: a combination of rules from OECD Guidelines 409 and 452. Report date: 1975. MoS was calculated based on this data.

Phototoxicity: Ma be photo toxic

Skin Irritation: Causes skin irritation. In vivo studies on rabbits were conducted. The substance was found to be moderately irritating to the skin. (ECHA)

Skin Sensitisation: May cause an allergic skin reaction. LLNA in vivo examinations were conducted, using mouse tests to find evidence for skin sensitisation. The test results showed that the chemical is a skin sensitiser. (ECHA)

Product Name

Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION

Citrus Aurantium Dulcis Peel Oil (naturallythinking) (Masking,Skin Conditioning,Perfuming)

EU INCI: Citrus Aurantium Dulcis Peel Oil.

CTFA INCI: Citrus Aurantium Dulcis (Orange) Peel Oil.

Trade Name: Orange sweet oil.

CAS Number: 8008-57-9.

Description: Citrus Aurantium Dulcis (Orange) Peel Oil is the volatile oil obtained by expression from the peel of Citrus sinensis, Rutaceae

Synonyms: Orange oil, Citrus aurantium, Citrus sinensis

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY

Odour: Characteristic

Specific Gravity: 0.842-0.86 at 25°C

Boiling Point: 175°C

Colour: Yellow to deep orange liquid

Density: 0.843 g/cm3 at 25°C

Flash Point: 54°C

Physical State: Liquid.

REGULATORY REQUIREMENTS

Labelling Requirements: Proposed from 2023: The presence of the substance or substances shall be indicated as 'Citrus Aurantium Peel 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).

Regulatory Controls: 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 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

GHS Classification: Not classified as per GHS. Self classified: H226 Flammable liquid and vapour.

Region : Europe Type : Cosmetic Restriction : Allergens declaration as required Label Review : Proposed from 2023: The presence of the substance or substances shall be indicated as 'Citrus Aurantium Peel 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: Citrus Aurantium Dulcis Peel Oil is an masking, perfuming and skin conditioning ingredient. There is limited toxicological information according to the toxicological safety of this substance. There is no evidence of eye and skin irritation potential as well as skin sensitisation potential. It shows low acute toxicity with LD50 above 5000 mg/kg bw in oral and dermal 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 as intended.

TOXICOLOGICAL PROFILE

Eye Irritation: Based on the available toxicological data there is no evidence of eye irritation or corrosivity potential.

LD50: LD50 (oral, rat) > 5,000 mg/kg (ref. Chemblink); LD50 (dermal, rabbit) > 5,000 mg/kg (ref. Chemblink)

NOAEL Oral: NOAEL value is not available for mixtures. 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: Based on the available toxicological data there is no evidence of skin allergy potential.

Product Name

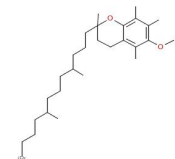
Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION

Tocopheryl Acetate (Antioxidant, Skin Conditioning)

EU INCI: Tocopheryl Acetate.
CTFA INCI: Tocopheryl Acetate.
CNSA 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 was 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-α-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 for 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)

Product Name

Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION

Juniperus Communis (Juniper Berry) Fruit Oil (naturallythinking) (Masking,Perfuming)

EU INCI: Juniperus Communis Fruit Oil.

CTFA INCI: Oils, juniper.

CNDA INCI: Oils, juniper.

CAS Number: 8002-68-4(73049-62-4)84603-69-0.

EINECS Number: - / - / 283-268-3.

Description: "JuniperOil"; "Juniberry Oil". Juniperus Communis Fruit Oil is the volatile oil obtained from the berries of the Juniper, Juniperus communis L., Cupressaceae. ISO 8897:2010

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY

Water Solubility: 49 mg/L

Boiling Point: 171,1°C at 1013hPa

Density: 0,858 g/cm3 at 20°C

Flammability: Flammable

Flash Point: 38.5°C at 1013 hPa

Physical State: Oil.

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: H226: Flammable liquid and vapour. H315: Causes skin irritation. H319: Causes serious eye irritation. H317: May cause an allergic skin reaction. H304: May be fatal if swallowed and enters airways. H411: Toxic to aquatic life with long lasting effects..

Region : Europe Type : Cosmetic Restriction : Allergens declaration as required.

Region : UK Type : Cosmetic Restriction : Allergens declaration as required.

TOXICITY REVIEW

General Toxicity Review: Juniperus Communis Fruit Oil is used as cosmetic ingredient. When it comes to local toxicity, the substance is classified as skin sensitizer. Based on the available toxicological information, the chemical is irritating to the skin and eyes. It shows low acute toxicity with LD50 above 5000 mg/kg bw in oral 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: Based on the available toxicological information, the substance is classified as eye irritant, Category 2 based on the GHS criteria. (ECHA)

Genotoxicity: In vitro: negative (S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and E. coli WP2)

LD50: LD50 (Oral, rat) > 5 000 mg/kg bw (OECD Guideline 401 (Acute Oral Toxicity)) (ECHA)

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: Moderate skin irritant. Based on the available toxicological information, the substance is a skin irritant and classified as Category 2 based on the GHS criteria. (ECHA)

Skin Sensitisation: Based on the available toxicological information, the substance is considered as skin sensitizer and classified as Category 1 based on the GHS criteria. (ECHA)

UV absorption photo-induced toxicity: 279-633 Pa ay 25°C

Product Name

Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

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.

CNSA INCI: Limonene.

CAS Number: 5989-27-5(68606-81-5)138-86-3.

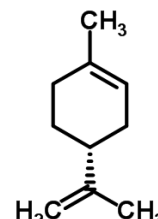
EINECS Number: 227-813-5.

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-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 to be potent sensitizers. d-, l- and dl-Limonene 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 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

Acute Toxicology: 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)

Product Name

Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION

Tocopherol (Antioxidant, Masking, Skin Conditioning, Perfuming)

EU INCI: Tocopherol.

CTFA INCI: Tocopherol.

CND A 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.

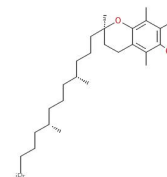
Symbol: C29H50O2.

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

Acute Toxicology: 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 sensitizer 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 Maximisation Test: 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)

Product Name

Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION

Citral (3,7-Dimethyl-2,6-octadienal) (Perfuming,Flavouring)

EU INCI: Citral.

CTFA INCI: Citral.

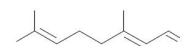
CAS Number: 5392-40-5.

EINECS Number: 226-394-6.

Symbol: C10H16O.

Molecular Weight: 152.23.

IUPAC Name: (2E)-3,7-dimethylocta-2,6-dienal



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY

Oxidising Properties: No oxidising properties

Viscosity: 2.42 mm2/s at 20° C

Water Solubility: 0.42 g/l @20C (practically insoluble)

Partial Coefficient logPow: 2.76 at 25°C

Boiling Point: 226-228 °C

Colour: Slightly yellowish

Density: 0.89 at 20 deg C

Flammability: Non flammable

Flash Point: 98°C at 1013.25 hPa

Vapour Pressure: <130Pa at 100 °C

LogP Log Kow: 2.76 at 25 °C

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: RESTRICTION LIMITS IN THE FINISHED PRODUCT (%): Category 1 0.11 %; Category 2 0.032 %; Category 3 0.10 %; Category 4 0.60 %; Category 5A 0.15 %; Category 5B 0.15 %; Category 5C 0.15 %; Category 5D 0.051 %; Category 6 0.35 %; Category 7A 0.20 %; Category 7B 0.20 %; Category 8 0.051 %; Category 9 1.2 %; Category 10A 1.2 %; Category 10B 4.2 %; Category 11A 0.051 %; Category 11B 0.051 %; Category 12 No Restriction. 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 February 10, 2021; For existing fragrance compounds February 10, 2022. Publication date 2020 (Amendment 49)

CLP Regulation (EC) No 1272/2008: Classified as: Skin Irrit. 2 H315; Skin Sens. 1 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 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. H315: Causes skin 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 severely irritating to the eyes and skin, may cause tissue damage, necrosis. 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

AcuteToxicology: ORAL (LD50): Acute: 4960 mg/kg [Rat]. 6000 mg/kg [Mouse]. (SIDS Initial Assessment Report) DERMAL (LD50): Acute: 2550 mg/kg [Rabbit]

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) Additionally, the substance is classified as Eye Irrit. 2 and Causes serious eye irritation.

Developmental toxicity: NOAEL 60 mg/kg bw/day Study type: Developmental toxicity / teratogenicity; Endpoint:developmental toxicity; Guideline:OECD Guideline 414 (Prenatal Developmental Toxicity Study); Species:rabbit; Source: ECHA

Genotoxicity: Negative in vitro gene mutation study in bacteria. (S. typhimurium TA 1535, TA 1537, TA 98 and TA 100) Negative in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus. (ECHA)

LD50: LD50 (oral, rat) 6800 mg/kg bw; Method: BASF-test according to internal SOP; Description: Acute toxicity studies via oral route of administration in rats demonstrated very low toxicity of the substance. LD50 (dermal, rat) > 2 000 mg/kg bw; internal BASF-Test: single dose group; Description: Acute toxicity studies via dermal route of exposure in rats showed that the substance has low skin toxicity. (ECHA)

Local Toxicity: Skin Irritant. Skin sensitiser.

Mutagenicity: Non-mutagenic

NOAEL Dermal: NOEL 1400ug/cm2 (opdyke, 1979)

NOAEL Inhalation: NOAEC 215 mg/m3 (34 ppm). Study type: Repeated dose toxicity. Endpoint: Repeated dose toxicity. Species: Rat. Report date 1992 (ECHA) MoS was calculated based on this data

NOAEL Oral: NOAEL 200 mg/kg bw (one-generation reproductive toxicity, parental toxicity) (Yoshimura 2002); Source: ECHA, Mos was calculated based on this data

Skin Irritation: In the in vivo studies on rabbits with occlusive coverage the substance was found to be irritating. 20 h exposure to the substance cause severe irritations and necroses (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 sensitising, edema and erythema were observed (ECHA)

Toxicokinetics: Citral is rapidly absorbed from the gastrointestinal tract. Much of an applied dermal dose of citral was lost due to its extreme volatility, but the chemical remaining on the skin was fairly well absorbed. It was rapidly metabolised and excreted as metabolites, neral and geranial. Urine was the major route of elimination (OECD, 2004).

Allergens LLNAEC3: EC3 (%) 5.7 Moderate

Carcinogenicity: Under the conditions of 2-year feed study, there was no evidence of carcinogenic activity of citral in male or female F344/N rats. (ECHA)

OTHER

Biodegradability (Environmental): Biodegradation in water: screening tests. Result: >90% biodegradation after 28 d Conclusion: readily biodegradable. (OECD Guideline 301 C). (ECHA)

LC50 (Environmental): Fish: LC50 Leuciscus idus 6.78 mg/L - 96h (German national standard guideline DIN 38412); Algae: EC50 Scenedesmus subspicatus Chodat 103.84 mg/l- 72h (German national test guideline DIN 38412, Part L9) (ECHA)

Product Name

Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION

Linalool (1,6-Octadien-3-ol, 3,7-dimethyl-) (Perfuming,Deodorant)

EU INCI: Linalool.

CTFA INCI: Linalool.

CNSA INCI: Linalool.

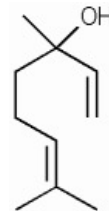
CAS Number: 78-70-6.

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 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). 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 semioclusive 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 than 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)

Product Name

Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION

Citronellol (Perfuming)

EU INCI: Citronellol.

CTFA INCI: Citronellol.

CNSA INCI: Citronellol.

CAS Number: 106-22-9(26489-01-0)(7540-51-4)(1117-61-9).

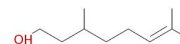
EINECS Number: 203-375-0 / 247-737-6 / 231-415-7 / 214-250-5.

Symbol: C10H20O.

Molecular Weight: 156.27.

IUPAC Name: 3,7-dimethyloct-6-en-1-ol

Synonyms: 3,7-Dimethyl-6-octen-1-ol; 6-Octen-1-ol, 3,7-dimethyl-; Citronellol; dl-Citronellol; Rhodinol pure (commercial name)



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY

Viscosity: 11.3 mPa.s at 20 °C; 5.33 mPa.s at 40 °C

Water Solubility: 307 mg/l at 25 °C

Partial Coefficient logPow: 3.41 at 25 °C

Boiling Point: 224 °C at 1013.25 hPa

Colour: Colourless

Density: 0.8549 g/cm3 at 20 °C

Flammability: Non flammable

Flash Point: 107 °C at 1013 hPa

Vapour Pressure: 0.086 hPa at 20 °C

Melting Point: The melting/freezing point is below -20°C

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: Restriction limits in the finished product: Category 1: 2.2 %; Category 2: 0.67 %; Category 3: 1.3 %; Category 4: 1.2 %; Category 5A: 3.2 %; Category 5B: 3.2 %; Category 5C: 3.2 %; Category 5D: 3.2 %; Category 6: 7.3 %; Category 7A: 25 %; Category 7B: 25 %; Category 8: 1.3 %; Category 9: 24 %; Category 10A: 87 %; Category 10B: 87 %; Category 11A: 48 %; Category 11B: 48 %; Category 12: No Restriction. 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 dates: For new submissions*: February 10, 2021 For existing fragrance compounds*: February 10, 2022

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: The presence of 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. H317: May cause an allergic skin reaction. H319: Causes serious eye irritation..

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. Reactions such as distinct redness and turgor/swelling of conjunctiva were observed. Substance is classified as 'causing serious eye irritation' (ECHA)

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: LC50 (inhalation, acute, rats) > 2.12 mg/L

LD50: LD50 (oral, rat) 3 450 mg/kg bw ; Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity of the substance. LD50 (dermal, rabbit) 2 650 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 Dermal: NOEL 3000 µg/cm2. Study type Human date. Source and date RIFM 2007

NOAEL Inhalation: NOAEC 63 mg/m3 (0.063mg/l). Study type Repeated dose toxicity. Endpoint short-term repeated dose toxicity: inhalation. Method OECD Guideline 412 (Subacute Inhalation Toxicity: 28-Day Study). Species Rats. Source data 2012; Source: ECHA, MoS was calculated based on this data

NOAEL Oral: NOAEL 1000 mg/kg bw. Study type: Repeated dose toxicity. Endpoint sub-chronic toxicity:oral. Species: Mouse. Source: ECHA, MoS was calculated based on this data

Reproductive Toxicology: NOAEL 300 mg/kg bw/day Study type: Toxicity to reproduction; Endpoint:screening for reproductive / developmental toxicity; Report date:2010; Guideline:OECD Guideline 421 (Reproduction / Developmental Toxicity Screening Test); Species:rat; Report date:2010; Source: ECHA

Skin Irritation: In the in vivo studies on rabbits with semiocclusive coverage the substance was found to be irritating (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)

Carcinogenicity: Not carcinogenic

OTHER

Hazard Class and Category Code(s): Skin Sens. 1B

Hazard statement Code(s): H317

Biodegradability (Environmental): Biodegradation in water: screening tests. Result: 80 - 90 % degradation after 28 days. Conclusion: readily biodegradable (German standard DIN 38409 part 51 and 43 a BOD5*100/COD of 61) (ECHA)

LC50 (Environmental): Fish: LC50 Leuciscus idus 14.66 mg/l - 96h (German standard DIN 38 412, part L15); Algae: EC50 Scenedesmus subspicatus 2.4 mg/l (Algae inhibition test supported by the UBA) (ECHA)

Product Name

Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION

Toluene (Antioxidant,Solvent,Perfuming)

EU INCI: Toluene.

CTFA INCI: Toluene.

Trade Name: Toluene.

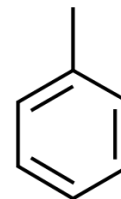
CAS Number: 108-88-3.

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. H361d: 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 Method 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.

Product Name

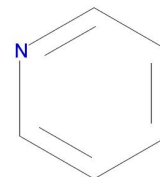
Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

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 carcinogen 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.

Product Name

Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION

Chromium (Not Reported)

EU INCI: Chromium (Prohibited).
CTFA INCI: Chromium (Prohibited).
Chinese: 铬.
CAS Number: 7440-47-3.
EINECS Number: 231-157-5.
Symbol: Cr.
Molecular Weight: 52.00.

Cr

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY

Water Solubility: Practically insoluble.
Boiling Point: 2 672 °C
Particle Size: D10 57.5 µm, D50 104 µm and D90 104.0 µm.
Colour: Grey
Density: 7.19 g/cm³ at 20 °C
Vapour Pressure: 1 atm at 2 482 °C; 130 Pa at 1 610 °C
Melting Point: 1863 °C
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.
Region : Europe Type : Cosmetic Restriction : Prohibited in cosmetic products.
Region : UK Type : Cosmetic Restriction : Prohibited in cosmetic products.

TOXICITY REVIEW

General Toxicity Review: In vivo studies resulted in scoring the chemical as not irritating to eyes and skin. Non-LLNA in vivo study indicated that the substance is not sensitising. It shows very low acute toxicity potential above 5 000 mg/kg bw in oral administration route. Repeated dose toxicity study indicated NOAEL oral at 1 216 mg/kg bw/day. It was reported that chromium agglomerates in lungs, liver, kidney and adrenals in people exposed to it daily. Workers exhibit elevated chromium levels in the urine. Long term in vivo carcinogenicity studies of chromium mela and chromium (III) oxide have indicated that it does not pose a risk in repeated exposure.

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: 1988; Source: ECHA.

Genotoxicity: In vitro: negative; Method: according to OECD Guideline 476 (In Vitro Mammalian Cell Gene Mutation Test); Species: Chinese hamster; Report date: 2005; Source: ECHA. In vivo: negative; Method: according to OECD Guideline 474, EU Method B.12 and EPA OPP 84-2; Species: mouse; Report date: 1992; Source: ECHA.

LD50: LD50 (oral, rat) > 5 000 mg/kg bw; Route of exposure: oral, Species: rat, Method: according to OECD Guideline 420, Report date: 1988; Description: Acute toxicity studies via oral route of administration in rats demonstrated slight toxicity of the substance. Source: ECHA.

NOAEL Inhalation: LOAEC 4.4 mg/m³ air (0.0044 mg/L). Study type migrated information: read-across from supporting substance. Endpoint sub-chronic toxicity: inhalation. Species rat. Duration 13 weeks. Methods OECD Guideline 413. Reference date 1999 (ECHA)

NOAEL Oral: NOAEL 1 216 mg/kg bw/day (female); 1 368 mg/kg bw/day (male) Study type migrated information: read-across from supporting substance. Endpoint short-term repeated dose toxicity: oral. Species rat. Duration 90 days. Methods Chromium(III) oxide was baked into bread at concentrations of 2% and 5% and this bread was fed to animals 5 days/week for a period of 90 days.. Reference date 1975 (ECHA)

Reproductive Toxicology: NOAEL 44 mg/kg bw; Method: equivalent to OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day); Species: rat; Route of administration: inhalation; Report date: 1999; Source: ECHA.

ADME (Absorption, Distribution, Metabolism, Excretion): Chromium(III) and chromium(VI) exhibit different absorption characteristics. Chromium(III) is poorly absorbed, regardless of route of exposure, whereas chromium(VI) is more readily absorbed (Hamilton and Wetterhahn, 1988). In one study, for example, animals absorbed approximately 10% of an orally administered dose of Cr (VI), but less than 0.5% of the orally administered Cr(III) (Langard, 1982); therefore, the reduction of Cr(VI) to Cr(III) (which can occur in the stomach) may result in decreased absorption. In another study, humans and rats absorbed approximately 2% of the chromium that was administered orally as Na251CrO4 and measured in the urine (humans) and feces (rat) as 51Cr (Donaldson and Barreras 1966). The detection of chromium in the urine, serum, and red blood cells (RBC) of humans exposed in the workplace suggests that the metal is absorbed following inhalation exposure. Limited experimental data indicate that water-soluble inhaled Cr(VI) is absorbed rapidly (Langard et al., 1978).

Humans and animals exhibit similar patterns of distribution for chromium. Workers exposed to chromium by inhalation had levels of the metal in the lung, liver, kidney, and adrenals that were 300-fold, 2- to 4-fold, 10-fold, and 10- to 50-fold higher, respectively, than those in of controls (Langard, 1982). Workers also exhibit elevated chromium levels in the urine, serum [Cr(III) and Cr(VI)] and RBC [Cr(VI) only] (ATSDR, 1989). Animals exposed by intratracheal or intravenous injection distributed both Cr(III) and Cr(VI) throughout the body, but mainly to the lungs, spleen, bone marrow, liver, and kidney (Bragt and van Dura, 1983; Hamilton and Wetterhahn, 1988). Chromium (given in drinking water to rats for one year as potassium chromate or chromic chloride and to dogs for 4 years as potassium chromate) was distributed to the bone (rat only), liver, kidney, and spleen (MacKenzie et al. 1958; Anwar et al., 1961). Other studies have demonstrated higher tissue levels in animals receiving Cr(VI) in the drinking water than those receiving Cr(III) (ATSDR, 1989).

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: 1988; Source: ECHA.

Skin Sensitisation: The substance was tested in vivo to examine skin sensitising potential. Endpoint: Not sensitising; Report date: 2009; Source: ECHA.

Carcinogenicity: Long term in vivo studies with chromium metal, chromium(III) oxide and stainless steel do not show any evidence that metallic chromium would be a potential carcinogen. Human exposure observations and international carcinogenicity evaluations also conclude that trivalent chromium compounds are not classifiable for carcinogenicity. (ECHA)

Product Name

Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION

Tin (Surfactant)

EU INCI: Tin.

CTFA INCI: Tin.

CAS Number: 7440-31-5.

EINECS Number: 231-141-8.

Symbol: Sn.

Molecular Weight: 118.71.

Synonyms: AT-SN; AT-Sn600; C.I. 77860; C.I. Pigment Metal 5; FSn 2; G-Sn; Metallic tin; PO 1; PO 2; SNE 06PB; Silver Matt Powder; Sn-HWQ; Sn-S 200; Sn-S-HW Flake; Tin Paste 62-1177; Tin Powder; Tin element; W-Sn; Wang

Sn

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY

Odour: Odourless

Water Solubility: 0.004 mg/L at 20 °C

Boiling Point: 2240-2625 °C .

Colour: Grey-white

Density: 7.26-7.31 g/cm³ at 20 deg C

Vapour Pressure: 1 Pa at 1224 °C

Melting Point: 231.9 °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.

GHS Classification: Not classified as per GHS.

Region : Europe Type : Cosmetic Restriction : None

Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW

General Toxicity Review: Based on the available information the substance is not associated with the skin sensitisation, skin and may cause only slight eye irritation. It shows low acute toxicity with LD50 >2000 mg/kg bw in both dermal and oral exposure. It also have low chronic toxicity where oral 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 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 slightly irritating. (ECHA)

Genotoxicity: In vitro: negative (S. typhimurium, other: TA 1535, TA 1537, TA 98, TA 100 and TA 102) (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, rat) > 2 000 mg/kg bw; OECD Guideline 402 (Acute Dermal Toxicity); Description: Acute toxicity studies via dermal route of exposure in rats (semioclusive type of coverage) showed that the substance has low skin toxicity. (ECHA)

NOAEL Oral: NOAEL > 1 000 mg/kg bw/day Study type Type of information: Endpoint short-term repeated dose toxicity: oral. Species rat. Duration 28 days. Methods OECD Guideline 407. Reference date 2010 (ECHA)

Read-across: Not susceptible to microbiological contamination

Reproductive Toxicology: In accordance with the criteria for classification as defined in Annex I, Regulation (EC) No 1272/2008, the substance does not require classification with respect to reproductive or developmental toxicity (teratogenicity) as the available data indicates that there is no cause for concern. (ECHA)

Skin Irritation: In the in vivo studies on rabbits with semioclusive coverage 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: In accordance with the criteria for classification as defined in Annex I, Regulation (EC) No 1272/2008, the substance does not require classification with respect to carcinogenicity as the available data indicates that there is no reason for concern. (ECHA)

Product Name

Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION

Copper (Cosmetic Colorant)

EU INCI: CI 77400.
CTFA INCI: Copper powder.
CND A INCI: Copper.
Chinese: 铜粉.
CAS Number: 7440-50-8.
EINECS Number: 231-159-6.
Symbol: Cu.
Molecular Weight: 63.546.
Synonyms: granulated copper

Cu

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY

Odour: Odourless
Water Solubility: Insoluble
Boiling Point: 2595 °C
Particle Size: Particle size distribution (PSD) and D50 of 138 µm
Colour: Reddish / Brown
Density: 8.94 g/cm³
Vapour Pressure: 0 Pa
LogP Log Kow: -0.57 (calculated)
Melting Point: 1083 °C
Physical State: Solid.

REGULATORY REQUIREMENTS

CLP Regulation (EC) No 1272/2008: Granulated copper with particle length: from 0,9 mm to 6,0 mm; particle width: from 0,494 to 0,949 mm is listed in CLP Regulation (EC) 1272/2008 and classified as Aquatic Chronic cat.2 H411
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. Listed in the Annex IV to (EC) No 1223/2009
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW

General Toxicity Review: The substance was tested in vivo and it was concluded that it is not irritating to eyes and skin. May cause mechanical irritation. Acute oral toxicity study indicated that copper shows medium toxicity potential with medial lethal dose at 300-500 mg/kg bw. NOAEL was determined at 1 000 ppm and showed high toxicity potential 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 not considered to be of toxicological concern when used in consumer products

TOXICOLOGICAL PROFILE

Acute Toxicology: LC50 (inhalation, rat) > 5.11 mg/L air (inhalation, rat, 4h, 2011, OECD Guideline 436); Description: The substance when tested for acute toxicity via inhalation for 4 hours was found to be slightly toxic. LD50 (dermal, rat) > 2 000 mg/kg bw (dermal, rat, 2001, OECD Guideline 402) Description: Acute toxicity studies via dermal route of exposure in rats (semiclosed type of coverage) showed that the substance has low skin toxicity. (ECHA)
Eye Irritation: The substance was tested in vivo to examine ocular irritation potential. Endpoint: slightly irritating; Method: according to OECD Guideline 405 and EU Method B.5. Species: rabbit; Report date: 2001; Source: ECHA.
Genotoxicity: Negative in vitro gene mutation study in bacteria. Negative in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus (ECHA)
Inhalation: Toxic if inhaled
LD50: LD50 300 - 500 mg/kg bw; Route of administration:oral, Species: rat, Report date:2001, Method: according to OECD Guideline 423; Description: Acute toxicity studies via oral route of administration in rats demonstrated moderate toxicity of the substance. source: ECHA.
Mutagenicity: No evidence of mutagenicity
NOAEL Inhalation: NOAEL 2 mg/m³ (0.002 mg/L). Study type Repeated dose toxicity. Endpoint short-term repeated dose toxicity. Method OECD Guideline 412 (Subacute Inhalation Toxicity: 28-Day Study). Study date 2010 (ECHA)
NOAEL Oral: NOAEL 1000 ppm (0.1 mg/kg bw). Study type Repeated dose toxicity. Endpoint sub-chronic toxicity. Methods EU Method B.26 (Sub-Chronic Oral Toxicity Test: Repeated Dose 90-Day Oral Toxicity Study in Rodents). Report date 1993 (ECHA)
Percutaneous Absorption: 0.1106%
Skin Irritation: The substance was tested in vivo to examine skin irritation potential. Endpoint: not irritating; Method: according to OECD Guideline 404 and EU Method B.4; Species: rabbit; Report date: 2001; Source: ECHA.
Skin Sensitisation: The substance was tested in vivo to examine skin sensitising potential. Endpoint: not sensitising; Method: according to OECD Guideline 406 and EU Method B.6; Species: guinea pig; Report date: 2001; Source: ECHA.

OTHER

Hazard Class and Category Code(s): (H411) Aquatic Chronic 2
LC50 (Environmental): LC50 193 µg/L; Species: fish, Exposure duration: 96h, Report date:1987, measurements were conducted by standard EPA methods; Source: ECHA.

Product Name

Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

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: C₂ 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 deliver 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

Product Name

Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

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 µm, 97.1%<10 µm, 0.61%<5.5 µm, 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)

Product Name

Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

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 negligible 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 threshold 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

Product Name

Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION

Cadmium (Not Reported)

EU INCI: Cadmium (Prohibited).
CTFA INCI: Cadmium (Prohibited).

Chinese: 鎘.

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)

Product Name

Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR UE/UK passed

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 consumer 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)

Product Name

**Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR
UE/UK passed**

Manufacturer

**Eresos Health + Wellbeing LTD
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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.

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INSTRUCTION OF USE

Hands & Body - Apply a small amount to hands or your body, letting it gently absorb to nourish and replenish the skin. Bath - Add 10ml to running bath water and let the body soak, allowing the sweet citrusy notes stimulate your mind.

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.

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REASONING**TOXICOLOGICAL ASSESSMENT****EFFECT ON SKIN**

May cause slight temporary skin irritation.

The product contains perfume materials that are known to cause allergic reactions, however, the risk of inducing allergy is low for the general populations due to their low concentration.

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.

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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.

This product is considered safe and in compliance with Schedule 34 of the Product Safety & Metrology etc (Amendment etc) (EU Exit) Regulations 2019 UK Cosmetics Regulation and subsequent amendments.

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

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IMPURITIES

CAS No	IMPURITY	SOURCE CHEMICAL	Concentration in finished product[%]
59-02-9(10191-41-0) (1406-66-2)1406-18-4(54 28.41(g/mmol)	Tocopherol	Tocopheryl Acetate	0.0014683500
108-88-3	Toluene	Tocopheryl Acetate	0.0000234936
110-86-1	Pyridine	Tocopheryl Acetate	0.0000234936
7440-47-3	Chromium	Caprylic/Capric Triglyceride	0.0000111105
7440-38-2	Arsenic and its compounds	Caprylic/Capric Triglyceride	0.0000111105
7440-02-0	Nickel	Caprylic/Capric Triglyceride	0.0000044442
7440-50-8	Copper	Caprylic/Capric Triglyceride	0.0000022221
7439-92-1	Lead and its compounds	Caprylic/Capric Triglyceride	0.0000022221
7440-31-5	Tin	Caprylic/Capric Triglyceride	0.0000022221
7439-92-1	Lead and its compounds	Tocopheryl Acetate	0.0000005873
7440-38-2	Arsenic and its compounds	Tocopheryl Acetate	0.0000002937
7440-02-0	Nickel	Tocopheryl Acetate	0.0000002937
7440-43-9	Cadmium	Tocopheryl Acetate	0.0000001468
7439-97-6	Mercury and its compounds	Tocopheryl Acetate	0.0000000294

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EXPOSURE TO POTENTIAL IMPURITIES

SED Product = 311.166667 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
Tocopherol	0.0014683500	18.67	0.00456902	500	54716.379562
Toluene	0.0000234936	18.67	0.00007310	625	4274717.153251
Pyridine	0.0000234936	18.67	0.00007310	7	47876.832116
Arsenic and its compounds	0.0000114042	18.67	0.00003549	0.0008	11.272044
Chromium	0.0000111105	18.67	0.00003457	1216	17586374.682007
Nickel	0.0000047379	18.67	0.00001474	2.2	74613.244857
Lead and its compounds	0.0000028094	18.67	0.00000874	7.8	446119.610363
Tin	0.0000022221	18.67	0.00000691	1000	72312395.896408
Copper	0.0000022221	18.67	0.00000691	0.1	7231.23959
Cadmium	0.0000001468	18.67	0.00000046	3	3282982.773697
Mercury and its compounds	0.0000000294	18.67	0.00000009	0.005	27358.189781

*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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LITERATURE SOURCES

Agency for Toxic Substances and Disease Registry (ATSDR)	Accessed Date:	23/12/2022
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Annex XVII	Accessed Date:	10/01/2023
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20221217&from=EN		
Annex XVII list of substances with specific concentration limits	Accessed Date:	23/12/2022
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Product Name

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LITERATURE SOURCES

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Product Name

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LITERATURE SOURCES

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Product Name

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LITERATURE SOURCES

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Product Name

**Sweet Almond Hand & Body Oil 4000mg (2022-753-5055) (variant) CPSR
UE/UK passed**

Manufacturer

**Eresos Health + Wellbeing LTD
14 A Commercial Road
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N18 1TP**
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Product Name

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Product Name

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Product Name

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Product Name

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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) – Nolicem Sp. z o.o. (Poland – EU)
- **Toxicologist, Regulatory and Safety Assessor** (2nd June 2014 – present) - Nolicem 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
-

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.*

- 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 Animals 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)

- 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 Warcholek, 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