eurofins | Consumer Product Testing

Laboratory Test Report

Report Number: 2022-753-5061

Prepared for:	Eresos Health + Wellbeing LTD
Address:	14 A Commercial Road London N18 1TP
Customer Sample Description:	Active Muscle Therapy Balm 1000mg
Eurofins Registration Number:	2022-753-5061
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)

GMae LL

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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.

Eurofins Product Testing Services Limited
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Tel: +44 (0)161 868 7600
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i54 Business Park, Valiant Way
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Vat Number: 887 1276 83

Job No	**NCH1140**
Report No	**008259**
Issue Date	**23/01/2023**
Version No	**1**

Product Name

Active Muscle Therapy Balm 1000mg (2022-753-5061) (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:	2022-753-5061
Client Name:	Eurofins Consumer Product Testing Services
Contact Name:	Georgia Lees-Lowe

PRODUCT CHARACTERISTICS

Product Group:	Body balm
Type Of Product:	Leave On
Physical State:	Gel
Nominal Size:	95g
Type Of Package:	PP airless bottle with pump

PHYSICAL/CHEMICAL CHARACTERISTICS

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

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DOCUMENT CONTENT

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

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Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

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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	90.909	None
Vitis Vinifera (Grape) Seed Oil	85594-37-2(84929-27-1)8024-22-4	4.6851	None
Helianthus Annuus (Sunflower) Seed Oil	8001-21-6	3.1464	None
Glycerin	56-81-5	1.183	None
Cannabidiol (CBD)	13956-29-1	1.100	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).
Phenoxyethanol	122-99-6	0.91	1%
Ethylhexylglycerin	70445-33-9	0.91	None
Carbomer	9007-20-9(9003-01-4)76050-42-5(9062-04-8)9007-16-3(9007-17-4)	0.637	None
Eucalyptus Globulus Leaf Oil (Naturallythinking)	8000-48-4	0.5	Allergens declaration as required Proposed from 2023: The presence of the substance or substances shall be indicated as 'Eucalyptus Globulus Oil' in the list of ingredients referred to in Article 19(1), point (g), when the concentration of the substance or substances exceeds: - 0,001 % in leave-on products, - 0,01 % in rinse-off products.
Melaleuca Alternifolia Leaf Oil (Naturallythinking)	68647-73-4(85085-48-9)8022-72-8	0.5	Allergens declaration as required
Polysorbate 20	9005-64-5	0.455	None
Aloe Barbadensis Leaf Juice Powder	85507-69-3(94349-62-9)	0.455	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
Fucus Vesiculosus Extract	84696-13-9	0.273	None
Salvia Sclarea (Sage) Oil (naturallythinking)	8016-63-5(84775-83-7)	0.0345	Allergens declaration as required.
Salvia Officinalis Oil (naturallythinking)	8022-56-8(84776-73-8)	0.0345	Allergens declaration as required
Mentha Piperita (Peppermint) Oil (naturallythinking)	8006-90-4(84082-70-2)	0.022	Allergens declaration as required Proposed from 2023: The presence of the substance shall be indicated in the list of ingredients referred to in Article 19(1), point (g), when its concentration exceeds: - 0,001 % in leave-on products - 0,01 % in rinse-off products.
Citrus Grandis (Grapefruit) Peel Oil (naturallythinking)	90045-43-5(8016-20-4)	0.022	Prohibited Furocoumarines (e.g. trioxysalen (INN), 8-methoxypsoralen, 5-methoxypsoralen) except for normal content in natural essences used. In sun protection and in bronzingproducts, furocoumarines shall be below 1 mg/kg
Lavandula Angustifolia Flower Oil (naturallythinking)	90063-37-9	0.0207	Allergens declaration as required.
Rosmarinus Officinalis Leaf Oil (naturallythinking)	84604-14-8(8000-25-7)	0.0207	Allergens declaration as required.
Piper Nigrum Fruit Oil (naturallythinking)	84929-41-9	0.0207	Allergens declaration as required
Tocopheryl Acetate	7695-91-2(58-95-7)	0.0207	None

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PERFUME OR AROMATIC COMPOSITIONS

SED Product = 1.19144863 mg / cm2

Perfume	Name / Code : Eucalyptus Globulus Leaf Oil (Naturallythinking) (Supplier : Naturallythinking)					
Allergens Material	**Cas. No**	**Concentration in Perfume[%]**	***Safe Concentration[%]**	***SED Concentration [µg / cm2] for surface area**	**Final Product[%]**	**Mos**
d-Limonene ((R)-p-Mentha-1,8-diene; (4R)-1-Methyl-4-(1-methylethenyl) cyclohexene)	5989-27-5 (68606-81-5)138-86-3	13.000000	0.800	0.774442	0.065000	1291.252936

Perfume	Name / Code : Lavandula Angustifolia Flower Oil (naturallythinking) (Supplier : Naturallythinking)					
Allergens Material	**Cas. No**	**Concentration in Perfume[%]**	***Safe Concentration[%]**	***SED Concentration [µg / cm2] for surface area**	**Final Product[%]**	**Mos**
Linalool (1,6-Octadien-3-ol, 3,7-dimethyl-)	78-70-6	45.000000	0.800	0.110983	0.009315	4971.011905
Geraniol	106-24-1	2.940000	0.600	0.007251	0.000609	55165.428252
d-Limonene ((R)-p-Mentha-1,8-diene; (4R)-1-Methyl-4-(1-methylethenyl) cyclohexene)	5989-27-5 (68606-81-5)138-86-3	1.000000	0.800	0.002466	0.000207	405465.897653
Eugenol	97-53-0	0.004800	0.800	0.000012	0.000001	49889199.825077

Perfume	Name / Code : Melaleuca Alternifolia Leaf Oil (Naturallythinking) (Supplier : Naturallythinking)					
Allergens Material	**Cas. No**	**Concentration in Perfume[%]**	***Safe Concentration[%]**	***SED Concentration [µg / cm2] for surface area**	**Final Product[%]**	**Mos**
d-Limonene ((R)-p-Mentha-1,8-diene; (4R)-1-Methyl-4-(1-methylethenyl) cyclohexene)	5989-27-5 (68606-81-5)138-86-3	4.000000	0.800	0.238290	0.020000	4196.572041

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PERFUME OR AROMATIC COMPOSITIONS

SED Product = 1.19144863 mg / cm2

Perfume	Name / Code : Mentha Piperita (Peppermint) Oil (naturallythinking) (Supplier : Naturallythinking)					
Allergens Material	**Cas. No**	**Concentration in Perfume[%]**	***Safe Concentration[%]**	***SED Concentration [µg / cm2] for surface area**	**Final Product[%]**	**Mos**
d-Limonene ((R)-p-Mentha-1,8-diene; (4R)-1-Methyl-4-(1-methylethenyl) cyclohexene)	5989-27-5 (68606-81-5)138-86-3	5.000000	0.800	0.013106	0.001100	76301.309831

Perfume	Name / Code : Piper Nigrum Fruit Oil (naturallythinking) (Supplier : Naturallythinking)					
Allergens Material	**Cas. No**	**Concentration in Perfume[%]**	***Safe Concentration[%]**	***SED Concentration [µg / cm2] for surface area**	**Final Product[%]**	**Mos**
d-Limonene ((R)-p-Mentha-1,8-diene; (4R)-1-Methyl-4-(1-methylethenyl) cyclohexene)	5989-27-5 (68606-81-5)138-86-3	17.000000	0.800	0.041927	0.003519	23850.935156
Linalool (1,6-Octadien-3-ol, 3,7-dimethyl-)	78-70-6	1.000000	0.800	0.002466	0.000207	223695.535735

Perfume	Name / Code : Rosmarinus Officinalis Leaf Oil (naturallythinking) (Supplier : Naturallythinking)					
Allergens Material	**Cas. No**	**Concentration in Perfume[%]**	***Safe Concentration[%]**	***SED Concentration [µg / cm2] for surface area**	**Final Product[%]**	**Mos**
d-Limonene ((R)-p-Mentha-1,8-diene; (4R)-1-Methyl-4-(1-methylethenyl) cyclohexene)	5989-27-5 (68606-81-5)138-86-3	3.000000	0.800	0.007399	0.000621	135155.299218
Linalool (1,6-Octadien-3-ol, 3,7-dimethyl-)	78-70-6	2.000000	0.800	0.004933	0.000414	111847.767868
Eugenol	97-53-0	1.000000	0.800	0.002466	0.000207	239468.159154

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PERFUME OR AROMATIC COMPOSITIONS

SED Product = 1.19144863 mg / cm2

Perfume	Name / Code : Salvia Officinalis Oil (naturallythinking) (Supplier : Naturallythinking)					
Allergens Material	**Cas. No**	**Concentration in Perfume[%]**	***Safe Concentration[%]**	***SED Concentration [µg / cm2] for surface area**	**Final Product[%]**	**Mos**
Linalool (1,6-Octadien-3-ol, 3,7-dimethyl-)	78-70-6	24.000000	0.800	0.098652	0.008280	5592.388393
Geraniol	106-24-1	2.200000	0.600	0.009043	0.000759	44232.64338
d-Limonene ((R)-p-Mentha-1,8-diene; (4R)-1-Methyl-4-(1-methylethenyl) cyclohexene)	5989-27-5 (68606-81-5)138-86-3	1.000000	0.800	0.004110	0.000345	243279.538592

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

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

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

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STABILITY OF THE COSMETIC PRODUCT

PRODUCT STABILITY:

The product underwent 6-months stability testing and was monitored for changes in the product appearance and colour at the ambient temperature conditions. The test report showed no significant changes to the product. The samples passed the manufacturer's stability criteria.

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: 9 months from manufacturing

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MICROBIOLOGICAL QUALITY

MESOPHILIC AEROBIC BACTERIA COUNT: < 10 cfu/g

YEAST AND MOULDS: < 10 cfu/g

PATHOGENS: Absent in 1g

CHALLENGE TEST:

The samples of the muscle massage oil 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 balm intended for use by adults.

EXPOSURE TO THE Cosmetic PRODUCT

The site(s) of application:	Body
The surface area(s) of application:	15670 cm^2
The amount of product applied:	18.67 g
Exposure time:	Leave On
The duration and frequency of use:	Twice per day
The normal and reasonably foreseeable exposure route(s):	Skin.
The targeted (or exposed) population(s):	16+

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

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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	90.909000	18.67	100.000	282.87850500	Not available	No MoS calculated as no NOAEL available
Vitis Vinifera (Grape) Seed Oil	4.685100	18.67	100.000	14.57846950	Not available	No MoS calculated as no NOAEL available
Helianthus Annuus (Sunflower) Seed Oil	3.146400	18.67	100.000	9.79054800	Not available	No MoS calculated as no NOAEL available
Glycerin	1.183000	18.67	100.000	3.68110167	5040	1369.155339
Cannabidiol (CBD)	1.100000	18.67	100.000	3.42283333	Not available	No MoS calculated as no NOAEL available
Phenoxyethanol	0.910000	18.67	90.000	2.54845500	500	196.197304
Ethylhexylglycerin	0.910000	18.67	10.500	0.29732374	Not available	No MoS calculated as no NOAEL available
Carbomer	0.637000	18.67	100.000	1.98213167	Not available	No MoS calculated as no NOAEL available
Melaleuca Alternifolia Leaf Oil (Naturallythinking)	0.500000	18.67	100.000	1.55583333	Not available	No MoS calculated as no NOAEL available
Eucalyptus Globulus Leaf Oil (Naturallythinking)	0.500000	18.67	100.000	1.55583333	Not available	No MoS calculated as no NOAEL available
Polysorbate 20	0.455000	18.67	100.000	1.41580833	Not available	No MoS calculated as no NOAEL available
Aloe Barbadensis Leaf Juice Powder	0.455000	18.67	100.000	1.41580833	Not available	No MoS calculated as no NOAEL available
Fucus Vesiculosus Extract	0.273000	18.67	100.000	0.84948500	Not available	No MoS calculated as no NOAEL available

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INCI / Chemical Name	Concentration in finished product [C %]	* Daily exposure of product (a g/day)	**Dermal Absorption (Dap %)	***Systemic Exposure Dose (SED mg/kg bw/ day)	NOAELs (mg/kg bw/day)	MoS
d-Limonene ((R)-p-Mentha-1,8-diene; (4R)-1-Methyl-4-(1-methylethenyl)cyclohexene)	0.091137	18.67	100.000	0.28358797	Not available	No MoS calculated as no NOAEL available
Salvia Sclarea (Sage) Oil (naturallythinking)	0.034500	18.67	100.000	0.10735250	Not available	No MoS calculated as no NOAEL available
Salvia Officinalis Oil (naturallythinking)	0.034500	18.67	100.000	0.10735250	Not available	No MoS calculated as no NOAEL available
Linalool (1,6-Octadien-3-ol, 3,7-dimethyl-)	0.026496	18.67	100.000	0.08244672	250	3032.26132
Mentha Piperita (Peppermint) Oil (naturallythinking)	0.022000	18.67	100.000	0.06845667	Not available	No MoS calculated as no NOAEL available
Citrus Grandis (Grapefruit) Peel Oil (naturallythinking)	0.022000	18.67	100.000	0.06845667	Not available	No MoS calculated as no NOAEL available
Tocopheryl Acetate	0.020700	18.67	100.000	0.06441150	Not available	No MoS calculated as no NOAEL available
Rosmarinus Officinalis Leaf Oil (naturallythinking)	0.020700	18.67	100.000	0.06441150	Not available	No MoS calculated as no NOAEL available
Piper Nigrum Fruit Oil (naturallythinking)	0.020700	18.67	100.000	0.06441150	Not available	No MoS calculated as no NOAEL available
Lavandula Angustifolia Flower Oil (naturallythinking)	0.020700	18.67	100.000	0.06441150	Not available	No MoS calculated as no NOAEL available
Geraniol	0.002127	18.67	100.000	0.00661721	300	45336.340563
Eugenol	0.000208	18.67	100.000	0.00064721	Not available	No MoS calculated as no NOAEL available

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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

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

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EXPOSURE TO THE SUBSTANCES (DERMAL) - ALLERGEN SUMMARY

SED Product = 311.166667 mg / kg bw / day

INCI / Chemical Name	Concentration in finished product [C %]	* Daily exposure of product (a g/day)	**Dermal Absorption (Dap %)	***Systemic Exposure Dose (SED mg/kg bw/ day)	NOAELs (mg/kg bw/day)	MoS
d-Limonene ((R)-p-Mentha-1,8-diene; (4R)-1-Methyl-4-(1-methylethenyl)cyclohexene)	0.091137	18.67	100.000	0.28358797	Not available	No MoS calculated as no NOAEL available
Linalool (1,6-Octadien-3-ol, 3,7-dimethyl-)	0.026496	18.67	100.000	0.08244672	250	3032.26132
Geraniol	0.002127	18.67	100.000	0.00661721	300	45336.340563
Eugenol	0.000208	18.67	100.000	0.00064721	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	90.909000	18.67	282.87850500	Not Available	No MoS calculated as no NOAEL available
Vitis Vinifera (Grape) Seed Oil	4.685100	18.67	14.57846950	Not Available	No MoS calculated as no NOAEL available
Helianthus Annuus (Sunflower) Seed Oil	3.146400	18.67	9.79054800	Not Available	No MoS calculated as no NOAEL available
Glycerin	1.183000	18.67	3.68110167	8000	1086.631221
Cannabidiol (CBD)	1.100000	18.67	3.42283333	Not Available	No MoS calculated as no NOAEL available
Phenoxyethanol	0.910000	18.67	2.83161667	369	65.157125
Ethylhexylglycerin	0.910000	18.67	2.83161667	50	8.828879
Carbomer	0.637000	18.67	1.98213167	40	10.090147
Melaleuca Alternifolia Leaf Oil (Naturallythinking)	0.500000	18.67	1.55583333	45	14.461703
Eucalyptus Globulus Leaf Oil (Naturallythinking)	0.500000	18.67	1.55583333	300	96.411355
Polysorbate 20	0.455000	18.67	1.41580833	5000	1765.775735
Aloe Barbadensis Leaf Juice Powder	0.455000	18.67	1.41580833	Not Available	No MoS calculated as no NOAEL available
Fucus Vesiculosus Extract	0.273000	18.67	0.84948500	Not Available	No MoS calculated as no NOAEL available
d-Limonene ((R)-p-Mentha-1,8-diene; (4R)-1-Methyl-4-(1-methylethenyl)cyclohexene)	0.091137	18.67	0.28358797	825	1454.575126
Salvia Sclarea (Sage) Oil (naturallythinking)	0.034500	18.67	0.10735250	Not Available	No MoS calculated as no NOAEL available
Salvia Officinalis Oil (naturallythinking)	0.034500	18.67	0.10735250	Not Available	No MoS calculated as no NOAEL available
Linalool (1,6-Octadien-3-ol, 3,7-dimethyl-)	0.026496	18.67	0.08244672	160	970.323622
Mentha Piperita (Peppermint) Oil (naturallythinking)	0.022000	18.67	0.06845667	400	2921.556216
Citrus Grandis (Grapefruit) Peel Oil (naturallythinking)	0.022000	18.67	0.06845667	Not Available	No MoS calculated as no NOAEL available
Tocopheryl Acetate	0.020700	18.67	0.06441150	800	6210.071183

Product Name
Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

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

EXPOSURE TO THE SUBSTANCES (ORAL)

SED Product = 311.166667 mg / kg bw / day

INCI / Chemical Name	Concentration in finished product [C %]	* Daily exposure of product (a g/day)	***Systemic Exposure Dose (SED mg/kg bw/ day)	NOAELs (mg/kg bw/day)	MoS
Rosmarinus Officinalis Leaf Oil (naturallythinking)	0.020700	18.67	0.06441150	300	2328.776694
Piper Nigrum Fruit Oil (naturallythinking)	0.020700	18.67	0.06441150	Not Available	No MoS calculated as no NOAEL available
Lavandula Angustifolia Flower Oil (naturallythinking)	0.020700	18.67	0.06441150	160	1242.014237
Geraniol	0.002127	18.67	0.00661721	550	41558.312183
Eugenol	0.000208	18.67	0.00064721	79.3	61263.26692

*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
Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

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

EXPOSURE TO THE SUBSTANCES (ORAL) - ALLERGEN SUMMARY

SED Product = 311.166667 mg / kg bw / day

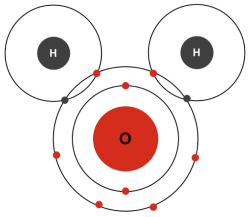
INCI / Chemical Name	Concentration in finished product [C %]	* Daily exposure of product (a g/day)	***Systemic Exposure Dose (SED mg/kg bw/ day)	NOAELs (mg/kg bw/day)	MoS
d-Limonene ((R)-p-Mentha-1,8-diene; (4R)-1-Methyl-4-(1-methylethenyl)cyclohexene)	0.091137	18.67	0.28358797	825	1454.575126
Linalool (1,6-Octadien-3-ol, 3,7-dimethyl-)	0.026496	18.67	0.08244672	160	970.323622
Geraniol	0.002127	18.67	0.00661721	550	41558.312183
Eugenol	0.000208	18.67	0.00064721	79.3	61263.26692

*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

Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

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

Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Vitis Vinifera (Grape) Seed Oil (Emollient,Skin Conditioning)
EU INCI: Vitis Vinifera Seed Oil.
CTFA INCI: Vitis Vinifera (Grape) Seed Oil.
CNDA INCI: Vitis Vinifera (Grape) Seed Oil.
Chinese: 葡萄(VITIS VINIFERA)籽油.
Trade Name: Grape Seed Oil.
CAS Number: 85594-37-2(84929-27-1)8024-22-4.
EINECS Number: 287-896-9 / 284-511-6 /.
Description: Vitis Vinifera Seed Oil is the fixed oil, consisting primarily of the glycerides of the fatty acids, obtained by pressing the seeds of the Grape, Vitis Vinifera L., Vitaceae

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Mild odor
Specific Gravity: 0.913-0.930 g/cm3
Water Solubility: Insoluble
Boiling Point: 230˚C
Particle Size: The non-solid or granular form does not require the particle size distribution study.
Colour: Pale yellowish green to green
Density: 0.915 - 0.925 @ 20°C
Flash Point: 310 °C
Physical State: Liquid.

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

TOXICITY REVIEW
General Toxicity Review: Grape seed oil is a well-known substance used also in food industry. The substance is not associated with the skin sensitisation, skin and eye irritation. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is considered to be safe when used as intended.

TOXICOLOGICAL PROFILE
Eye Irritation: Based on the available toxicological data there is no evidence of eye irritation or corrosivity potential.
NOAEL Oral: The NOAEL value was not found, however, based on a history of safe use, this chemical material is considered safe for use in cosmetics. The chemical is unlikely to produce systemic toxicity following skin contact. In conclusion, at the given concentration in the final product, the ingredient is not considered to be of toxicological concern when used as intended.
Skin Irritation: Based on the available toxicological data there is no evidence of skin irritation potential.
Skin Sensitisation: Based on the available toxicological data there is no evidence of skin allergy potential.
Allergens Patch Test: Human Patch tests show no signs of irritation or sensitivity. HRIPTs of several products containing: 39% of the substance ina preshave lotion; 90% of the subsance in a fragranced oil were conducted. There was no skin irritation or sensitisation observed. (CIR)
Carcinogenicity: Not associated with carcinogenic, mutagenic and reprotoxic (CMR) chemicals.

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

Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

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

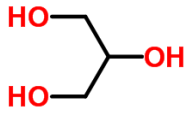
TOXICITY REVIEW
General Toxicity Review: Sunflower seed oil is commonly used as emollient, masking and skin conditioning. There is no evidence of skin or eyes irritation or skin sensitisation potential. The ingredient characteristic suggests that interactions of the material with other substances would 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.

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.

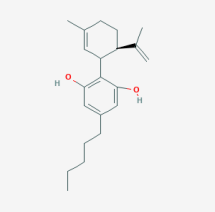
OTHER
Biodegradability (Environmental): Readily biodegradable in water. The study was conducted using industrial activated sludge. The substance was almost completely degraded within 24h. (ECHA)
LC50 (Environmental): Fish: LC50 fathead minnow >885 mg/L – 96h (Polyol 80 contained 86% glycerol); LC50 Cyprinodon 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

Active Muscle Therapy Balm 1000mg (2022-753-5061) (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).

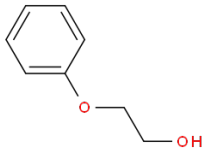
TOXICITY REVIEW
General Toxicity Review: Cannabidiol is suspected of damaging fertility or the unborn child. Cannabidiol (CBD) as such, irrespective of its source, is not listed in the Schedules of the 1961 Single Convention on Narcotic Drugs. However, it shall be prohibited from use in cosmetic products (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.

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)

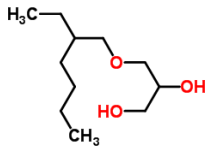
Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Active Muscle Therapy Balm 1000mg (2022-753-5061) (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

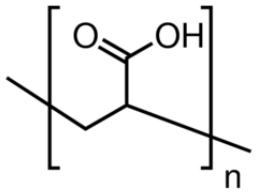
TOXICITY REVIEW
General Toxicity Review: The chemical is known deodorant and skin conditioner. Data derived in vivo (animal data) showed that ethylhexylglycerin is slightly irritating to skin and does not have sensitising properties. Ocular irritation potential study showed that the substance causes 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.

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)

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Melaleuca Alternifolia Leaf Oil (Naturallythinking) (Perfuming,Antioxidant)
EU INCI: Melaleuca Alternifolia Leaf Oil.
CTFA INCI: Melaleuca Alternifolia Leaf Oil.
Trade Name: AUSTRALIAN TEA TREE OIL.
CAS Number: 68647-73-4(85085-48-9)8022-72-8.
EINECS Number: 285-377-1.
Description: Melaleuca Alternifolia Leaf Oil is the oil distilled from the leaves of the Tea Tree, Melaleuca alternifolia, Myrtaceae

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Characteristic, earthy, aromatic, myristic
Specific Gravity: 0.885- 0.906 at 20°C
Viscosity: 1.52-2.54 (cSt)
Water Solubility: Insoluble
Boiling Point: 165 °C (329 °F)
Colour: Colourless to pale yellow
Density: 0.898 g/cm3 at 25 °C (77 °F)
Flammability: Flammable
Flash Point: 57°C (Pensky Martens Closed Cup Method)
Vapour Pressure: 2.1 kPa
Microbiological stability: Total Plate Count < 1,000cfu/g Mold and Yeast < 100cfu/g
Physical State: Liquid.

REGULATORY REQUIREMENTS
IFRA Standard: IFRA class 1 to 10 with maximum concentration 10%
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: H226: Flammable liquid and vapour. H315: Causes skin irritation. H302: Harmful if swallowed. H304: May be fatal if swallowed and enters airways. H332: Harmful if inhaled. H411: Toxic to aquatic life with long lasting effects. Self classified: H317 May cause an allergic skin reaction. H319 Causes serious eye irritation..
Region : Europe Type : Cosmetic Restriction : Allergens declaration as required
Region : UK Type : Cosmetic Restriction : Allergens declaration as required.

TOXICITY REVIEW
General Toxicity Review: Melaleuca Alternifolia Leaf Oil is commonly used as fragrance component. It causes skin irritation and mild irritation to eyes. The substance is not associated with skin sensitisation. It shows low oral and dermal toxicity with respectively LD50 1 691 mg/kg bw and LD50 > 2 000 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: 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 and EU Method B.5; Species: rabbits; Report date: 2013; Source: ECHA.
Genotoxicity: In vitro: negative (Chinese hamster lung fibroblasts (V79)) (ECHA)
LD50: LD50 (Dermal, rabbits) >2000 mg/kg (Sigma Aldrich: 5000 mg/kg) LD50 (Oral, rat) 1900 mg/kg LD50 (oral, SPF rats) 2.6 mL/kg bw; LD50 (oral, non-SPF rats) 1.9 ml/kg bw. (equivalent to 1 691 mg/kg bw) Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity of the substance. LC50 (inhalation, rat) 4 780 mg/m³ air Description: The substance when tested for acute toxicity via inhalation was found to be slightly-toxic. LD50 (dermal, rabbit) > 2 000 mg/kg bw Description: Acute toxicity studies via dermal route of exposure in rabbits showed that the substance has low skin toxicity. (ECHA)
Mutagenicity: Not mutagenic by the ames test
NOAEL Oral: NOAEL 45 mg/kg/day. Study type Repeated dose toxicity. Endpoints: sub-chronic toxicity. Route of administration: oral. Species: rat. Methods: OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity Study in Rodents). Report date: 2017. Source: ECHA. MoS was calculated based on this data.
Read-across: Not susceptible to microbiological contamination
Skin Irritation: The substance was tested in vivo to examine skin irritation potential. Results: Irritation reactions were observed on both intact and abraded skin after treatment with the test sample. Endpoint: The substance was found to be irritating to the skin. Method: according to OECD Guideline 404 and EU Method B.4 semiocclusive coverage; Species: rabbits; Report date: 1989; 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: Guinea pig maximisation test; Species: guinea pig; Report date:1989; Source: ECHA.

OTHER
Biodegradability (Environmental): Biodegradation in water. Results: 82.8% degradation (CO2 evolution) after 28 days. Conclusion: readily biodegradable (OECD Guideline 310 (Ready Biodegradability - CO2 in Sealed Vessels (Headspace Test). Source: ECHA
LC50 (Environmental): EC50 Raphidocelis subcapitata, 35.9 mg/L, 96h (EU-method C.3 and OECD guideline 201) (ECHA)

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

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Eucalyptus Globulus Leaf Oil (Naturallythinking) (Perfuming,Skin Conditioning)
EU INCI: Eucalyptus Globulus Leaf Oil.
CTFA INCI: Eucalyptus Globulus Leaf Oil.
CNDA INCI: Eucalyptus Globulus Leaf Oil.
CAS Number: 8000-48-4.
EINECS Number: -.
Description: Eucalyptus Globulus Leaf Oil is the volatile oil obtained from the fresh leaves of the Eucaluptus, Eucalyptus globulus and other species of Eucalyptus, Myrtaceae. Syn. Yuukari Yu (Japanese).Eucalyptus oil is obtained by tesifying the oil distilled from leaves of various species of Eucalyptus. The major active ingredient is cineole (eucalyptol). Medicinal eucalyptus oil contains not less than 70 % W/W of cineole; it also contains pinene and other terpenes and may contain small quantities of phellandrene (Reynolds, 1982).

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Fresh, penetrating, reminding of cineol
Specific Gravity: 0.905-0.925 at 20°C
Water Solubility: Insoluble
Boiling Point: 176°C to 177°C
Colour: Colourless to yellow.
Density: 0.915 at 20°C
Flammability: Flammable liquid and vapour.
Flash Point: 47°C (closed cup)
Physical State: Liquid.

REGULATORY REQUIREMENTS
Labelling Requirements: Proposed from 2023: The presence of the substance or substances shall be indicated as 'Eucalyptus Globulus Oil' in the list of ingredients referred to in Article 19(1), point (g), when the concentration of the substance or substances exceeds: - 0,001 % in leave-on products, - 0,01 % in rinse-off products..
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI. Fragrance composition contains hazardous substances classified as H317 - May cause an allergic skin reaction. Concerning the requirements of the CLP Regulation (Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures), the label on the packaging of mixtures that are not classified as sensitising but containing at least one substance classified as sensitising and present in a concentration equal to or greater than that specified in Annex I of the CLP shall bear the statement: 'Contains (name of sensitising substance). May produce an allergic reaction'.
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
Regulatory Controls: Proposed restrictions as per the EC public consultation published on 18th March 2019; When its concentration exceeds:- 0,001 % in leave-on products- 0,01 % in rinse-off products the presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g).
GHS Classification: H226 Flammable liquid and vapour, H304 May be fatal if swallowed and enters airways, H315 Causes skin irritation, H317 May cause an allergic skin reaction. Self classified: H411 Toxic to aquatic life with long-lasting effects..
Region : Europe Type : Cosmetic Restriction : Allergens declaration as required Label Review : Proposed from 2023: The presence of the substance or substances shall be indicated as 'Eucalyptus Globulus Oil' in the list of ingredients referred to in Article 19(1), point (g), when the concentration of the substance or substances exceeds: - 0,001 % in leave-on products, - 0,01 % in rinse-off products.
Region : UK Type : Cosmetic Restriction : Allergens declaration as required

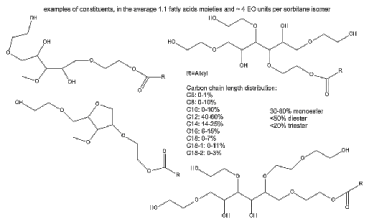
TOXICITY REVIEW
General Toxicity Review: Eucalyptus Globulus Leaf Oil is the volatile oil obtained from the fresh leaves of the Eucaluptus. The substance is not associated with the eyes irritation. However, data derived from animal studies demonstrate that the substance is irritating and sensitising to the skin. It shows low acute toxicity with LD50 above 2500 mg/kg bw and practically non above 5000 mg/kg bw in oral and dermal route of exposure, respectively. Repeated dose toxicity study was conducted and the NOAEL was determined to be around 300 mg/kg bw for rats and therefore it is considered as moderately systemic toxic oral route of administration. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is considered to be safe when used as intended.

TOXICOLOGICAL PROFILE
Eye Irritation: The eyes of New Zealand White rabbits were treated by the substance. After 72 hours' observation all treated eyes appeared normal. Based on the results, the substance is classified as not irritating to eyes (ECHA).
Genotoxicity: In vitro: negative (S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and E. coli WP2) (ECHA)
Inhalation: Inhalation of the liquid or aerosol can be directly toxic to the lungs. No data available on systemic absorption via the lungs in humans.
LD50: LD50 (oral, rat) > 2500 mg/kg bw. LD50 (dermal, rabbit) > 5000 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 occlusive type of coverage showed that the substance has practically non skin toxicity. (ECHA)
NOAEL Oral: NOAEL 300 mg/kg bw. Study type: repeated dose toxicity. Endpoint: short-term repeated dose toxicity. 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.
Repeated Dose Toxicity: Chronic effects have not been reported.
ADME (Absorption, Distribution, Metabolism, Excretion): Well absorped orally. Gastrointestinal absorption is rapid. It is lipid soluble and absorption is likely to be enhanced with foods such as milk. It is excreted via the lungs, urine, skin and faeces (MacPherson, 1925).
Skin Irritation: Causes skin irritation. The decision of classification as skin irritant was based on existing data on constituents (additivity principles): the registered substance has more than 10% of its constituents classified as Skin irritant Category 2 and should be classified as a skin irritant without further testing according to the rules for classification of mixtures of Regulation (EC) No 1272/2008 (ECHA).
Skin Sensitisation: May cause an allergic skin reaction. The registered substance has not been tested itself in appropriate in vitro or in vivo tests but some of its constituents are classified as skin sensitisers Cat.1B and are all potentially present above the CLP generic concentration limit of 1% that triggers classification of the mixture (ECHA).

Product Name

Active Muscle Therapy Balm 1000mg (2022-753-5061) (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

Active Muscle Therapy Balm 1000mg (2022-753-5061) (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

Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Fucus Vesiculosus Extract (Emollient,Skin Conditioning,Smoothing,Soothing)
EU INCI: Fucus Vesiculosus Extract.
CTFA INCI: Fucus Vesiculosus Extract.
CAS Number: 84696-13-9.
EINECS Number: 283-633-7.
Description: Fucus Vesiculosus Extract is an extract of the dried thallus of the Bladderwrack (seaweed) Fucus vesiculosus L., Fucaceae

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
pH: 4.0 – 6.5
Particle Size: The non-solid or granular form does not require the particle size distribution study.
Colour: Yellow to ocher
Density: 1.020 – 1.080
Microbiological stability: Susceptible to microbiological contamination
Physical State: Liquid.

REGULATORY REQUIREMENTS
CITES (Trade in Endangered Species of Wild Fauna and Flora): Not Listed
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: Fucus Vesiculosus Extract is an extract of the dried thallus of the Bladderwrack (seaweed) Fucus vesiculosus L., Fucaceae. The available toxicological data demonstrate that there is no evidence of eye irritation or corrosivity potential of this ingredient. Moreover, there is no evidence of skin irritation potential. However, it may cause an allergic reaction. It has been recorded that some people may suffer from allergic reaction via oral exposure.

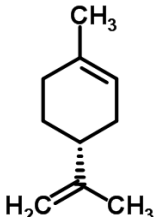
TOXICOLOGICAL PROFILE
AcuteToxicology: The extract of seaweed is of a low acute toxicity. Originally iodine was obtained from the Fucus vesiculosus in order to treat thyroid. It was however recorded that some individuals may suffer from an allergic reaction to the iodine from the seaweed .
Chronic Toxicity: NOAELs were not available. It is use in medicine to treat thyroid disorder.
Eye Irritation: Based on the available toxicological information, the substance has a low potential to cause eye irritation.
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 information, the substance has a low potential to cause skin irritation.
Skin Sensitisation: It may cause an allergic reaction. It has been recorded that some people may suffer from allergic reaction via oral exposure.
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

Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



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

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

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

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

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

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

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

Product Name

Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Salvia Sclarea (Sage) Oil (naturallythinking) (Masking,Tonic)
EU INCI: Salvia Sclarea Oil.
CTFA INCI: Sage oil.
CNDA INCI: Oils, clary sage.
CAS Number: 8016-63-5(84775-83-7).
EINECS Number: - / 283-911-8.
Description: Salvia Sclarea Oil is a volatile oil obtained from the Clary Sage, Salvia sclarea L., Lamiaceae

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Water Solubility: 20.12 mg/L at 25°C
Partial Coefficient logPow: log Pow= 3.93
Boiling Point: 189.2°C
Density: 0.897 g/cm³ at 20°C
Flash Point: 84.5 °C at 1013 hPa
Vapour Pressure: 14.8 Pa at 25°C
Physical State: Oil.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI.
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
Regulatory Controls: It is noted that the full composition of the fragrance and technical data haven't been disclosed and therefore the manufacture (responsible person) must ensure that the fragrance does not contain any materials which are prohibited or restricted for the intended use. The presence of the fragrance substance must be indicated in the list of ingredients referred to in Article 19(1)g when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products
GHS Classification: H317: May cause an allergic skin reaction. H412: Harmful to aquatic life with long lasting effects..
Region : Europe Type : Cosmetic Restriction : Allergens declaration as required.
Region : UK Type : Cosmetic Restriction : Allergens declaration as required.

TOXICITY REVIEW
General Toxicity Review: Salvia Sclarea Oil is commonly used as cosmetic substance. When it comes to local toxicity the substance does not induce or elicit skin allergy. Data derived from in vitro studies demonstrate that the substance is not irritating to eyes and skin. It shows low acute toxicity with LD50 of 5600 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: The substance was tested in vitro on EpiOcular cornea epithelial model to examine ocular irritation. The studies resulted in scoring the substance as non-irritating. (ECHA)
Genotoxicity: In vitro: negative (S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and E. coli WP2)
LD50: LD50 (Oral, rat) 5 600 mg/kg bw (OECD Guideline 401) (ref. ECHA)
NOAEL Oral: The NOAELs were not available in order to review however based on a history of safe use in consumer products this material is considered safe when used as intended. In conclusion, at the given concentration in the final product, the ingredient is not considered to be of toxicological concern when used as intended.
Skin Irritation: In vitro studies on EPISKIN reconstructed human epidermis were conducted. The substance was found to be not irritating. (ECHA)
Skin Sensitisation: Considered as moderate skin sensitiser. LLNA in vivo examinations were conducted, using mouse tests to find evidence for skin sensitisation. The test results showed that the substance is moderate skin sensitiser and classified as category 1B according to the GHS criteria. (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
Salvia Officinalis Oil (naturallythinking) (Masking,Tonic,Perfuming)
EU INCI: Salvia Officinalis Oil.
CTFA INCI: Salvia Officinalis Oil.
CAS Number: 8022-56-8(84776-73-8).
EINECS Number: - / 282-025-9.
Description: Salvia Officinalis Oil is the essential oil derived from the herbal plant the Sage, Salvia officinalis L., Lamiaceae

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Characteristic
Water Solubility: Partly soluble
Boiling Point: 189.3 °C at 101.3 kPa
Colour: Light yellow to yellow
Density: 0.915g/cm³ at 20 °C
Flammability: Flammable liquid and vapour.
Flash Point: 54 °C at 101 325 Pa
LogP Log Kow: Log Kow is in the range between 2.5 and 6.6 at 25°C
Physical State: Liquid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Not classified
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
GHS Classification: H304: May be fatal if swallowed and enters airways. H226: Flammable liquid and vapour. H315: Causes skin irritation. H371: May cause damage to organs. H317: May cause an allergic skin reaction. H412: Harmful to aquatic life with long lasting effects..
Region : Europe Type : Cosmetic Restriction : Allergens declaration as required
Region : UK Type : Cosmetic Restriction : Allergens declaration as required

TOXICITY REVIEW
General Toxicity Review: Salvia Officinalis Oil is the essential oil derived from the herbal plant the Sage, Salvia officinalis L., Lamiaceae. Data derived from animal studies demonstrate that the substance is not irritating to eyes. However, it may cause an allergic skin reaction and mild skin irritation. It shows low acute toxicity with LD50 2600 mg/kg bw in oral route of exposure. Overall, the ingredient is considered to be safe when used as intended.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vitro to examine ocular irritation potential. Endpoint: under the test conditions the substance was not irritating to eyes; Method: according to guideline OECD 492; Report date: 2018; Source: ECHA.
Genotoxicity: In vitro:negative; Species/strain: S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and E. coli WP2; Method: acording to OECD Guideline 471; Report date: 2018; Source: ECHA.
LD50: LD50 = 2 600 mg/kg bw (oral, rat, 1972, principles of methid: Forty male albino rats Wistar strain, 10 per group, were fasted for a minimum of 16 hours prior to administration of the test material. The drug was administered as a concentrate.) (ref. ECHA)
NOAEL Oral: The NOAELs were not available in order to review however based on a history of safe use in consumer products this material is considered safe when used as intended. In conclusion, at the given concentration in the final product, the ingredient is not considered to be of toxicological concern when used as intended.
Skin Irritation: The substance was tested in vivo to examine skin irritation potential. Endpoint: Under the test condition the substance caused mild skin irritation. Method: according to OECD Guideline 431; Species: human skin model; Report date: 2018; Source: ECHA.
Skin Sensitisation: The substance was tested in vitro to examine skin sensitising potential. Endpoint: May cause an allergic skin reaction. Report date: 2017; 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
Mentha Piperita (Peppermint) Oil (naturallythinking) (Masking,Perfuming,Refreshing,Tonic)
EU INCI: Mentha Piperita Oil.
CTFA INCI: Mentha Piperita (Peppermint) Oil.
Trade Name: Peppermint Oil Piperita.
CAS Number: 8006-90-4(84082-70-2).
EINECS Number: 282-015-4.
Symbol: C62H108O7.
Molecular Weight: 965.5 g/mol.
Description: Mentha Piperita Oil is the volatile oil obtained from the whole plant of the Peppermint, Mentha piperita (L.), Labiatae

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Viscosity: 7.71 mm2/s at 20°C
Boiling Point: 176°C
Flash Point: 72°C
Microbiological stability: Susceptible to microbiological contamination
Physical State: Oil.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
Regulatory Controls: It is noted that the full composition of the fragrance and technical data haven't been disclosed and therefore the manufacture (responsible person) must ensure that the fragrance does not contain any materials which are prohibited or restricted for the intended use. The presence of the fragrance substance must be indicated in the list of ingredients referred to in Article 19(1)g when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products
GHS Classification: H315: Causes skin irritation. H319: Causes serious eye irritation. H317: May cause an allergic skin reaction. H412: Harmful to aquatic life with long lasting effects..
Region : Europe Type : Cosmetic Restriction : Allergens declaration as required Label Review : Proposed from 2023: The presence of the substance shall be indicated in the list of ingredients referred to in Article 19(1), point (g), when its concentration exceeds: - 0,001 % in leave-on products - 0,01 % in rinse-off products.
Region : UK Type : Cosmetic Restriction : Allergens declaration as required

TOXICITY REVIEW
General Toxicity Review: Peppermint oil is commonly used in cosmetic products. The substance may cause skin irritation and serious eye irritation. Peppermint oil may cause an allergic skin reaction due to the presence of allergens. It shows low acute toxicity with LD50 well above 2000 mg/kg bw in both dermal and oral exposure. It has moderate chronic toxicity where oral systematic exposure is considered. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is not considered to be of toxicological concern when used in consumer products.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vitro on bovine to examine ocular irritation after application. The studies resulted in scoring the substance as not irritating to eyes. According to the GHS classification the substance causes serious eye irritation. (ECHA)
Genotoxicity: In vitro: negative (human lymphocytes whole peripheral blood culture) (ECHA)
Inhalation: When tested on animals (rats) the NOAEL was established at 50 mg/kg (sub-chronic toxicity (90 day study) inhalation)
LD50: LD50 (oral, rat) 2650 mg/kg; OECD Guideline 401 (Acute Oral Toxicity); Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity of the substance. LD50 (dermal, rabbit) > 5 000 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)
NOAEL Inhalation: NOAEL 50 ppm Study type: repeated dose toxicity; Endpoint:sub-chronic toxicity: inhalation; Species:mouse; Guideline:OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study); Year:2006; SOurce: ECHA, MoS was calculated based on this data
NOAEL Oral: NOAEL 400 mg/kg bw/day Study type: repeated dose toxicity; Endpoint:short-term repeated dose toxicity: oral; Species:rat; Guideline:OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity Study in Rodents); Report date:1990; Source: ECHA, MoS was calculated based on this data
Read-across: Susceptible to microbiological contamination
Skin Irritation: According to the GHS classification the substance causes skin irritation. In vivo studies on rabbits with semiocclusive coverage were conducted. The substance was found to be slightly/moderately irritating. (ECHA)
Skin Sensitisation: According to the GHS classification the substance may cause an allergic skin reaction. Non-LLNA in vivo examinations were conducted, using guinea pig tests to find evidence for skin sensitisation. The test results showed that the substance is not sensitising to the skin. (ECHA)

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

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Citrus Grandis (Grapefruit) Peel Oil (naturallythinking) (Masking,Perfuming,Skin Conditioning)
EU INCI: Citrus Grandis Peel Oil.
CTFA INCI: Citrus Grandis (Grapefruit) Peel Oil.
Trade Name: GRAPEFRUIT OIL, COLD PRESSED.
CAS Number: 90045-43-5(8016-20-4).
EINECS Number: 289-904-6 / -.
Description: Citrus Grandis Peel Oil is the volatile oil obtained from the peel of the Grapefruit, Citrus grandis, Rutaceae

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Characteristic, Grapefruit. Citrus-like
Specific Gravity: 0.848-0.856
Water Solubility: Insoluble
Colour: Yellow. Reddish-orange.
Flammability: Flammable
Flash Point: 44°C/111°F (Closed cup)
Physical State: Oil.

REGULATORY REQUIREMENTS
IFRA Standard: Restriction limits in the finished product:Category 1, 2, 3, 4, 5A, 5B, 5C, 5D, 6, 7B, 8, 10B, 11B: 0.0015 % (5-MOP); Category 7A, 9, 10A,12: No restriction. Where the Bergapten (5-Methoxypsoralen, (5-MOP)) content of all relevant oils present in a compound has been determined, it is recommended that for applications on areas of skin exposed to UV-light, the total level of Bergapten in the consumer products should not exceed 0.0015% (15 ppm). This upper concentration level only applies to applications on skin exposed to UV-light, excluding rinse-off products and incidental skin contact products as detailed in the Guidance for the use of IFRA Standards. Where the level of Bergapten has not been determined by appropriate methods, the limits specified in the guidelines on individual oils should apply. In those cases, where such oils are used in combination with other furocoumarin-containing phototoxic fragrance ingredients (extracts), the additive effect has to be taken into consideration and the concentration levels have to be reduced accordingly. The sum of the concentrations of all furocoumarin-containing phototoxic fragrance ingredients (extracts), expressed in % of their recommended upper concentration level in the finished consumer product, shall not exceed 100. Flavour requirements: Due to the possible ingestion of small amounts of fragrance ingredients from their use in products in Categories 1 and 6, materials must not only comply with IFRA Standards but must also be recognized as safe as a flavouring ingredient as defined by the IOFI Code of Practice (www.iofi.org). For more details see chapter 1 of the Guidance for the use of IFRA Standards. Implementation dates: For new submissions*: February 10, 2021; For existing fragrance compounds*: February 10, 2022
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI.
REACH Annex XVII: Not listed in the Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
Regulatory Controls: Prohibited Furocoumarines (e.g. trioxysalen (INN), 8-methoxypsoralen, 5-methoxypsoralen) except for normal content in natural essences used. In sun protection and in bronzingproducts, furocoumarines shall be below 1 mg/kg
GHS Classification: H226: Flammable liquid and vapour. H304: May be fatal if swallowed and enters airways. H315: Causes skin irritation. H317: May cause an allergic skin reaction. H411: Toxic to aquatic life with long lasting effects..
Region : Europe Type : Cosmetic Restriction : Prohibited Furocoumarines (e.g. trioxysalen (INN), 8-methoxypsoralen, 5-methoxypsoralen) except for normal content in natural essences used. In sun protection and in bronzingproducts, furocoumarines shall be below 1 mg/kg
Region : UK Type : Cosmetic Restriction : Prohibited Furocoumarines (e.g. trioxysalen (INN), 8-methoxypsoralen, 5-methoxypsoralen) except for normal content in natural essences used. In sun protection and in bronzingproducts, furocoumarines shall be below 1 mg/kg

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

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo on rabbits to examine ocular irritation after application. The studies resulted in scoring the substance as not irritating to eyes. (ECHA)
Genotoxicity: In vitro: negative. (S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and E. coli WP2 uvr A). (ECHA)
Inhalation: May cause irritation of respiratory tract.
LD50: LD50 (Oral, rat) > 5 000 mg/kg bw (OECD Guideline 401 (Acute Oral Toxicity)); LD50 (dermal, rabbit) > 5000 mg/kg (OECD Guideline 402 (Acute Dermal Toxicity)) (ECHA)
NOAEL Oral: NOAEL 1 000 mg/kg bw/day (actual dose received). Study type: Repeated dose toxicity. Endpoints: sub-chronic toxicity. Route of administration: oral. Species: dog- Japanese beagle. Methods: a combination of rules from OECD Guidelines 409 and 452. Report date: 1975. MoS was calculated based on this data.
Phototoxicity: Ma be photo toxic
Skin Irritation: Causes skin irritation. In vivo studies on rabbits were conducted. The substance was found to be moderately irritating to the skin. (ECHA)
Skin Sensitisation: May cause an allergic skin reaction. LLNA in vivo examinations were conducted, using mouse tests to find evidence for skin sensitisation. The test results showed that the chemical is a skin sensitiser. (ECHA)

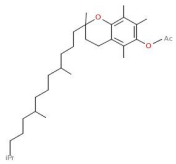
Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

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.

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Rosmarinus Officinalis Leaf Oil (naturallythinking) (Perfuming,Skin Conditioning)
EU INCI: Rosmarinus Officinalis Leaf Oil.
CTFA INCI: Rosmarinus Officinalis (Rosemary) Leaf Oil.
Trade Name: Rosemary Oil.
CAS Number: 84604-14-8(8000-25-7).
EINECS Number: 283-291-9.

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Characteristic - cineole and camphor notes
Water Solubility: 0.088 mg/L at 20 °C
Boiling Point: 158 - 210 °C at 1 034 hPa
Colour: Colourless to pale yellow
Density: 0.895 - 0.905 g/cm3 at 20 °C
Flammability: Flammable
Flash Point: 47.3 °C (closed cup)
Vapour Pressure: 9 Pa at 25 °C
Melting Point: 43.42 °C at 101 325 Pa
Physical State: Liquid.

REGULATORY REQUIREMENTS
IFRA Standard: IFRA class 9 with maximum concentration 3.48 %. IFRA Category 10B with maximum concentration 12.80%. IFRA Category 12 with no restriction. IFRA Category 5B and 5C with maximum concentration 2.32%. IFRA Category 5A with maximum concentration 8.00%; IFRA Category 5D with maximum concentration 0.76%
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: H226: Flammable liquid and vapour. H304: May be fatal if swallowed and enters airways. H315: Causes skin irritation. H317: May cause an allergic skin reaction. H319: Causes serious eye irritation. H371: May cause damage to organs <or state all organs affected, if known> <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.H411: Toxic to aquatic life with long lasting effects. Self-classified: H410 Very toxic to aquatic life with long lasting effects..
Region : Europe Type : Cosmetic Restriction : Allergens declaration as required.
Region : UK Type : Cosmetic Restriction : Allergens declaration as required.

TOXICITY REVIEW
General Toxicity Review: Rosemary essential oil is commonly used in cosmetics. Based on the available toxicological data the substance may cause skin irritation and allergic reaction. Data derived from animal studies demonstrate that the substance is not expected to cause eye irritation. It has high chronic toxicity where oral systematic exposure is considered. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is not considered to be of toxicological concern when used in consumer products.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vitro / ex vivo (cattle eyes) to examine ocular irritation after application. Based on the testing results the substance is not expected to cause eye irritation. (ECHA)
Genotoxicity: In vitro: negative (S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and E. coli WP2).
LD50: LD50 (oral, rat) > 10mL/kg bw. LD50 (dermal, rabbit) > 10 mL/kg bw.Acute toxicity studies via oral route of administration in rats demonstrated low toxicity. Acute toxicity studies via dermal route of exposure (occlusive type of coverage) on rabbits showed that the substance is not acute toxic.
NOAEL Oral: NOAEL 300 mg/kg bw/day (female) and 1000 mg/kg bw/day (male). Study type; Repeated dose toxicity. Endpoints; short-term repeated dose toxicity. Route of administration: oral. Species; rat. Methods; 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: Based on the available toxicological data the substance is skin irritating (ECHA).
Skin Sensitisation: Based on the available toxicological data the substance may cause an allergic skin reaction (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
Piper Nigrum Fruit Oil (naturallythinking) (Perfuming)
EU INCI: Piper Nigrum Fruit Oil.
CTFA INCI: Piper Nigrum (Black Pepper) Fruit Oil.
Trade Name: Black Pepper Oil.
CAS Number: 84929-41-9.
EINECS Number: 284-524-7.
Description: This oil is obtained by the steam distillation of the dried berries of Piper Nigum L.

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Characteristic of powdered black pepper
Specific Gravity: 0.8724 at 25 deg.C
Water Solubility: Insoluble
Colour: Colourless to light green; pale yellow to green
Density: 0.864 – 0.884 at 20°C
Flammability: Flammable liquid and vapour.
Flash Point: 46.0 - 50.00°C
Microbiological stability: Bacillus Cereus: <10 cfu/g; Coliforms: <10 cfu/g; E.coli: negative(<3 MPN/g); Listeria: negative in 25g; Salmonella: Absent in 25g; TPC: <500 cfu/g; Yeast&mould: <50 cfu/g; Enterobactireace: <10 cfu/g; Staphylococcus aureus: <10 ORG/g
Physical State: Liquid.

REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Not classified as per CLP, Annex VI.
REACH Annex XVII: Not listed in Annex XVII.
REACH SVHC: Not included in SVHC list (Annex XIV).
Regulatory Controls: It is noted that the full composition of the fragrance and technical data haven't been disclosed and therefore the manufacture (responsible person) must ensure that the fragrance does not contain any materials which are prohibited or restricted for the intended use. The presence of the fragrance substance must be indicated in the list of ingredients referred to in Article 19(1)g when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products
GHS Classification: H226: Flammable liquid and vapour. H304: May be fatal if swallowed and enters airways. H315: Causes skin irritation. H317: May cause an allergic skin reaction. H411: Toxic to aquatic life with long lasting effects. Self classified: H410 Very toxic to aquatic life with long lasting effects..
Region : Europe Type : Cosmetic Restriction : Allergens declaration as required
Region : UK Type : Cosmetic Restriction : Allergens declaration as required

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

TOXICOLOGICAL PROFILE
Eye Irritation: Based on the read-across information for Olibanum Oil and in vitro eye corrosion test, the substance is considered as not 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) > 5 000 mg/kg bw (OECD Guideline 401 (Acute Oral Toxicity))
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: Causes skin irritation. In vitro skin corrosion test were conducted. The substance was found to be irritating to the skin. (ECHA)
Skin Sensitisation: May cause an allergic skin reaction. Based on the available toxicological information and calculation rules for mixtures, the substance was found to be a skin sensitiser and classified as per Category 1 based on the GHS criteria. (ECHA)

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Lavandula Angustifolia Flower Oil (naturallythinking) (Perfuming)
EU INCI: Lavandula Angustifolia Flower Oil.
Trade Name: Lavender, Essential Oil.
CAS Number: 90063-37-9.
Description: Lavandula Angustifolia Flower Oil is the volatile oil obtained from the flowers of Lavandula angustifolia, Lamiaceae.

PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Odour: Characteristic
Water Solubility: Insoluble
Boiling Point: 172 °C
Colour: Colourless to pale yellow
Density: 0.8789 g/cm3 at 20°C
Flash Point: 71°C
Physical State: Liquid.

REGULATORY REQUIREMENTS
IFRA Standard: IFRA Category 2 with maximum concentration 5.5%. IFRA Categories 3, 4, 5A, 5B, 5C, 7A, 7B, 9, 10A, 10B with maximum concentration 10.0%. IFRA Categories 5D, 8, 11A, 11B with maximum concentration 8.7%.
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: It is noted that the full composition of the fragrance and technical data haven't been disclosed and therefore the manufacture (responsible person) must ensure that the fragrance does not contain any materials which are prohibited or restricted for the intended use.The presence of the fragrance substance must be indicated in the list of ingredients referred to in Article 19(1)g when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products
GHS Classification: H319: Causes serious eye irritation. H317: May cause an allergic skin reaction. H304: May be fatal if swallowed and enters airways. H412: Harmful to aquatic life with long lasting effects. Self classified: H315: Causes skin irritation. H411: Toxic to aquatic life with long lasting effects..
Region : Europe Type : Cosmetic Restriction : Allergens declaration as required.
Region : UK Type : Cosmetic Restriction : Allergens declaration as required.

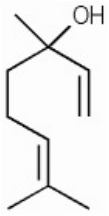
TOXICITY REVIEW
General Toxicity Review: Lavandula Angustifolia Flower Oil is well-known cosmetic substance. When it comes to local toxicity the substance is sensitising and classified as category 1B. Data derived from animal studies demonstrate that the substance is irritating to eyes and classified as category 2. In vitro studies on human skin model showed that the chemical is not irritating to skin. It shows low acute toxicity with LD50 above 5000 mg/kg bw in dermal exposure. It has high chronic toxicity where oral systematic exposure is considered. The ingredient characteristic suggests that interactions of the material with other substances would not lead to any synergistic or unpredictable adverse effects. Overall, the ingredient is not considered to be of toxicological concern when used in consumer products.

TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vitro on reconstructed human cornea-like epithelium tissues to examine ocular irritation. The studies resulted that the substance is irritating to eyes and classified as category 2 according to the GHS criteria. (ECHA)
Genotoxicity: In vitro: negative (S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and E. coli WP2).
LD50: LD50 (Oral, rat) > 4.1 - < 5.9 mL/kg bw; LD50 (Dermal, rabbit) > 5 000 mg/kg bw
NOAEL Oral: NOAEL 160 mg/kg bw/day. Study type: Repeated dose toxicity. Endpoints: short-term repeated dose toxicity. Route of administration: oral. Species: rat. Methods: OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity Study in Rodents). Report date: 1990. MoS was calculated based on this data.
Skin Irritation: In vitro studies on EPISKIN reconstructed human epidermis model were conducted. The substance was found to be not irritating to the skin. (ECHA)
Skin Sensitisation: LLNA in vivo examinations were conducted, using mouse test to find evidence for skin sensitisation. The test results showed that the substance is sensitising and classified as Category 1B according to GHS criteria. (ECHA)

Product Name

Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



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

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

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

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

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

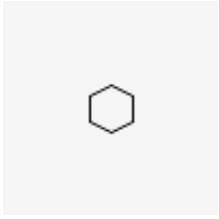
OTHER
Biodegradability (Environmental): Biodegradation in water: screening test. Result: 64.2% biodegradation in 28 days. Conclusion: readily biodegradable (OECD TG 301 D). (ECHA)
LC50 (Environmental): Fish: LC50 Salmo gairdneri 27.8 mg/L - 96h (OECD guideline 203); Algae:Desmodesmus subspicatus EC50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

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

Product Name

Active Muscle Therapy Balm 1000mg (2022-753-5061) (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.

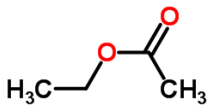
TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as causing the irreversible effect on the eye. (ECHA)
Genotoxicity: Negative in vitro gene mutation study in mammalian cells (Chinese 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.

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)

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)

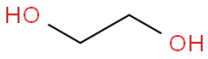
Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Active Muscle Therapy Balm 1000mg (2022-753-5061) (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.

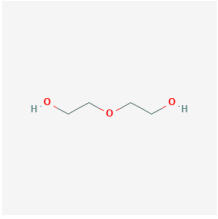
TOXICOLOGICAL PROFILE
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as not irritating. (ECHA)
Genotoxicity: Negative in vitro gene mutation study in bacteria and in vivo mammalian germ cell study: 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

Active Muscle Therapy Balm 1000mg (2022-753-5061) (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

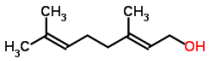
TOXICITY REVIEW
General Toxicity Review: Data obtained in vivo and in vitro/ ex vivo (animal and human skin model studies) was found to be not irritating to eyes, and skin. The substance was found to be non-sensitising in guinea pig maximisation test. Overall, the ingredient is considered to be of toxicological 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.

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
Geraniol (Perfuming,Tonic)
EU INCI: Geraniol.
CTFA INCI: Geraniol.
CAS Number: 106-24-1.
EINECS Number: 203-377-1.
Symbol: C10H18O.
Molecular Weight: 154.25.
IUPAC Name: (2E)-3,7-dimethylocta-2,6-dien-1-ol
Synonyms: geranyl alcohol; geranol; lemonol; 3,7-dimethyl-2,6-octadien-1-ol, (E)-



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY
Oxidising Properties: No oxidising properties
Viscosity: 8.21 mPa · s (dynamic) at 20 °C
Water Solubility: 100 mg/L at 25 °C
Partial Coefficient logPow: 2.6 at 25 °C
Boiling Point: 229-230 °C at 1013 hPa
Density: 0.88 - 0.89 g/cm³ at 20 °C
Flammability: Non flammable upon ignition.
Flash Point: 76 ºC
Vapour Pressure: 0.0000796 hPa at 20 °C
LogP Log Kow: 2.6 at 25 °C
Melting Point: -15 °C
Physical State: Liquid.

REGULATORY REQUIREMENTS
Labelling Requirements: The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)g when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products.
IFRA Standard: Restriction limits in the finished product: Category 1: 0.85 %; Category 2: 0.25 %; Category 3 :5.1 % ; Category 4 :4.7 % ;Category 5A: 1.2 %; Category 5B :1.2 %; Category 5C :1.2 % ; Category 5D 1.2 %; Category 6: 2.8 %; Category 7A: 9.6%; Category 7B: 9.6 %; Category 8: 0.5 %; Category 9: 9.2 %; Category 10A: 33 %; Category 10B: 33%; Category 11A: 18 %; Category 11B: 18 %;Category 12: No Restriction. Flavour requirements: Due to the possible ingestion of small amounts of fragrance ingredients from their use in products in Categories 1 and 6, materials must not only comply with IFRA Standards but must also be recognized as safe as a flavoring ingredient as defined by the IOFI Code of Practice (www.iofi.org). For more details see chapter 1 of the Guidance for the use of IFRA Standards. Implementation dates: For new submissions*: February 10, 2021 For existing fragrance compounds*: February 10, 2022
CLP Regulation (EC) No 1272/2008: Classified as: Skin Sens. 1 H317. Proposed classification: Skin Sens. 1A, H317 (ECHA accessed 23.04.21)
REACH Annex XVII: Not listed in the Annex XVII
REACH SVHC: Not included in SVHC list (Annex XIV)
Regulatory Controls: Proposed restrictions as per the EC public consultation published on 18th March 2019; When its concentration exceeds: 0,001 % in leave-on products and 0,01 % in rinse-off products the presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)(g).
GHS Classification: H315: Causes skin irritation. H317: May cause an allergic skin reaction. H318: Causes serious eye damage..
Region : Europe Type : Cosmetic Restriction : Allergen declaration as required Label Review : The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)g when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products
Region : UK Type : Cosmetic Restriction : Allergen declaration as required Label Review : The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)g when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products

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

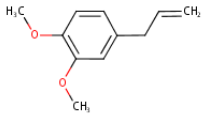
TOXICOLOGICAL PROFILE
Endocrine Effects: Not regarded as endocrine active substance.
Eye Irritation: The substance was tested in vivo (rabbits) to examine ocular irritation after application. The studies resulted in scoring the chemical as severely irritating and causing serious eye damage. (ECHA)
Genotoxicity: Negative in vitro gene mutation study in bacteria (S. typhimurium TA 1535, TA 1537, TA 98 and TA 100, TA92, TA94, TA2637) and in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus (mouse) (ECHA)
LD50: LD50 (oral, rat) 3 600 mg/kg bw; Description: Acute toxicity studies via oral route of administration in rats demonstrated low toxicity of the substance. LD50 (dermal, rabbit) > 5 000 mg/kg bw; Description: Acute toxicity studies via dermal route of exposure in rabbits (occlusive type of coverage) showed that the substance is practically non-toxic. (ECHA)
Mutagenicity: Non-mutagenic
NOAEL Dermal: NOAEL 300 mg/kg bw. Study type Repeated dose toxicity. Endpoint Repeated dose toxicity. Method OECD Guideline 421 (Reproduction/Developmental Toxicity Screening test). Species Rats. Remark Effect seen skin irritation. Report date 2010 (ECHA) MoS was calculated based on this data. NOEL 3061 µg/cm2. Study type Human data. Source and date Basketter et al.2005.
NOAEL Oral: NOEL 550 mg/kg bw. Study type Repeated dose toxicity. Endpoint: sub-chronic toxicity: oral. Species:rat, Source: ECHA, MoS was calculated based on this data
Reproductive Toxicology: NOAEL 300 mg/kg bw/day; Study type: Toxicity to reproduction; Endpoint:screening for reproductive / developmental toxicity; Species:rat; Guideline:OECD Guideline 421 (Reproduction / Developmental Toxicity Screening Test); Report date:2010; Source: ECHA
Skin Irritation: In the in vivo studies on rabbits the substance was found to be irritating, changes were not fully reversible within 7 days. (ECHA)
Skin Sensitisation: LLNA in vivo examinations were conducted, using mouse local lymph node assay (LLNA) test, to find evidence for skin sensitisation. The test results showed that the chemical is sensitising. (ECHA)
Carcinogenicity: Not associated with carcinogenic, mutagenic, or toxic for reproduction (CMR) materials.

OTHER
Biodegradability (Environmental): Biodegradation in water: screening tests. Result: 94% degradation after 28 days. Conclusion: readily biodegradable. OECD guideline 301F (ECHA)
LC50 (Environmental): Fish: LC50 Danio rerio 22 mg/l - 96h (OECD guideline 203) - acutely harmful to fish; Algae: EC50 Desmodesmus subspicatus 13.9 mg/l (NOEC: 1.0 mg/l) -72h (OECD 201) - Acutely harmful for aquatic algae (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
Methyl Eugenol (Perfuming)
EU INCI: Methyl Eugenol.
CTFA INCI: Methyl Eugenol.
CNDA INCI: Methyl Eugenol.
CAS Number: 93-15-2.
EINECS Number: 202-223-0.
Symbol: C11H14O2.
Molecular Weight: 178.22 g/mol.
Synonyms: 1,2-Dimethoxy-4-(2-propenyl)-benzene; 1-allyl-3,4-dimethoxybenzene; 1,3,4-eugenol methyl ether; 4-allyl-1,2-dimethoxybenzene



PHYSICOCHEMICAL PROPERTIES and MICROBIOLOGICAL STABILITY

Physical State: Liquid.

REGULATORY REQUIREMENTS
IFRA Standard: INTRINSIC PROPERTY DRIVING RIS MANAGEMENT: DERMAL SENSITIZATION AND SYSTEMIC TOXICITY. FLAVOR REQUIREMENTS: Due to the possible ingestion of small amounts of fragrance ingredients from their use in products in Categories 1 and 6, materials must not only comply with IFRA Standards but must also be recognized as safe as a flavoring ingredient as defined by the IOFI Code of Practice (www.iofi.org). For more details see chapter 1 of the Guidance for the use of IFRA Standards. RESTRICTION LIMITS IN THE FINISHED PRODUCT (%): Category 1 0.00058 %; Category 2 0.0023 %; Category 3 0.00029 %; Category 4 0.016 %; Category 5A 0.0020 %; Category 5B 0.00058 %; Category 5C 0.00058 %; Category 5D 0.00019 %; Category 6 0.0014 %; Category 7A 0.00058 %; Category 7B 0.00058 %; Category 10A 0.00087 %; Category 10B 0.0032 %; Category 11A 0.00019 %; Category 11B 0.00019 %; Category 12 0.097 %. Implementation dates: For new submissions February 10, 2021; For existing fragrance compounds February 10, 2022. Publication dates 2020 (Amendment 49)
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.
Regulatory Controls: Restricted in Annex III in already made products as follows; (a) Fine fragrance 0.01%(b) Eau de toilette 0.004%(c) Fragrance cream 0.002%(d) Other leave-on products and oral products 0.0002%(e) Rinse-off products 0.001%.
GHS Classification: H302: Harmful if swallowed. H402: Harmful to aquatic life..
Region : Europe Type : Cosmetic Restriction : (a) Fine fragrance -0.01%,(b) Eau de toilette - 0.004%, (c) Fragrance cream - 0.002%,(d) Other leave-on products and oral products - 0.0002%, (e) Rinse-off products - 0.001%.
Region : UK Type : Cosmetic Restriction : (a) Fine fragrance -0.01%,(b) Eau de toilette - 0.004%, (c) Fragrance cream - 0.002%,(d) Other leave-on products and oral products - 0.0002%, (e) Rinse-off products - 0.001%.

TOXICITY REVIEW
General Toxicity Review: Methyl Eugenol is commonly used as perfuming ingredient. When it comes to local toxicity the chemical does not induce or elicit skin allergy. Data derived from in vitro/ ex vivo human studies demonstrate that the substance is not irritating to the skin and eyes. It shows low acute toxicity with LD50 well above 2000 mg/kg bw in both dermal and oral exposure. 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 vitro / ex vivo (human) to examine ocular irritation after application. Based on the testing results the substance is classified as not irritating. (ECHA)
LD50: LD50 (oral, rat) 2 500 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 rabbits (semiocclusive type of coverage) showed that the substance has low skin toxicity. (ECHA)
NOAEL Oral: NOAEL 300 mg/kg bw/day Study type: repeated dose toxicity; Endpoint:short-term repeated dose toxicity: oral; Species:rat; Guideline:OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test); Report date:2019; Source: ECHA; MoS was calculated based on this data
Precutaneous Absorption: 40%
Repeated Dose Toxicity: Repeated oral exposure to the chemical is not considered to cause serious damage to health. However, studies in rats and mice indicated that the chemical was specifically toxic to the liver and the glandular stomach at high doses. This could be due to the high lipophilicity of the chemical and rapid absorption through the stomach.
Safety evaluation: The Opinion has only considered the genotoxicity and carcinogenicity of methyleugenol. A risk assessment has been made on the basis of a long-term carcinogenicity study on rats.Methyleugenol should not be intentionally added as a cosmetic ingredient.However, when fragrance compounds containing methyleugenol naturally present in essential oils are used as components in cosmetic products, the highest concentration of methyleugenol in the finished products must not exceed 0.01 % in fine fragrance, 0.004 % in eau de toilette, 0.002 % in a fragrance cream, 0.0002 % in other leave-on products and in oral hygiene products, and 0.001% in rinse-off products.
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: Negative in the skin sensitisation assay by direct peptide reactivity assay (DPRA)(endpoint: skin sensitisation: in chemico)
Carcinogenicity: Based on the available rodent data, the chemical is considered to be carcinogenic, warranting hazard classification. As the metabolic pathways for the chemical are considered similar in rats and humans, the chemical is expected to be a carcinogen in humans.

Product Name

Active Muscle Therapy Balm 1000mg (2022-753-5061) (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.

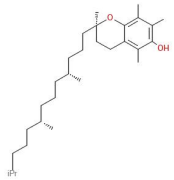
Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

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



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

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

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

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

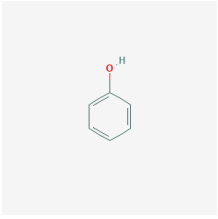
OTHER
Biodegradability (Environmental): Biodegradation in water: screening test. Result: 30-40% degradation after 39 days. Conclusion: inherently biodegradable. (ECHA)
LC50 (Environmental): Fish: LC50 Oncorhynchus mykiss (rainbow trout) 10 mg/L - 96h; OECD Guideline 203; Algae: EC10 or NOEC Selenastrum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

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

Product Name

Active Muscle Therapy Balm 1000mg (2022-753-5061) (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)

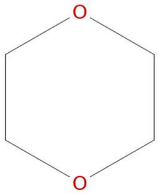
Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Active Muscle Therapy Balm 1000mg (2022-753-5061) (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

Active Muscle Therapy Balm 1000mg (2022-753-5061) (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.

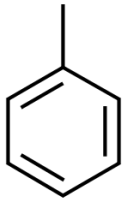
REGULATORY REQUIREMENTS
CLP Regulation (EC) No 1272/2008: Classified as: Acute Tox. 3 * H331; Acute Tox. 3 * H301; Aquatic Acute 1 H400; Aquatic Chronic 1 H410
REACH Annex XVII: Listed in the Annex XVII. Conditions of restriction: 1. Shall not be placed on the market, or used, as substances or in mixtures 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.

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



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

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

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

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

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

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

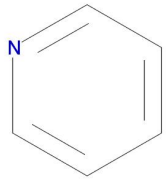
Ingredients Data that includes physicochemical and toxicological properties of each raw material is publicly available. In order to obtain additional information on any of the data that was used in preparing this assessment or a given conclusion, please contact the toxicological safety assessor.

Product Name

Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

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



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

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

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

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

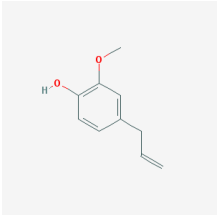
OTHER
LC50 (Environmental): LC50 4 900 ppm, Route of exposure: inhalation: vapour, nose only, Method: 4h, according to EPA OPPTS 870.1300, Report date: 1984; Source: ECHA.

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

Product Name

Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

TOXICOLOGICAL PROFILE OF THE SUBSTANCES



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

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

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

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

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

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

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

TOXICOLOGICAL PROFILE OF THE SUBSTANCES

IDENTIFICATION
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

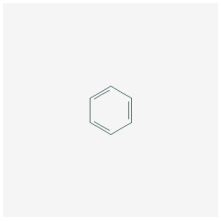
OTHER
Biodegradability (Environmental): Ethylene oxide is readily biodegradable according to OECD criteria.

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

Active Muscle Therapy Balm 1000mg (2022-753-5061) (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

Active Muscle Therapy Balm 1000mg (2022-753-5061) (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.

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

Active Muscle Therapy Balm 1000mg (2022-753-5061) (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.

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)

Product Name
Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

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

UNDESIRABLE EFFECTS AND SERIOUS UNDESIRABLE EFFECTS MONITORING POST MARKETING SURVEILLANCE

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

AMOUNT OF UNITS SOLD: New product – no data.

REMARKS: New product – no data.

INFORMATION ON THE COSMETIC PRODUCT DERMATOLOGICAL TESTS

It is unclear whether the product name refers solely to its cosmetic functions as per the definition of cosmetic product laid done in the requirements of Article 2 of the EU and UK Cosmetic Regulation. It is the responsibility of the Responsible Person who introduces the product to the desired markets to ensure that the presentation of the product meets the requirements of cosmetic products and that claims are adequately substantiated.

LABELLED WARNINGS

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

Product Name
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INSTRUCTION OF USE

Massage gently into the problem area to help soothe tired and aching muscles. For maximum benefit Eresos recommends that you apply twice daily. For any physical injuries always consult a doctor.

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
Active Muscle Therapy Balm 1000mg (2022-753-5061) (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 contains perfume materials that are known to cause allergic reactions, however, the risk of inducing allergy is low for the general populations due to their low concentration.

EFFECT ON EYES
May 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.

Product Name
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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
Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

Manufacturer
Eresos Health + Wellbeing LTD
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London
N18 1TP

IMPURITIES

CAS No	IMPURITY	SOURCE CHEMICAL	Concentration in finished product[C %]
79-10-7	Acrylic acid	Carbomer	0.0063700000
110-82-7	Cyclohexane	Carbomer	0.0063700000
141-78-6	Ethyl Acetate	Carbomer	0.0031850000
110-54-3	Hexane	Carbomer	0.0012740000
111-46-6	Diethylene glycol	Glycerin	0.0011830000
107-21-1	Glycol (Ethylene glycol)	Glycerin	0.0011830000
93-15-2	Methyl Eugenol	Melaleuca Alternifolia Leaf Oil (Naturallythinking)	0.0005000000
16887-00-6	Chloride	Glycerin	0.0004140500
59-02-9(10191-41-0) (1406-66-2)1406-18-4(54 -28-4)(gamma)	Tocopherol	Tocopheryl Acetate	0.0001035000
75-21-8	Ethylene oxide	Phenoxyethanol	0.0000182000
108-95-2	Phenol	Phenoxyethanol	0.0000091000
7439-92-1	Lead and its compounds	Glycerin	0.0000059150
123-91-1	1,4-Dioxane	Polysorbate 20	0.0000045500
7440-38-2	Arsenic and its compounds	Glycerin	0.0000035490
108-88-3	Toluene	Tocopheryl Acetate	0.0000016560
110-86-1	Pyridine	Tocopheryl Acetate	0.0000016560
7440-38-2	Arsenic and its compounds	Carbomer	0.0000012740
7439-97-6	Mercury and its compounds	Glycerin	0.0000011830
7440-43-9	Cadmium	Glycerin	0.0000011830
123-91-1	1,4-Dioxane	Phenoxyethanol	0.0000009100
75-21-8	Ethylene oxide	Polysorbate 20	0.0000004550
71-43-2	Benzene	Carbomer	0.0000003185
7440-38-2	Arsenic and its compounds	Piper Nigrum Fruit Oil (naturallythinking)	0.0000000621
7439-92-1	Lead and its compounds	Tocopheryl Acetate	0.0000000414
7439-92-1	Lead and its compounds	Piper Nigrum Fruit Oil (naturallythinking)	0.0000000414
7440-38-2	Arsenic and its compounds	Tocopheryl Acetate	0.0000000207
7440-02-0	Nickel	Tocopheryl Acetate	0.0000000207
7440-43-9	Cadmium	Tocopheryl Acetate	0.0000000104
7439-97-6	Mercury and its compounds	Tocopheryl Acetate	0.0000000021

Product Name
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Manufacturer
Eresos Health + Wellbeing LTD
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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
Cyclohexane	0.0063700000	18.67	0.01982132	Not Available	No MoS calculated as no NOAEL available
Acrylic acid	0.0063700000	18.67	0.01982132	83	2093.705514
Ethyl Acetate	0.0031850000	18.67	0.00991066	900	45405.66175
Hexane	0.0012740000	18.67	0.00396426	568	71640.044094
Glycol (Ethylene glycol)	0.0011830000	18.67	0.00368110	150	20374.3354
Diethylene glycol	0.0011830000	18.67	0.00368110	128	17386.099542
Methyl Eugenol	0.0005000000	18.67	0.00155583	300	96411.355115
Chloride	0.0004140500	18.67	0.00128839	Not Available	No MoS calculated as no NOAEL available
Tocopherol	0.0001035000	18.67	0.00032206	500	776258.897868
Ethylene oxide	0.0000186550	18.67	0.00005805	30	258406.205079
Phenol	0.0000091000	18.67	0.00002832	450	7945990.806185
Lead and its compounds	0.0000059978	18.67	0.00001866	7.8	208967.890977
1,4-Dioxane	0.0000054600	18.67	0.00001699	9.6	282524.117554
Arsenic and its compounds	0.0000049058	18.67	0.00001527	0.0008	26.203366
Toluene	0.0000016560	18.67	0.00000515	625	60645226.395908
Pyridine	0.0000016560	18.67	0.00000515	7	679226.535634
Cadmium	0.0000011934	18.67	0.00000371	3	403952.550024
Mercury and its compounds	0.0000011851	18.67	0.00000369	0.005	677.95823
Benzene	0.0000003185	18.67	0.00000099	100	50450735.279121
Nickel	0.0000000207	18.67	0.00000006	2.2	17077695.753088

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

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LITERATURE SOURCES

Agency for Toxic Substances and Disease Registry (ATSDR)	**Accessed Date:**	23/12/2022
https://www.atsdr.cdc.gov/toxprofiles/tp46-c2.pdf		
Amended Annex VI Part 3 of the Commission Regulation (EU) 2020/1182 May 2020	**Accessed Date:**	16/01/2023
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R1182&from=EN		
Annex XVII	**Accessed Date:**	18/01/2023
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20221217&from=EN		
Annex XVII 17.12.2022	**Accessed Date:**	11/01/2023
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20221217&from=EN		
Annex XVII list of substances with specific concentration limits	**Accessed Date:**	23/12/2022
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		
ASM Journal	**Accessed Date:**	12/01/2023
https://journals.asm.org/doi/10.1128/aem.01102-15?permanently=true		
Assembly Bill A6295A	**Accessed Date:**	23/12/2022
https://www.nysenate.gov/legislation/bills/2019/a6295/amendment/a		
ATSDR	**Accessed Date:**	13/01/2023
https://www.atsdr.cdc.gov/toxprofiles/tp113.pdf		
Australia - industrial chemicals inventory	**Accessed Date:**	16/01/2023
https://www.industrialchemicals.gov.au/chemicals/benzene-12-dimethoxy-4-2-propenyl		
Australia - industrial chemicals inventory	**Accessed Date:**	23/12/2022
https://www.industrialchemicals.gov.au/search-inventory		
Australia Chemical Inventory	**Accessed Date:**	12/01/2023
https://www.industrialchemicals.gov.au/chemicals/16-octadien-3-ol-37-dimethyl		
Australia Chemical Inventory	**Accessed Date:**	10/01/2023
https://www.industrialchemicals.gov.au/chemicals/aloe-vera-ext		
Australia Chemical Inventory	**Accessed Date:**	12/01/2023
https://www.industrialchemicals.gov.au/chemicals/cyclohexene-1-methyl-4-1-methylethenyl-r		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	23/12/2022
https://www.industrialchemicals.gov.au/chemicals/12-ethanediol		

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Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

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LITERATURE SOURCES

Australian Inventory of Industrial Chemicals	**Accessed Date:**	23/12/2022
https://www.industrialchemicals.gov.au/chemicals/12-propanediol-3-2-ethylhexyloxy		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	23/12/2022
https://www.industrialchemicals.gov.au/chemicals/123-propanetriol		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	23/12/2022
https://www.industrialchemicals.gov.au/chemicals/14-dioxane		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	09/01/2023
https://www.industrialchemicals.gov.au/chemicals/2-propenoic-acid		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	23/12/2022
https://www.industrialchemicals.gov.au/chemicals/2h-1-benzopyran-6-ol-34-dihydro-2578-tetramethyl-2-4812-trimethyltridecyl-acetate		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	23/12/2022
https://www.industrialchemicals.gov.au/chemicals/acetic-acid-ethyl-ester		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	23/12/2022
https://www.industrialchemicals.gov.au/chemicals/arsenic		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	23/12/2022
https://www.industrialchemicals.gov.au/chemicals/cadmium		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	10/01/2023
https://www.industrialchemicals.gov.au/chemicals/carboxyvinyl-polymer		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	23/12/2022
https://www.industrialchemicals.gov.au/chemicals/ethanol-2-phenoxy		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	23/12/2022
https://www.industrialchemicals.gov.au/chemicals/ethanol-22-oxybis		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	02/01/2023
https://www.industrialchemicals.gov.au/chemicals/grape-seed-oil		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	13/01/2023
https://www.industrialchemicals.gov.au/chemicals/hexane		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	23/12/2022
https://www.industrialchemicals.gov.au/chemicals/lead		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	23/12/2022
https://www.industrialchemicals.gov.au/chemicals/mercury		

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Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

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LITERATURE SOURCES

Australian Inventory of Industrial Chemicals	**Accessed Date:**	23/12/2022
https://www.industrialchemicals.gov.au/chemicals/nickel		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	23/12/2022
https://www.industrialchemicals.gov.au/chemicals/oxirane		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	23/12/2022
https://www.industrialchemicals.gov.au/chemicals/phenol		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	04/01/2023
https://www.industrialchemicals.gov.au/chemicals/sorbitan-monododecanoate-polyoxy-12-ethanediyl-derivs		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	09/01/2023
https://www.industrialchemicals.gov.au/chemicals/sunflower-oil		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	23/12/2022
https://www.industrialchemicals.gov.au/search-inventory		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	12/01/2023
https://www.industrialchemicals.gov.au/search-inventory?casnumber=106-24-1		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	23/12/2022
https://www.industrialchemicals.gov.au/search-inventory?casnumber=108-88-3		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	13/01/2023
https://www.industrialchemicals.gov.au/search-inventory?casnumber=110-82-7		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	23/12/2022
https://www.industrialchemicals.gov.au/search-inventory?casnumber=110-86-1		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	13/01/2023
https://www.industrialchemicals.gov.au/search-inventory?casnumber=71-43-2		
Australian Inventory of Industrial Chemicals	**Accessed Date:**	13/01/2023
https://www.industrialchemicals.gov.au/search-inventory?casnumber=97-53-0		
California Proposition 65	**Accessed Date:**	23/12/2022
https://newsletter.sgs.com/eNewsletterPro/uploadedimages/000006/SafeGuardS_09407_Prop_65_lead_in_cosmetic_products.pdf		
Canada DSL	**Accessed Date:**	12/01/2023
https://pollution-waste.canada.ca/substances-search/Substance/DisplaySubstanceDetails?Id=106-24-1		
Canada DSL	**Accessed Date:**	13/01/2023
https://pollution-waste.canada.ca/substances-search/Substance/DisplaySubstanceDetails?Id=110-54-3		

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Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

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LITERATURE SOURCES

Canada DSL	**Accessed Date:**	13/01/2023
https://pollution-waste.canada.ca/substances-search/Substance/DisplaySubstanceDetails?Id=110-82-7		
Canada DSL	**Accessed Date:**	23/12/2022
https://pollution-waste.canada.ca/substances-search/Substance/DisplaySubstanceDetails?Id=122-99-6		
Canada DSL	**Accessed Date:**	23/12/2022
https://pollution-waste.canada.ca/substances-search/Substance/DisplaySubstanceDetails?Id=59-02-9		
Canada DSL	**Accessed Date:**	12/01/2023
https://pollution-waste.canada.ca/substances-search/Substance/DisplaySubstanceDetails?Id=5989-27-5		
Canada DSL	**Accessed Date:**	18/01/2023
https://pollution-waste.canada.ca/substances-search/Substance/DisplaySubstanceDetails?Id=68647-73-4		
Canada DSL	**Accessed Date:**	23/12/2022
https://pollution-waste.canada.ca/substances-search/Substance/DisplaySubstanceDetails?Id=70445-33-9		
Canada DSL	**Accessed Date:**	23/12/2022
https://pollution-waste.canada.ca/substances-search/Substance/DisplaySubstanceDetails?Id=7695-91-2		
Canada DSL	**Accessed Date:**	23/12/2022
https://pollution-waste.canada.ca/substances-search/Substance/DisplaySubstanceDetails?Id=7732-18-5		
Canada DSL	**Accessed Date:**	12/01/2023
https://pollution-waste.canada.ca/substances-search/Substance/DisplaySubstanceDetails?Id=78-70-6		
Canada DSL	**Accessed Date:**	09/01/2023
https://pollution-waste.canada.ca/substances-search/Substance/DisplaySubstanceDetails?Id=79-10-7		
Canada DSL	**Accessed Date:**	18/01/2023
https://pollution-waste.canada.ca/substances-search/Substance/DisplaySubstanceDetails?Id=8016-63-5		
Canada DSL	**Accessed Date:**	10/01/2023
https://pollution-waste.canada.ca/substances-search/Substance/DisplaySubstanceDetails?Id=85507-69-3		
Canada DSL	**Accessed Date:**	04/01/2023
https://pollution-waste.canada.ca/substances-search/Substance/DisplaySubstanceDetails?Id=9005-64-5		
Canada DSL	**Accessed Date:**	10/01/2023
https://pollution-waste.canada.ca/substances-search/Substance/DisplaySubstanceDetails?Id=9007-20-9		
Canada DSL	**Accessed Date:**	16/01/2023
https://pollution-waste.canada.ca/substances-search/Substance/DisplaySubstanceDetails?Id=93-15-2		

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LITERATURE SOURCES

Canada DSL	**Accessed Date:**	13/01/2023
https://pollution-waste.canada.ca/substances-search/Substance/DisplaySubstanceDetails?Id=97-53-0		
Canada DSL	**Accessed Date:**	23/12/2022
https://pollution-waste.canada.ca/substances-search/Substance/DisplaySubstanceDetails?Name=Arsenic&SearchLang=en		
Canada DSL	**Accessed Date:**	23/12/2022
https://pollution-waste.canada.ca/substances-search/Substance/DisplaySubstanceDetails?Name=Arsenic%20%28and%20its%20compounds%29&SearchLang=en		
Canada DSL	**Accessed Date:**	23/12/2022
https://pollution-waste.canada.ca/substances-search/Substance/DisplaySubstanceDetails?Name=Mercury&SearchLang=en		
Canada Gazette Publication	**Accessed Date:**	10/01/2023
http://www.gazette.gc.ca/rp-pr/p2/2019/2019-06-26/html/sor-dors206-eng.html		
Canada Hotlist	**Accessed Date:**	18/01/2023
https://www.canada.ca/en/health-canada/services/consumer-product-safety/cosmetics/cosmetic-ingredient-hotlist-prohibited-restricted-ingredients/hotlist.html#tbl1		
Candidate List of SVHC	**Accessed Date:**	17/01/2023
https://echa.europa.eu/candidate-list-table		
Candidate List of SVHC	**Accessed Date:**	12/01/2023
https://echa.europa.eu/en/candidate-list-table		
Candidate List of SVHC	**Accessed Date:**	18/01/2023
https://echa.europa.eu/pl/candidate-list-table		
Candidate List of SVHC for Authorisation	**Accessed Date:**	16/01/2023
https://echa.europa.eu/candidate-list-table		
Chemblink	**Accessed Date:**	12/01/2023
http://www.chemblink.com/products/106-24-1.htm		
Chemblink	**Accessed Date:**	23/12/2022
https://www.chemblink.com/moreProducts/more16887-00-6.htm		
Chemblink	**Accessed Date:**	18/01/2023
https://www.chemblink.com/moreProducts/more84776-73-8.htm		
Chemblink	**Accessed Date:**	23/12/2022
https://www.chemblink.com/MSDS/MSDSFiles/56-81-5_Sigma-Aldrich.pdf		
Chemblink	**Accessed Date:**	23/12/2022
https://www.chemblink.com/MSDS/MSDSFiles/59-02-9_Sigma-Aldrich.pdf		

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LITERATURE SOURCES

Chemblink	**Accessed Date:**	09/01/2023
https://www.chemblink.com/MSDS/MSDSFiles/8001-21-6_Sigma-Aldrich.pdf		
Chemblink	**Accessed Date:**	04/01/2023
https://www.chemblink.com/MSDS/MSDSFiles/9005-64-5_Sigma-Aldrich.pdf		
Chemblink	**Accessed Date:**	23/12/2022
https://www.chemblink.com/products/107-21-1.htm		
Chemblink	**Accessed Date:**	23/12/2022
https://www.chemblink.com/products/108-88-3.htm		
Chemblink	**Accessed Date:**	23/12/2022
https://www.chemblink.com/products/108-95-2.htm		
Chemblink	**Accessed Date:**	13/01/2023
https://www.chemblink.com/products/110-54-3.htm		
Chemblink	**Accessed Date:**	13/01/2023
https://www.chemblink.com/products/110-82-7.htm		
Chemblink	**Accessed Date:**	23/12/2022
https://www.chemblink.com/products/110-86-1.htm		
Chemblink	**Accessed Date:**	23/12/2022
https://www.chemblink.com/products/122-99-6.htm		
Chemblink	**Accessed Date:**	23/12/2022
https://www.chemblink.com/products/123-91-1.htm		
Chemblink	**Accessed Date:**	10/01/2023
https://www.chemblink.com/products/13956-29-1.htm		
Chemblink	**Accessed Date:**	23/12/2022
https://www.chemblink.com/products/141-78-6.htm		
Chemblink	**Accessed Date:**	12/01/2023
https://www.chemblink.com/products/5989-54-8.htm		
Chemblink	**Accessed Date:**	23/12/2022
https://www.chemblink.com/products/70445-33-9.htm		
Chemblink	**Accessed Date:**	13/01/2023
https://www.chemblink.com/products/71-43-2.htm		

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Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

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LITERATURE SOURCES

Chemblink	**Accessed Date:**	23/12/2022
https://www.chemblink.com/products/7439-92-1.htm		
Chemblink	**Accessed Date:**	23/12/2022
https://www.chemblink.com/products/7439-97-6.htm		
Chemblink	**Accessed Date:**	23/12/2022
https://www.chemblink.com/products/7440-02-0.htm		
Chemblink	**Accessed Date:**	23/12/2022
https://www.chemblink.com/products/7440-38-2.htm		
Chemblink	**Accessed Date:**	23/12/2022
https://www.chemblink.com/products/7440-43-9.htm		
Chemblink	**Accessed Date:**	23/12/2022
https://www.chemblink.com/products/7732-18-5.htm		
Chemblink	**Accessed Date:**	18/01/2023
https://www.chemblink.com/products/8000-48-4.htm		
Chemblink	**Accessed Date:**	11/01/2023
https://www.chemblink.com/products/84696-13-9.htm		
Chemblink	**Accessed Date:**	04/01/2023
https://www.chemblink.com/products/9005-64-5.htm		
ChemSpider	**Accessed Date:**	23/12/2022
http://www.chemspider.com/Chemical-Structure.1108.html?rid=a4586b57-1bc1-49e7-950d-1933538b872a		
ChemSpider	**Accessed Date:**	23/12/2022
http://www.chemspider.com/Chemical-Structure.22408.html?rid=a357bbe0-5244-4557-8fdb-0ee87a438332		
ChemSpider	**Accessed Date:**	13/01/2023
http://www.chemspider.com/Chemical-Structure.7787.html?rid=5f2af082-3c17-4a73-8a22-7f50b56fba91		
ChemSpider	**Accessed Date:**	23/12/2022
http://www.chemspider.com/Chemical-Structure.8034793.html?rid=c1ac2583-7aac-4f01-b1c5-670198d2317e		
ChemSpider	**Accessed Date:**	23/12/2022
https://www.chemspider.com/Chemical-Structure.29015.html?rid=bd327d96-323b-4a95-bb2f-d1c17a7a21e1		
CIR	**Accessed Date:**	04/01/2023
https://cir-safety.org/sites/default/files/qrt-r.pdf		

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LITERATURE SOURCES

CIR	**Accessed Date:**	23/12/2022
https://www.cir-safety.org/sites/default/files/QRT_Dec2014_posted031815.pdf		
CIR 2014	**Accessed Date:**	23/12/2022
https://www.cir-safety.org/sites/default/files/glycer_092014_Tent.pdf		
CLP 17 ATP	**Accessed Date:**	23/12/2022
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0849&from=EN		
CLP ATP	**Accessed Date:**	12/01/2023
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R1182&from=EN		
CLP Regulation	**Accessed Date:**	18/01/2023
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1272-20221217&from=EN		
CLP Regulation 17.12.2022	**Accessed Date:**	11/01/2023
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1272-20221217&from=EN		
COMMISSION REGULATION (EC) No 1170/2009	**Accessed Date:**	23/12/2022
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1170&from=EN		
COMMISSION REGULATION (EU) No 655/2013	**Accessed Date:**	13/01/2023
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0655&from=EN		
Cosing	**Accessed Date:**	23/12/2022
http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=28401		
Cosing	**Accessed Date:**	13/01/2023
http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=33097		
Cosing	**Accessed Date:**	12/01/2023
http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=33991		
Cosing	**Accessed Date:**	23/12/2022
http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=34128		
Cosing	**Accessed Date:**	09/01/2023
http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=34238		
Cosing	**Accessed Date:**	12/01/2023
http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=35016		
Cosing	**Accessed Date:**	10/01/2023
http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=55376		

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LITERATURE SOURCES

Cosing	**Accessed Date:**	10/01/2023
http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=74820		
Cosing	**Accessed Date:**	23/12/2022
http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=80273		
Cosing	**Accessed Date:**	02/01/2023
http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=80653		
Cosing	**Accessed Date:**	23/12/2022
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=28680		
Cosing	**Accessed Date:**	23/12/2022
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=28880		
Cosing	**Accessed Date:**	13/01/2023
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=28884		
Cosing	**Accessed Date:**	23/12/2022
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=29394		
Cosing	**Accessed Date:**	23/12/2022
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=29454		
Cosing	**Accessed Date:**	13/01/2023
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=30026		
Cosing	**Accessed Date:**	23/12/2022
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=30120		
Cosing	**Accessed Date:**	23/12/2022
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=31351		
Cosing	**Accessed Date:**	23/12/2022
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=31959		
Cosing	**Accessed Date:**	23/12/2022
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=33805		
Cosing	**Accessed Date:**	23/12/2022
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=33896		
Cosing	**Accessed Date:**	13/01/2023
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=33910		

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Manufacturer
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LITERATURE SOURCES

Cosing	**Accessed Date:**	23/12/2022
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=34040		
Cosing	**Accessed Date:**	23/12/2022
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=36522		
Cosing	**Accessed Date:**	23/12/2022
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=38627		
Cosing	**Accessed Date:**	18/01/2023
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=40048		
Cosing	**Accessed Date:**	17/01/2023
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=40918		
Cosing	**Accessed Date:**	10/01/2023
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=54348		
Cosing	**Accessed Date:**	12/01/2023
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=57187		
Cosing	**Accessed Date:**	18/01/2023
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=76052		
Cosing	**Accessed Date:**	11/01/2023
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=76329		
Cosing	**Accessed Date:**	17/01/2023
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=79866		
Cosing	**Accessed Date:**	18/01/2023
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=80201		
Cosing	**Accessed Date:**	17/01/2023
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=80204		
Cosing	**Accessed Date:**	23/12/2022
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=80273		
Cosing	**Accessed Date:**	23/12/2022
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=80281		
Cosing	**Accessed Date:**	23/12/2022
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=80919		

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Cosing	**Accessed Date:**	23/12/2022
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=81067		
Cosing	**Accessed Date:**	17/01/2023
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=84257		
Cosing	**Accessed Date:**	23/12/2022
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=87717		
Cosing	**Accessed Date:**	16/01/2023
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=87815		
Cosing	**Accessed Date:**	09/01/2023
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=89223		
Cosing	**Accessed Date:**	17/01/2023
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=96168		
Cosing	**Accessed Date:**	10/01/2023
https://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.details_v2&id=96287		
DIRECTIVE 2002/46/EC	**Accessed Date:**	23/12/2022
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32002L0046&from=EN		
DrugFuture	**Accessed Date:**	10/01/2023
https://www.drugfuture.com/toxic/q124-q425.html		
EC Public consultation on fragrance allergens 2019	**Accessed Date:**	17/01/2023
https://ec.europa.eu/docsroom/documents/34512		
ECHA C&L Inventory	**Accessed Date:**	12/01/2023
https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/79785		
ECHA CLH	**Accessed Date:**	13/01/2023
https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e1860766fb?utm_source=echa-weekly		
ECHA CLH December 2022	**Accessed Date:**	13/01/2023
https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e18772ab72?utm_source=echa-weekly		
ECHA Information on biocides	**Accessed Date:**	23/12/2022
https://echa.europa.eu/information-on-chemicals/biocidal-active-substances		
ECHA Information on biocides	**Accessed Date:**	23/12/2022
https://echa.europa.eu/pl/information-on-chemicals/biocidal-active-substances		

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Eresos Health + Wellbeing LTD
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LITERATURE SOURCES

ECHA Registered Substances	**Accessed Date:**	13/01/2023
https://echa.europa.eu/da/registration-dossier/-/registered-dossier/13694/1		
ECHA Registered Substances	**Accessed Date:**	23/12/2022
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/13377		
ECHA Registered Substances	**Accessed Date:**	04/01/2023
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/13525		
ECHA Registered Substances	**Accessed Date:**	23/12/2022
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/13681/2/1		
ECHA Registered Substances	**Accessed Date:**	12/01/2023
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/14184/2/1		
ECHA Registered Substances	**Accessed Date:**	23/12/2022
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/14481		
ECHA Registered Substances	**Accessed Date:**	23/12/2022
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/14481/7/6/4		
ECHA Registered Substances	**Accessed Date:**	12/01/2023
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/14501		
ECHA Registered Substances	**Accessed Date:**	17/01/2023
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/14548		
ECHA Registered Substances	**Accessed Date:**	18/01/2023
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/14864/2/1		
ECHA Registered Substances	**Accessed Date:**	23/12/2022
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/15160/1/1		
ECHA Registered Substances	**Accessed Date:**	12/01/2023
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/15256/1		
ECHA Registered Substances	**Accessed Date:**	23/12/2022
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/15342		
ECHA Registered Substances	**Accessed Date:**	23/12/2022
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/15437		
ECHA Registered Substances	**Accessed Date:**	13/01/2023
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/15483		

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Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

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LITERATURE SOURCES

ECHA Registered Substances	**Accessed Date:**	23/12/2022
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/15508		
ECHA Registered Substances	**Accessed Date:**	23/12/2022
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/15538/7/8		
ECHA Registered Substances	**Accessed Date:**	23/12/2022
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/15544		
ECHA Registered Substances	**Accessed Date:**	13/01/2023
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/15741		
ECHA Registered Substances	**Accessed Date:**	23/12/2022
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/15766		
ECHA Registered Substances	**Accessed Date:**	09/01/2023
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/15803/1		
ECHA Registered Substances	**Accessed Date:**	23/12/2022
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/15813/4/8		
ECHA Registered Substances	**Accessed Date:**	23/12/2022
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/15842/1		
ECHA Registered Substances	**Accessed Date:**	23/12/2022
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/15973		
ECHA Registered Substances	**Accessed Date:**	23/12/2022
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/16063		
ECHA Registered Substances	**Accessed Date:**	13/01/2023
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/16102/7/6/3		
ECHA Registered Substances	**Accessed Date:**	23/12/2022
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/16725		
ECHA Registered Substances	**Accessed Date:**	10/01/2023
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/17475/1/1		
ECHA Registered Substances	**Accessed Date:**	17/01/2023
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/20488		
ECHA Registered Substances	**Accessed Date:**	18/01/2023
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/20921/7/6/2		

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Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

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LITERATURE SOURCES

ECHA Registered Substances	**Accessed Date:**	17/01/2023
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/21156		
ECHA Registered Substances	**Accessed Date:**	10/01/2023
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/22071		
ECHA Registered Substances	**Accessed Date:**	18/01/2023
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/22343		
ECHA Registered Substances	**Accessed Date:**	23/12/2022
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/22366		
ECHA Registered Substances	**Accessed Date:**	16/01/2023
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/23881/1		
ECHA Registered Substances	**Accessed Date:**	18/01/2023
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/25026		
ECHA Registered Substances	**Accessed Date:**	23/12/2022
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/5169		
ECHA Registered Substances	**Accessed Date:**	17/01/2023
https://echa.europa.eu/pl/registration-dossier/-/registered-dossier/5479		
ECHA Registered Substances	**Accessed Date:**	23/12/2022
https://echa.europa.eu/registration-dossier/-/registered-dossier/11202/1		
ECHA Substance information	**Accessed Date:**	10/01/2023
https://echa.europa.eu/pl/substance-information/-/substanceinfo/100.215.986		
ECHA Summary of Classification and Labelling	**Accessed Date:**	10/01/2023
https://echa.europa.eu/pl/information-on-chemicals/cl-inventory-database/-/discli/details/221242		
EMEA	**Accessed Date:**	23/12/2022
https://www.ema.europa.eu/documents/scientific-guideline/note-guidance-quality-water-pharmaceutical-use_en.pdf		
EOD	**Accessed Date:**	17/01/2023
https://www.essentialoilsdirect.co.uk/aromatherapy/msds/peppermint_oil%20_piperita_essential_oil.pdf		
EPA	**Accessed Date:**	23/12/2022
https://www.epa.gov/sites/production/files/2016-09/documents/ethylene-oxide.pdf		
EPA	**Accessed Date:**	18/01/2023
https://www.epa.govt.nz/assets/Uploads/Documents/Hazardous-Substances/2017-Group-Standards/46a81f194f/Cosmetic-Products-Group-Standard-Schedules-4-8.pdf		

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Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

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LITERATURE SOURCES

EU Fragrance Allergens Legislative Proposal from 2023	**Accessed Date:**	17/01/2023
https://members.wto.org/crnattachments/2022/TBT/EEC/22_6171_00_e.pdf		
European Union - Classification & Labelling	**Accessed Date:**	23/12/2022
https://echa.europa.eu/substance-information/-/substanceinfo/100.004.173		
FDA	**Accessed Date:**	13/01/2023
https://www.fda.gov/cosmetics/cosmetic-ingredient-names/color-additives-permitted-use-cosmetics		
FDA Guidance for Industry	**Accessed Date:**	23/12/2022
https://www.fda.gov/media/71029/download		
FDA report	**Accessed Date:**	23/12/2022
https://www.fda.gov/media/87682/download		
FDA.gov	**Accessed Date:**	18/01/2023
https://www.fda.gov/cosmetics/cosmetic-ingredient-names/color-additives-permitted-use-cosmetics		
FDA.gov	**Accessed Date:**	09/01/2023
https://www.fda.gov/cosmetics/cosmetic-products-ingredients		
Final Report on the Safety Assessment of Phenoxyethanol	**Accessed Date:**	23/12/2022
https://journals.sagepub.com/doi/10.3109/10915819009078737		
GHS classification	**Accessed Date:**	23/12/2022
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R0217&from=EN		
IFRA (International Fragrance Assocication)	**Accessed Date:**	12/01/2023
https://ifrafragrance.org/pdf/web/viewer.html?file=/standards/IFRA_STD_186.pdf		
IFRA (International Fragrance Assocication)	**Accessed Date:**	16/01/2023
https://ifrafragrance.org/standards/IFRA_STD48_0185.pdf		
INCHEM	**Accessed Date:**	18/01/2023
http://www.inchem.org/documents/pims/pharm/pim031.htm#PartTitle:1.%20%20NAME		
Journal of the European Academy of Dermatology and Venereology	**Accessed Date:**	23/12/2022
https://onlinelibrary.wiley.com/doi/full/10.1111/jdv.15944		
MATTILSYNET	**Accessed Date:**	23/12/2022
https://www.mattilsynet.no/kosmetikk/stoffer_i_kosmetikk/risk_profile_vitamin_e_280e.11322/binary/Risk%20Profile%20Vitamin%20E%20280e		
Medical Devices Directive	**Accessed Date:**	09/01/2023
https://echa.europa.eu/eu-medical_devices-anx_i_7_8		

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Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

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LITERATURE SOURCES

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		
National Toxicology Program (NTP)	**Accessed Date:**	23/12/2022
https://pubchem.ncbi.nlm.nih.gov/compound/962		
NCBI	**Accessed Date:**	10/01/2023
https://pubchem.ncbi.nlm.nih.gov/compound/26346		
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/		
New Zealand gov	**Accessed Date:**	09/01/2023
https://www.epa.govt.nz/industry-areas/hazardous-substances/guidance-for-importers-and-manufacturers/cosmetics/		
NHR Organic Oils	**Accessed Date:**	17/01/2023
https://www.nhrorganicoils.com/uploads/20161019112122e_Black_Pepper_SDS.pdf		
NHR Organic Oils	**Accessed Date:**	17/01/2023
https://www.nhrorganicoils.com/uploads/20171212101730e_Black_Pepper_Allergens.pdf		
NICNAS	**Accessed Date:**	10/01/2023
https://www.industrialchemicals.gov.au/chemicals/aloe-vera-ext		
NICNAS	**Accessed Date:**	17/01/2023
https://www.industrialchemicals.gov.au/chemicals/oils-clary-sage		
NICNAS	**Accessed Date:**	12/01/2023
https://www.industrialchemicals.gov.au/search-inventory?casnumber=106-24-1		
NICNAS	**Accessed Date:**	23/12/2022
https://www.industrialchemicals.gov.au/search-inventory?casnumber=56-81-5		
NICNAS	**Accessed Date:**	12/01/2023
https://www.industrialchemicals.gov.au/search-inventory?casnumber=78-70-6		
NICNAS	**Accessed Date:**	13/01/2023
https://www.industrialchemicals.gov.au/search-inventory?casnumber=97-53-0		

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LITERATURE SOURCES

Official Journal (OJ)	**Accessed Date:**	23/12/2022
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2021:188:FULL&from=ES		
Pb heavy metal Food and Drug Act Canada / USA	**Accessed Date:**	23/12/2022
https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/industry-professionals/guidance-heavy-metal-impurities-cosmetics.html		
Proposal for Harmonised Classification and Labelling, 2018	**Accessed Date:**	12/01/2023
https://echa.europa.eu/documents/10162/12123341-9b50-7500-7e79-36f06a9400f1		
Proposition 65 List, February 2022	**Accessed Date:**	18/01/2023
https://oehha.ca.gov/media/downloads/proposition-65//p65chemicalslistsinglelisttable2021p.pdf		
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:**	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:**	13/01/2023
https://pubchem.ncbi.nlm.nih.gov/compound/241#section=Experimental-Properties		
PubChem	**Accessed Date:**	23/12/2022
https://pubchem.ncbi.nlm.nih.gov/compound/312		
PubChem	**Accessed Date:**	23/12/2022
https://pubchem.ncbi.nlm.nih.gov/compound/31275		
PubChem	**Accessed Date:**	23/12/2022
https://pubchem.ncbi.nlm.nih.gov/compound/5352425		
PubChem	**Accessed Date:**	23/12/2022
https://pubchem.ncbi.nlm.nih.gov/compound/5359596		
PubChem	**Accessed Date:**	10/01/2023
https://pubchem.ncbi.nlm.nih.gov/compound/644019		
PubChem	**Accessed Date:**	17/01/2023
https://pubchem.ncbi.nlm.nih.gov/compound/6850741		

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LITERATURE SOURCES

PubChem	**Accessed Date:**	13/01/2023
https://pubchem.ncbi.nlm.nih.gov/compound/8058		
PubChem	**Accessed Date:**	13/01/2023
https://pubchem.ncbi.nlm.nih.gov/compound/8078		
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:**	17/01/2023
https://pubchem.ncbi.nlm.nih.gov/substance/135333140		
PubChem	**Accessed Date:**	18/01/2023
https://pubchem.ncbi.nlm.nih.gov/substance/254785203		
PubChem	**Accessed Date:**	11/01/2023
https://pubchem.ncbi.nlm.nih.gov/substance/363907296		
PubMed	**Accessed Date:**	23/12/2022
https://pubmed.ncbi.nlm.nih.gov/31588615/		
PubMed	**Accessed Date:**	10/01/2023
https://www.ncbi.nlm.nih.gov/pubmed/17613130		
PubMed - NCBI	**Accessed Date:**	13/01/2023
https://pubchem.ncbi.nlm.nih.gov/compound/8078		
PubMed - NCBI	**Accessed Date:**	23/12/2022
https://pubmed.ncbi.nlm.nih.gov/16759740/		
RAC Opinion	**Accessed Date:**	23/12/2022
https://echa.europa.eu/documents/10162/13579/rac_mandate_art77_3c_lead_en.pdf/da03fe7b-19a1-5dfa-3086-6e0c2973dc65		
RAC Opinion	**Accessed Date:**	13/01/2023
https://echa.europa.eu/documents/10162/13641/benzene_opinion_en.pdf/4fec9aac-9ed5-2aae-7b70-5226705358c7		
RAC Opinion	**Accessed Date:**	23/12/2022
https://echa.europa.eu/documents/10162/13641/nickel_opinion_en.pdf/9e050da5-b45c-c8e5-9e5e-a1a2ce908335		

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LITERATURE SOURCES

RAC Opinion November 2014	**Accessed Date:**	13/01/2023
https://echa.europa.eu/documents/10162/13641/rac_opinion_adopted_benzene_in_natural_gas_en.pdf/0881315c-0b10-4998-baf6-d336f14611aa		
Registry of CLH intentions	**Accessed Date:**	12/01/2023
https://echa.europa.eu/hr/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e180de1f34		
Registry of CLH intentions	**Accessed Date:**	12/01/2023
https://echa.europa.eu/pl/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e1806438d3		
Registry of CLH intentions	**Accessed Date:**	12/01/2023
https://echa.europa.eu/pl/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e180665794		
Registry of SVHC intentions	**Accessed Date:**	23/12/2022
https://echa.europa.eu/pl/registry-of-svhc-intentions/-/dislist/details/0b0236e1857f0d76		
Regulation (EC) No 1223/2009 Dec 2022	**Accessed Date:**	18/01/2023
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009R1223-20221217&from=EN		
Regulation (EC) No 1223/2009 UK	**Accessed Date:**	17/01/2023
https://www.legislation.gov.uk/eur/2009/1223		
Regulation (EC) No 1223/2009 UK	**Accessed Date:**	23/12/2022
https://www.legislation.gov.uk/eur/2009/1223/annex/II		
Regulation (EC) No 1223/2009 UK	**Accessed Date:**	18/01/2023
https://www.legislation.gov.uk/eur/2009/1223/contents		
Regulation (EC) No 1223/2009 UK Annex II	**Accessed Date:**	13/01/2023
https://www.legislation.gov.uk/eur/2009/1223/annex/II		
Regulation (EC) No 1223/2009 UK Annex III	**Accessed Date:**	16/01/2023
https://www.legislation.gov.uk/eur/2009/1223/annex/III		
Regulation (EC) No 1223/2009 UK, Annex II	**Accessed Date:**	13/01/2023
https://www.legislation.gov.uk/eur/2009/1223/annex/II		
Regulation EC NO 2017/1112	**Accessed Date:**	23/12/2022
https://eur-lex.europa.eu/legal-content/PL/TXT/PDF/?uri=CELEX:32017R1112&from=LT		
Safety review of phenoxyethanol	**Accessed Date:**	23/12/2022
https://onlinelibrary.wiley.com/doi/full/10.1111/jdv.15944		
SCCP/1181/08	**Accessed Date:**	23/12/2022
https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_139.pdf		

Product Name
Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

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

LITERATURE SOURCES

SCCS 2001	**Accessed Date:**	13/01/2023
https://ec.europa.eu/health/ph_risk/committees/sccp/documents/out149_en.pdf		
SCCS 2004	**Accessed Date:**	13/01/2023
https://ec.europa.eu/health/ph_risk/committees/sccp/documents/out278_en.pdf		
SCCS Opinions	**Accessed Date:**	18/01/2023
https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_160.pdf		
SCCS Opinions	**Accessed Date:**	23/12/2022
https://ec.europa.eu/health/ph_risk/committees/sccp/documents/out148_en.pdf		
SCCS Opinions	**Accessed Date:**	16/01/2023
https://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/sccnfp_opinions_97_04/sccp_out126_en.htm		
SCCS Opinions 2016	**Accessed Date:**	23/12/2022
https://ec.europa.eu/health/sites/default/files/scientific_committees/consumer_safety/docs/sccs_o_195.pdf		
SCCS/1359/10	**Accessed Date:**	23/12/2022
https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_056.pdf		
Schedules of the 1961 Single Convention on Narcotic Drugs	**Accessed Date:**	10/01/2023
https://www.incb.org/documents/Narcotic-Drugs/1961-Convention/convention_1961_en.pdf		
ScienceDirect	**Accessed Date:**	09/01/2023
https://www.sciencedirect.com/topics/chemistry/acrylic-acid		
SCIENTIFIC COMMITTEE ON CONSUMERS SAFETY	**Accessed Date:**	23/12/2022
http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_q_126.pdf		
Scientific Committees EU	**Accessed Date:**	16/01/2023
https://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/sccnfp_opinions_97_04/sccp_out126_en.htm		
Spectrum Chemical	**Accessed Date:**	10/01/2023
https://www.spectrumchemical.com/MSDS/G1047_AGHS.pdf		
Standards for Cosmetics Japan	**Accessed Date:**	23/12/2022
https://www.mhlw.go.jp/english/dl/cosmetics.pdf		
The Risk Assessment Information System	**Accessed Date:**	23/12/2022
https://rais.ornl.gov/tox/profiles/arsenic.html		
The Toys Safety Regulations 2011 UK	**Accessed Date:**	12/01/2023
https://www.legislation.gov.uk/uksi/2011/1881/contents/made		

Product Name
Active Muscle Therapy Balm 1000mg (2022-753-5061) (variant) CPSR EU/UK passed under condition

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

LITERATURE SOURCES

ToxNet	**Accessed Date:**	10/01/2023
https://chem.nlm.nih.gov/chemidplus/rn/13956-29-1		
Toy Directive	**Accessed Date:**	23/12/2022
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009L0048-20191118&from=EN		
Toy Directive	**Accessed Date:**	23/12/2022
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009L0048-20191118&qid=1587975177700&from=en		
U.S. National Library of Medicine	**Accessed Date:**	11/01/2023
https://medlineplus.gov/druginfo/natural/726.html		
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.*

4 Lime Crescent, Willand, Cullompton, Devon, EX15 2S, UK
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