eurofins | Consumer Product Testing

Laboratory Test Report

Prepared for:	Eresos Health + Wellbeing LTD
Address:	14 A Commercial Road London N18 1TP
Customer Sample Description:	Cocoa Hand & Body Butter 2000mg
Eurofins Registration Number:	2022-753-5050
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)

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Georgia Lees-Lowe
Technical Account Executive

Date: 06/02/2023

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

Job No	**NCH1140**
Report No	**008233**
Issue Date	**23/01/2023**
Version No	**1**

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

Manufacturer

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

Cosmetic Product Safety Report

PRODUCT IDENTIFICATION

Product Category:	Cosmetic
Requirements:	Regulation (EC) 1223/2009 and UK
Reference Number:	2022-753-5050
Client Name:	Eurofins Consumer Product Testing Services
Contact Name:	Georgia Lees-Lowe

PRODUCT CHARACTERISTICS

Product Group:	Body butter
Type Of Product:	Leave On
Physical State:	Cream
Nominal Size:	146 g
Type Of Package:	PET jar with PP lid

PHYSICAL/CHEMICAL CHARACTERISTICS

Appearence:	Light yellow opaque cream	**Specific Gravity [20°c]:**	Not Available
Odour:	Characteristic	**Particles Size:**	Not Applicable
pH:	4 - 6	**Density:**	Not Available
Viscosity[cp]:	Not Available	**Flash Point:**	Not Applicable
Solubility:	Partly soluble in water	**Loss On Drying:**	Not Applicable
Proportion Of Non-propellant In The Spray	Not Applicable	**Fraction Reaching Alveoli:**	Not Applicable

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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.

Product Name
Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

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
Aqua	7732-18-5	54.06843	None
Cocos Nucifera Oil	8001-31-8	27.31347	None
Caprylic/Capric Triglyceride	73398-61-5(65381-09-1)	4.77388	None
Butyrospermum Parkii Butter	194043-92-0(91080-23-8)	3.58041	None
Glycerin	56-81-5	2.90901	None
Glyceryl Stearate	31566-31-1(123-94-4)	2.69828	None
PEG-100 Stearate	9004-99-3	2.69828	None
Glyceryl Stearate SE	11099-07-3	2.69828	None
Helianthus Annuus (Sunflower) Seed Oil	8001-21-6	2.38694	None
Cetyl Alcohol	36653-82-4	1.5567	None
Cannabidiol (CBD)	13956-29-1	1.370	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).
Stearic Acid	57-11-4	1.19347	None
Theobroma Cacao (Cocoa) Seed Butter	84649-99-0(8002-31-1)	1.19347	None
Ceteareth-20	68439-49-6	0.77835	None
Phenoxyethanol	122-99-6	0.7251	1%
Ethylhexylglycerin	70445-33-9	0.7251	None
Polysorbate 20	9005-64-5	0.622	None
Isopropyl Myristate	110-27-0	0.5189	None
Carbomer	9007-20-9(9003-01-4)76050-42-5(9062-04-8)9007-16-3(9007-17-4)	0.44503	None

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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
Squalane	111-01-3	0.36323	None
Camellia Kissi Seed Oil	94333-92-3	0.36323	None
Sodium Hydroxide	1310-73-2	0.36255	a) Nail cuticle solvent 5% b) Hair straightener general use 2% Professional use 4,5% c) pH adjuster for depilatories pH<12,7 d) Other uses as pH adjuster pH<11 a)Contains alkali Avoid contact with eyes Can cause blindness Keep out of reach of children b) 1) Contains alkali Avoid contact with eyes Can cause blindness Keep out of reach of children 2)For professional use only Avoid contact with eyes Can cause blindness c)Keep out of reach of children Avoid contact with eyes
Tocopheryl Acetate	7695-91-2(58-95-7)	0.15567	None
Aloe Barbadensis Leaf Juice Powder	85507-69-3(94349-62-9)	0.1031	None

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STABILITY OF THE COSMETIC PRODUCT

PRODUCT STABILITY:

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

PACKAGING SPECIFICATION:

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

GENERAL RECOMMENDATION:

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

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

PRODUCT DURABILITY:

Shelf life: 24 months from manufacturing

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MICROBIOLOGICAL QUALITY

MESOPHILIC AEROBIC BACTERIA COUNT: < 100 cfu/g

YEAST AND MOULDS: < 100 cfu/g

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

CHALLENGE TEST:

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

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

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

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

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

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

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IMPURITIES, TRACES, INFORMATION ABOUT THE PACKAGING MATERIAL

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

NORMAL AND REASONABLY FORESEEABLE USE

Body and hands butter intended for use by adults.

EXPOSURE TO THE Cosmetic PRODUCT

The site(s) of application:	Body
The surface area(s) of application:	17500 cm^2
The amount of product applied:	18.67 g
Exposure time:	Leave On
The duration and frequency of use:	Once per day
The normal and reasonably foreseeable exposure route(s):	Skin
The targeted (or exposed) population(s):	16+

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

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EXPOSURE TO THE SUBSTANCES (DERMAL)

SED Product = 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
Aqua	54.068430	18.67	100.000	168.24293135	Not available	No MoS calculated as no NOAEL available
Cocos Nucifera Oil	27.313470	18.67	100.000	84.99041415	Not available	No MoS calculated as no NOAEL available
Caprylic/Capric Triglyceride	4.773880	18.67	100.000	14.85472327	1875	126.222479
Butyrospermum Parkii Butter	3.580410	18.67	100.000	11.14104245	Not available	No MoS calculated as no NOAEL available
Glycerin	2.909010	18.67	100.000	9.05186945	5040	556.791062
PEG-100 Stearate	2.698280	18.67	100.000	8.39614793	Not available	No MoS calculated as no NOAEL available
Glyceryl Stearate SE	2.698280	18.67	100.000	8.39614793	Not available	No MoS calculated as no NOAEL available
Glyceryl Stearate	2.698280	18.67	100.000	8.39614793	2000	238.204474
Helianthus Annuus (Sunflower) Seed Oil	2.386940	18.67	100.000	7.42736163	Not available	No MoS calculated as no NOAEL available
Cetyl Alcohol	1.556700	18.67	100.000	4.84393150	1000	206.443877
Cannabidiol (CBD)	1.370000	18.67	100.000	4.26298333	Not available	No MoS calculated as no NOAEL available
Theobroma Cacao (Cocoa) Seed Butter	1.193470	18.67	100.000	3.71368082	Not available	No MoS calculated as no NOAEL available
Stearic Acid	1.193470	18.67	100.000	3.71368082	Not available	No MoS calculated as no NOAEL available
Ceteareth-20	0.778350	18.67	100.000	2.42196575	Not available	No MoS calculated as no NOAEL available
Phenoxyethanol	0.725100	18.67	90.000	2.03064255	500	246.227481

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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
Ethylhexylglycerin	0.725100	18.67	10.500	0.23691148	Not available	No MoS calculated as no NOAEL available
Polysorbate 20	0.622000	18.67	100.000	1.93545667	Not available	No MoS calculated as no NOAEL available
Isopropyl Myristate	0.518900	18.67	100.000	1.61464383	Not available	No MoS calculated as no NOAEL available
Carbomer	0.445030	18.67	100.000	1.38478502	Not available	No MoS calculated as no NOAEL available
Squalane	0.363230	18.67	100.000	1.13025068	Not available	No MoS calculated as no NOAEL available
Camellia Kissi Seed Oil	0.363230	18.67	100.000	1.13025068	Not available	No MoS calculated as no NOAEL available
Sodium Hydroxide	0.362550	18.67	100.000	1.12813475	Not available	No MoS calculated as no NOAEL available
Tocopheryl Acetate	0.155670	18.67	100.000	0.48439315	Not available	No MoS calculated as no NOAEL available
Aloe Barbadensis Leaf Juice Powder	0.103100	18.67	100.000	0.32081283	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

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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
Aqua	54.068430	18.67	168.24293135	Not Available	No MoS calculated as no NOAEL available
Cocos Nucifera Oil	27.313470	18.67	84.99041415	Not Available	No MoS calculated as no NOAEL available
Caprylic/Capric Triglyceride	4.773880	18.67	14.85472327	5000	168.296639
Butyrospermum Parkii Butter	3.580410	18.67	11.14104245	Not Available	No MoS calculated as no NOAEL available
Glycerin	2.909010	18.67	9.05186945	8000	441.897668
PEG-100 Stearate	2.698280	18.67	8.39614793	Not Available	No MoS calculated as no NOAEL available
Glyceryl Stearate SE	2.698280	18.67	8.39614793	2500	148.877796
Glyceryl Stearate	2.698280	18.67	8.39614793	1000	59.551118
Helianthus Annuus (Sunflower) Seed Oil	2.386940	18.67	7.42736163	Not Available	No MoS calculated as no NOAEL available
Cetyl Alcohol	1.556700	18.67	4.84393150	4257	439.415793
Cannabidiol (CBD)	1.370000	18.67	4.26298333	Not Available	No MoS calculated as no NOAEL available
Theobroma Cacao (Cocoa) Seed Butter	1.193470	18.67	3.71368082	Not Available	No MoS calculated as no NOAEL available
Stearic Acid	1.193470	18.67	3.71368082	1000	134.637311
Ceteareth-20	0.778350	18.67	2.42196575	500	103.221939
Phenoxyethanol	0.725100	18.67	2.25626950	369	81.772146
Ethylhexylglycerin	0.725100	18.67	2.25626950	50	11.080237
Polysorbate 20	0.622000	18.67	1.93545667	5000	1291.684822
Isopropyl Myristate	0.518900	18.67	1.61464383	5500	1703.161987
Carbomer	0.445030	18.67	1.38478502	40	14.442675
Squalane	0.363230	18.67	1.13025068	10000	4423.79737
Camellia Kissi Seed Oil	0.363230	18.67	1.13025068	Not Available	No MoS calculated as no NOAEL available
Sodium Hydroxide	0.362550	18.67	1.12813475	1000	443.209466
Tocopheryl Acetate	0.155670	18.67	0.48439315	800	825.775509
Aloe Barbadensis Leaf Juice Powder	0.103100	18.67	0.32081283	Not Available	No MoS calculated as no NOAEL available

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Manufacturer
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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

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

Product Name

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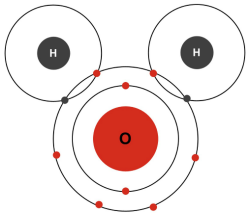
TOXICOLOGICAL PROFILE OF THE SUBSTANCES



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

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

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

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

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

OTHER
Detergent Class: Dilutant

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Cocos Nucifera Oil (Hair Conditioning,Masking,Perfuming,Skin Conditioning)
EU INCI: Cocos Nucifera Oil.
CTFA INCI: Cocos Nucifera (Coconut) Oil.
CNDA INCI: Cocos Nucifera (Coconut) Oil.
CAS Number: 8001-31-8.
EINECS Number: 232-282-8.
Description: Cocos Nucifera Oil is the fixed oil obtained by expression of the kernels of the seeds of the Coconut, Cocos nucifera L., Palmaceae

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Odorless or slight odor characteristic of Coconut.
Oxidising Properties: Not oxidizing
Specific Gravity: 0.9-0.9115 (Water = 1)
Water Solubility: Insoluble in water
Boiling Point: >450°C (842°F)
Colour: White to yellowish.
Density: 0.903 at 0-4°C
Flash Point: Closed cup : 216°C (420.8°F).
Melting Point: 21- 25°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: Not classified as hazardous to human health.
GHS Classification: Not classified as per GHS.
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

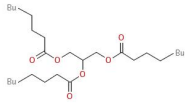
TOXICITY REVIEW
General Toxicity Review: Cocos Nucifera Oil is the fixed oil obtained by expression of the kernels of the seeds of the Coconut, Cocos nucifera L., Palmaceae. The substance is not associated with the skin sensitisation and skin irritation. Moreover, it is classified as not irritating to eyes. However, minimal eye irritation was observed in some of the animals during tests. It shows low acute toxicity with LD50 equal 5 g/kg in oral route of exposure. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is not considered to be of toxicological concern when used in consumer products.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested for ocular irritation in rabbits. Only minimal eye irritation was observed in some of the animals. (CIR)
Inhalation: Inhalation of mist or vapor may cause respiratory tract irritation.
LD50: LD50 (oral, rat) 5 g/kg; No deaths were observed in 10 rats after single dose of coconut oil. The substance is considered as non-toxic. (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.
Phototoxicity: Bar soap with 13% Cocos Nucifera (Coconut) Oil was tested as a 3% aqueous solution using 10 subjects. Similar soap prepared as 1 or 3% aqueous solutions was tested on 52 panelists. No evidence of photosensitization was found (CIR).
Skin Irritation: No skin irritation was observed after 24h single occlusive patch test in 9 rabbits.(CIR)
Skin Sensitisation: Magnusson-Kligman Maximization test on guinea pigs was conducted in order to determine sensitising potential of the coconut oil. The substance was scored as non-sensitising. (CIR)
Allergens HRIPT: ,,A HRIPT was performed using 103 participants with a tanning butter containing 2.5% Cocos nucifera (coconut) oil; no erythematous reactions were seen at challenge; A bar soap containing 13% Cocos nucifera (coconut) oil produced very mild irritation when tested as a 1% aqueous solution on 106 participants, and it was minimally to mildly irritating in a soap chamber test with a 8% aqueous solution; the soap produced no unusual irritation response in a 2-week normal use test; undiluted Cocos nucifera (coconut) oil was not an allergen in 12 participants" (CIR).
Carcinogenicity: Not associated with carcinogenic, mutagenic and reprotoxic (CMR) chemicals.

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

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Caprylic/Capric Triglyceride (Masking,Perfuming,Skin Conditioning)
EU INCI: Caprylic/Capric Triglyceride.
CTFA INCI: Caprylic/Capric Triglyceride.
CNDA 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 belongsto chemical group known as medium chain triglyceride (MCT). IT is a mix of tri-esters with carbon chains of C8 and C and Glycerin.



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: Sligthly 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 occured). (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 MaximisationTest: The substance was classified as non-sensistising 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)

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

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Butyrospermum Parkii Butter (Skin Conditioning,Viscosity Controlling)
EU INCI: Butyrospermum Parkii Butter.
CTFA INCI: Butyrospermum Parkii (Shea) Butter.
CNDA INCI: Butyrospermum Parkii (Shea) Butter.
CAS Number: 194043-92-0(91080-23-8).
EINECS Number: 293-515-7.
Description: Shea butter is a vegetable fat obtained from the fruit of a tree native to Africa, Butyrospermum parkii. Shea butter is primarily composed of fatty acids such as stearic and oleic acids.
EINECS No.: 293-515-7

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Water Solubility: Insoluble
Boiling Point: > 350 °C (> 662 °F)
Colour: Whitish
Flash Point: > 200 °C (> 392 °F)
Melting Point: 32-46 (28-42) oC
Microbiological stability: Not susceptible to microbiological contamination
Peroxide value: 5.0 max
Physical State: Paste.

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: Shea butter is a vegetable fat obtained from the fruit of a tree native to Africa, Butyrospermum parkii. Shea butter is primarily composed of fatty acids such as stearic and oleic acids. Data derived from animal studies demonstrate that the substance is not irritating to eyes and skin. Moreover, the substance is not a skin sensitizer. It shows low acute toxicity with LD50 above 2000 mg/kg bw and above 5000 mg/kg bw in dermal and oral and dermal route of exposure respectively. Overall, the ingredient is not considered to be of toxicological concern when used in consumer products.

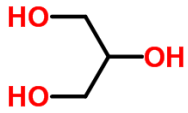
TOXICOLOGICAL PROFILE
Endocrine Effects: Not regarded as endocrine active substance.
Eye Irritation: The substance was monitored for ocular irritation on rabbits. Undiluted substance was applied to rabbits eyes. Only mild conjunctival reactions were observed, the substance was classified as not irritating. (CIR)
Genotoxicity: Ames test of Butyrospermum Parkii (Shea) Butter (70%) and Butyrospermum Parkii (Shea) Butter Unsaponifiables (30%) was conducted. The material was found not mutagenic. (CIR)
LD50: LD50 (oral, rat) > 5000 mg/kg bw; LD50 (dermal, rat) > 2000 mg/kg bw. Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity. Acute toxicity studies via dermal route of exposure in rats showed that the substance has low skin toxicity. (SDS)
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.
Phototoxicity: Not a phototoxic material. Studies of 10% Butyrospermum parkii (shea) butter and 20% in acetone were conducted on 10 Pirbright white guinea pigs. The substance was found non phototoxic. (CIR)
Reproductive Toxicology: There was no evidence of reproductive toxicity following dietary exposure of shea olein and hydrogenated shea olein in rats at levels equating to greater than 15% (7.5 g/kg/day) (CIR).
Skin Irritation: 0.5 ml of Shea butter was applied to rabbit skin and left under occlusive patch for 4h. Very slight erythema was observed. No skin irritation was observed in a HRIPT (60% of Shea butter, 111 participants). (CIR)
Skin Sensitisation: The substance underwent Maximization study with Freund's completeadjuvant (FCA) during induction (rabbits/ guinea pigs). Concentration of Shea butter was 75% (induction phase) and 20-50% (challenge phase). No skin sensitisation or delayed hypersevsitivity were observed. No skin sensitisation was observed in a HRIPT study (60% of Shea butter, 111 participants). (CIR)
Allergens HRIPT: Shea butter underwent HRIPT testing in the concentrations such as: 0.1%; 2%; 4%; 23,5%; 23,7%, 24,1%, 45% and 60% in a various types of cosmetic formulations. The number of volunteers for each study was >100. Based on the testing results no sensitisation was observed, irritation was observed only in one participant. The substance is not a dermal irritant or sensitiser. (CIR)
Carcinogenicity: None of the findings in this study were considered to be adverse effects and that shea olein showed no tumorigenic potential at 15% (7.5 g/kg/day) in the rat (CIR).

OTHER
Saponification Value: mgKOH/g: 175 – 195

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

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

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



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

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

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

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

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

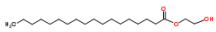
Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
PEG-100 Stearate (Surfactant,Cleansing)
EU INCI: PEG-100 Stearate.
CTFA INCI: PEG-100 Stearate.
CNDA INCI: PEG-100 Stearate.
CAS Number: 9004-99-3.
Symbol: C20H40O3.
Molecular Weight: 328.530 Da.
Description: Poly(oxy-1,2-ethanediyl), .alpha.-(1-oxooctadecyl)-.omega.-hydroxy- (100 mol EO average molar ratio)



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Faint fatty odour
Water Solubility: Soluble
Colour: Cream-colored
Flash Point: 500 deg F OC
Melting Point: 60.5°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 the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: Not Classified as per GHS. Self classified: H315: Causes skin irritation. H319: Causes serious eye irritation. H335: May cause respiratory irritation..
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: The substance is not associated with skin sensitisation. Based on the available toxicological information, the substance may cause serious eye irritation and skin irritation. It shows moderate acute toxicity with LD50 of 200 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.

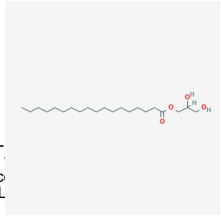
TOXICOLOGICAL PROFILE
Eye Irritation: 38 notifiers suggest, that the substance may cause serious eye irritation (ECHA).
LD50: LD50 (oral, mouse) 200 mg/kg; Description: Acute toxicity studies via oral route of administration in mice demonstrated high toxicity of the substance.
NOAEL Oral: The NOAEL value 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: Undiluted PEG-100 Stearate was patch-tested on 10 individuals. There were no adverse effects. Based on the results, the substance is not skin irritating (CIR).
Skin Sensitisation: Undiluted PEG-100 Stearate was patch-tested on 10 individuals. There were no adverse effects. Based on the results, the substance is not skin sensitiser (CIR).
Allergens HRIPT: HRIPT of skin conditioner containing 1%-3% PEG-100 Stearate (without fragrance) was conducted on 188 individuals. There was no skin reaction observed. (CIR)
Allergens Patch Test: Patch test for undiluted PEG-100 Stearate was conducted on 10 individuals. After two 48h patches application, there was no skin irritation or sensitisation effect observed. (CIR)
Carcinogenicity: Not associated with Carcinogenic, mutagenic and reprotoxic (CMR) chemicals.

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



IDENTIFICATION
Glyceryl Stearate SE (Emulsifying)
EU INCI: Glyceryl Stearate SE.
CTFA INCI: Glyceryl Stearate SE.
CAS Number: 11099-07-3.
EINECS Number: 234-325-6.
Symbol: C18H36O2.x(C3H8O3).
Description: Glyceryl Stearate SE (self-emulsifying) is a lipid.
Synonyms: 1-Glyceryl stearate1-Monostearoylglycerol1-octadecanoyl-rac-glycerol2,3-dihydroxypropyl octadecanoate2,3-Dihydroxypropylstearat (±)-
octadecanoylglycerol(±)-1-stearoylglycerol(±)-2,3-dihydroxypropyl octadecanoate(±)-glyceryl monostearate(1)-2,3-Dihydroxypropyl stearate1,2,3-Propanetriol
Propanetriol monooctadecanoate1-Glyceryl monooctadecanoate1-Monooctadecanoyl-rac-glycerol1-Monostearin1-Mono-Stearin1-Monostearoyl-rac-glyc
stearoylglycerol1-Stearoyl-glycerol1-Stearoyl-rac-glycerol2,3-Dihydroxypropyl 9-octadecanoate2,3-Dihydroxypropylstearate3-Stearoyloxy-1,2-propanediol3-STEAROYL

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Mild, ester-like
Water Solubility: Insoluble in water
Density: 0.908 (70 °C)
Flash Point: > 93.3 °C
Vapour Pressure: <1.13Pa (25 °C))
Melting Point: 133-134 ºC*
Microbiological stability: Not susceptible to microbiological contamination
Physical State: Flakes.

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: Not classified as hazardous to human health.
GHS Classification: Not classified as per GHS.
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: Glyceryl Stearate SE is commonly used as emulsifying. Data derived in vivo indicated that the substance is mildly irritating or non-irritating to eyes and skin, it is not sensitising to skin. It shows very low acute toxicity potential with LD50 above 5 000 mg/kg bw. Repeated dose toxicity was evaluated and NOAEL value was determined to be at 2 500 mg/kg bw. 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: In primary eye irritation studies, Glyceryl Stearate SE at concentrations up to 100% were mildly irritating or non irritating when instilled in the eyes of rabbits (CIR Safety).
LD50: LD50 (oral, rat) > 5000 mg/kg. In acute oral toxicity studies in rats, Glyceryl Stearate SE is nontoxic or mildly toxic.
NOAEL Oral: NOAEL 2500 mg/kg bw. Study type: Repeated dose toxicity. Duration: 90 day study. Reference source: CoCAM, 2014 (because of similarity, the results are based on the Glyceryl Stearate)
Skin Irritation: Glyceryl Stearate SE at concentrations of up to 100% was reported to be mildly irritating or non irritating to the skin of rabbits. After applying 0.5 mL for 4-hour semiocclusive patch, animals were observed for 72 hours. No erythema or edema were observed (CIR Safety).
Skin Sensitisation: Based on the conducted test, the substance is classified as not sensitising to skin. After applying 0.5 mL for 4-hour semiocclusive patch, animals were observed for 72 hours. No erythema or edema were observed (CIR Safety).
Allergens HRIPT: Glyceryl Stearate in a concentration of 20% was used in a HRIPT study on 61 subjects. The substance was applied under occlusive patches and left for 24 hours. 10-15 applications were made during 2-3 weeks. After 10-14 days of rest time, a challenge patch was applied to the previously untreated site. The substance did not cause skin sensitisation. (CIR)
Allergens Patch Test: The Single Insult Patch Test was conducted on 20 volunteers using blemish stick and cream containing 13.8% and 5% of Glyceryl Stearate. Mild skin irritation was observed. 12.5% Glyceryl Stearate was applied under occlusion and left for 24h. 21 applications were made. The substance was classified as not irritating. (CIR)
Carcinogenicity: Not associated with carcinogenic, mutagenic and reprotoxic (CMR) chemicals.

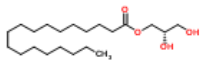
Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Glyceryl Stearate (Emollient,Emulsifying)
EU INCI: Glyceryl Stearate.
CTFA INCI: Glyceryl Stearate.
CNDA INCI: Glyceryl Stearate.
CAS Number: 31566-31-1(123-94-4).
EINECS Number: 250-705-4/286-490-9.
Symbol: C21H42O4.
Molecular Weight: 358.556 Da.
Description: Glyceryl Stearate SE (self-emulsifying) is a lipid used as surfactant and emulsifying agent.
Synonyms: Glyceryl monostearate



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Oxidising Properties: Not oxidising.
Water Solubility: < 1 mg/L Insoluble
Density: 920 - 960 kg/m³ at 20 °C
Flammability: Non flammable.
Flash Point: 240 °C at 1013 hPa (closed cup)
Vapour Pressure: < 0.0001 Pa at 20 °C
LogP Log Kow: 6.1
Melting Point: 66.7 °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: Listed as 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: Glyceryl Stearate SE (self-emulsifying) is a well-known lipid used as surfactant and emulsifying agent. The available toxicological data demonstrate that the substance is not irritating to eyes. It was also found to be not irritating and not corrosive. However, slight erythema was observed. The chemical is found to be non-sensitising to skin. It shows low acute toxicity with LD50 above 5000 mg/kg bw in oral route of exposure and LD50 above 2000 mg/kg bw in dermal route of exposure. It has low chronic toxicity where both oral and dermal 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
Endocrine Effects: No endocrine effects are known from using this material in cosmetics.
Eye Irritation: The substance was tested in vivo to examine ocular irritation potential. Endpoint: The studies resulted in scoring the substance as no irritating. Method: according to OECD Guideline 405, EU Method B.5, EPA OTS 798.4500; Species: rabbits; Report date: 1999; Source: ECHA.
Genotoxicity: In vitro: negative (Chinese hamster Ovary (CHO)). In vivo: negative (mouse) (ECHA)
LD50: LD50 (Oral, mouse) >5000 mg/kg bw; Description: Acute toxicity studies via oral route of administration in mice demonstrated slight toxicity of the substance. LD50 (Dermal, rats) >2000 mg/kg bw; Description: Acute toxicity studies via dermal route of exposure in rats (semiocclusive type of coverage) showed that the substance has slight skin toxicity. (ECHA)
NOAEL Dermal: NOAEL 2000 mg/kg bw. Study type Repeated dose toxicity. Endpoints Short-term repeated dose toxicity. Species Rabbit. Source date 1980 (ECHA) MoS was calculated based on this data
NOAEL Oral: NOAEL 1000 mg/kg bw. Study type Toxicity to reproduction. Endpoint Screening for reproductive / developmental toxicity. Method OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test). Species Rat. Report date 2010 (ECHA) MoS was calculated based on this data.
Skin Irritation: The substance was tested in vivo to examine skin irritation potential. Results: very slight erythema was observed, but effect fully disappeared after 7 days observation. Endpoint: The substance was found to be not irritating to the skin. Method: according to OECD Guideline 404, EU Method B.4, EPA OTS 798.4470 semiocclusive type of coverage; Species: rabbits; Report date: 1999; Source: ECHA. In primary irritation studies on rabbits glyceryl stearate was found to be mildly irritating or not irritating (CIR).
Skin Sensitisation: The substance was tested in vivo (Non-LLNA) to examine skin sensitising potential. Endpoint: The substance was found to be non-sensitising. Method: OECD Guideline 406, EU Method B.6 (Skin Sensitisation), Species: guinea pig; Report date:1998; Source: ECHA. In skin sensitisation studies: Landsteiner/Jacobs Method and the Kligman Maximization Procedure in guinea pigs, the substance was found non-sensitising. (CIR)
Allergens HRIPT: Repeated Insult Patch Test was conducted on 61 subjects. The substance (20% of Glyceryl Stearate in Mineral oil/ petrolatum) was applied 10-15 times by the time of 3 weeks. After 2 weeks rest, the challenge phase was applied. No skin sensitisation was observed. In a different study Glyceryl Stearate (20%) was applied for 3 days on the arm skin. The study involved 1206 volunteers. No allergic reactions were observed. (CIR)
Allergens Patch Test: Single Insult Patch test was conducted on 20 volunteers. After 24 h only mild skin irritation was observed. The Glyceryl Stearate was considered to be 'essentially non irritating.' (CIR)
Carcinogenicity: Not associated with CMR materials.

OTHER
Biodegradability (Environmental): Biodegradation in water. Results: 95 % (O2 consumption) degradation after 28 days. Conclusion: readily biodegradable. (OECD 301D) (ECHA)
LC50 (Environmental): No toxic effects observed up to the limit of water solubility (< 1 mg/L) for Danio rerio (OECD 203) and Scenedesmus subspicatus (OECD 201) No toxic effects up to the limit of water solubility (< 1 mg/L) for Daphnia magna (OECD 202) (read across information ECHA)

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

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Helianthus Annuus (Sunflower) Seed Oil (Emollient,Masking,Skin Conditioning)
EU INCI: Helianthus Annuus Seed Oil.
CTFA INCI: Helianthus Annuus (Sunflower) Seed Oil.
CNDA INCI: Helianthus Annuus (Sunflower) Seed Oil.
CAS Number: 8001-21-6.
EINECS Number: 232-273-9.
Description: Helianthus Annuus Seed Oil is the oil expressed from the seeds of the Sunflower, Helianthus annuus L., Compositae
Synonyms: Sunflower seed oil from Helianthus annuus; Florasun 90; Gina; Gina (glyceride); Haioru 75B; Helianthus annuus oil

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Specific Gravity: 0.9 (Water = 1)
Water Solubility: Insoluble
Boiling Point: > 100 °C (> 212 °F)
Colour: Pale yellow to yellow
Density: 0.920 g/cm3
Flammability: May be combustible at high temperature.
Flash Point: > 110 °C (> 230 °F). Closed Cup: >287.78°C (550°F)
Melting Point: 0 degC
Microbiological stability: Not susceptible to microbiological contamination
Physical State: Oily liquid.

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

TOXICITY REVIEW
General Toxicity Review: Sunflower seed oil is commonly used as emollient, masking and skin conditioning. There is no evidence of skin or eyes irritation or skin sensitisation potential. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is 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.
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 HRIPT: Several HRIPTs were performed in products containing Helianthus annuus (sunflower) seed oil in different concentration (6%, 20%, 0.264%, 1%, 39.8%). In all tests there was no evidence of skin irritation or sensitisation. (CIR)
Allergens Patch Test: There was a case of 1 woman with delayed positive reaction to sunflower oil in a skin prick test. 10 control participant had negative reaction. Oral challenge test was conducted, reaction was observed again. (CIR)
Carcinogenicity: Not associated with Carcinogenic, mutagenic and reprotoxic (CMR) chemicals.

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Cetyl Alcohol (Emollient,Emulsifying,Emulsion Stabilising,Foam Boosting,Masking,Opacifying,Surfactant,Viscosity Controlling)
EU INCI: Cetyl Alcohol.
CTFA INCI: Cetyl Alcohol.
CNDA INCI: Cetyl Alcohol.
CAS Number: 36653-82-4.
EINECS Number: 253-149-0.
Symbol: C16H34O1.
Description: Cetyl Alcohol is a synthetic fatty alcohol. It belongs to the type of surfactants named nonionic surfactant.

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Odourless
Oxidising Properties: Non oxidising.
Viscosity: 3.394 mm²/s (static) at 100 °C
Water Solubility: 0.024 mg/L at 25 °C
Partial Coefficient logPow: 6.65
Boiling Point: 319 °C at 101.3 kPa
Colour: Colourless
Density: 0.889 g/cm³ at 20 °C
Flash Point: 149 °C at 101 325 Pa
Vapour Pressure: 0 Pa at 25 °C
Melting Point: 49 °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 Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: Not classified as per GHS. Self classified: H319: Causes serious eye irritation H400: Very toxic to aquatic life. H411: Toxic to aquatic life with long lasting effects..
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: The substance is not associated with skin sensitisation and skin irritation. Data derived from animal studies demonstrate that the substance is not irritating to eyes. It shows low acute toxicity with LD50 above 2000 mg/kg bw in oral exposure and very low skin toxicity with LD50 of 8000 mg/kg bw in dermal exposure. It has low chronic toxicity where oral and dermal systematic exposure is considered. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is not considered to be of toxicological concern when used in consumer products.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo to examine ocular irritation potential. Endpoint: The studies resulted in scoring the substance as non-irritating. Method: according to OECD Guideline 405 (Acute Eye Irritation / Corrosion); Species:New Zealand White rabbit; Report date: 1996; Source: ECHA. The substance is self classified by some of the raw material manufacturer's (Flinn Scientific) as serious eye irritant (H319)
LD50: LD50 (oral, rat) >2000 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) 8000 mg/kg bw; Description: Acute toxicity studies via dermal route of exposure in rabbits (occlusive type of coverage) showed that the substance has very low skin toxicity. (ECHA)
Mutagenicity: No adverse effect observed
NOAEL Dermal: NOAEL 1 000 mg/kg bw/day Study type: repeated dose toxicity; Endpoint: chronic toxicity: dermal; Guideline:OECD Guideline 411 (Subchronic Dermal Toxicity: 90-Day Study); Species:rat; Report date:1995; Source: ECHA, MoS was calculated based on this data
NOAEL Oral: NOAEL > 4 257 mg/kg bw. Study type: Repeated dose toxicity. Endpoints: sub-chronic toxicity. Route of administration: oral. Species: rat. Report date: 1966. Source: ECHA, MoS was calculated based on this data.
Skin Irritation: The substance was tested in vivo to examine skin irritation potential. Results: Erythema observed at 1 hour after removal of dressings regressed in the first 24 hours. Endpoint: The substance was found to be not irritating to the skin. Method: according to OECD Guideline 404 and EU Method B.4 semiocclusive coverage; Species: rabbits; Report date: 1994; Source: ECHA.
Skin Sensitisation: The substance was tested in vivo (Non-LLNA) to examine skin sensitising potential. Endpoint: The substance was found to be non-sensitising. Method: According to OECD Guideline 406, guinea pig maximisation test; Species: guinea pig; Report date:1978; Source: ECHA.
Carcinogenicity: Not associated with CMR materials.

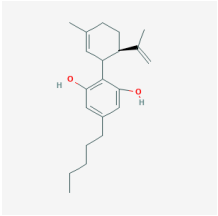
OTHER
Biodegradability (Environmental): Biodegradation in water. Results: 82.4% on the end of the study in 28 days.Conclusion: readily biodegradable. (ECHA)
LC50 (Environmental): EC 50> 100 mg product/L. Method: Chronic bacterial toxicity according to test method DIN 38412 p.8.; LC50>to 100 mg product/L Method: ISO 7346/2 (semistatic)

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



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

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

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

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

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

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Theobroma Cacao (Cocoa) Seed Butter (Emollient,Masking,Skin Conditioning,Skin Protecting)
EU INCI: Theobroma Cacao Seed Butter.
CTFA INCI: Theobroma Cacao (Cocoa) Seed Butter.
CNDA INCI: Theobroma Cacao (Cocoa) Seed Butter.
CAS Number: 84649-99-0(8002-31-1).
EINECS Number: 283-480-6.
Description: Cocoa Butter is extracted from the roasted seeds of Theobroma cacao, a tree native to the Americas.This butter is obtained from Cocoa mass. This mass is obtained from fermentation, drying and several cleansing of roasted organically grown beansof “Theobroma cacao”*.

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Slight cocoa odour (close to chocolate odour)
Specific Gravity: 0.95
Water Solubility: Insoluble
Colour: Pale yellow to yellow
Flash Point: > 250°C
Melting Point: 33-38°C
Physical State: Solid.

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

TOXICITY REVIEW
General Toxicity Review: There is limited toxicological data for the Cocoa seed butter. However, there is no evidence of potential irritating properties for skin and eyes. The substance is not expected to cause skin sensitisation. 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 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: The substance is not a dermal irritant in HRIPT test with 150 mL 50.1% solution of the test material in semi-occlucive type of coverage (CIR).
Skin Sensitisation: The substance is not a dermal sensitizer in HRIPT test with 150 mL 50.1% solution of the test material in semi-occlucive type of coverage (CIR).
Allergens HRIPT: Lip balm containing 50.1% of Theobroma Cacao (Cocoa) Seed Butter was used in a HRIPT study. The test material was applied under semi-occlusion. The substance was not considered to be a dermal irritant or sensitiser. (CIR)
Carcinogenicity: Not associated with carcinogenic, mutagenic and reprotoxic (CMR) chemicals.

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Stearic Acid (Cleansing,Emulsifying,Emulsion Stabilising,Masking,Refatting,Surfactant)
EU INCI: Stearic Acid.
CTFA INCI: Stearic Acid.
CAS Number: 57-11-4.
EINECS Number: 200-313-4.
Symbol: C18H36O2.
Molecular Weight: 284.48 g/mol.
Description: Stearic acid is a saturated fatty acid with an 18-carbon chain derived from animal or vegetable feedstocks. SA is obtained from fats and oils by the sapo
Commercial stearic acid is usually a mixture of stearic and palmitic acids.
IUPAC Name: Octadecanoic acid

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Characteristic
Oxidising Properties: Not an oxidising solid
Viscosity: 9.87 mPa s (dynamic) at 70 °C or 12 mm2/s at 70 °C (kinematic).
Water Solubility: Easily soluble in diethyl ether. Soluble in acetone. Insoluble in cold water, hot water. Slightly soluble in Ethanol. Soluble in alcohol, chloroform, carbon disulfide, carbon tetrachloride, amyl acetate, toluene. 1 gram dissolves in 21 ml alcohol, 5 ml benzene, 2 ml chloroform, 26 ml acetone, 6 ml carbon tetrachloride, 3.4 ml carbon disulfide.
Boiling Point: 370 °Cat 1,013 hPa
Colour: White
Density: 0.87 mg/cm3 at 20 °C.
Flammability: The substance is combustible when exposed to heat or flame.
Flash Point: 196.11°C (385°F) or 365°F, 180°C (COC)
Vapour Pressure: 1 hPa at 173,7 °C, < 0.1 hPa at 20°C
LogP Log Kow: 8.23
Melting Point: 53.0 - 59.0 ° C
Physical State: Solid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI.
REACH Annex XVII: Not listed in 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: Stearic Acid is well-known cleansing, emulsifying, masking ingredient. In vivo studies resulted in vivo 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 and above 2 000 mg/kg bw via oral and dermal exposure respectively. Repeated dose toxicity study indicated NOAEL at 1 000 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
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). In ocular irritation studies, Stearic Acid neat and at concentrations ranging from 1 to 19.4% in cosmetic product formulations produced no to minimal irritation after single and multiple (daily, 14-day) instillations into the eyes of albino rabbits (CIR).
Genotoxicity: In vitro: negative (Chinese hamster lung (CHL) cells) (ECHA)
LD50: LD50 (oral, rat) > 5 000 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. ; LD50 (dermal, rabbit) > 2 000 mg/kg bw; OECD Guideline 434 (Acute Dermal Toxicity - Fixed Dose Procedure); Description: Acute toxicity studies via dermal route of exposure in rabbits (occlusive type of coverage) showed that the substance has low skin toxicity. (ECHA)
NOAEL Oral: NOAEL 1000 mg/ kg bw. Study type Repeated dose toxicity. Endpoint:sub-chronic toxicity: oral; Species:rat; Guideline:OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test); Source: ECHA, MoS was calculated based on this data
Reproductive Toxicology: NOAEL 1000 mg/ kg bw. Study type Toxicity to reproduction. Endpoint: screening for reproductive / developmental toxicity: oral; Species:rat; Guideline:OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test); Source: ECHA,
ADME (Absorption, Distribution, Metabolism, Excretion): The dermal absorption is definitely lower than the absorption after oral uptake. (ECHA)
Skin Irritation: In vivo studies on rabbits with occlusive type of coverage, the substance was found to be not irritating (ECHA). In clinical repeated insult patch tests (open, occlusive, and semi-occlusive), maximization tests, and prophetic patch tests with cosmetic product formulations containing Stearic Acid at concentrations ranging from < 1 to 13%, no primary or cumulative irritation was reported (CIR).
Skin Sensitisation: Non-LLNA in vivo examinations were conducted, using guinea pig testing, to find evidence for skin sensitisation. The test results showed that the chemical is non-sensitising (ECHA). In clinical repeated insult patch tests (open, occlusive, and semi-occlusive), maximization tests, and prophetic patch tests with cosmetic product formulations containing Stearic Acid at concentrations ranging from < 1 to 13%, no primary or cumulative sensitization was reported (CIR).
Allergens HRIPT: Cosmetics containing 5% of Stearic acid produced moderate skin irritation in 13-week dermal toxicity studies (rats, 4 ml/kg and 227 mg/kg). (CIR)
Allergens MaximisationTest: Stearic acid showed few and minimal reactions to challenge application in a guinea pig maximisation study (3.5% in the applied product). (CIR)
Allergens Patch Test: Stearic acid in the concentration of 35-65% underwent single insult occlusie patch test. Moderate erythema and slight edema were observed in some of the tested animals (rabbits). (CIR) In skin sensitising studies on 25 human volunteers there was no reaction observed. (ECHA)
Carcinogenicity: Carcinogenicity - mouse - Implant Tumorigenic:Equivocal tumorigenic agent by RTECS criteria. Kidney, Ureter, Bladder:Tumors.IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IAR

OTHER
Detergent Class: Non-ionic surfactant
Biodegradability (Environmental): Biodegradation in water: screening tests. Considered as readily biodegradable in water. Biodegradation in water and sediment: simulation tests and Biodegradation in soil: No tests are required due to ready biodegradability of category members Fatty Acids.
LC50 (Environmental): LC50 - no effects for fish within water solubility; EC50, NOEC50 no effects for algae within water solubility

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

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Ceteareth-20 (Cleansing, Emulsifying, Surfactant)
EU INCI: Ceteareth-20.
CTFA INCI: Ceteareth-20.
Chinese: 乙氧基化 C16-18-醇.
CAS Number: 68439-49-6.
EINECS Number: -.
Symbol: C24H50O5.
Molecular Weight: 418.37.
Description: Ceteareth-20 is the polyethylene glycol ether of cetearyl alcohol; may contain potentially toxic impurities such as 1,4-dioxane. C16-18 alcohols, ethoxylated (20 mol EO average molar ratio)
Synonyms: PEG-20 CETOSTEARYL ALCOHOL; PEG-20 CETYL/STEARYL ETHER; POLYETHYLENE GLYCOL 1000 CETYL/STEARYL ETHER; POLYOXYETHYLENE (20) CETYL/STEARYL ETHER

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Oxidising Properties: No oxidising properties.
Specific Gravity: approx 1.015 @ 40°C
Water Solubility: 0.04 mg/L at 25 °C
Boiling Point: 345 °C at 1013hPa
Density: Bulk density= 0.87 g/cm³ at 21 °C
Flammability: Non flammable
Flash Point: > 250°C
LogP Log Kow: Log Pow: 7.07 at 25°C
Melting Point: 49.6°C at 1013hPa
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: Not classified as hazardous to human health.
GHS Classification: H411: Toxic to aquatic life with long lasting effects..
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

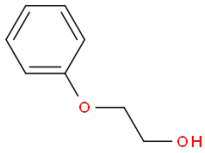
TOXICITY REVIEW
General Toxicity Review: In vivo studies resulted resulted in scoring the chemical as not irritating to eyes and skin. Non-LLNA in vivo study indicated that the substance is not sensitising. It shows very low acute toxicity potential above 10 000 mg/kg bw and above 2 000 mg/kg bw via oral and dermal exposure respectively. Median lethal concentration via inhalation route of exposure was found to be above 1 600 mg/m3 air. Repeated dose toxicity study indicated NOAEL at above 500 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
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)
Developmental toxicity: NOAEL >= 250 mg/kg bw/day study type: Developmental toxicity / teratogenicity; Endpoint:developmental toxicity; Species:rat; Report date:1985; Source: ECHA
Genotoxicity: Negative in vitro gene mutation study in mammalian cells (ECHA)
LD50: LD50 (oral, rat) >10 000 mg/kg bw; OECD Guideline 401 (Acute Oral Toxicity); 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; OECD Guideline 402 (Acute Dermal Toxicity); Description: Acute toxicity studies via dermal route of exposure in rats (occlusive type of coverage) showed that the substance has low skin toxicity. LC50 (inhalation, rat) > 1 600 mg/m³ air; OECD Guideline 403 (Acute Inhalation Toxicity); Description: The substance when tested for acute toxicity via inhalation for 4 hours (aerosol) was found to have low toxicity. (ECHA)
NOAEL Oral: NOAEL >= 500 mg/kg bw/day Study type: Repeated dose toxicity. Endpoint: sub-chronic toxicity: oral; Guideline: OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity Study in Rodents); Species:rat; 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 not irritating. (ECHA)
Skin Sensitisation: Non-LLNA in vivo examinations were conducted, using guinea pigs, Buehler test, to find evidence for skin sensitisation. The test results showed that the chemical is non-sensitising. (ECHA)
Carcinogenicity: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by IARC, ACGIH, NTP, & OSHA

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

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

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



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

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

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

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

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

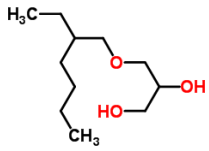
Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Ethylhexylglycerin (Deodorant,Skin Conditioning)
EU INCI: Ethylhexylglycerin.
CTFA INCI: Ethylhexylglycerin.
CNDA INCI: Ethylhexylglycerin.
Chinese: 乙基己基甘油.
CAS Number: 70445-33-9.
EINECS Number: 408-080-2.
Symbol: C11H24O3.
Molecular Weight: 204.307 Da.
Description: Ethylhexylglycerin is a glyceryl ether.
Synonyms: 3-[2-(Ethylhexyl)oxyl]-1,2-propandiol



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
pH: 6.0-7.0 (2 g/l aq.)
Viscosity: ca. 144 dynamic viscosity (mPa s) at 20°C
Water Solubility: 1.8 g/L at 22.5 °C
Boiling Point: 325 ºC
Density: 0.962 g/ml
Flash Point: 152 °C at 103.8 kPa
Vapour Pressure: 0.3 Pa at 25°C
LogP Log Kow: 2.53 at 20 deg. C
Melting Point: < -76 °C at 1 013 hPa
Microbiological stability: Not susceptible to microbiological contamination
Physical State: Liquid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as: Eye Dam. 1, H318; Aquatic Chronic 3, H412.
REACH Annex XVII: Not listed in Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: H412: Harmful to aquatic life with long lasting effects. H332: Harmful if inhaled. H318: Causes serious eye damage..
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: The chemical is known deodorant and skin conditioner. Data derived in vivo (animal data) showed that ethylhexylglycerin is slightly irritating to skin and does not have sensitising properties. Ocular irritation potential study showed that the substance causes serious eye damage to eyes. Acute toxicity studies via oral and dermal routes of administration in rats demonstrated low toxicity of the substance. The available NOAEL (repeated dose toxicity) were determined to be 50 mg/kg/bw/day for rats and the findings would be considered to be of relatively high systemic toxic.

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 test results showed that the substance causes serious eye damage (ECHA). Undiluted ethylhexylglycerin was instilled into the left conjunctival sac of each of 3 rabbits. Conjunctival redness andchemosis were observed in all animals and irritation scores of 2 or 3 predominated. It was concluded that the substance cause severe damage to the eyes of rabbits (CIR).
Genotoxicity: In vitro: negative (S. typhimurium TA 100) In vivo: negative (mouse) (ECHA)
Inhalation: Harmful if inhaled. May cause respiratory irritation.
LD50: LD50 (oral, rat) > 2 000 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. LD50 (dermal, rat) > 2 000 mg/kg bw, OECD Guideline 402 (Acute Dermal Toxicity), Description: Acute toxicity studies via dermal route of exposure in rats (semiocclusive type of coverage) showed that the substance has low skin toxicity. (ECHA)
NOAEL Oral: NOAEL 100 mg/kg bw. Study type: repeated dose toxicity (28-day). Endpoint: short-term repeated dose toxicity. Route of administration: oral. Species: rat. Method: OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity Study in Rodents). Report date: 1992.Source: ECHA. MoS was calculated based on this data. NOAEL 50 mg/kg/day Repeated dose toxicity (rat, Method: OECD 471) (Lipoid Kosmetik tox. summary) MoS was calculated based on this data.
Precutaneous Absorption: 10%. In case MW > 500 Da and log Pow is smaller than – 1 or higher than 4, a value of 10 % dermal absorption can be considered, ref. Guidelines on Annex I).
Skin Irritation: In vivo studies on rabbits with semiocclusive coverage were conducted. The substance was found to be slightly irritating to the skin (ECHA). Based on the studies conducted on New Zealand White rabbits (undiluted Ethylhexylglycerin (0.5 mL), the substance was classified as mild skin irritant (CIR).
Skin Sensitisation: Non-LLNA in vivo examinations were conducted, using guinea pig testing, to find evidence for skin sensitisation. The test results showed that the substance is not a dermal sensitizer (ECHA). Local lymph node assay was evaluated at the substance concentrations up to 50%. The substance was found not a sensitizer. (CIR)
Allergens LLNAEC3: When tested at concentrations up to 50% on tritiated thymidine and LLNA method, Ethylhexylglycerin was found to be not sensitising. (CIR)
Allergens MaximisationTest: In the maximization test conducted according to Guideline OECD TG 406 test method, the skin sensitization potential of ethylhexylglycerin was evaluated using 2 groups of 20 guinea pigs. one of the 2 groups served as the negative control. The test substance (0.1 mL) was injectedintradermally into the neck region at concentrations of 0.5% in peanut oil and 0.5% in Freund complete adjuvant/saline 1:1, respectively; and at a third pair of sites with Freund's complete adjuvant/water 1:1. Sensitization was not observed in any of the animals tested. Source: CIR
Allergens Patch Test: Patch test was conducted on 111 participants using cosmetic preparation with 0.995% of Ethylhexylglycerin. A semiocclusive patch test was applied 3 times per week and a challenge patch test conducted after 3 weeks. . No irritations or allergic reaction were observed. Allergic contact dermatitis can be only a rare event in sensitive patients. Source: CIR
Carcinogenicity: Not associated with carcinogenic, mutagenic and reprotoxic (CMR) chemicals.

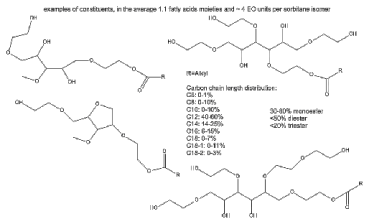
OTHER
Biodegradability (Environmental): Biodegradation in water: Result: 20.6%, after 28 days. Conclusion: readily biodegradable (OECD Test Guideline 301D) (ECHA)
Ecological toxicity: Long-term toxicity to fish: NOEC = 1.5 mg/L after 35d (Danio rerio; OECD Test Guideline 210; 2002); Toxicity to aquatic algae: EC50 48.28 mg/L; NOEC 22.17 mg/L (Desmodesmus subspicatus, 72h, OECD Guideline 201, 1995) (ECHA) (ECHA)
LC50 (Environmental): Short-term toxicity to fish: LC50 = 60.2 mg/L (Danio rerio; OECD Test Guideline 203; 96h, 1991) (ECHA)

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



IDENTIFICATION
Polysorbate 20 (Emulsifying,Surfactant)
EU INCI: Polysorbate 20.
CTFA INCI: Polysorbate 20.
CNDA INCI: Polysorbate 20.
CAS Number: 9005-64-5.
EINECS Number: 500-018-3.
Symbol: C18H34O6.(C2H4O)n.
Molecular Weight: 1227.72 g/mole.
IUPAC Name: Lauric acid, monoester with sorbitan, ethoxylated
Synonyms: Polyoxyethylene sorbitan monolaurate

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Oxidising Properties: Not oxidising
pH: 6.0-7.5 (potassium chloride solution 0,03%) 5.0-7.0 (5% w/w at 25 °C)
Water Solubility: Soluble, < 0.2 mg/L at 20 °C, pH=6.3 - 7.9
Boiling Point: 100 °C (212 °F)
Density: 1.1050 g/cm3, 0.9850 g/cm3, 1.095 g/cm³ at 20 °C
Flammability: Non flammable
Flash Point: 101 °C (230 °F) - closed cup; >150°C (302°F) Open cup
Vapour Pressure: < 1.33 hPa (< 1.00 mmHg)
LogP Log Kow: log pow = 1.23 - 3.86
Melting Point: approx. 15°C
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: Not listed in Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
Regulatory Controls: Not classified as hazardous to human health.
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 substance is commonly used as emulsifying and surfactant. Data derived from animal studies indicated that the substance is not irritating to eyes, not irritating to skin and non-sensitising. However, in the Magnusson-Kligman guinea pig maximization test there were moderate and strong skin responses. Several studies on rabbits showed that the substance is not eye irritating or causes minimal eye irritation. The substance shows low acute toxicity with LD50 at 36 700 mg/kg bw in oral and above 3 000 mg/kg bw in dermal route of exposure. The substance is not considered genotoxic. The available NOAEL (repeated dose toxicity) was determined to be around 5000 mg/kg/bw/day and therefore the substance is considered to have low systemic toxicity potential. Overall, the ingredient is not considered to be of toxicological concern when used as intended.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo to examine ocular irritation potential. Endpoint: The studies resulted in scoring the substance as non-irritating. Method: according to OECD Guideline 405; Species: rabbits; Report date: 1963; Source: ECHA.Several studies on rabbits showed that the substance is not eye irritating or causes minimal eye irritation. The substance was classified as minimal to mild irritating. (CIR)
Genotoxicity: In vitro: negative (S. typhimurium TA 1535, TA 1537, TA 98 and TA 100; E. coli WP2 uvr A) (ECHA)
LD50: LD50 (oral, rat) 36 700 mg/kg bw; OECD Guideline 401 (Acute Oral Toxicity); Description: Acute toxicity studies via oral route of administration in rats demonstrated that the substance is practically non-toxic. LD50 (dermal, guinea pig) > 3 000 mg/kg bw; Description: Acute toxicity studies via dermal route of exposure in guinea pigs (occlusive type of coverage) showed that the substance has low skin toxicity. (ECHA)
NOAEL Oral: NOAEL 5000 mg/kg bw. Study type: Developmental toxicity / teratogenicity. Endpoint: Developmental toxicity. Method: OECD Guideline 414 (Prenatal Developmental Toxicity Study). Species: Rat. Report date: 1992. MoS was calculated based on this data.
ADME (Absorption, Distribution, Metabolism, Excretion): Estimated dermal permeability coefficient (Kp) of 0.000826 (1 EO) and 2.18 e-006 (7 EO) cm/hr and a dermal absoprtion rate of 0.00034 mg/cm²/h (=0.0000861 mg/cm²/event, 1 EO) and 0.0000024 mg/cm²/h (=0.00000064 mg/cm²/event, 7 EO). The substance is considered to have low dermal adsorption. (CIR)
Skin Irritation: The substance was tested in vivo to examine skin irritation potential. Endpoint: The substance was found to be not irritating to the skin. Method: according to OECD Guideline 404 and EU Method B.4 semiocclusive coverage; Species: rabbits; Report date: 2012; Source: ECHA. The substance was tested to find evidence of primary irritation on rabbits. There was no signs of irritation observed. (CIR)
Skin Sensitisation: The substance was tested in vivo (Non-LLNA) to examine skin sensitising potential. Endpoint: The substance was found to be non-sensitising. Method: OECD Guideline 406, EU Method B.6, EPA OPPTS 870.2600; Species: guinea pig; Report date: 2012; Source: ECHA.The Magnusson-Kligman guinea pig maximization test was conducted. There were moderate and strong skin responses. (CIR)
Allergens HRIPT: HRIPT of shaving preparation with 2.4% Polysorbate 20 was conducted on the 101 subjects. There was minimal irritation and no sensitisation observed. In other studies of different products containing Polysorbate 20 there was the same results observed. (CIR)
Allergens MaximisationTest: Bubble bath with 6.0% Polysorbate 20 was tested in Kligman maximization test. The product was found not sensitising. (CIR)
Allergens Patch Test: The substance underwent Schwartz-Peck patch test (open and closed 48h patches, repeated after 14 days) in a form of shaving product 2.4% of Polysorbate 20. No skin reactions such as irritation and sensitisation were reported. (CIR) When bubble bath 0.3 Polysorbate 20 (5% aqueous dilution of product containing 6%) was tested on 103 subjects, there was minimal irritation in 3 subjects and no sensitization observed (CIR). Bubble bath with: 0.03% Polysorbate 20 (0.5% aqueous dilution of product containing 6%) and 6.0% Polysorbate 20 was tested in cumulative irritancy test (daily 23-hour occlusive patch for 21 days). The product was found moderately and highly irritating respectively. (CIR)
Carcinogenicity: Not a CMR material.

OTHER
Biodegradability (Environmental): Biodegradation in water. Results: 62.5% (O2 consumption) in 28 days. Conclusion: Readily biodegradable.

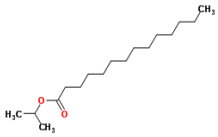
Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Isopropyl Myristate (Binding,Emollient,Masking,Perfuming)
EU INCI: Isopropyl Myristate.
CTFA INCI: Isopropyl Myristate.
CNDA INCI: Isopropyl Myristate.
CAS Number: 110-27-0.
EINECS Number: 203-751-4.
Symbol: C17H34O2.
Molecular Weight: 270.45.
Synonyms: Isopropyl tetradecanoate; Tetradecanoic acid 1-methylethyl ester



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Viscosity: 3.932 mm²/s at 40 °C
Water Solubility: 0.05 mg/L at 20 °C (experimental); 0.00473 mg/L at 25° C (QSAR calculation)
Partial Coefficient logPow: log Kow = 7.71
Boiling Point: 193 °C at 20 mmHg (decomposition at normal pressure probable)
Density: 853.2 kg/m³ at 20 °C
Flammability: Non flammable
Flash Point: 150 - 168 °C
Vapour Pressure: 0.01246 Pa at 25 °C
Melting Point: ca. 3 °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: The substance is not associated with the skin irritation and eye irritation. When it comes to local toxicity the chemical does not induce or elicit skin allergy. It shows low acute toxicity with LD50 above 2000 mg/kg bw in oral exposure. It also has 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 not considered to be of toxicological concern when used in consumer products.

TOXICOLOGICAL PROFILE
AcuteToxicology: DNEL/DMEL (General population)Acute - systemic effects, dermal no DN(M)EL derivation: assessment of hazard sufficiently covered by derivation of therespective DNEL for long-term exposure.Acute - systemic effects, inhalation no DN(M)EL derivation: assessment of hazard sufficiently covered by derivation of therespective DNEL for long-term exposure.Acute - systemic effects, oral no DN(M)EL derivation: assessment of hazard sufficiently covered by derivation of therespective DNEL for long-term exposure.Acute - local effects, dermal no DN(M)EL derivation: No hazard identified.Acute - local effects, inhalation no DN(M)EL derivation: No hazard identified.
Chronic Toxicity: Long-term - systemic effects, dermal 16 mg/kg bodyweight/day with assessment factor: 600 (inter species factor 2.5, allometricscaling factor 4, intra species factor 10, exposure duration factor 6; dermal absorption of 10%was considered)Long-term - local effects, dermal no DN(M)EL derivation: No hazard identified.Long-term - local effects, inhalation no DN(M)EL derivation: No hazard identified.
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as not irritating (ECHA)
Genotoxicity: Negative in the in vitro gene mutation study in bacteria (S. typhimurium TA 1535, TA 1537, TA 98 and TA 100, E. coli WP2 uvr A) (ECHA)
LD50: LD50 (oral, rat) > 2 000 mg/kg bw; OECD Guideline 401 (Acute Oral Toxicity); Description: Acute toxicity studies via oral route of administration in rats showed slight toxicity of the substance. (ECHA); LD50 (oral, mouse) 49700 mg/kg; Description: Acute toxicity studies via oral route in mice showed that the substance is practically non-toxic.
NOAEL Oral: NOAEL 5500 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); Publication date: 2004; Source: ECHA; MoS was calculated based on this data
Reproductive Toxicology: NOAEL 5 500 mg/kg bw/day Study type: Repeated dose toxicity. Endpoints: sub-chronic toxicity. Route of administration: oral. Species: rat. Methods: 1993 FDA draft "Redbook II" guidelines (Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food). Report date: 2004. Source: ECHA. MoS was calculated based on this data.
Skin Irritation: In vivo studies on rabbits with semiocclusive coverage showed that the substance was found to be not irritating and not corrosive (ECHA)
Skin Sensitisation: Non-LLNA in vivo examinations were conducted, using guinea pig maximisation test, to find evidence for skin sensitisation. The test results showed that the chemical is non-sensitising (ECHA)
Carcinogenicity: Not considered to be a CMR material.

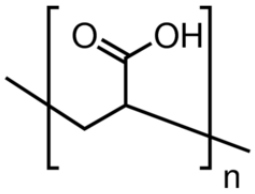
OTHER
Biodegradability (Environmental): Biodegradation in water: screening test. Result: 91.4% degradation after 28 days. Conclusion: readily biodegradable. (ECHA)
LC50 (Environmental): Fish: LC50 Lepomis macrochirus > 1000 mg/L - 96h; Algae: ErL50 Skeletonema costatum 281.4 mg/L - 72h; ISO 10253(ECHA)

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



IDENTIFICATION
Carbomer (Emulsion Stabilising,Gel Forming,Viscosity Controlling)
EU INCI: Carbomer.
CTFA INCI: Carbomer.
CNDA INCI: Carbomer.
Chinese: 卡波姆.
CAS Number: 9007-20-9(9003-01-4)76050-42-5(9062-04-8)9007-16-3(9007-17-4).
EINECS Number: Polymer.
Description: Carbomer is a large polymeric chemical composed of acrylic acid monomers. Some grades of Carbomer may contain Benzene.
Synonyms: 2-Propenoic acid, polymer with 2,2-bis(hydroxymethyl)propane-1,3-diol 2-propenyl ether, Poly(acrylic acid),

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Oxidising Properties: Non oxidising
pH: >= 3.59 - <= 3.63
Water Solubility: 546 g/L
Boiling Point: 193.9 °C
Particle Size: The non-solid or granular form does not require the particle size distribution study.
Colour: Colourless
Density: 1.206 at 20 deg. C
Flash Point: 93.5 °C
Vapour Pressure: 357 Pa
LogP Log Kow: 0.27
Melting Point: -60 °C
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: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
Regulatory Controls: Raw Material CARBOPOL® 940 Polymer contains less than 0.5% Benzene. It is recommended to use Benzene free cosmetic grades materials only, for example Carbopol® Ultrez 10 polymer or similar.
GHS Classification: H302: Harmful if swallowed. H318: Causes serious eye damage. H335: May cause respiratory irritation. H400: Very toxic to aquatic life. H411: Toxic to aquatic life with long lasting effects..
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : Synthetic water-insoluble polymers of =< 5mm are prohibited in the UK as per the requirements of Environmental Protection (Microbeads) (England) Regulations 2017.

TOXICITY REVIEW
General Toxicity Review: In vivo studies resulted in scoring the chemical as causing serious eye irritation and corrosive to eyes and not irritating to skin. Non-LLNA in vivo study indicated that the substance is not sensitising. It shows low acute toxicity potential above 1 500 mg/kg bw and above 2 000 mg/kg bw via oral and dermal exposure respectively. Repeated dose toxicity study indicated NOAEL at 40 mg/kg bw/day (male) and 375 mg/kg bw/day (female). The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is not considered to be of toxicological concern when used as intended.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted that the substance is corrosive and causes serious eye irritation. (ECHA)
Genotoxicity: In vitro: negative (Chinese hamster Ovary (CHO)) In vivo: negative (rat). (ECHA)
LD50: LD50 (oral, rat) 1 500 mg/kg bw;OECD Guideline 401 (Acute Oral Toxicity); Description: Acute toxicity studies via oral route of administration in rats demonstrated moderate toxicity of the substance. LD50 (dermal, rabbit) > 2 000 mg/kg bw; OECD Guideline 402 (Acute Dermal Toxicity); Description: Acute toxicity studies via dermal route of exposure in rabbits (occlusive type of coverage) showed that the substance has low skin toxicity. (ECHA)
Mutagenicity: No evidence of mutagenicity.
NOAEL Oral: NOAEL (male rats) 40 mg/kg bw/day; NOAEL (female rats) 375 mg/kg bw/day. Study type: Repeated dose toxicity. Endpoints: chronic toxicity. Route of administration: oral. Species: rats. Methods: OECD Guideline 452 (Chronic Toxicity Studies). Report date: 1987. Source: ECHA. MoS was calculated on this data.
Skin Irritation: In vivo studies on rabbits with semiocclusive type of coverage, the substance was found to be not irritating. (ECHA)
Skin Sensitisation: Non-LLNA in vivo examinations were conducted, using guinea pig testing, to find evidence for skin sensitisation. The test results showed that the substance is non-sensitising. (ECHA)
Allergens HRIPT: When Carbomer was tested on humans at 1.0% concentration, it demonstrated low potential for skin irritation and sensitization. (CIR)
Carcinogenicity: Not associated with carcinogenic, mutagenic and reprotoxic (CMR) chemicals.

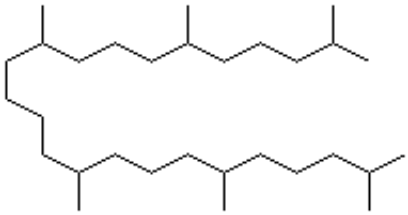
OTHER
Biodegradability (Environmental): Biodegradation in water. Results: 87.4% degradation (O2 consumption) after 28 days. Conclusion: readily biodegradable. (OECD Guideline 301 F (Ready Biodegradability: Manometric Respirometry Test)) (ECHA)
Ecological toxicity: Toxic to aquatic life with long lasting effects.
LC50 (Environmental): LC50 27 mg/L, Oncorhynchus mykiss, 96h (read across); EC50 0.13 mg/L, Desmodesmus subspicatus, 72h; EC10 or NOEC 0.03 mg/L, Desmodesmus subspicatus, 72h (read across) (ECHA)

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



IDENTIFICATION
Squalane (Emollient,Hair Conditioning,Refatting,Skin Conditioning)
EU INCI: Squalane.
CTFA INCI: Squalane.
CNDA INCI: Squalane.
CAS Number: 111-01-3.
EINECS Number: 203-825-6.
Symbol: C30H62.
Molecular Weight: 422.81.
Description: Squalane is a vegetable squalane obtained by hydrogenation of olive squalene.
IUPAC Name: 2,6,10,15,19,23-Hexamethyltetracosane
Synonyms: Cosbiol; 2,6,10,15,19,23-Hexamethyltetracosane; Perhydrosqualene; Robane.

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Characteristic
Viscosity: 18.8 dynamic viscosity (in mPa s) at 40°C; 48.2 dynamic viscosity (in mPa s) at 20°C
Water Solubility: 0 mg/L at 25 °C
Boiling Point: 176 °C at 0.07 hPa
Colour: 0.8227 ± 0.0001 g/cm3 at 20°C
Density: 0.81 g/mL at 25 °C (relative)
Flash Point: 215 °C ± 1 °C
Vapour Pressure: 0 Pa at 20 °C and 25 °C
LogP Log Kow: 17 at 25 °C
Melting Point: >= 0.28 - <= 0.38 °C
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: 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: Squalane is a well-known cosmetic substance. Squalane is a vegetable squalane obtained by hydrogenation of olive squalene. Data derived from animal studies demonstrate that the substance is not irritating to the skin and eyes. Moreover, it is not sensitising to the skin. It shows low acute toxicity with LD50 above > 1 000 mg/kg bw in oral route of exposure. It has low chronic toxicity where oral systematic exposure is considered. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is considered to be safe 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 substance was found to be not irritating (ECHA). Undiluted squalane did not produce irritation or damage in the eyes of rabbits, regardless of whether the eyes had been washed after instillation (CIR).
Genotoxicity: In vitro: negative; Method: according to OECD Guideline 471; Species/ strain: S. typhimurium TA 97a, TA 100, TA 98, TA 1535, E. coli WP2 uvr A; Report date: 2011; Source: ECHA.
LD50: LD50 (oral, rat) > 1 000 mg/kg bw; No mortality was observed during the study. Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity of the substance. (ECHA)
NOAEL Oral: NOAEL ca. 10 000 mg/kg bw/day (nominal). Study type: Repeated dose toxicity. Endpoint: sub-chronic toxicity: oral. Route of administration: oral. Species: rat. Method: OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)Report date: 2013.,Source: ECHA. MoS was calculated based on this data.
Skin Irritation: In vivo studies on rabbits with semiocclusive type of coverage.The substance was assessed as not irritating to the skin (ECHA). Undiluted squalane (0.5 ml) did not produce irritation in three rabbits when applied to intact and abraded skin for 24 hours (CIR).
Skin Sensitisation: The substance was tested in vivo to examine skin sensitising potential. The test results showed that the chemical is not sensitising (ECHA). Twenty subjects were patch-tested with repeated 48-hour applications made three weeks apart with 8.0% w/w squalane in a lip emollient. Nineteen responses to both patches were negative; one response was not reported (CIR).
Allergens HRIPT: Patch test with repeated 48-hour applications of an lip emollient with 8.0% Squalane was conducted on 20 subjects. The product was found negative in 19 responses, one response was not reported. Patch test of blushing cream with 16.8% Squalane was conducted on 103 females. There was no contact allergy or irritant reaction observed (CIR).
Allergens LLNAEC3: LLNA in vivo examinations were conducted, using mouse testing, to find evidence for skin sensitisation. Endpoint: The substance was found to be not sensitising. Method: according to guideline EU Method B.42; Species: mouse; Report date: 2011; Source: ECHA.
Carcinogenicity: Not a CMR material.

OTHER
Biodegradability (Environmental): Biodegradation in water. Results: 64.7% degradation (CO2 evolution) after 28 days. Conclusion: readily biodegradable, but failing 10-day window. (OECD Guideline 301 B (Ready Biodegradability: CO2 Evolution Test)) (ECHA)
LC50 (Environmental): LC0 Danio rerio, > 100 mg/L, 96h (OECD Guideline 203 (Fish, Acute Toxicity Test)); NOEC Raphidocelis subcapitata > 100 mg/L, 72h (OECD Guideline 201 (Alga, Growth Inhibition Test)) (ECHA)

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Camellia Kissi Seed Oil (Skin Conditioning,Emollient)
EU INCI: Camellia Kissi Seed Oil.
CAS Number: 94333-92-3.
EINECS Number: 305-071-4 .
Description: Camellia Kissi Seed Oil is the fixed oil derived from the seeds of Camellia kissi, Theaceae

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY

Physical State: Oil.

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: 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. 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.
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.

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Sodium Hydroxide (Buffering,Denaturant)
EU INCI: Sodium Hydroxide.
CTFA INCI: Sodium Hydroxide.
CNDA INCI: Sodium Hydroxide.
Chinese: 氢氧化钠.
CAS Number: 1310-73-2.
EINECS Number: 215-185-5.
Symbol: NaOH.
Molecular Weight: 40.00 g/mol.
Description: At room temperature sodium hydroxide is a white orthorhombic crystal and is hygroscopic. It has no specific odour and it is an inorganic substance.
EINECS No.: 215-185-5
IUPAC Name: Sodium hydroxide

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Odourless
Oxidising Properties: Non oxidising
pH: >13
Water Solubility: 100 g/100g H2O at 25°C
Boiling Point: 1 388 °C at 101325 Pa
Colour: White
Density: 2.13 g/cm3 at 20°C
Flammability: Non flammable
Vapour Pressure: < 0 hPa
Melting Point: 318.4C at 101.3 kPa
Physical State: Crystalline.

REGULATORY REQUIREMENTS
Labelling Requirements: a)Contains alkali Avoid contact with eyes Can cause blindness Keep out of reach of children b) 1) Contains alkali Avoid contact with eyes Can cause blindness Keep out of reach of children 2)For professional use only Avoid contact with eyes Can cause blindness c)Keep out of reach of children Avoid contact with eyes.
Specific Conc. Limits, M-factors and ATEs: Skin Corr. 1A (H314): C ≥ 5 %; Skin Corr. 1B (H314) 2 % ≤ C <5 %; Skin Irrit. 2 (H315): 0,5 % ≤ C <2 %; Eye Irrit.2 (H319): 0,5 % ≤ C <2 %
CLP Regulation (EC) No 1272/2008: Classified as Skin Corr. 1A, H314 .
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
Regulatory Controls: Restriction(a) Nail cuticle solvent 5%(b) Hair straightener:General use 2%Professional use 4,5%(c) pH adjuster for depilatories pH < 12,7(d) Other uses as pH adjuster pH < 11Wording of conditions of use and warnings:(a) Contains alkali Avoid contact with eyes Can cause blindness Keep out of reach of children (b) 1. Contains alkali Avoid contact with eyes Can cause blindness Keep out of reach of children 2. For professional use only Avoid contact with eyes Can cause blindness (c) Keep out of reach of children Avoid contact with eyes
GHS Classification: H290: May be corrosive to metals. H314: Causes severe skin burns and eye damage. H315: Causes skin irritation. H319: Causes serious eye irritation..
Region : Europe Type : Cosmetic Restriction : a) Nail cuticle solvent 5% b) Hair straightener general use 2% Professional use 4,5% c) pH adjuster for depilatories pH<12,7 d) Other uses as pH adjuster pH<11 Label Review : a)Contains alkali Avoid contact with eyes Can cause blindness Keep out of reach of children b) 1) Contains alkali Avoid contact with eyes Can cause blindness Keep out of reach of children 2)For professional use only Avoid contact with eyes Can cause blindness c)Keep out of reach of children Avoid contact with eyes
Region : UK Type : Cosmetic Restriction : a)Nail cuticle solvent 5%b)Hair straightener general use 2% Professional use 4,5%c) pH adjuster for depilatories pH<12,7d)Other uses as pH adjuster pH<11 Label Review : a)Contains alkali Avoid contact with eyes Can cause blindness Keep out of reach of children b) 1) Contains alkali Avoid contact with eyes Can cause blindness Keep out of reach of children 2)For professional use only Avoid contact with eyes Can cause blindness c)Keep out of reach of children Avoid contact with eyes

TOXICITY REVIEW
General Toxicity Review: Sodium Hydroxide is commonly used as buffering and denaturant. In vivo studies (animal data) have shown that the substance causes severe eye damage and is irritating and corrosive to skin. It was found to be not sensitising to skin. It shows low acute toxicity with LD50 around 325 mg/kg bw via oral route of exposure. Repeated dose toxicity was examined and NOAEL was determined at 1000 mg/kg bw/day. The ingredient is not considered to be of toxicological concern when used as intended.

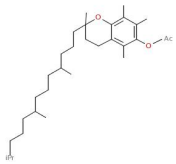
TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo to examine ocular irritation potential. Result: corneal opacity and conjunctivitis was observed; Endpoint: The studies resulted in scoring the substance as irritating, sodium hydroxide can hydrolyze protein and lead to severe eye damage. Method: according to OECD Guideline 405; Species: rabbits; Report date: 1992; Source: ECHA. Acute eye irritation/corrosion study in 6 New Zealand white rabbits was carried on. 2% caused moderate corneal injury (score = 2.0 out of 4); severe conjunctival irritation was observed between 4 and 96 h (CIR).
Genotoxicity: In vitro and the in vivo genetic toxicity test indicated no evidence for a mutagenic activity. In vitro: negative (S. typhimurium, other: TA 1535, TA 1537, TA 1538, TA 98, TA 100). In vivo: negative (mouse). (ECHA)
Inhalation: Inhalation of sodium hydroxide dust, mist, or aerosol may cause irritation of the mucous membranes of the nose, throat, and respiratory tract (CDC.GOV).
LD50: LD50 (Oral, rat) 325 mg/kg bw; Description: Acute toxicity studies via oral route of administration in rats demonstrated high toxicity of the substance. (ECHA)
Mutagenicity: Non-mutagenic. No evidence of mutagenicity in Ames test.
NOAEL Oral: NOAEL 1000 mg/kg bw/day (read-across to magnesium hydroxide). Study type; Reproductive and developmental toxicity. Endpoints; parental systemic effects, parental reproductive effects, and offspring effects in one generation rat study (CIR)
Reproductive Toxicology: The substance is not expected to reach the foetus nor reach male and female reproductive organs. (ECHA)
Skin Irritation: The substance was tested in vitro / ex vivo to examine ocular irritation potential. Endpoint: The substance was found to be irritating to the skin. Method: OECD Guideline 435 (In Vitro Membrane Barrier Test Method for Skin Corrosion); Species: corrositex assay; Report date: 2003; Source: ECHA. Sodium Hydroxide was irritating/corrosive in a concentration-dependent manner in rat, rabbit, and pig studies. In humans, Sodium Hydroxide was irritating at concentrations as low as 0.5%. Because of the large number of studies that include Sodium Hydroxide as a positive control (CIR).
Skin Sensitisation: The substance was tested in vivo (Non-LLNA) to examine skin sensitising potential. Endpoint: The substance was found to be non-sensitising. Method: Patch testing for 24 hours; Species: human; Report date:1995; Source: ECHA.Modified HRIPT in 15 male subjects with induction 0.63% to 1.0% resulted in the statement, that the test substance is not a skin sensitiser (CIR).
Allergens HRIPT: Sodium Hydroxide was not sensitising in a HRIPT study (concentration up to 1%). However, irritation was observed. (CIR)
Allergens Patch Test: Patch test of 0.5% Sodium Hydroxide was conducted on 30 subjects. It was found that the substance is irritating to the skin. Maximum exposure time was limited to 1 h. (CIR)
Carcinogenicity: Not associated with carcinogenic, mutagenic and reprotoxic (CMR) chemicals.

OTHER
UN number (Transport): 1823
Detergent Class: Soap
Bioaccumulation (Environmental): According to the REACH Regulation, the study does not need to be conducted if the substance has a low potential for bioaccumulation. Moreover, considering its high water solubility, NaOH is not expected to bioconcentrate in organisms (ECHA).
Biodegradability (Environmental): Inorganic substance - not biodegradable
Ecological toxicity: Harmful to aquatic life
LC50 (Environmental): Fish: various species, LC50 35 - 189 mg/l - 96h ; Aquatic invertebrates: Crustaceans, Ceriodaphnia sp., EC50, 48 h, 40.4 mg/l (ECHA)

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

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

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



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

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

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

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

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

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

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

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

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

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

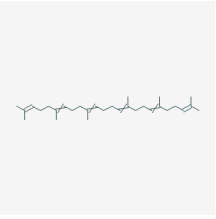
TOXICOLOGICAL PROFILE
Eye Irritation: May cause a mechanical eye irritation - expert judgement.
Inhalation: May cause upper respiratory tract irritation - expert judgement.
NOAEL Oral: The NOAEL value was not found, however, based on a history of safe use, this chemical material is considered safe for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

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



IDENTIFICATION
Iso-squalane (Not Reported)
EU INCI: Isosqualane.
CTFA INCI: Isosqualane.
CAS Number: 1350472-07-9.
EINECS Number: -.
Symbol: C30H62.
Molecular Weight: 422.813.

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY

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: There is limited toxicological data for the Isosqualane. However, there is no evidence of potential irritating properties for skin and eyes. The substance is not expected to cause skin sensitisation. 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 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.

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
C30 Hydrocarbons (Not Reported)
CAS Number: -.
EINECS Number: -.
Description: Can be generated by bio-based farnesene derived from fermantation of renewable carbons.

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY

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: There is limited toxicological information. 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.

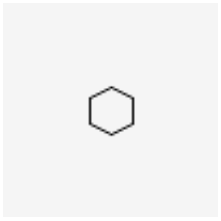
TOXICOLOGICAL PROFILE
Eye Irritation: Based on the available toxicological data there is no evidence of eye irritation or corrosivity potential.
NOAEL Oral: The NOAELs were not available in order to review however based on a history of safe use in consumer products this material is considered safe when 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.

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



IDENTIFICATION
Cyclohexane (Solvent)
EU INCI: Cyclohexane.
CTFA INCI: Cyclohexane.
CAS Number: 110-82-7.
EINECS Number: 203-806-2.
Symbol: C6H12.
Molecular Weight: 84.160.
IUPAC Name: Cyclohexane

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Characteristic sweet, chloroform-like odour
Viscosity: 0.894 mPa · s (dynamic) at 20 °C
Water Solubility: 52 mg/L at 23.5˚C
Partial Coefficient logPow: 3.44 at 20 °C
Boiling Point: 80.7 °C at 101325 Pa
Particle Size: The non-solid or granular form does not require the particle size distribution study.
Colour: Colourless
Density: 0.7739 g.cm-3 at 25°C.
Flammability: Highly flammable liquid and vapour.
Flash Point: -20 °C at 101325 Pa
Vapour Pressure: 124 hPa at 24˚C
Melting Point: 6.5 °C at 101325 Pa
Physical State: Liquid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as: Flam. Liq. 2, H225; Asp. Tox. 1, H304; Skin Irrit. 2,H315; STOT SE 3,H336; 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 for the first time after 27 June 2010, for supply to the general public, as a constituent of neoprene-based contact adhesives in concentrations equal to or greater than 0,1 % by weight in package sizes greater than 350 g.2. Neoprene-based contact adhesives containing cyclohexane and not conforming to paragraph 1 shall not be placed on the market for supply to the general public after 27 December 2010.3. Without prejudice to other Community legislation concerning the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that neoprene-based contact adhesives containing cyclohexane in concentrations equal to or greater than 0,1 % by weight that are placed on the market for supply to the general public after 27 December 2010 are visibly, legibly and indelibly marked as follows:'— This product is not to be used under conditions of poor ventilation.— This product is not to be used for carpet laying.'.
REACH SVHC: Not included in SVHC.
Regulatory Controls:
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. H410: Very toxic to aquatic life with long lasting effects. H400: Very toxic to aquatic life..
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: Cyclohexane is commonly used as solvent. When it comes to local toxicity the chemical does not induce or elicit skin allergy. The substance may cause skin irritation and slight eye irritation. . It shows low acute toxicity with LD50 well above 2000 mg/kg bw in both dermal and 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: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as slightly irritating. (ECHA)
LD50: LD50 (oral, rat) > 5 000 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. LD50 (dermal, rabbit) > 2 000 mg/kg bw; OECD Guideline 402 (Acute Dermal Toxicity); Description: Acute toxicity studies via dermal route of exposure in rabbits showed that the substance has low skin toxicity. (ECHA)
NOAEL Oral: The NOAEL value was not found, however, based on a history of safe use, this chemical material is considered safe for use in cosmetics. The chemical is unlikely to produce systemic toxicity following skin contact.
Skin Irritation: In the in vivo studies on rabbits with occlusive coverage the substance was found to be not irritating. However, according to the GHS classification the substance causes skin irritation (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)
Carcinogenicity: Not associated with carcinogenic, mutagenic and reprotoxic (CMR) chemicals.

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

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Acrylic acid (Nail Conditioning)
EU INCI: Acrylic acid.
CTFA INCI: Acrylic acid.
CNDA INCI: Acrylic acid.
Chinese: 丙烯酸.
CAS Number: 79-10-7.
EINECS Number: 201-177-9.
Symbol: C3H4O2.
Molecular Weight: 72.063 Da.
Description: Acrylic Acid is the organic compound
IUPAC Name: prop-2-enoic acid
Synonyms: 2-Propenoic Acid,

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Oxidising Properties: Not oxidising
Viscosity: 1.149 mPa.s (dynamic) at 25°C
Water Solubility: 1 000 g/L at 25°C
Boiling Point: 141°C at 1013 hPa
Colour: Colourless
Density: 1.05 at 20°C
Flammability: Flammable liquid and vapour
Flash Point: 48.5 °C at 1 013 hPa
Vapour Pressure: 5.29 hPa
LogP Log Kow: 0.46
Melting Point: 13 °C
Physical State: Liquid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as: Flam. Liq. 3, H226; Acute Tox. 4 *, H332; Acute Tox. 4 *, H312; Acute Tox. 4 *, H302; Skin Corr. 1A, H314; Aquatic Acute 1, H400; STOT SE 3; H335: C ≥ 1 %
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. H332: Harmful if inhaled. H312:Harmful in contact with skin. H302: Harmful if swallowed. H314: Causes severe skin burns and eye damage. H400: Very toxic to aquatic life. H335 May cause respiratory irritation (STOT SE3) - Specific concentration limit: STOT SE 3; H335: C ≥ 1 %.
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: Acrylic acid is commonly used as nail conditioning ingredient. When it comes to local toxicity the chemical does not induce or elicit skin allergy. Data derived from animal studies demonstrate that the substance is corrosive to skin and eyes. 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 causing the irreversible effect on the eye. (ECHA)
Genotoxicity: Negative in vitro gene mutation study in mammalian cells (Chinese hamster Ovary (CHO)). Negative in vivo mammalian somatic cell study: cytogenicity / bone marrow chromosome aberration (rat) (ECHA)
Inhalation: May cause respiratory irritation
LD50: LD50 (oral, rat) 1 000 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 high toxicity of the substance.; LD50 (dermal, rabbit) > 2 000 mg/kg bw; OECD Guideline 402 (Acute Dermal Toxicity); Description: Acute toxicity studies via dermal route of exposure in rabbits (occlusive type of coverage) showed that the substance has low skin toxicity. (ECHA)
Mutagenicity: Non mutagenic in mammalian cells in vitro (ECHA)
NOAEL Inhalation: NOAEC 0.015 mg/l air. Study type: repeated dose toxicity. Endpoint:sub-chronic toxicity: inhalation; Guideline:OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study); Species:mouse; Report date:1979; Source: ECHA, MoS was calculated based on this data
NOAEL Oral: NOAEL 83 mg/kg bw/day. Study type Repeated dose toxicity. Endpoint sub-chronic toxicity. Report date 1993: Source: ECHA; MoS was calculated based on this data
Read-across: Not susceptible to microbiological contamination
Reproductive Toxicology: NOAEL 250 mg/kg bw/day Study type: one-generation reproductive toxicity (oral, rat, 1980, OECD 415) (ref. ECHA)
Skin Irritation: In the in vivo studies on rabbits with semiocclusive coverage the substance was found to be corrosive. (ECHA)
Skin Sensitisation: Non-LLNA in vivo examinations were conducted, using guinea pig, Modified Maguire Method to find evidence for skin sensitisation. The test results showed that the chemical is non-sensitising. (ECHA)
Allergens Patch Test: Reported to cause skin sensitisation as a result of polymerisation of acrylic resins where about 16% of was released.
Carcinogenicity: There is no evidence that the Acrylic acid is carcinogenic according to 2- year study (oral- drinking water, rat, dose 78 mg/kg bw/day) (ECHA)

OTHER
Hazard Class and Category Code(s): Flam. Liq.3, Acute Tox.4, Skin Corr. 1A, Aquatic Acute
Hazard statement Code(s): H226, H332, H312, H302, H314, H400
Bioaccumulation (Environmental): Acrylic acid does not accumulate in organisms.
Biodegradability (Environmental): Biodegradation in water; Results: 81 % biodegradation (O2 consumption) within 28 days. Conclusion: readily biodegradable (OECD Guideline 302B). Acrylic acid was readily biodegradable in a sandy loam soil under aerobic conditions at 25°C in the dark. The DT50 under these conditions was estimated to be < 1 day. Acrylic acid is also susceptible to degradation by anaerobic microbes. (ECHA)
LC50 (Environmental): Fish: LC50 27 mg/L (measured), Salmo gairdneri, 96h (EPA OTS 797.1400); LC50 236 mg/L (measured), Cyprinodon variegatus, 96h (OECD TG 203); Algae: EC50 0.13 mg/L (nominal), Scenedes: mus subspicatus, 72 h (79/831/EEC, C.3); EC10 0.03 mg/L (nominal), Scenedesmus subspicatus, 72h (92/69/EEC, C.3) (ECHA)

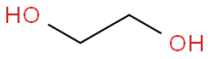
Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

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



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

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

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

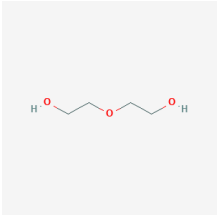
TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as not irritating. (ECHA)
Genotoxicity: Negative in vitro gene mutation study in bacteria and in vivo mammalian germ cell study: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

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



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

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

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

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

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

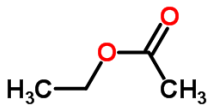
Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Ethyl Acetate (Perfuming,Solvent)
EU INCI: Ethyl Acetate.
CTFA INCI: Ethyl Acetate.
CAS Number: 141-78-6.
EINECS Number: 205-500-4.
Symbol: C4H8O2.
Molecular Weight: 88.105 Da.
Description: Organic compound with a characteristic sweet smell.
IUPAC Name: Ethyl acetate
Synonyms: N-butyl acetate



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Sweet, ester like, fruity
Specific Gravity: 0.902 at 20C
Viscosity: 0.45 mPa · s (dynamic) at 20 °C
Water Solubility: 80 000 mg/L at 25 °. Miscible in water (CIR)
Boiling Point: 126.2 °C (101 325 Pa)
Particle Size: The non-solid or granular form does not require the particle size distribution study.
Colour: Colourless
Density: 900.3 kg/m3 at 20C
Flammability: Highly flammable
Flash Point: 27 °C (101 325 Pa)
Vapour Pressure: 10.3 kPa at 21 °C
LogP Log Kow: 0.68 at 25 °C
Melting Point: 189 K at 101 325 Pa
Physical State: Liquid.

REGULATORY REQUIREMENTS
German Water Hazard Class (WGK): Slightly hazardous to water (WGK 1)
CLP Regulation (EC) No 1272/2008: Classified as: Flam. Liq. 2 H225; Eye Irrit. 2 H319; STOT SE 3 H336
REACH Annex XVII: Not listed in Annex XVII
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness. H225 Highly flammable liquid and vapour..
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: Ethyl acetate is also known as n-butyl acetate and is commonly used as perfuming agent and solvent. It is classified as per GHS and may cause drowsiness and dizziness, it also causes serious eye irritation. In vivo studies (animal data) indicated that it causes moderate eye irritation, mild skin irritation and it is non-sensitising. Acute toxicity study determined the median lethal dose at 5 620 mg/kg bw via oral route and at 20 000 mg/kg bw via dermal route. repeated dose toxicity study determined NOAEL value at 500 ppm via inhalation and 125 mg/kg bw/day via oral route and indicated that it has moderate toxicity potential.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation. The studies resulted in scoring as not irritating. However, the moderately irritation to eyes appeared, but all eye responses disappeared within 7 days (ECHA). Studies of a nail polish remover formulation containing 16.5% Ethyl Acetate was conducted on rabbits. The product was found to cause corneal dullness, slight conjunctivitis, and 35% corneal vascularization. (CIR)
Genotoxicity: Negative in vitro gene mutation study in mammalian cells (S. typhimurium TA 1535, TA 1537, TA 98 and TA 1000); Negative in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus. (hamster) (ECHA)
LD50: LD50 (oral, rat) 5 620 mg/kg bw; Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity of the substance. LD50 (dermal, rabbit) > 20000 mg/kg bw; Description: Acute toxicity studies via dermal route of exposure in rabbits (occlusive type of coverage) showed that the substance has low skin toxicity. (ECHA) LC50 (inhalation, rats) 16,000 ppm after 6 h (CIR)
Mutagenicity: No evidence of mutagenic potential.
NOAEL Inhalation: NOAEC 500 ppm. Study type Repeated dose toxicity. Endpoint sub-chronic toxicity. Method EPA OTS 798.2450 (90-Day Inhalation Toxicity). Reference date 1996 (ECHA). NOAEL 350 ppm (1.28 mg/L) NOAEL 900 mg/kg bw/dayStudy type: repeated dose toxicity; Endpoint:sub-chronic toxicity: oral; Species:rat; Guideline:EPA OTS 795.2600 (Subchronic Oral Toxicity Test); Report date:1988 (ECHA)
NOAEL Oral: The NOAEL in this study is 125 mg/kg bw/d in a 90-day toxicity study caused CNS effects in the highest dose group (ataxia and hypoactivity). NOAEL 900 mg/kg bw. Study type: repeated dose toxicity. Endpoint: sub-chronic toxicity: oral. Route of administration: oral.Species: rat. Method: EPA OTS 795.2600 (Subchronic Oral Toxicity Test) Report date: 1988. Source: ECHA. MoS was calculated based on this data.
Phototoxicity: Photopatch test of Ethyl Acetate (6.5% in nail color) was conducted on 30 subjects. The product was found not phototoxic and not photoallergenic. (CIR)
Skin Irritation: In vivo studies on rabbits with open type of test were conducted. No skin irritation was observed. Test results were inconclusive due to non-occluded coverage and small application volume. The substance cannot be assessed as not irritating (ECHA). Studies of a nail polish formulation containing 10% Ethyl Acetate was conducted on New Zealand White rabbits. The product was found not skin irritating. (CIR)
Skin Sensitisation: Non-LLNA in vivo examinations were conducted, using guinea pig maximization test, to find evidence for skin sensitisation. The test results showed that the substance is non-sensitising (ECHA).
Allergens MaximisationTest: Maximisation test of product containing 97% Ethyl Acetate was conducted on 25 subjects (18-48 years old). The product was found not skin sensitiser. (CIR)
Allergens Patch Test: Ethyl Acetate, 10% in petrolatum was tested on 25 male subjects (21-48 years old). There was no observed reaction after patch removal. (CIR) Prophetic patch test of of a nail polish remover containing 16.5% Ethyl Acetate was performed on 118 subjects (18-65 years old). The product was not associated with skin sensitisation or irritation. (CIR)
Carcinogenicity: No evidence of carcinogenic potential.

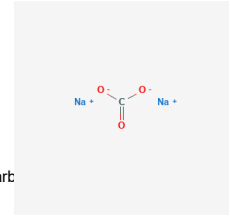
OTHER
Biodegradability (Environmental): Biodegradation in water. Results: 94 % CO2 Evolution test (OECD 301B) after 8 days. Conclusion: readily biodegradable.
LC50 (Environmental): Fish: LC50 - Pimephales promelas – 230 mg/l – 96h; LC50 - Poecilia reticulata (Guppy) – 210 mg/l – 48h (EPA methodology); Algae: NOEC - Scenedesmus subspicatus – 100 mg/l – 72h (OECD TG 201) (ECHA)

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



IDENTIFICATION
Sodium Carbonate (Buffering,Bulking)
EU INCI: Sodium Carbonate.
CTFA INCI: Sodium Carbonate.
Chinese: 碳酸钠.
CAS Number: 497-19-8.
EINECS Number: 207-838-8.
Symbol: Na2CO3.
Molecular Weight: 105.99.
IUPAC Name: Sodium carbonate
Synonyms: natrii carbonas; monosodium carbonate, monohydrate; sodium carbonate; sodium carbonate (2:3), dihydrate; sodium carbonate (4:5) ;sodium carb
carbonate, hydrate; disodium carbonate, heptahydrate; disodium carbonate, monohydrate

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Odourless
Oxidising Properties: No oxidising
pH: 11.6 (concentration 0.1 : Molar aqueous solution)
Water Solubility: 212.5 g/L at 20 ˚C
Colour: White
Density: 2.52-2.53 g/cm3 at 20 ˚C
Flammability: Non flammable
Melting Point: 851 ˚C
Physical State: Powder.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as: Eye Irrit. 2, H319
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: H319: Causes serious eye irritation..
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: Based on the available toxicological data there is no evidence of eye irritation or corrosivity potential of Sodium Carbonate. However, it causes serious eye irritation. The substance shows low acute toxicity with LD50 above 2000 mg/kg bw in dermal and LD50 equal 2 800 mg/kg bw in oral route of exposure. Repeated dose toxicity study was conducted and the NOAEL was determined to be around 245 mg/kg bw for rats and therefore it is considered as moderately systemic toxic via oral route of administration.

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. However, according to the GHS classification the substance causes serious eye irritation (ECHA)
Genotoxicity: In vitro: negative (S. typhimurium, other: TA 92, 94, 98, 100, 1535, 1537) (ECHA)
Inhalation: May cause damage to upper respiratory tract, lung irritant
LD50: LD50 (oral, rat) 2800 mg/kg bw; Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity of the substance. LD50 (dermal, rabbit) > 2 000 mg/kg bw; EPA 16 CFR 1500.40; Description: Acute toxicity studies via dermal route of exposure in rabbits showed that the substance has low skin toxicity. (ECHA) LDL (Lowest Published Lethal Dose) [Man] - Route: Oral; Dose: 714 mg/kg
NOAEL Inhalation: NOAEL > 10 mg/m³ air Study type: repeated dose toxicity: inhalation (2015, Humans have been regularly exposed to sodium carbonate in various guises over a considerable length of time. There has been no significant reports of ill health caused by inhalation of sodium carbonate either in powder or aerosol form) (ref.echa)
NOAEL Oral: NOAEL 245 mg/kg bw. Study type Developmental toxicity / teratogenicity. Endpoint developmental toxicity. Exposure and species Oral , rats. Study date 1974 (ECHA)
Reproductive Toxicology: May cause adverse reproductive effects based on animal test data
Skin Irritation: In the in vivo studies on rabbits with occlusive coverage the substance was found to be not irritating. (ECHA)
Skin Sensitisation: Based on the available toxicological data there is no evidence of skin allergy potential.
Allergens Patch Test: Modification of the Draize test for human sensitization of a bar soap product containing 0.25% Sodium Carbonate was performed on 109 subjects. It was found that the soap product was neither a strong irritant nor a contact sensitizer. (CIR)
Carcinogenicity: Not associated with carcinogenic, mutagenic and reprotoxic (CMR) chemicals.

OTHER
Hazard Class and Category Code(s): Eye Irrit. 2
Hazard statement Code(s):
Hazard statement Code(s): H319
Hazard statement Code(s): H319
Signal Word Code(s), Pictogram: GHS07 Wng
Detergent Class: zeolite, builder

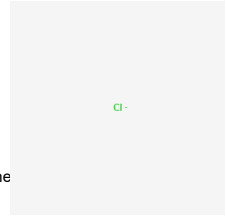
Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

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



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

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

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

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

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Hexane (Not Reported)
EU INCI: Hexane (Prohibited).
CTFA INCI: Hexane (Prohibited).
CAS Number: 110-54-3.
EINECS Number: 203-777-6.
Symbol: C6H14.
Molecular Weight: 86.18.
Description: Highly volatile hydrocarbon obtained mainly by refining crude oil.

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Characteristic
Viscosity: 0.47 to 0.55 mm2/s at 20°C
Water Solubility: 0.0098 g/l
Partial Coefficient logPow: 4
Boiling Point: > 65°C to 72°C
Density: 0.66 - 0.68 g/cm3
Flammability: Highly Flammable liquid and vapour
Flash Point: < -20°C
Vapour Pressure: 20 to 30 kPa
Melting Point: < -95°C
Physical State: Liquid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as: Flam. Liq. 2 H225; Repr. 2 H361f ***; Asp. Tox. 1 H304; STOT RE 2 * H373 **; Skin Irrit. 2 H315; STOT SE 3 H336; Aquatic Chronic 2 H411 Specific Conc. Limits, M-factors: STOT RE 2; H373: C ≥ 5 %
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC.
GHS Classification: H225 Highly Flammable liquid and vapour. H361f Suspected of damaging fertility. H304 May be fatal if swallowed and enters airways. H373 Causes damage to organs through prolonged or repeated exposure. H315 Causes skin irritation. H336 May cause drowsiness or dizziness. Specific Conc. Limits, M-factors: STOT RE 2; H373: C ≥ 5 %.
Region : Europe Type : Cosmetic Restriction : Prohibited
Region : UK Type : Cosmetic Restriction : Prohibited

TOXICITY REVIEW
General Toxicity Review: Hexene is considered as unsafe and is prohibited in cosmetic products. The substance may cause damage to fertility and organs through prolonged or repeated exposure. Overall, the ingredient is considered to be of toxicological concern when used in consumer products. Only unavoidable trace levels are acceptable.

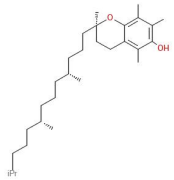
TOXICOLOGICAL PROFILE
Eye Irritation: Not expected to cause irritation. The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as not irritating. (ECHA)
Genotoxicity: Negative in vitro gene mutation study in bacteria (S. typhimurium, other: TA 1535, TA 1537, TA 1538, TA 98, and TA 100). Negative: in vivo mammalian germ cell study: cytogenicity / chromosome aberration (mouse). (ECHA)
Inhalation: May cause drowsiness or dizziness
LD50: LD50 (oral, rat) 24 mL/kg bw (~16 g/kg) (1971, OECD Guideline 401) Description: Acute toxicity studies via oral route of administration in rats demonstrated high toxicity of the substance. LD50 (dermal, rabbit) > 5 mL/kg bw (3.35 g/kg) (1970, OECD Guideline 402); Description: Acute toxicity studies via dermal route of exposure in rabbits showed that the substance is extremely toxic to skin. LC50 (inhalation, rat) 73 860 ppm (4h, vapour, 1970, OECD Guideline 403) Description: The substance when tested for acute toxicity via inhalation for 4 hours (aerosol) was found to be non-toxic. (ECHA)
Mutagenicity: Suspected of damaging fertility
NOAEL Inhalation: LOAEC 3 000 ppm Study type: sub-chronic toxicity: inhalation (vapour, rat, 1980, British Journal of Industrial Medicine, 37, 241-247) (ECHA)
NOAEL Oral: NOAEL 6.6 mmol/kg bw / 568 mg/kg bw/day Study type sub-chronic toxicity: oral (rat, 1980, Toxicology and Applied Pharmacology, 52, 433-441) (ECHA) MoS was calculated based on this data.
Precutaneous Absorption: Permeability of human skin to the solvent very low.
Repeated Dose Toxicity: Causes damage to organs through prolonged or repeated exposure
Skin Irritation: Causes skin irritation. In the in vivo studies on rabbits with semiocclusive coverage the substance was found to be irritating. (ECHA)
Skin Sensitisation: Not sensitising. LLNA in vivo examinations were conducted, using mouse local lymph node assay (LLNA) test, to find evidence for skin sensitisation. The test results showed that the chemical is not sensitising. (ECHA)
Carcinogenicity: -Hexane is not classified for carcinogenicity.

OTHER
LC50 (Environmental): LL50 12.51 mg/l (fish, 96h) (ECHA)

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

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

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



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

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

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

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

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

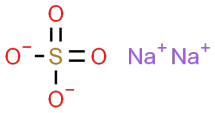
Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Sodium Sulfate (Bulking,Viscosity Controlling)
EU INCI: Sodium Sulfate.
CTFA INCI: Sodium Sulfate.
Chinese: 硫酸钠.
CAS Number: 7727-73-3(7757-82-6).
EINECS Number: 231-820-9.
Symbol: Na2O4S.
Molecular Weight: 142.042.
IUPAC Name: Sodium sulphate
Ph. Eur. Name: natrii sulfas



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Odourless
pH: 6-8 (1% solution)
Viscosity: 2.481 mPa s (dynamic) at 20°C
Water Solubility: 445.5 g/L at 20.0 °C and pH of 5.23
Boiling Point: > 300˚C
Colour: White
Density: 2.7 g/cm3 at 20 ˚C
LogP Log Kow: -4.38
Melting Point: 880-886 °C
Physical State: Powder.

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

TOXICITY REVIEW
General Toxicity Review: Sodium Sulfate is commonly used as bulking and viscosity controlling agent. The substance was tested in vivo and scored as not irritating to eyes and skin. Non-LLNA examination shown that the chemical is not sensitising vial dermal route of exposure. It shows low acute toxicity with LD50 above 2 000 mg/kg bw in oral exposure. Repeated dose toxicity study indicated the NOAEL at 1 000 mg/kg bw/day 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: No adverse effects expected but dust may cause mechanical irritation. The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as not irritating. (ECHA)
Genotoxicity: In vitro: negative (S. Typhimurium TA1535, TA1537, TA100, TA98). In vivo: negative (mouse) (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. (ECHA)
NOAEL Dermal: LOAEL 2 ml/kg/day (Study type experimental study. Endpoint sub-chronic toxicity. Species rabbit. Duration 91 days. Methods OECD Guideline 411 (Subchronic Dermal Toxicity: 90-Day Study). Reference date 1977. MoS was calculated based on this data. (ECHA)
NOAEL Oral: NOAEL 1 000 mg/kg bw/day (Study type experimental study. Endpoint repeated dose toxicity: oral. Species rat. Duration males: 4 weeks, females: 7 weeks. Methods OECD Guideline 421 (Reproduction / Developmental Toxicity Screening Test). Reference date 2010. MoS was calculated based on this data. (ECHA)
Skin Irritation: Not expected to be skin irritant. In vivo studies on rabbits with occlusive coverage, the substance was found to be not irritating (ECHA).
Skin Sensitisation: Non-LLNA in vivo examinations were conducted, using guinea pig maximisation test, to find evidence for skin sensitisation. The test results showed that the chemical is non-sensitising (ECHA).
Allergens HRIPT: In a sensitisation study sodium sulfate in a concentration 1.01% was used. The insult patch test was conducted on 61 participants. Mild erythema was observed in one subject during the induction phase. No adverse reactions were reported during the challenge phase. (CIR)
Allergens Patch Test: In the single occlusive patch test the bath product containing 9.7% Sodium sulfate was used. The study involved 19 subjects. Adverse reaction was observed in one participant. (CIR)
Carcinogenicity: Not associated with carcinogenic, mutagenic and reprotoxic (CMR) chemicals.

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Sodium Chloride (Bulking,Masking,Oral Care,Viscosity Controlling)
EU INCI: Sodium Chloride.
CTFA INCI: Sodium Chloride.
Chinese: 氯化钠.
CAS Number: 7647-14-5.
EINECS Number: 231-598-3.
Symbol: NaCl.
Molecular Weight: 58.443 Da.
EINECS No.: 231-598-3
IUPAC Name: Sodium chloride
Synonyms: Sodium chloride; Sodium monochloride Salt; Table salt; Halite; Saline, Salt

Na^{+} Cl^{-}

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Odourless
pH: >= 7 - <= 10
Viscosity: 1.93 mPa-s
Water Solubility: 317 g/L at 20 °C
Boiling Point: 1461 ºC
Particle Size: Test reports of two different granular forms of sodium chloride confirm that the particle size is bigger than 100 µm. Thus, the particles are not inhalable (ECHA).
Colour: Colourless
Density: 2.163 g/cm³ at 20 °C
Flammability: Non flammable
Vapour Pressure: 1 mm Hg at 1589 ° F
Melting Point: 801 °C
Microbiological stability: Salt is known as an effective preservative system due to its intrinsic properties of reducing the water activity (aw) which is in the amount of unbound water available for microbial growth and chemical reactions.
Physical State: Solid.

REGULATORY REQUIREMENTS
Labelling Requirements: Recommended warnings: For external use only. Do not ingest..
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 Label Review : Recommended warnings: For external use only. Do not ingest.
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: Sodium Chloride is a well-known cosmetic substance. In vivo tests indicated that he substance is non-irritating to skin and not sensitising. The studies on rabbits resulted in scoring the substance as slightly irritating to eyes. It shows very low acute toxicity with LD50 equal 3 550 mg/kg bw in oral exposure and LD50 > 10 000 mg/kg bw in dermal exposure. Overall, the Sodium Chloride is considered to be safe when used as intended.

TOXICOLOGICAL PROFILE
AcuteToxicology: Reported human case of acute gastric toxicity induced by ingestion of a coarse salt solution (nearly 16 grams) of smaller volume (0.23g/kg versus 0.5 to 1 g/kg) but higher concentration than in animal experiments. This concentration explains the gastric lesions. The potential severe gastric toxicity of coarse salt, a common ingredient (ECHA data)
Eye Irritation: The substance was tested in vivo in rabbits to examine ocular irritation after application. The studies resulted that the substance causes slightly irritation.(ECHA)
Genotoxicity: In vitro: positive (mouse lymphoma L5178Y cells); In vivo: positive (rat) (ECHA)
Inhalation: May cause upper respiratory track irritation when inhaled in the powder form
LD50: LD50 (oral,rat) 3550 mg/kg bw, Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity of the substance. LD50 (dermal, rabbit) > 10 000 mg/kg bw, Description: Acute toxicity studies via dermal route of exposure in rabbits showed that the substance has low skin toxicity. (ECHA)
ADI (Acceptable Daily Intake): ADI 180 mg/kg of sodium expressed as sodium chloride,. Recommended Daily Intake (RDI) 17 mg/kg. WHO and the Food and Agriculture Organization (FAO) recommended the consumption of less than 5 grams sodium chloride (or 2 grams sodium) per day as a population nutrient intake goal, while ensuring that the salt is iodized (WHO, 2003) (ECHA data).
NOAEL Dermal: 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.
NOAEL Oral: LOEL 2533 mg/kg bw. Study type: Repeated dose toxicity. Endpoint: chronic toxicity. Method: OECD Guideline 453 (Combined Chronic Toxicity / Carcinogenicity Studies). Source date: 1986. MoS was calculated based on this data (ECHA)
Safety evaluation: Sodium chloride is related to fatalities from acutely eating salt especially by children. The lethal dose was estimated to be less than 10 g of sodium (<5 teaspoons of salt) in two children, and less than 25 g sodium in four adults (<4 tablespoons of salt) (ref. NCBI, 2017)
Skin Irritation: In vivo studies on rabbits (intact and abraded skin) were conducted. The substance was found to be non-irritating when applied on the intact skin in the undiluted form or solution. The irritation may appear when the substance was contact with abraded skin, depends on the concentration of the salt solution. The test report concluded that `strong solutions (20% or better) result in scab and scar formation after a few applications. Weaker solutions (10% or 5%) produce slight irritation which delays healing without scarring` (ECHA).
Skin Sensitisation: The substance was tested in vitro to examine skin sensitising potential. Endpoint: The substance was found to be non-sensitising. Species: mice; Report date:1995; Source: ECHA.
Carcinogenicity: Not associated with carcinogenic, mutagenic and reprotoxic (CMR) chemicals. Not classified as a carcinogen. (ECHA)

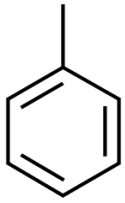
OTHER
LC50 (Environmental): LC50 bluegill sunfish -Lepomis macrochirus, 5840 mg/L , 96h; EC50 Nitzschia linearis, 2430 mg/L, 120 h (study Setter 1982) (ECHA)

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



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

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

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

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

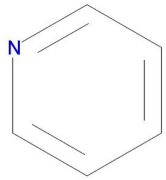
TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo to examine ocular irritation potential. Endpoint: Slightly irritating; Method: according to OECD Guideline 405; Species: rabbit; Report date: 1995; Source: ECHA.
Genotoxicity: In vitro: negative; Method: according to EU Method B.13/14;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

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

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

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

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



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

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

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

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

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

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

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

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

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

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

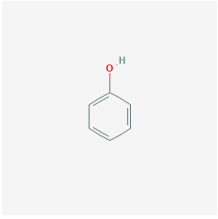
TOXICOLOGICAL PROFILE
Eye Irritation: The instillation of Arsenic Metal, Powder <0.2 mm, >99.99% into the eye of the male rabbit resulted in corneal opacity, congestion, swelling, moderate circumcorneal hyperemia, in diffuse beefy red conjunctivae and in chemosis. Based on the results, the substance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

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



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

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

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

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

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

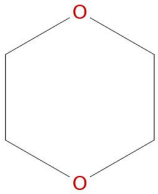
Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

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



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

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

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

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

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

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

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

Fe

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

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

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

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

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Manganese (Not Reported)
EU INCI: Manganese.
CAS Number: 7439-96-5.
EINECS Number: 231-105-1.
Symbol: Mn.
Molecular Weight: 54.938.

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Water Solubility: 0.7 mg/L at 20 °C
Boiling Point: 1,962 °C
Colour: Brown/silver/gray
Density: 7.4 g/cm3 at 20 deg C
Vapour Pressure: 0 Pa at 20 °C
Melting Point: 1 246 °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 : None
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: The substance is not associated with skin irritation and sensitisation. Data derived from studies on reconstituted corneal epithelium demonstrate that the chemical is not irritating to eyes. It shows low acute toxicity with LD50 above 2000 mg/kg bw in oral exposure. Overall, the ingredient is considered to be safe when used as intended.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vitro / ex vivo (Reconstituted Corneal Epithelium) to examine ocular irritation after application. Based on the testing results the substance is classified as not irritating. (ECHA)
LD50: LD50 (oral, rat) > 2 000 mg/kg bw; OECD Guideline 420 (Acute Oral Toxicity - Fixed Dose Method); Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity of the substance. (ECHA)
NOAEL Inhalation: NOAEL 0.5 u/L (0.5ppm / mg/kg). Study type Repeated dose toxicity. Endpoint sub-chronic toxicity. Study date 2016 (ECHA) MoS was calculated based on this data
ADME (Absorption, Distribution, Metabolism, Excretion): Intestinal absorption has been estimated to be between 3 and 10% of the amount of manganese ingested and is a multiple-step process similar to and involving some of the same binding sites as in iron absorption (EPA 1995). Experiments with isolated rat intestines indicate that manganese absorption is carrier-mediated with saturation occurring at 0.5 mM (Testolin et al. 1993). The absorption of manganese by inhalation depends on the particle size. The larger particles are cleared from the respiratory tract by the cilia and swallowed; whereas, the fine particles (< 2.5 microns) are deposited in the lungs and must be cleared by absorption into the blood and lymph circulation (EPA 1995). It is estimated that 60 to 70% of the inhaled particles are eventually swallowed (Stokinger 1981). Once absorbed, manganese is transported to organs rich in mitochondria (in particular the liver, pancreas, and pituitary) where it is rapidly concentrated. Accumulation of manganese in the central nervous system following an intraperitoneal or intramuscular injection occurs slowly reaching a maximum in about 30 days. Distribution is homogeneous in the brain with lower concentrations in the spinal cord. The average turnover time in the central nervous system is reported to be about 110 days following intraperitoneal injection and about 55 days for intramuscular injection (Stokinger 1981).
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: LLNA in vivo examinations were conducted, using mouse local lymph node assay (LLNA) test, to find evidence for skin sensitisation. The test results showed that the chemical is not sensitising. (ECHA)

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

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
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 exibit 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: accrding 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

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Zinc (Antioxidant)
EU INCI: Zinc.
CTFA INCI: Zinc.
CNDA INCI: Zinc.
CAS Number: 7440-66-6.
EINECS Number: 231-175-3 .
Symbol: Zn.
Molecular Weight: 65.39.

Zn

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Odourless
Water Solubility: 0.1 mg/L at 20 °C
Particle Size: D50 of zinc powder is 71 µm, the D80 is 148 µm
Colour: Light grey
Density: 7.1 g/cm3
Flammability: Non flammable
Melting Point: 409 °C
Physical State: Powder.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as: Water-react. 1 H260; Pyr. Sol. 1 H250; Aquatic Acute 1 H400; Aquatic Chronic 1 H410
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: H260: In contact with water releases flammable gases which may ignite spontaneously. H250: Catches fire spontaneously if exposed to air. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects..
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

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 2 000 mg/kg bw/day. Repeated dose toxicity study indicated NOAEL via inhalation 2.7 mg/m3 air and NOAEL oral at 3 000 ppm, 15 mg/kg bw/day.

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. The substance may cause only mechanical eye irritation. (ECHA)
LD50: LD50 (oral, rat) > 2 000 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: NOAEL 2.7 mg/m³ air (analytical) (0.0027 mg/l). Study type: repeated dose toxicity: inhalation (aerosol - nose only, guinea pig, 1988, principles of method: duration 5 day, exposure to ZnO particles 3 h/d for 5 d) (ref. ECHA)
NOAEL Oral: NOEL 3 000 ppm Study type: repeated dose sub-chronic toxicity oral (rat, 1981, OECD 408); NOAEL 15 mg/kg bw/day Study type: two-generation reproductive toxicity (oral, rat, 2007, OECD 416) MoS was calculated based on this data; NOAEL 88 mg/kg bw/day Study type: developmental toxicity (oral, hamster, 1973,principles of method: duration - 6-10 days, dose 88 mg ZnSO4/kg bw)(ref. ECHA)
ADME (Absorption, Distribution, Metabolism, Excretion): Gastrointestinal absorption of zinc is variable (20-80%) and depends on chemical characteristics of the compound, on the amount of zinc in the body, and on the dietary levels of other nutrients (U.S. EPA, 1984). High dietary levels of phytate, calcium, or phosphorus reduce absorption, but protein enhances uptake (ATSDR, 1989). In individuals with normal zinc levels in the body, gastrointestinal absorption is 20-30%. Information on pulmonary absorption is limited and complicated by the potential for gastrointestinal absorption following mucociliary clearance and swallowing. Zinc is present in all tissues, but the highest concentrations occur in the prostate gland (Bertholf, 1988). Concentrations in the kidney, liver, heart, and pancreas are also high (Stokinger, 1981). After absorption into the body, zinc becomes bound to protein complexes, the most important of which is metallothionein, which acts as a carrier and transport mechanism (Stokinger, 1981). As an element zinc is not metabolized per se; however, it is a vital component of many metalloenzymes such as carbonic anhydrase, which regulates CO2 exchange (Stokinger, 1981). Other enzyme systems in which zinc plays a role are RNA polymerase, superoxide dismutase, carboxypeptidase, isocitric dehydrogenase, alcohol dehydrogenase, and ceruloplasmin. Homeostatic mechanisms control zinc absorption and excretion. Metallothionein in the mucosal cells lining the gastrointestinal tract binds with zinc and regulates uptake in the body (ATSDR, 1989). Under conditions where there is a physiological excess of zinc, the metallothionein-zinc complex is eliminated from the body when the mucosal cells are sloughed off. Mass balance studies indicate that most zinc is excreted in the feces, with small amounts in the urine, sweat and semen (Schroeder et al., 1967); however, a significant amount may be lost in sweat in hot climates (Prasad et al., 1963).
Skin Irritation: In the in vivo studies on rabbits with occlusive coverage the substance was found to be not irritating. (ECHA)
Skin Sensitisation: Non-LLNA in vivo examinations were conducted, using guinea pig maximisation test, to find evidence for skin sensitisation. The test results showed that the chemical is non-sensitising. (ECHA)

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Magnesium (Reducing)
EU INCI: Magnesium powder.
CTFA INCI: Magnesium powder.
Trade Name: Magnesium rod.
CAS Number: 7439-95-4.
Symbol: Mg.
Molecular Weight: 24.305.
Description: Magnesium Powder is an inorganic metal consisting of powdered magnesium

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Water Solubility: 6.7 mg/L at 21 °C (pH 10.8)
Boiling Point: 1095°C
Particle Size: D50 52.7 µm
Colour: Silvery-white
Density: 1.76 g/cm3 at 23.0 °C +/- 0.2 °C
Vapour Pressure: 1.33 hPa at 621 °C
Melting Point: 650°C
Physical State: Solid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as. Water-react. 1 H260; Pyr. Sol. 1 H250
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC.
GHS Classification: H250: Catches fire spontaneously if exposed to air. H260: In contact with water releases flammable gases which may ignite spontaneously..
Region : Europe Type : Cosmetic Restriction : None
Region : UK Type : Cosmetic Restriction : None

TOXICITY REVIEW
General Toxicity Review: Magnesium powder is an reducing ingredient. It is not associated with skin, eye irritation and skin sensitisation. It shows slight toxicity with LD50 > 2 000 mg/kg bw for 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 considered to be safe when used as intended.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as not irritating. (ECHA)
Developmental toxicity: NOAEL> 800 mg/kg bw/day Study type: Toxicity to reproduction; Endpoint:developmental toxicity; Species:rat; Bibliographic source:Bull. Natl. Inst. Health Sci., 114: 16-20. (1996); 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. (ECHA)
NOAEL Oral: NOAEL 299 mg/kg bw Study type: Repeated dose toxicity; Endpoint:sub-chronic toxicity: oral. Endpoint sub-chronic toxicity: oral. Species: rat. Duration .90 days Methods OECD Guideline 408. Reference date 2000 (ECHA) MoS was calculated based on this data
Read-across: Not susceptible to microbiological contamination
Skin Irritation: In the in vitro studies the substance was found to be not irritating and not corrosive. (ECHA)
Skin Sensitisation: Non-LLNA in vivo examinations were conducted, using guinea pig maximisation test, to find evidence for skin sensitisation. The test results showed that the chemical is non-sensitising. (ECHA)
Carcinogenicity: Not associated with CMR

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Cobalt (Not Reported)
EU INCI: Cobalt (Prohibited).
CTFA INCI: Cobalt (Prohibited).
Chinese: 钴.
CAS Number: 7440-48-4.
EINECS Number: 231-158-0.
Symbol: Co.
Molecular Weight: 58.93.

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Odourless
Water Solubility: Practically insoluble, 2.94 mg/L at 20 °C
Boiling Point: 2927 °C at 101.325 kPa
Colour: Metallic
Density: 8.86 g/cm³ at 20 °C
Vapour Pressure: 0 Pa at 20 °C
Melting Point: 1 494 °C
Physical State: Powder.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as: Carc. 1B H350; Muta. 2 H341; Repr. 1B H360F; Resp. Sens. 1, H334; Skin Sens. 1, H317; Aquatic Chronic 4, H413
REACH Annex XVII: Listed in Annex XVII. Reason: Carcinogens: Category 1 B; Reproductive toxicants: Category 1 B.
REACH SVHC: Not included in SVHC list (Annex XIV)
GHS Classification: H302: Harmful if swallowed. H317: May cause an allergic skin reaction. H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. H350: May cause cancer by inhalation. H361: Suspected of damaging fertility or the unborn child. H413: May cause long lasting harmful effects to aquatic life..
Region : Europe Type : Cosmetic Restriction : Prohibited
Region : UK Type : Cosmetic Restriction : Prohibited

TOXICITY REVIEW
General Toxicity Review: Cobalt is considered as unsafe and is prohibited in cosmetic products. The substance is eye irritating and may cause an allergic skin reaction. It is not expected to cause skin irritation. It is slightly toxic with LD50 ca. 550 mg/kg bw for oral exposure. Cobalt has low acute toxicity for dermal exposure with LD50 > 2 000 mg/kg bw. It is highly toxic with LC50 < 0.05 mg/L air 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: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as irritating (ECHA).
Genotoxicity: Suspected of causing genetic defects. In vitro: negative (S. typhimurium, other: TA97a); In vivo: negative (rat) (ECHA).
Inhalation: May cause allergy or asthma symptoms or breathing difficulties if inhaled
LD50: LD50 (oral, rat) ca. 550 mg/kg bw. Description: Acute toxicity studies via oral route of administration in rats showed that the substance is slightly toxic. LD50 (dermal, rat) > 2 000 mg/kg bw. Description: Acute toxicity studies via dermal route of exposure in rabbits (semiocclusive type of coverage) showed that the substance has low skin toxicity. LC50 (inhalation, rat) < 0.05 mg/L air. Description: The substance when tested for acute toxicity via inhalation for 4 hours (dust) was found to be highly toxic. (ECHA)
NOAEL Inhalation: LOAEC 0.31 mg/L air Study type experimental study. Endpoint repeated dose toxicity: inhalation. Species rat. Duration 105 weeks. Methods Groups of 50 male and 50 female rats were exposed to aerosols containing 0, 0.3, 1.0, or 3.0 mg/m³ cobalt sulfate heptahydrate 6 hours per day, 5 days per week, for 105 weeks. Reference date 1999 (ECHA)
NOAEL Oral: NOAEL 3 mg/kg bw/day Study type experimental study. Endpoint sub-chronic toxicity: oral. Species rat. Duration 90 days. Methods OECD Guideline 408. Reference date 2015 (ECHA) MoS was calculated based on this data.
Reproductive Toxicology: May damage fertility
Sensitisation via inhalation: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
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: May cause an allergic skin reaction
Carcinogenicity: May cause cancer

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Barium (Not Reported)
EU INCI: Barium.
CTFA INCI: Barium.
CNDA INCI: Barium.
CAS Number: 7440-39-3.
EINECS Number: 231-149-1.
Symbol: Ba.

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Colour: Silver- white
Density: 3.62 g/cm3 at 20°C
Flammability: Flammable solid
Melting Point: 727 °C
Physical State: Solid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as: Acute Tox. 4 *, H332; Acute Tox. 4 *, H302
REACH Annex XVII: Not listed in Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
Regulatory Controls: Prohibited: Barium salts(barium chloride, barium gluconate, barium hexaferrite), with the exception of barium sulphide under the conditions laid down in Annex III, and of barium sulfate, lakes, salts and pigments prepared from colouring agents when listed in Annex IV.
GHS Classification: H228: Flammable solid. H260: In contact with water releases flammable gases which may ignite spontaneously. H314: Causes severe skin burns and eye damage. H318: Causes serious eye damage. H301: Toxic if swallowed..
Region : Europe Type : Cosmetic Restriction : Prohibited: Barium salts, with the exception of barium sulphide under the conditions laid down in Annex III, and of barium sulfate, lakes, salts and pigments prepared from colouring agents when listed in Annex IV.
Region : UK Type : Cosmetic Restriction : Prohibited: Barium salts, with the exception of barium sulphide under the conditions laid down in Annex III, and of barium sulfate, lakes, salts and pigments prepared from colouring agents when listed in Annex IV.

TOXICITY REVIEW
General Toxicity Review: In vivo studies resulted in scoring the chemical as severely irritating to eyes and skin. It was not necessary to conduct skin sensitisation study due to the fact that the substance in contact with water forms strong base solution and causes damage to skin. The substance shows high toxicity potential via oral route of administration with median lethal dose at 132 - 277 mg/kg bw. The German Institute of BfR recommends that cosmetic products (both for oral and not oral exposure) contain less than 10 mg/kg (0.01%) of Ba in the produces as a part of the recommended safe level for heavy metals in cosmetics in Europe.

TOXICOLOGICAL PROFILE
Eye Irritation: Based on the available toxicological information it causes serious eye damage.
Genotoxicity: In vitro: negative; Method: according to OECD Guideline 486; Species: mouse lymphoma L5178Y cells; Report date: 2010; Source: ECHA.
LD50: LD50 (oral) 132 to 277 mg barium/kg. Ingestion: Eating or drinking very large amounts of barium compounds that dissolve in water or in the stomach can cause changes in heart rhythm or paralysis in humans.
ADI (Acceptable Daily Intake): TDI of 0.2 mg barium/kg bw/day
NOAEL Oral: NOAEL 0.21 mg/kg bw. Study type. Clinical studies with 11 healthy men. Route of exposure: oral, drinking water (WHO).
Reproductive Toxicology: NOAEL 201.5 and 179.5 mg Ba/kg bw/d to male and and female rats, respectively. Study type: Toxicity to reproduction. Endpoints: fertility, other. Species: rats. Route of exposure: oral: drinking water (ECHA)
Safety evaluation: Barium compounds such as barium acetate, barium chloride, barium hydroxide, barium nitrate, and barium sulfide that dissolve in water can cause harmful health effects. Barium carbonate does not dissolve in water, but does dissolve in the stomach; it can also cause harmful health effects.
Skin Irritation: Based on the available toxicological information it causes severe skin burns.
Skin Sensitisation: Based on the available toxicological information it causes severe skin burns and therefore it is not necessary to conduct skin sensitisation study.

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Selenium and its compounds (Not Reported)
EU INCI: Selenium and its compounds (Prohibited).
CTFA INCI: Selenium and its compounds (Prohibited).
CNDA INCI: Selenium and its compounds (Prohibited).
Chinese: 硒及其化合物.
CAS Number: 7782-49-2.
EINECS Number: 231-957-4.
Symbol: Se.
Molecular Weight: 78.96.

Se

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Water Solubility: 3.774 µg/L at 21.2 °C
Boiling Point: 685 °C
Particle Size: L50 15.83 µm; L10 3.35 µm; L90 54.93 µm
Colour: Black
Density: 4.809 g/cm3 at 20 deg C
Vapour Pressure: 0.133 Pa at 20 °C
Melting Point: 220.8 °C
Microbiological stability: Not susceptible to microbiological contamination
Physical State: Solid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Listed in CLP Regulation (EC) No 1272/2008. Acute Tox. 3 * H331; Acute Tox. 3 * H301; STOT RE 2 * H373; Aquatic Chronic 4 H413
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
Regulatory Controls: Selenium and its compounds with the exception of selenium disulphide under the conditions set out under reference No 49 in Annex III
GHS Classification: H301+H331: Toxic if swallowed or if inhaled. H373: May cause damage to organs through prolonged or repeated exposure. H413: May cause long lasting harmful effects to aquatic life..
Region : Europe Type : Cosmetic Restriction : Prohibited in cosmetic products.
Region : UK Type : Cosmetic Restriction : Prohibited in cosmetic products.

TOXICITY REVIEW
General Toxicity Review: Selenium and its compounds is considered as unsafe and is prohibited in cosmetic products. There is no evidence on eye, skin irritation or sensitisation potential of the substance. It is practically non-toxic with LD50 > 5000 mg/kg bw (powder) in oral route of exposure. It is slightly toxic with LC50 > 5.67 mg/L air (analytical) (fine powder) 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: Not irritating. The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as not irritating (ECHA).
Genotoxicity: In vitro: negative (mouse lymphoma L5178Y cells); In vivo: negative (mouse) (ECHA).
Inhalation: Toxic if inhaled.
LD50: LD0 5 000 mg/kg bw (oral, rat, OECD Guideline 401, 1996). LD50 (oral, rat) > 5000 mg/kg bw Selenium (powder). Description: Acute toxicity studies via oral route of administration in rats demonstrated that the substance is practically non-toxic (ECHA). LC50 (inhalation, rat) > 5.67 mg/L air (analytical) Selenium (fine powder). Description: The substance when tested for acute toxicity via inhalation for 4 hours (aerosol) was found to be slightly toxic. (ECHA)
NOAEL Oral: NOAEL 0.4 mg/kg bw/day Study type migrated information: read-across from supporting substance. Endpoint sub-chronic toxicity: oral. Species rat. Duration 13 weeks. Methods OECD Guideline 408. Reference date 1994 (ECHA)
Reproductive Toxicology: May cause damage to the liver and the reproductive system through prolonged or repeated exposure. Route of exposure: Oral.
ADME (Absorption, Distribution, Metabolism, Excretion): Gastrointestinal absorption in humans for various selenium compounds ranges from about 44% to 95% of the ingested dose (Thomson and Stewart, 1974; Bopp et al., 1982; Thomson, 1974). Absorption is highest when the compound is administered in solution and lowest when it is administered as a solid. Absorption is also more efficient after a single dose than after repetitive daily doses. In studies on rats, mice and dogs, gastrointestinal absorption rates of 87% or more have been reported for [75Se]-selenite (selenious acid) (Bopp et al., 1982; U.S. EPA, 1989: Furchner et al.,1975). Absorption is highest following gavage administration, but may be only 50% when the compound is administered in feed (Weissmann et al., 1983). Selenium is found in all tissues at concentrations that vary with the amount ingested in the diet and the type of tissue. Highest concentrations occur in the kidney, liver, spleen, and pancreas (Schroeder and Mitchener, 1971a; Schroeder and Mitchener, 1972; Jacobs and Forst, 1981a; Julius et al., 1983; Shamberger, 1984; Echevarria et al., 1988). Selenium is also concentrated in erythrocytes relative to the amount in blood plasma (Butler et al., 1990). As a result of occupational exposures, high concentrations can also be found in peribronchial nodes, lung, hair, and nails (Diskin et al., 1979).
Skin Irritation: Not irritating. In the in vitro / ex vivo studies on the human skin model the substance was found to be not irritating. (ECHA)
Skin Sensitisation: Not sensitising. LLNA in vivo examinations were conducted, using mouse local lymph node assay (LLNA) test, to find evidence for skin sensitisation. The test results showed that the chemical is not sensitising. (ECHA)
Carcinogenicity: There is no evidence to support a causal association between any of these selenium compounds and cancer in humans. In fact, some epidemiological and experimental evidence suggests that selenium exposure under certain conditions may contribute to a reduction in cancer risk. The chemopreventive potential of supplemental selenium is currently under research. (ECHA)

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

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

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

Ca
(v0)

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

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

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

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

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

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

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

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

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

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

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

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 (semiocclusive 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 semiocclusive 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)

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Copper (Cosmetic Colorant)
EU INCI: CI 77400.
CTFA INCI: Copper powder.
CNDA 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 um
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
AcuteToxicology: 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 (semiocclusive 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 muitagenicity
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)
Precutaneous 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.

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

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

Pb

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

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

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

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

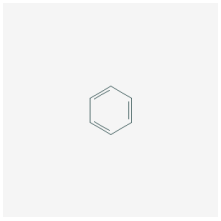
OTHER
Ecological toxicity: Very toxic to aquatic life with long lasting effects

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



IDENTIFICATION
Benzene (Not Reported)
EU INCI: Benzene (Prohibited).
CTFA INCI: Benzene (Prohibited).
CAS Number: 71-43-2.
EINECS Number: 200-753-7.
Symbol: C6H6.
Molecular Weight: 78.11.

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Characteristic, aromatic, petroleum-like
Viscosity: 0.604 mPa s at 25°C
Water Solubility: 1.88g/L at 23.5˚C
Partial Coefficient logPow: 2.13 at 20 °C
Boiling Point: 80.09 °C at 101 325 Pa
Colour: Colourless
Density: 0.8765 g/cm³ at 20˚C
Flammability: Highly flammable liquid and vapour
Flash Point: -11 °C at 101 325 Pa
Vapour Pressure: 10 kPa at 20 °C
Melting Point: 5.49 °C at 101 325 Pa
Physical State: Liquid.

REGULATORY REQUIREMENTS
IFRA Standard: Benzene should not be used as a fragrance ingredient.The level of Benzene has to be kept as low as practicable and should never exceed 1 ppm in the fragrance compound/mixture or fragrance oil.
CLP Regulation (EC) No 1272/2008: Classified as: Flam. Liq. 2 H225; Carc. 1A H350; Muta. 1B H340; STOT RE 1 H372 **; Asp. Tox. 1 H304; Eye Irrit. 2 H319; Skin Irrit. 2 H315
REACH Annex XVII: Listed in Annex XVII. Reason of inclusion: Carcinogenic 1A, Mutagenic 1B. Maximum concentration limits by weight inhomogeneous materials: 5 mg/kg. 1.Shall not be used in toys or parts of toys where the concentration of benzene in the free state is greater than 5 mg/kg (0,0005 %) of the weight of the toy orpart of toy. 2. Toys and parts of toys not complying with paragraph 1 shall not be placed on the market. 3. Shall not be placed on the market, or used, as a substance, as a constituent of other substances, or in mixtures, in concentrations equal to, or greater than 0,1 % by weight. 4. However, paragraph 3 shall not apply to: (a) motor fuels which are covered by Directive 98/70/EC; (b) substances and mixtures for use in industrial processes not allowing for the emission of benzene in quantities in excess of those laid down in existing legislation; (c) natural gas placed on the market for use by consumers, provided that the concentration of benzene remains below 0,1 % volume/volume.
REACH SVHC: Not included in SVHC.
Regulatory Controls: Prohibited as a constituent of other substances, or in mixtures, in concentrations equal to, or greater than 0.1% by weight
GHS Classification: H225: Highly Flammable liquid and vapour. H350: May cause cancer. H340: May cause genetic defects. H372: Causes damage to organs through prolonged or repeated exposure. H304: May be fatal if swallowed and enters airways. H319: Causes serious eye irritation. H315: Causes skin irritation. 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: Benzene is prohibited in cosmetic products. The substance causes skin irritation and serious eye irritation. The substance may cause damage damage to organs and cancer. Therefore, the substance is a concern for safe use in cosmetics. Only trace levels are allowed.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as mildly irritating. (ECHA) According to the CLP classification the substance causes serious eye irritation.
LD50: LD50 (oral, rat) > 2 000 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. LD50 (dermal, rabbit and guinea pig) > 9.4 mL/kg bw; OECD Guideline 402 (Acute Dermal Toxicity); Description: Acute toxicity studies via dermal route of exposure in rabbits (occlusive type of coverage) showed that the substance has low skin toxicity. (ECHA)
Mutagenicity: Mutagenic 1B
NOAEL Inhalation: NOAEC 32 mg/m³ air Study type: chronic toxicity: inhalation (vapour, whole body, mouse, 1985, Am. J. Ind. Med. 7, 447-456) (ref.echa)
NOAEL Oral: NOAEL 100 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); Report date:1986; Source: ECHA, MoS was calculated based on this data
Repeated Dose Toxicity: Causes damage to organs through prolonged or repeated exposure
Safety evaluation: Based on the assumptions and conditions set out in the RIVM report, RAC is of the opinion that consumer exposure to benzene present in natural gas at a concentration greater than 0.1% (w/w) but below 0.1% (v/v) during regular use of natural gas as fuel for cooking and heating does not represent a risk for consumers that is not adequately controlled. However, this opinion does not cover the consumer exposure and risk arising from exposure scenarios other than those described in the RIVM report. RAC therefore cannot confirm that for any conditions or equipment other than those described in the RIVM report the risks for consumers are adequately controlled.
Skin Irritation: In the in vivo studies on rabbits the substance was found to be irritating. (ECHA)
Skin Sensitisation: Non-LLNA in vivo examinations were conducted, using GPMT and mouse ear swelling test (MEST), to find evidence for skin sensitisation. The test results showed that the chemical is non-sensitising. (ECHA)
Carcinogenicity: Carcinogenic 1A

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Antimony and its compounds (Not Reported)
EU INCI: Antimony and its compounds (Prohibited).
CTFA INCI: Antimony and its compounds (Prohibited).
Chinese: 锑及其化合物.
CAS Number: 7440-36-0.
EINECS Number: 231-146-5.
Symbol: Sb.
Molecular Weight: 13968-50-8.

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Odourless (antimony)
Water Solubility: 18.2 mg/L at 20 °C (antimony)
Boiling Point: > 600°C (antimony)
Colour: Grey (antimony)
Density: 7.05 g/cm3 at 20C (antimony)
Melting Point: >600C (antimony)
Physical State: Powder.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Antimony trichloride and antimony pentachloride are classified as: Skin Corr. 1B, H314; Aquatic Chronic 2, H411. Antimony trifluoride is classified as: Acute Tox. 3 *, H331; Acute Tox. 3 *, H311; Acute Tox. 3 *, H301; Aquatic Chronic 2, H411. Antimony trioxide is classified as: Carc. 2, H351. Antimony compounds, with the exception of the tetroxide (Sb2O4), pentoxide (Sb2O5), trisulphide (Sb2S3), pentasulphide (Sb2S5) are classified as: Acute Tox. 4 *, H332; Acute Tox. 4 *, H302; Aquatic Chronic 2, H411
REACH Annex XVII: Not listed in Annex XVII
REACH SVHC: Not included in SVHC.
GHS Classification: H360: May damage fertility or the unborn child. H362: May cause harm to breast-fed children. 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: Antimony and its salts are considered as damaging fertility or the unborn child and that may cause harm to breast-fed children. In vivo studies resulted in scoring the chemical as damaging eyes and causing severe skin burns. Skin sensitisation study indicated that it is non-sensitising. It shows veyr low acute toxicity potential with median lethal dose at above 8 300 mg/kg bw via dermal route. Repeated dose toxicity study indicated NOAEL at 1 686 mg/kg bw/day via oral route.

TOXICOLOGICAL PROFILE
Eye Irritation: Causes eye damage (antimony trichloride and antimony pentachloride). The substance (antimony) was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as not irritating. (ECHA)
Genotoxicity: In vitro: negative (S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and TA 102); In vivo: negative (rat) (ECHA)
Inhalation: Harmful if inhaled
LD50: LD50 (dermal, rabbit) > 8 300 mg/kg bw; route of exposure: dermal, Species: rabbit, Reprt date: 1955; Description: Acute toxicity studies via oral route of administration in rats demonstrated practically non-toxicity of the substance. Source: ECHA.
NOAEL Oral: NOAEL 1 686 mg/kg bw/day; Route of exposure: oral; Species: rat, Report date: 1999, Method: according to OECD guideline 408, Source: ECHA.
ADME (Absorption, Distribution, Metabolism, Excretion): Absorption rate - dermal (%): 0.1 (ECHA)
Skin Irritation: Causes severe skin burns (antimony trichloride and antimony pentachloride). In the in vivo studies on rabbits with occlusive coverage the substance (antimony) was found to be not irritating and not corrosive. (ECHA)
Skin Sensitisation: Not sensitising (antimony) 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 (antimony) is non-sensitising. (ECHA)
Carcinogenicity: "The combined animal and human exposure data support a Carcinogenicity category 2 via inhalation classification for Sb trioxide. Based on physical form/particle size, water solubility, and Sb speciation/valency, the same classification can be applied to Sb metal and Sb trisulfide. Sb trichloride and Sb tris (ethylene glycolate) do not satisfy the criteria to be grouped with Sb metal, Sb trioxude and Sb trisulfide for purpose of lung carcinogenicity classification, and are not classified for carcinogenicity." (Source: ECHA 2020 https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/16124/7/8)

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

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

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

Ni

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

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

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

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

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

Cd

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

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

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

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

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

Product Name

Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

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

Hg

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

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

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

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

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

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

UNDESIRABLE EFFECTS AND SERIOUS UNDESIRABLE EFFECTS MONITORING POST MARKETING SURVEILLANCE

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

AMOUNT OF UNITS SOLD: New product – no data.

REMARKS: New product – no data.

INFORMATION ON THE COSMETIC PRODUCT DERMATOLOGICAL TESTS

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

LABELLED WARNINGS

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

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Manufacturer
Eresos Health + Wellbeing LTD
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INSTRUCTION OF USE

Body – Apply a generous amount to hands to cover the entire body, using circular sweeping movements rub into the body and let our natural blend detoxify you. Hands – Apply a small amount to your hand and let it gently absorb nourishing and replenishing the skin with a combination of the finest oils.

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.

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

Product Name
Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

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REASONING
TOXICOLOGICAL ASSESSMENT

EFFECT ON SKIN
May cause slight temporary skin irritation.

The product does not contain perfume materials or other chemicals that are known to cause allergic reactions, the risk of inducing allergy is reduced.

EFFECT ON EYES
May irritate the eye.

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 and with Schedule 34 of the Product Safety & Metrology etc (Amendment etc) (EU Exit) Regulations 2019 UK Cosmetics Regulation and subsequent amendments under the conditions that the efficacy of the preservative system and microbiological stability (TVC, mould, fungi, absence of pathogens) meet the acceptance criteria based on the positive evaluation prior to marketing.

The product must be manufactured according to Good Manufacturing Practice.

TOXICOLOGICAL AND REGULATORY ASSESSOR

23 January 2023

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

SAFETY ASSESSOR

23 January 2023

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

Product Name
Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

Manufacturer
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N18 1TP

IMPURITIES

CAS No	IMPURITY	SOURCE CHEMICAL	Concentration in finished product[C %]
1350472-07-9	Iso-squalane	Squalane	0.0163453500
-	C30 Hydrocarbons	Squalane	0.0076278300
79-10-7	Acrylic acid	Carbomer	0.0044503000
110-82-7	Cyclohexane	Carbomer	0.0044503000
111-46-6	Diethylene glycol	Glycerin	0.0029090100
107-21-1	Glycol (Ethylene glycol)	Glycerin	0.0029090100
141-78-6	Ethyl Acetate	Carbomer	0.0022251500
497-19-8	Sodium Carbonate	Sodium Hydroxide	0.0015227100
16887-00-6	Chloride	Glycerin	0.0010181535
110-54-3	Hexane	Carbomer	0.0008900600
59-02-9(10191-41-0)(1406-66-2)1406-18-4(54-28-4)(gamma)	Tocopherol	Tocopheryl Acetate	0.0007783500
7727-73-3(7757-82-6)	Sodium Sulfate	Sodium Hydroxide	0.0000543825
7647-14-5	Sodium Chloride	Sodium Hydroxide	0.0000362550
7439-92-1	Lead and its compounds	Glycerin	0.0000145451
75-21-8	Ethylene oxide	Phenoxyethanol	0.0000145020
108-88-3	Toluene	Tocopheryl Acetate	0.0000124536
110-86-1	Pyridine	Tocopheryl Acetate	0.0000124536
7440-38-2	Arsenic and its compounds	Glyceryl Stearate	0.0000107931
7440-38-2	Arsenic and its compounds	Glycerin	0.0000087270
108-95-2	Phenol	Phenoxyethanol	0.0000072510
123-91-1	1,4-Dioxane	Polysorbate 20	0.0000062200
7439-92-1	Lead and its compounds	Glyceryl Stearate	0.0000053966
7439-89-6	Iron Powder	Sodium Hydroxide	0.0000036255
7439-97-6	Mercury and its compounds	Glycerin	0.0000029090
7440-43-9	Cadmium	Glycerin	0.0000029090
7439-97-6	Mercury and its compounds	Glyceryl Stearate	0.0000026983
7440-43-9	Cadmium	Glyceryl Stearate	0.0000026983
7440-47-3	Chromium	Caprylic/Capric Triglyceride	0.0000023869
7440-38-2	Arsenic and its compounds	Caprylic/Capric Triglyceride	0.0000023869
7439-92-1	Lead and its compounds	Sodium Hydroxide	0.0000018128
7440-47-3	Chromium	Sodium Hydroxide	0.0000018128
7440-02-0	Nickel	Sodium Hydroxide	0.0000018128
7439-96-5	Manganese	Sodium Hydroxide	0.0000018128

Product Name
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Manufacturer
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N18 1TP

IMPURITIES

CAS No	IMPURITY	SOURCE CHEMICAL	Concentration in finished product[C %]
7440-43-9	Cadmium	Sodium Hydroxide	0.0000014502
7440-66-6	Zinc	Sodium Hydroxide	0.0000014502
7439-95-4	Magnesium	Sodium Hydroxide	0.0000014502
7440-48-4	Cobalt	Sodium Hydroxide	0.0000014502
7440-39-3	Barium	Sodium Hydroxide	0.0000010877
7440-02-0	Nickel	Caprylic/Capric Triglyceride	0.0000009548
7782-49-2	Selenium and its compounds	Sodium Hydroxide	0.0000009064
7440-38-2	Arsenic and its compounds	Carbomer	0.0000008901
123-91-1	1,4-Dioxane	Phenoxyethanol	0.0000007251
7440-70-2	Calcium	Sodium Hydroxide	0.0000007251
75-21-8	Ethylene oxide	Polysorbate 20	0.0000006220
7440-38-2	Arsenic and its compounds	Sodium Hydroxide	0.0000005438
7440-50-8	Copper	Caprylic/Capric Triglyceride	0.0000004774
7439-92-1	Lead and its compounds	Caprylic/Capric Triglyceride	0.0000004774
7440-31-5	Tin	Caprylic/Capric Triglyceride	0.0000004774
7440-50-8	Copper	Sodium Hydroxide	0.0000003626
7439-92-1	Lead and its compounds	Tocopheryl Acetate	0.0000003113
71-43-2	Benzene	Carbomer	0.0000002225
7439-97-6	Mercury and its compounds	Sodium Hydroxide	0.0000001813
7440-36-0	Antimony and its compounds	Sodium Hydroxide	0.0000001813
7440-38-2	Arsenic and its compounds	Tocopheryl Acetate	0.0000001557
7440-02-0	Nickel	Tocopheryl Acetate	0.0000001557
7440-43-9	Cadmium	Tocopheryl Acetate	0.0000000778
7439-97-6	Mercury and its compounds	Tocopheryl Acetate	0.0000000156

Product Name
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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
Iso-squalane	0.0163453500	18.67	0.05086128	Not Available	No MoS calculated as no NOAEL available
C30 Hydrocarbons	0.0076278300	18.67	0.02373526	Not Available	No MoS calculated as no NOAEL available
Cyclohexane	0.0044503000	18.67	0.01384785	Not Available	No MoS calculated as no NOAEL available
Acrylic acid	0.0044503000	18.67	0.01384785	83	2996.855071
Glycol (Ethylene glycol)	0.0029090100	18.67	0.00905187	150	8285.581273
Diethylene glycol	0.0029090100	18.67	0.00905187	128	7070.362686
Ethyl Acetate	0.0022251500	18.67	0.00692393	900	64992.037693
Sodium Carbonate	0.0015227100	18.67	0.00473817	245	25853.88551
Chloride	0.0010181535	18.67	0.00316815	Not Available	No MoS calculated as no NOAEL available
Hexane	0.0008900600	18.67	0.00276957	568	102542.992805
Tocopherol	0.0007783500	18.67	0.00242197	500	103221.938626
Sodium Sulfate	0.0000543825	18.67	0.00016922	1000	2954729.772603
Sodium Chloride	0.0000362550	18.67	0.00011281	2533	11226495.771006
Arsenic and its compounds	0.0000234966	18.67	0.00007311	0.0008	5.470929
Lead and its compounds	0.0000225431	18.67	0.00007015	7.8	55597.86736
Ethylene oxide	0.0000151240	18.67	0.00004706	30	318736.296995
Toluene	0.0000124536	18.67	0.00003875	625	8064213.955131
Pyridine	0.0000124536	18.67	0.00003875	7	90319.196297
Phenol	0.0000072510	18.67	0.00002256	450	9972212.982536
Cadmium	0.0000071353	18.67	0.00002220	3	67559.189746
1,4-Dioxane	0.0000069451	18.67	0.00002161	9.6	222110.794926
Mercury and its compounds	0.0000058041	18.67	0.00001806	0.005	138.423447
Chromium	0.0000041997	18.67	0.00001307	1216	46525738.733228
Iron Powder	0.0000036255	18.67	0.00001128	Not Available	No MoS calculated as no NOAEL available
Nickel	0.0000029232	18.67	0.00000910	2.2	120932.124322
Manganese	0.0000018128	18.67	0.00000564	Not Available	No MoS calculated as no NOAEL available
Zinc	0.0000014502	18.67	0.00000451	15	1662035.497089
Magnesium	0.0000014502	18.67	0.00000451	299	33129907.575314

Product Name
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London
N18 1TP

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
Cobalt	0.0000014502	18.67	0.00000451	3	332407.099418
Barium	0.0000010877	18.67	0.00000338	0.21	31024.662612
Selenium and its compounds	0.0000009064	18.67	0.00000282	0.4	70913.514542
Copper	0.0000008399	18.67	0.00000261	0.1	19130.64915
Calcium	0.0000007251	18.67	0.00000226	Not Available	No MoS calculated as no NOAEL available
Tin	0.0000004774	18.67	0.00000149	1000	336593278.119666
Benzene	0.0000002225	18.67	0.00000069	100	72213375.218
Antimony and its compounds	0.0000001813	18.67	0.00000056	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
Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

Manufacturer
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N18 1TP

LITERATURE SOURCES

Agency for Toxic Substances and Disease Registry (ATSDR)	**Accessed Date:**	23/12/2022
https://www.atsdr.cdc.gov/toxprofiles/tp46-c2.pdf		
Amendments to Annex 2 UK (prohibited substances)	**Accessed Date:**	23/12/2022
https://members.wto.org/crnattachments/2022/TBT/GBR/22_2823_00_e.pdf		
Annex II, IV and VI amendment	**Accessed Date:**	23/12/2022
https://members.wto.org/crnattachments/2020/TBT/EEC/20_6954_01_e.pdf		
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:**	03/01/2023
https://members.wto.org/crnattachments/2020/TBT/EEC/20_2471_01_e.pdf		
Annex XVII REACH	**Accessed Date:**	23/12/2022
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20221217&from=EN		
Assembly Bill A6295A	**Accessed Date:**	23/12/2022
https://www.nysenate.gov/legislation/bills/2019/a6295/amendment/a		
ATSDR	**Accessed Date:**	13/01/2023
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Manufacturer
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Product Name
Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

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

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Product Name
Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

Manufacturer
Eresos Health + Wellbeing LTD
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Product Name
Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

Manufacturer
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Product Name
Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

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

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Product Name
Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

Manufacturer
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Product Name
Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

Manufacturer
Eresos Health + Wellbeing LTD
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Product Name
Cocoa Hand & Body Butter 2000mg (2022-753-5050) (variant) CPSR EU/UK passed under condition

Manufacturer
Eresos Health + Wellbeing LTD
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Medical Devices Directive	**Accessed Date:**	23/12/2022
https://echa.europa.eu/pl/eu-medical_devices-anx_i_7_8		
MedScape	**Accessed Date:**	23/12/2022
https://www.medscape.com/viewarticle/730097_4		
Molbase	**Accessed Date:**	23/12/2022
http://www.molbase.com/en/1350472-07-9-moldata-2554974.html#tabs		
NAP	**Accessed Date:**	03/01/2023
https://www.nap.edu/read/11778/chapter/5		
National Institutes of Health	**Accessed Date:**	03/01/2023
https://ods.od.nih.gov/factsheets/Magnesium-HealthProfessional/		
National Toxicology Program (NTP)	**Accessed Date:**	23/12/2022
https://pubchem.ncbi.nlm.nih.gov/compound/962		
NCBI	**Accessed Date:**	23/12/2022
https://pubchem.ncbi.nlm.nih.gov/compound/1105		
NCBI	**Accessed Date:**	10/01/2023
https://pubchem.ncbi.nlm.nih.gov/compound/26346		

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NCBI	**Accessed Date:**	09/01/2023
https://pubchem.ncbi.nlm.nih.gov/compound/Acrylic-acid		
NCBI	**Accessed Date:**	23/12/2022
https://www.ncbi.nlm.nih.gov/books/NBK537009/		
NCBI	**Accessed Date:**	23/12/2022
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5537768/		
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NICNAS	**Accessed Date:**	10/01/2023
https://www.industrialchemicals.gov.au/chemicals/aloe-vera-ext		
NICNAS	**Accessed Date:**	23/12/2022
https://www.industrialchemicals.gov.au/chemicals/copper		
NICNAS	**Accessed Date:**	23/12/2022
https://www.industrialchemicals.gov.au/search-inventory?casnumber=56-81-5		
NICNAS	**Accessed Date:**	10/01/2023
https://www.industrialchemicals.gov.au/search-inventory?casnumber=68439-49-6		
Notified classification and labelling	**Accessed Date:**	23/12/2022
https://echa.europa.eu/pl/information-on-chemicals/cl-inventory-database/-/discli/details/34271		
Official Journal (OJ)	**Accessed Date:**	23/12/2022
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Patent	**Accessed Date:**	23/12/2022
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PubChem	**Accessed Date:**	23/12/2022
https://pubchem.ncbi.nlm.nih.gov/compound/104730		
PubChem	**Accessed Date:**	23/12/2022
https://pubchem.ncbi.nlm.nih.gov/compound/1049		
PubChem	**Accessed Date:**	23/12/2022
https://pubchem.ncbi.nlm.nih.gov/compound/174		
PubChem	**Accessed Date:**	03/01/2023
https://pubchem.ncbi.nlm.nih.gov/compound/23925		
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https://pubchem.ncbi.nlm.nih.gov/compound/23930#section=2D-Structure		
PubChem	**Accessed Date:**	23/12/2022
https://pubchem.ncbi.nlm.nih.gov/compound/23931		
PubChem	**Accessed Date:**	23/12/2022
https://pubchem.ncbi.nlm.nih.gov/compound/23973		
PubChem	**Accessed Date:**	23/12/2022
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https://pubchem.ncbi.nlm.nih.gov/compound/23978#section=Mechanism-of-Action		
PubChem	**Accessed Date:**	03/01/2023
https://pubchem.ncbi.nlm.nih.gov/compound/23994		
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https://pubchem.ncbi.nlm.nih.gov/compound/241#section=Experimental-Properties		
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PubChem	**Accessed Date:**	23/12/2022
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PubChem	**Accessed Date:**	13/01/2023
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PubChem	**Accessed Date:**	23/12/2022
https://pubchem.ncbi.nlm.nih.gov/compound/8117		
PubChem	**Accessed Date:**	23/12/2022
https://pubchem.ncbi.nlm.nih.gov/compound/935		
PubChem	**Accessed Date:**	23/12/2022
https://pubchem.ncbi.nlm.nih.gov/compound/996		
PubChem	**Accessed Date:**	23/12/2022
https://pubchem.ncbi.nlm.nih.gov/compound/Glyceryl-monostearate		
PubChem	**Accessed Date:**	03/01/2023
https://pubchem.ncbi.nlm.nih.gov/compound/Magnesium		
PubChem	**Accessed Date:**	03/01/2023
https://pubchem.ncbi.nlm.nih.gov/substance/349912580		
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https://pubmed.ncbi.nlm.nih.gov/31588615/		
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https://pubchem.ncbi.nlm.nih.gov/compound/8078		

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https://rais.ornl.gov/tox/profiles/chromium.html		
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ToxNet	**Accessed Date:**	10/01/2023
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Toy Directive	**Accessed Date:**	23/12/2022
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Vitamin E Toxicity	**Accessed Date:**	23/12/2022
https://www.ncbi.nlm.nih.gov/books/NBK564373/		
Water Activity in Glycerol–Water Mixtures	**Accessed Date:**	23/12/2022
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6839025/		
Water for Pharmacuetical Use	**Accessed Date:**	23/12/2022
https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-technical-guides/water-pharmacuetical-use		
Water Hazard Class (Germany)	**Accessed Date:**	23/12/2022
http://www.waproducts.co.uk/pdf/B28037.pdf		

Annex 1: Assessor Credentials

Curriculum Vitae

Agnieszka Teresa Nnolim

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

Employment

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

Qualification and Education

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

Skills and Expertise

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

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agnieszka.nnolim@nolichem.com / 0044(0)7883 751 622
www.nolichem.com

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

University Courses and Trainings (Selection)

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

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

Professional Membership

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

Languages

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

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Curriculum Vitae

Dominika Maria Warchołek, MSc, BSc

Professional Employment

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

Responsibilities:

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

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

Responsibilities:

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

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

Responsibilities:

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

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

Responsibilities:

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

Qualification and Education

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

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

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

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

Skills and Expertise

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

University Courses

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

Additionally:

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

Workshops and training in-house

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

Languages

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

Presentations in-house

- Cruelty-Free Certification – 14th January 2021

Publications in-house

- Dermatological tests of cosmetics – 13th April 2021

Conferences

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