



SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

Toxicological Safety Assessment of: Very Vapour

Client Name: Guardian Angel, 10 Pen Y Lan, Penclawdd, Swansea, SA4 3LL

Responsible Person: Daniela James, Guardian Angel, 10 Pen Y Lan, Penclawdd, Swansea, SA4 3LL

REF: C1008/05



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Composition of Formulation

CAS Number	INCI Name	Maximum Concentration %
8001-25-0	Olea Europaea Fruit Oil	41.23711
8001-31-8	Cocos Nucifera Oil	41.23711
8012-89-3	Cera Alba	16.49485
8006-90-4 (Essential Oils Direct)	Mentha Piperita Oil	0.3092784
84625-32-1 (Essential Oils Direct)	Eucalyptus Globulus Leaf Oil	0.3092784
84604-14-8 (Leaf Oil) (Essential Oils Direct)	Rosmarinus Officinalis Leaf Oil	0.2061856
84649-98-9 (Essential Oils Direct)	Cinnamomum Zeylanicum Leaf Oil	0.2061856



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Acronyms & Abbreviations used in this document

Acronym	Expanded form
CAS Number	Chemical Abstracts Service Number
bw	Body Weight
cfu	Colony Forming Units
EINECS	European Inventory of Existing Commercial chemical Substances
g	Grams
GI	Gastrointestinal
INCI	International Nomenclature of Cosmetic Ingredients
Kg	Kilograms
LD50	Lethal Dose 50 (Toxicology protocol)
mcg	Micrograms
mg	Milligrams
ml	Millilitres
MoS	Margin of Safety
N/A	Not Applicable
N/K	Not Known
NOAEL	No Observed Adverse Effect Level
PPM	Parts Per Million
qs	Quantity Sufficient
SCCS	Scientific Committee on Consumer Safety
SED	Systemic Exposure Dose
TVC	Total Viable Count



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Microbiological Quality

To comply with the guidelines on the microbiology quality (ssnfp/000498), the following maximum limits apply:

Category 1: Products specifically intended for children under 3 years, eye area and mucous membranes.

TVC: - 100 cfu/g or ml in 0.5g or ml of the product

Pseudomonas aeruginosa, staphylococcus aureus and candida albicans must not be detected in 0.5 g or ml of the cosmetic product.

Category 2: other cosmetic product.

TVC: - 1000 cfu/g or ml in 0.1g or ml of the product

Pseudomonas aeruginosa, staphylococcus aureus and candida albicans must not be detected in 0.1 g or ml of the cosmetic product.

The microbiology specifications for the product have been supplied and based upon the conclusions therein; meet the industry requirements specified in the guidelines on the Microbiology Quality of the Cosmetic product, 1999 edition.

The preservative challenge test results for this product have been supplied and based upon the conclusions made there in appear to meet the industry requirements specified in the notes of the guidance for testing of the cosmetic ingredients for their safety evaluation. Annex 8 – Guidelines on the microbiological quality of the cosmetic product, 1999 edition.



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Purity of raw materials

It is assumed that all raw materials used in Very Vapour either in a mixture/compound or 99.9% purity, are free from residual compounds and Nano.

The Regulation prohibits the use of substances recognized as carcinogenic, mutagenic or toxic for reproduction (classified as CMR), apart from in exceptional cases. It provides for a high level of protection of human health where nanomaterials are used in cosmetic products.



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Storage assumptions, Packaging and Stability

It is assumed that the responsible person Daniela James, Guardian Angel, 10 Pen Y Lan, Penclawdd, Swansea, SA4 3LL, has selected all pertinent criteria required of this cosmetic during reasonable foreseeable conditions of storage. The stability report provided by the suppliers and based upon the conclusions made therein. This cosmetic product appears to be stable under reasonable foreseeable storage conditions.

Very Vapour has proven to be inert when in contact with the final packaging



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Serious or Undesirable Effects

On request, the supplier has not supplied information of any known reports known to him of serious undesirable effects on the cosmetic product, or where relevant, other similar cosmetic products and this cannot be commented upon. If the supplier is aware of an abnormally high level of customer complaints the supplier must bring this to the attention of the safety assessor and submit this formulation for reassessment and notify the competent authorities of corrective actions taken.



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Animal Testing declaration

Directive 86/609/EEC is replaced by Directive Regulation (EC) No 1223/2009 on cosmetic products 11/07/2013 on the protection of animals used for scientific purposes with effect from 1 January 2013 with the exception of Article 13, which shall be repealed with effect from 10 May 2013.

The old Directive introduced for the first time legal provisions in the EU to harmonize national provisions covering the welfare of animals used for experimental and scientific purposes.

Very Vapour follows Directive 2010/63/EU in relation to animal testing.

None of the Raw materials or finished product has been tested on animals since 10/5/2013 for repeated-dose toxicity, skin sensitization, carcinogenicity, reproductive toxicity and toxicokinetics.

All Toxicological data used in this cosmetic safety assessment using animal models for the investigation of cosmetic products was published before 10/5/2013.



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General Manufacturing Procedure

The client follows the following GMP and has been designated the following GMP ref number: ISO22716

General Procedures

- The Work Area will be kept clean and tidy at all times
- No smoking, eating, drinking or food preparation in the work area during cosmetic production?
- Adequate ventilation will be maintained?
- Equipment will be checked before and after use for any defects; should any be found the item(s) will not be used until repaired or replaced?
- Equipment will be cleaned and stored immediately after use?
- Equipment will be kept separate from that used for food preparation and dining

Personal Hygiene, Health and Safety

- Good personal cleanliness will be maintained
- Designated clothing will be worn (footwear to cover all upper surface of feet, no sandal styles to be worn)
- Refrain from cosmetic making if suffering from skin infection or lesions (small cuts and abrasions on hands to be covered with food-grade dressing and vinyl gloves) until condition is cleared
- Refrain from cosmetic making if suffering from infectious or contagious condition (including Common Cold) or allergy until condition is cleared
- Hands to be washed before commencing production
- Ensure floor area is free from clutter and spillage
- Ensure hands are dry and that switches are in "off" position before plugging/unplugging electrical equipment
- Maintain good posture when lifting and carrying avoid twisting
- When cutting from soap block place it on secure surface and use downward action with knife; do not cut soap pieces held in hand
- Use safety gloves when handling hot equipment
- Use vinyl gloves when measuring/pouring Essential Oils or Fragrance Oils
- Ensure familiarity with ingredient MSDSs, particularly with regard to ingestion, inhalation and spills on skin
- Ensure good ventilation
- Clean up any spillages immediately and dispose of appropriately (see MSDSs)

Storage of Ingredients and Finished cosmetics

- Ingredients will be stored in the original containers from suppliers, particularly essential oils and fragrance oils in amber bottles, with original labels and batch numbers. These will be placed in plastic storage boxes with sealed lids.
- Finished products will be stored in plastic storage boxes with sealed lids.
- All storage at ambient room temperature (in coolest room during any heat-wave)
- All containers to be labeled
- Batch numbers and dates to be checked regularly



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Consumer Exposure and Toxicological and Regulatory Review Summary

Product Class:	4c
IFRA Category:	Body creams
Targeted Population:	Children
Number of uses per day:	Once
Amount per Application/g:	2 g
Total amount applied per day/g:	2 g
Estimated daily exposure (Daily):	0.03278689 g.(kg bw)-1.day-1
Average mean weight of Adult:	61 Kg
Average mean weight of Child:	16 Kg
Average mean weight of Baby:	5.9 Kg
Retention factor:	1
Exposure time neat:	3600 seconds
Exposure time dilute:	0 seconds



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Toxicological Summary

Very Vapour is a chest balm for use in adults and children over 6 years old. A small amount is applied to the hand and massaged into the skin. This product is not rinsed off. It has been estimated that the product will be applied Once a day totalling 2 g. It has been assumed for each ingredient in the formulation most involving the application of uncertainty factors to the lowest appropriate (NOAEL) to derive a human Tolerable Daily Intake (TDI), this defined as an estimate of the daily intake of a substance over a lifetime that is considered to be without appreciable health risk. It's units are commonly expressed in mg person-1 day-1 and assume a body mass of an adult is of 61.0 kg for an adult. The average body weight for a child is assumed to be 16 kg. The advised PAO for this type of product, with the advisable levels of preservative is 12 M.



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Effects of the finished product on specific organs and tissue types

Internal organs: Very Vapour is unlikely to cause damage to the internal organs following application.

Ocular area: Very Vapour may cause irritation to the eye area; instructions following eye irritation are printed on the packaging.

Ingestion: Very Vapour poses low risk from ingestion if used as directed. If swallowed the ingredients do not pose a significant acute hazard, although regular ingestion may be harmful. Upper GI Irritation such as nausea and vomiting and diarrhoea can be expected. If large amounts of Very Vapour is ingested medical assistance will be required. Appropriate warnings should be printed on the label for external use only & keep out of reach of children.

Upper gastrointestinal: Very Vapour is likely to cause upper gastrointestinal irritation.

Inhalation: Very Vapour is unlikely to cause irritation due to inhalation if the product is used as instructed.

Very Vapour is expected to have low acute toxicity if used correctly and following the Manufacturer's directions. Oral exposure is not a foreseeable route of exposure, if ingested the finished product might cause general GI irritation. If the manufacturing instructions are followed ocular irritation is not a foreseeable route of exposure.



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Fragrance Data

Fragrance allergens are subject to limitations as specified in the Annexes to Regulation (EC) No 1223/2009. This requires allergens to be within IFRA restrictions as to the maximum permissible concentration of allergens in the finished product. In addition lower thresholds have been set, whereby if the concentration of an allergen exceeds that lower threshold, it must be specifically labeled on the packaging as part of the ingredients. The tables below state the conclusions with regard to compliance with regard to IFRA restriction, and then the analysis with regard to labeling. In the cases of products that are combined or diluted prior to application, the combined or diluted concentrations are used to calculate allergen concentrations are within IFRA restrictions.

Very Vapour contains fragrance allergens at concentrations exceeding the EU labelling threshold and therefore the following fragrance allergens need to be listed to the outer packaging: Benzyl Benzoate, Cinnamaldehyde, Eugenol, Limonene, Linalool.

Conclusions with regard to IFRA restrictions on the product as applied:

CAS Number	% Concentration of formulation	% Limit for this type of product	Conclusion
120-51-4	0.006185568	26.7	Pass: Within limits
104-55-2	0.002783506	0.05	Pass: Within limits
97-53-0	0.1608248	0.5	Pass: Within limits

Analysis of notifiable allergens (Annex III restrictions) in the finished product:

INCI Name	CAS	% Concentration of formulation
Benzyl Benzoate	120-51-4	0.006185568
Cinnamaldehyde	104-55-2	0.002783506
Eugenol	97-53-0	0.1608248
Limonene	138-86-3	0.04773197
Linalool	78-70-6	0.00701031

INCI Name: Mentha Piperita Oil **CAS Number:** 8006-90-4 (Essential Oils Direct)

INCI Name	CAS	% Concentration of ingredient	% Concentration of formulation
d-Limonene	5989-27-5	3	0.009278352
Linalool	78-70-6	0.4	0.001237114

INCI Name: Eucalyptus Globulus Leaf Oil **CAS Number:** 84625-32-1 (Essential Oils Direct)

INCI Name	CAS	% Concentration of ingredient	% Concentration of formulation
d-Limonene	5989-27-5	8.1	0.02505155

INCI Name: Rosmarinus Officinalis Leaf Oil **CAS Number:** 84604-14-8 (Leaf Oil) (Essential Oils Direct)

INCI Name	CAS	% Concentration of ingredient	% Concentration of formulation
d-Limonene	5989-27-5	6	0.01237114
Linalool	78-70-6	0.8	0.001649485

INCI Name: Cinnamomum Zeylanicum Leaf Oil **CAS Number:** 84649-98-9 (Essential Oils Direct)



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INCI Name	CAS	% Concentration of ingredient	% Concentration of formulation
Benzyl Benzoate	120-51-4	3	0.006185568
Cinnamaldehyde	104-55-2	1.35	0.002783506
Eugenol	97-53-0	78	0.1608248
d-Limonene	5989-27-5	0.5	0.001030928
Linalool	78-70-6	2	0.004123712



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Conclusion

Very Vapour has been formulated with ingredients, widely used in the cosmetic industry, and has been safely used and unlikely to cause adverse effects. The formulation does not contain any impurities or residual chemicals that are toxic to human health.

If the consumer follows the directions and taking into account similar products containing similar raw materials with a long history of safety, Very Vapour is not expected to pose a risk to the health of the majority of consumers through any path of irritation.

The finished product Very Vapour and the raw material contained at the concentration used has no known or documented carcinogenic, mutagenic or reprotoxic effect.

The pathway of application would suggest that dermal irritation would be very low if used correctly, if new information comes to light of any of the raw materials then a new safety assessment will be issued.

As a result Very Vapour can be considered as SAFE.

Labelling requirements

The product label must state:

- For external use only.
- Do not use on cut, broken, or irritated skin.
- Avoid contact with eyes. In the event of contact with eye, rinse immediately with water.
- If irritation or rash appears, discontinue use.
- PAO: 12 M
- Ingredients: Olea Europaea Fruit Oil, Cocos Nucifera Oil, Cera Alba, Mentha Piperita Oil, Eucalyptus Globulus Leaf Oil, Rosmarinus Officinalis Leaf Oil, Cinnamomum Zeylanicum Leaf Oil, Eugenol, Limonene, Linalool, Benzyl Benzoate, Cinnamaldehyde



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REACH

The (Registration, Evaluation, Authorization and Restriction of Chemicals). REACH is a new European Union chemicals regulation that took effect on June 1, 2007. This regulation affects all industries, including the cosmetic industry.

It is important to note that all substances used in cosmetics are already regulated for human health by the European Union Cosmetics Directive. Therefore all of our formulations, packaging and transportation is covered by Guardian Angel, 10 Pen Y Lan, Penclawdd, Swansea, SA4 3LL and subsequent PIF (Public Information File) and therefore is compliant with REACH.

Guardian Angel, 10 Pen Y Lan, Penclawdd, Swansea, SA4 3LL are committed to selling only safe products and work diligently to ensure that our formulations, packaging, and ancillary products meet the standards put forth by global governmental, regulatory, and scientific bodies, as well as their own exceedingly high quality assurance standards.



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Assessor credentials

- I, Terence Hughes, BSc (Hons) Chem, MRSC, Member of the Royal Society Of Chemistry and with over 10 years industrial experience within the cosmetic industry, and duly authorized according to the Regulation of the European Parliament and of the Council on cosmetic products (recast) 2008/0035 (COD) dated 10 November 2009 (finally as 1223/2009 on 30 November 2009) which replaces all other regulations. I have taken into consideration the general toxicological profile of each ingredient used, the chemical structure, the CIR panel evaluation where available, the level of exposure (full technical data and/or toxicology files are held for each ingredient) and a total daily exposure has been calculated along with the margins of safety for each ingredient. As a result of our evaluation the product has been classified as: SAFE.
- Super Active Cosmetics Ltd, remains the owner of the intellectual property contained within this cosmetic safety assessment. As part of this work the client must not without the permission of Super Active Cosmetics Ltd:
 - Reproduce the work
 - Prepare "derivative" works based on the work, or copies of the work
 - Distribute copies of the work
 - Any infringement of these conditions will result in legal action and the safety assessment being withdrawn
- I have independently assessed the product declared above and I cannot confirm that a PIP (Product Information Pack) has been partially completed. A full evaluation of the product has been compiled and this product safety report has been issued. The product fully complies with the legislation listed above and complies with the various Annexes relating to banned, CMRs, and restricted ingredients; colour, preservatives and sunscreens. This product has been produced by a company certified to have good proven GMP and tested to ensure good microbiological quality.

Signature of safety assessor:

BSc Chem (Hons), MRSC, RSci

Date: 19/08/2016

Safety Administrator on behalf of
Super Active Cosmetics Ltd
31 Brindle Heath Road
Salford
Greater Manchester
M66GD

Registered in England and Wales: 8564424



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Chemical Name	Olea Europaea Fruit Oil is the oil expressed from the fruit of the olive
Function	Emollient
INCI Name	Olea Europaea Fruit Oil
CAS	8001-25-0
EINECS	232-277-0
SED(adult)	0.1352036 mg.(kg bw)-1.d-1
SED(child)	0.5154639 mg.(kg bw)-1.d-1
SED(baby)	1.397868 mg.(kg bw)-1.d-1
NOAEL	2000 mg.(kg bw)-1.d-1
Dermal penetration factor	0.01
MoS(adult)	14792.5
MoS(child)	3880
MoS(baby)	1430.75
Additional Notes	Olive oil has a history of safe use as a foodstuff. Whilst there is some evidence of a mild risk of dermal irritation, the risk of systemic toxicity is very low.
Type of test	LD50
Route of exposure	Oral
Species observed	Rat
Dose	980 mg/kg/Bw/day
Duration	
Observations	
Additional Notes	None
Type of test	LD50
Route of exposure	Dermal
Species observed	Rat
Dose	2000 mg/kg/Bw/day
Duration	
Observations	
Additional Notes	None
Type of test	LC50
Route of exposure	Inhalation
Species observed	Rabbit
Dose	1760 mg/kg/bw/50 H
Duration	
Observations	
Additional Notes	None
Type of test	Rec-assay, DNA effects (Test Category: EFFECTS ON NUCLEIC ACIDS Specific Test/Endpoint: DIFFERENTIAL KILLING-REC ASSAY)
Route of exposure	Invitro
Species observed	Escherichia coli polA (W3119 vs P3478)
Dose	
Duration	
Observations	
Additional Notes	Negative



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Type of test LD50
Route of exposure Oral
Species observed Rabbit
Dose 1730 mg/kg mg/kg/bw/day
Duration
Observations
Additional Notes

Type of test LD50
Route of exposure Dermal
Species observed Rabbit
Dose 1730 mg/kg/bw/day
Duration
Observations
Additional Notes

Type of test LC50
Route of exposure
Species observed Rat
Dose 0.95 mg/ml/1/H
Duration
Observations
Additional Notes

Type of test Skin irritancy & sensitization - The Repeated Insult (occlusive) Patch Test (HRIPT)
Route of exposure Dermal
Species observed Human - male
Dose
Duration
Observations Mild irritant especially under occlusion
Additional Notes

Conclusion It is believed that Olea Europaea Fruit Oil is safe for use in Very Vapour at this concentration and use as described, assuming the parameters stated.

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Chemical Name	Cocos Nucifera Oil
Function	Emollient
INCI Name	Cocos Nucifera Oil
CAS	8001-31-8
EINECS	232-282-8
SED(adult)	0.1352036 mg.(kg bw)-1.d-1
SED(child)	0.5154639 mg.(kg bw)-1.d-1
SED(baby)	1.397868 mg.(kg bw)-1.d-1
NOAEL	16400 mg.(kg bw)-1.d-1
Dermal penetration factor	0.01
MoS(adult)	121298.5
MoS(child)	31816
MoS(baby)	11732.15
Additional Notes	Reproductive Toxicity: Cocos Nucifera Oil is not reported to produce reproductive toxicity in humans. Mutagenicity: Cocos Nucifera Oil is not reported to produce mutagenic effects in humans. Embryotoxicity: Cocos Nucifera Oil is not reported to produce embryotoxic effects in humans. Teratogenicity: Cocos Nucifera Oil is not reported to produce teratogenic effects in humans. Cocos Nucifera Oil was not an eye or skin irritant and it was not phototoxic. In genotoxicity /Mutagenic tests in bacteria, Cocos Nucifera Oil was not genotoxic /Mutagenic
Type of test	Acute LD50
Route of exposure	Oral
Species observed	Rat
Dose	2000 mg/kg/bw/day
Duration	
Observations	
Additional Notes	
Type of test	LD50
Route of exposure	Dermal
Species observed	Rat
Dose	4000 mg/kg/bw/day
Duration	
Observations	
Additional Notes	
Type of test	LC50
Route of exposure	Inhalation
Species observed	Rat
Dose	57 ppm/24/H
Duration	
Observations	No conclusion
Additional Notes	
Type of test	Acute LD50
Route of exposure	Oral
Species observed	Rat
Dose	5000 mg/kg/bw/day
Duration	
Observations	
Additional Notes	



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Type of test LD50
Route of exposure Dermal
Species observed Rat
Dose 4000 mg/kg/bw/day
Duration
Observations
Additional Notes

Type of test LC50
Route of exposure Inhalation
Species observed Rat
Dose 57 ppm/24/H
Duration
Observations No conclusion
Additional Notes

Conclusion It is believed that Cocos Nucifera Oil is safe for use in Very Vapour at this concentration and use as described, assuming the parameters stated.

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Chemical Name	Cera Alba
Function	Emollient
INCI Name	Cera Alba
CAS	8012-89-3
EINECS	232-383-7
SED(adult)	0.05408148 mg.(kg bw)-1.d-1
SED(child)	0.2061856 mg.(kg bw)-1.d-1
SED(baby)	0.5591475 mg.(kg bw)-1.d-1
NOAEL	220 mg.(kg bw)-1.d-1
Dermal penetration factor	0.01
MoS(adult)	4067.936
MoS(child)	1067
MoS(baby)	393.4561
	Reproductive Toxicity: This product is not reported to produce reproductive toxicity in humans. Mutagenicity: This product is not reported to produce mutagenic effects in humans. Embryotoxicity: This product is not reported to produce embryotoxic effects in humans. Teratogenicity: This product is not reported to produce teratogenic effects in humans. Reproductive Toxicity: This product is not reported to produce reproductive effects in humans.\n\n
Additional Notes	The NOAEL of beeswax was determined to be 22mg.(kg bw)-1.d-1 in humans by EFSA for the purpose of a glazing agent, based on typical exposures, however noted that the analysis of the chemical constituents would suggest a much higher NOAEL (10-50x higher). Furthermore the oral penetration of beeswax components are very low, and it is expected that the dermal penetration is even lower. Most of the constituents are known to metabolise to endogenous substrates in vivo. The applied NOAEL in this calculation has been modified (1%) to account for the low dermal penetration expected from beeswax.
Type of test	LD50
Route of exposure	Oral
Species observed	Rat
Dose	5000 mg/kg/Bw/day
Duration	
Observations	
Additional Notes	None
Type of test	LD50
Route of exposure	Dermal
Species observed	Rat
Dose	7960 mg/kg/Bw/day
Duration	
Observations	
Additional Notes	None
Type of test	LC50
Route of exposure	Inhalation
Species observed	Rabbit
Dose	10 ppm/8 days
Duration	
Observations	
Additional Notes	None
Conclusion	It is believed that Cera Alba is safe for use in Very Vapour at this concentration and use as described, assuming the parameters stated. /



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Chemical Name	Mentha Piperita Oil
Function	Perfuming
INCI Name	Mentha Piperita Oil
CAS	8006-90-4 (Essential Oils Direct)
EINECS	282-015-4
SED(adult)	0.1014028 mg.(kg bw)-1.d-1
SED(child)	0.386598 mg.(kg bw)-1.d-1
SED(baby)	1.048401 mg.(kg bw)-1.d-1
NOAEL	300 mg.(kg bw)-1.d-1

Dermal penetration factor 1

MoS(adult)	2958.5
MoS(child)	775.9999
MoS(baby)	286.15

Peppermint Oil is used at a concentration of $\leq 3\%$ in rinse-off formulations and $\leq 0.2\%$ in leave on formulations. Peppermint Oil is composed primarily of menthol and menthone. Other possible constituents include pulegone, menthofuran, and limone. Most of the safety test data concern Peppermint Oil. The oil is considered to present the "worst case scenario" because of its many constituents, so data on the oil were considered relevant to the entire group of ingredients. Peppermint Oil was minimally toxic in acute oral studies. Short-term and sub-chronic oral studies reported cystlike lesions in the cerebellum in rats that were given doses of Peppermint Oil containing pulegone, pulegone alone, or large amounts (>200 mg/kg/day) of menthone. Pulegone is also a recognized hepatotoxin. Repeated intradermal dosing with Peppermint Oil produced moderate and severe reactions in rabbits, although Peppermint Oil did not appear to be phototoxic. Peppermint Oil was negative in the Ames test and a mouse lymphomamutagenesis assay but gave equivocal results in a Chinese hamster fibroblast cell chromosome aberration assay. In a carcinogenicity study of toothpaste and its components, no apparent differences were noted between mice treated with Peppermint Oil and those treated with the toothpaste base. Isolated clinical cases of irritation and/or sensitization to Peppermint Oil and/or its constituents have been reported, but Peppermint Oil (8%) was not a sensitizer when tested using a maximization protocol. It was expected that dermal absorption of Peppermint Oil would be rapid, following that of menthol, a major component, but in no case would be greater than absorption through the gastrointestinal tract. Because of the toxicity of pulegone, the safe concentration of this constituent was limited to $\leq 1\%$. This concentration was achievable both by controlling the time of harvest and processing technique. There is evidence that menthol can enhance penetration of other agents. Formulators were cautioned that this enhanced penetration can affect the use of other ingredients whose safety assessment was based on their lack of absorption. With the limitation that the concentration of pulegone in these ingredients should not exceed 1%, it was concluded that Mentha Piperita (Peppermint) Oil, Mentha Piperita (Peppermint) Extract, Mentha Piperita (Peppermint) Leaves, Mentha Piperita (Peppermint) Water are safe as used in cosmetic formulations.

Additional Notes

Type of test	LD50
Route of exposure	Oral
Species observed	Rat
Dose	2426 mg/kg
Duration	
Observations	
Additional Notes	

Type of test	LD50
Route of exposure	Dermal
Species observed	Rabbit
Dose	5000 mg/kg
Duration	
Observations	
Additional Notes	None

Type of test	LC50
Route of exposure	Inhalation
Species observed	Rat
Dose	0.5464mg/mL
Duration	
Observations	
Additional Notes	



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Type of test Mutagenicity - DNA repair
Route of exposure
Species observed Bacteria - Bacillus subtilis
Dose 5 mcL/disc
Duration
Observations
Additional Notes

Conclusion It is believed that Mentha Piperita Oil is safe for use in Very Vapour at this concentration and use as described, assuming the parameters stated.

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Chemical Name	Eucalyptus Globulus Leaf Oil is the volatile oil obtained from the fresh leaves of the Eucalyptus, Eucalyptus globulus and other species of Eucalyptus, Myrtaceae. Syn. Yuukari Yu (Japanese)
Function	Perfuming
INCI Name	Eucalyptus Globulus Leaf Oil
CAS	84625-32-1 (Essential Oils Direct)
EINECS	283-406-2
SED(adult)	0.1014028 mg.(kg bw)-1.d-1
SED(child)	0.386598 mg.(kg bw)-1.d-1
SED(baby)	1.048401 mg.(kg bw)-1.d-1
NOAEL	300 mg.(kg bw)-1.d-1
Dermal penetration factor 1	
MoS(adult)	2958.5
MoS(child)	775.9999
MoS(baby)	286.15
Additional Notes	Eucalyptus Globulus essential oil was evaluated for its fetotoxic potential on Mice. Pregnant dams were injected S.C. (135 mg essential oil/kg body weight) on days 6 to 15 of gestation. In this study, neither embryotoxicity nor fetotoxicity were observed.
Type of test	In-Vitro Dermal
Route of exposure	Oral
Species observed	Human
Dose	4400 mg/ Bw/Day
Duration	
Observations	
Additional Notes	
Type of test	LD50
Route of exposure	Dermal
Species observed	Rabbit
Dose	5000 mg/kg/Bw/Day
Duration	
Observations	
Additional Notes	None
Type of test	LC50
Route of exposure	Inhalation
Species observed	Rat
Dose	0.216 l/cm ²
Duration	
Observations	
Additional Notes	
Type of test	Dermal irritancy
Route of exposure	Dermal
Species observed	Rabbit
Dose	5000 mg.(kg bw)-1
Duration	14d observation
Observations	Dermal reactions noted were slight redness (5/10 rabbits), moderate redness (3/10 rabbits) and moderate oedema (10/10 rabbits) at the site of application. Irritant.
Additional Notes	



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Type of test OECD Guideline 405 (Acute Eye Irritation / Corrosion)
Route of exposure Ocular
Species observed Rabbit - New Zealand White
Dose 0.1 ml
Duration Observed upto 72hr post administration.
Observations Mean scores calculated for each animal over 24, 48 and 72 hours were 0.0/0.0/0.0 for cornea opacity, 0.0/0.0/0.0 for iris lesions, 0.7/1.0/0.7 for redness of the conjunctivae and 0.7/0.7/0.7 for chemosis. Non irritating

Additional Notes

Type of test OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)
Route of exposure Oral - gavage
Species observed Rat - Charles River
Dose 0, 100, 300 and 1000 mg.(kg bw)-1.d-1
Duration
Observations NOAEL F0 was 300 and 1000 mg.(kg bw)-1.d-1 for females and males respectively.
Additional Notes In a Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test conducted according to OECD Guideline 422 and in compliance with GLP, Eucalyptus oil was administered to groups of CrI:CD(SD) rats at 0, 100, 300 and 1000 mg/kg bw/day by oral (gavage). The F0 males were treated for two weeks before pairing up to necropsy after a minimum of five weeks. The F0 females were treated daily for two weeks before pairing, throughout pairing, gestation and lactation until the day prior to termination on Day 6 of lactation. During the study, data was recorded on mortality, clinical signs, behavioural assessments, body weight change, food consumption, haematology, blood chemistry. All animals were subjected to a gross necropsy examination, selected organs were weighed and histopathological evaluation of selected tissues was performed. One female receiving 1000 mg/kg bw/day was found dead on Day 15 after mating, this death was not attributed to treatment. During the first week of dosing, animals receiving 1000 mg/kg bw/day displayed transient post dosing signs of under activity and unsteady muscle reactions. Males and females receiving 1000 mg/kg bw/day also displayed chin rubbing and salivation; salivation was also recorded in females receiving 300 mg/kg bw/day. Detailed physical and arena observations, sensory reactivity, grip strength or motor activity assessments of the animals did not detect any changes attributed to the test material. Bodyweight gain of males receiving 1000 mg/kg bw/day was low for the Week 0-1 period. During gestation bodyweight gain and food consumption was low in females receiving 1000 mg/kg bw/day. Food consumption remained low for females receiving 1000 mg/kg bw/day during lactation. Changes in haematology parameters were considered not to be adverse at the degree observed. Biochemical analysis of blood plasma during Week 2 of dosing showed high alanine amino transferase activity and bile acid concentration in females receiving Eucalyptus oil at 1000 mg/kg bw/day. Urea concentration was high and triglyceride concentration was low in males receiving 1000 mg/kg bw/day. These changes may be associated with the microscopic changes to the liver and kidneys. Eucalyptus oil orally administered to male rats at all doses resulted in hyaline droplet nephropathy in the kidneys, accompanied by tubular casts and/or tubular degeneration/regeneration. Hyaline droplet nephropathy in the kidneys of male rats is caused by accumulation of alpha 2 microglobulin (produced by the male rat liver) in the proximal tubules, which leads to subsequent damage and regeneration of the tubular epithelium. It has been reported with a number of organic chemicals but it appears to be a male, rat-specific toxicological response that has no counterpart in man (for reviews see Hard et al 1993, Swenberg 1993). The absence of any tubular injury in the test article treated females supports the conclusion that the tubular degeneration is secondary to the male specific hyaline droplet accumulation. Treatment at all dose levels also resulted in centrilobular hepatocytic hypertrophy in the liver of males and an increase in glycogenic vacuolation in the liver of females. Minimal centrilobular hepatocytic hypertrophy of the male livers associated with liver weight increase is considered an adaptive change likely associated with microsomal enzyme induction. A slight increase in the incidence and severity of glycogenic vacuolation in the test article treated female livers compared with controls may be partially responsible for the liver weight increase. Although centrilobular hepatocytic hypertrophy was not recorded in the females, a minimal diffuse hypertrophy could account for the liver weight increase in this sex, but would be difficult to detect histologically. The liver changes are considered not adverse. There were no microscopic correlates for the decrease in spleen weight and the increase in adrenal weight of the 1000 mg/kg/day females. Under the test condition, the No Observed Adverse Effect Level (NOAEL) were considered to be: 300 mg/kg bw/day for systemic toxicity (female), based on lower body weight gain and food consumption during gestation. Both findings appeared to be associated with pregnancy status. It was not possible to link this effect to the taste of the substance since females had shown a significant duration of normal bodyweight and food performance prior to Day 6 of gestation and after birth of the pups. These latter observations appeared to indicate recovery in females ; 1000 mg/kg bw/day for systemic toxicity (males) since hyaline droplet nephropathy observed at all dose levels is considered to be rat specific and to have no counterpart in man.



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Type of test	OECD Guideline 476 (In vitro Mammalian Cell Gene Mutation Test)
Route of exposure	In vitro
Species observed	mouse lymphoma L5178Y cells
Dose	
Duration	
Observations	Negative with or without metabolic activation.
Additional Notes	Preliminary toxicity test: 9.77, 19.53, 39.06, 78.13, 156.25, 312.5, 625, 1250, 2500 and 5000 µg/mL, with S9 mix (3 h exposure) and without S9 mix (3 and 24 h exposure). Mutation tests: Without S9 mix (3 h exposure): 10, 100, 150, 200, 225, 250, 275 and 300 µg/mL; Without S9 mix (3 h exposure, additional test): 10, 100, 115, 130, 145, 160, 175, 190, 210, 225, 250 and 300 µg/mL; With S9 mix (3 h exposure): 10, 100, 115, 130, 145, 160, 175, 190, 210, 225, 250 and 300 µg/mL; Without S9 mix (24 h exposure): 10, 50, 100, 150, 175, 200, 225, 250, 275 and 300 µg/mL.
Conclusion	It is believed that Eucalyptus Globulus Leaf Oil is safe for use in Very Vapour at this concentration and use as described, assuming the parameters stated.

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SUPER ACTIVE COSMETICS
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Chemical Name	Rosmarinus Officinalis Leaf Oil is the oil expressed from the leaves of the rosemary plant Rosmarinus Officinalis.
Function	Perfuming
INCI Name	Rosmarinus Officinalis Leaf Oil
CAS	84604-14-8 (Leaf Oil) (Essential Oils Direct)
EINECS	283-291-9
SED(adult)	0.06760184 mg.(kg bw)-1.d-1
SED(child)	0.257732 mg.(kg bw)-1.d-1
SED(baby)	0.6989342 mg.(kg bw)-1.d-1
NOAEL	400 mg.(kg bw)-1.d-1
Dermal penetration factor 1	
MoS(adult)	5916.999
MoS(child)	1552
MoS(baby)	572.2999
Additional Notes	Reproductive Toxicity: Rosmarinus Officinalis Oil is not reported to produce reproductive toxicity in humans. Mutagenicity: Rosmarinus Officinalis Oil is not reported to produce mutagenic effects in humans. Embryotoxicity: Rosmarinus Officinalis Oil is not reported to produce embryotoxic effects in humans. Teratogenicity: Rosmarinus Officinalis Oil is not reported to produce teratogenic effects in humans. Reproductive Toxicity: Rosmarinus Officinalis Oil is not reported to produce reproductive effects in humans.
Type of test	Chronic oral toxicity
Route of exposure	Oral
Species observed	Rat
Dose	3 months
Duration	
Observations	NOAEL of 180 to 400 mg/kg bw/day
Additional Notes	Absence of any notable effect on reproductive organs.
Type of test	Acute LD50
Route of exposure	Oral
Species observed	Rabbit
Dose	3600 mg/kg/bw/day
Duration	
Observations	
Additional Notes	
Type of test	LD50
Route of exposure	Dermal
Species observed	Rabbit
Dose	10000 mg/kg/24H
Duration	
Observations	
Additional Notes	
Type of test	LC50
Route of exposure	Inhalation
Species observed	Rat
Dose	297.9 µL/L air
Duration	
Observations	
Additional Notes	
Conclusion	It is believed that Rosmarinus Officinalis Leaf Oil is safe for use in Very Vapour at this concentration and use as described, assuming the parameters stated.

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SUPER ACTIVE COSMETICS
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Chemical Name	Cinnamomum Zeylanicum Leaf Oil is the volatile oil expressed from the leaf of the Ceylon Cinnamon, Cinnamomum
Function	Perfuming, masking, tonic
INCI Name	Cinnamomum Zeylanicum Leaf Oil
CAS	84649-98-9 (Essential Oils Direct)
EINECS	283-479-0
SED(adult)	0.06760184 mg.(kg bw)-1.d-1
SED(child)	0.257732 mg.(kg bw)-1.d-1
SED(baby)	0.6989342 mg.(kg bw)-1.d-1
NOAEL	100 mg.(kg bw)-1.d-1
Dermal penetration factor 1	
MoS(adult)	1479.25
MoS(child)	387.9999
MoS(baby)	143.075
Additional Notes	Typically the key constituents of the oil are (E)-Cinnamaldehyde 63.1\22675.7%\r\nEugenol 2.0\22613.3%\r\n(E)-Cinnamyl acetate 0.3\22610.6%\r\nLinalool 0.2\2267.0%\r\nb-Caryophyllene 1.3\2265.8%\r\np-Cymene 1.7\2262.5%\r\nl,8-Cineole 0.4\2262.3%\r\nBenzaldehyde tr\2262.2%\r\nb-Phellandrene <1.5%\r\na-Terpineol 0.4\2261.4%\r\nCamphor tr\2261.4%\r\nTerpinen-4-ol 0.4\2261.1%\r\nBenzyl benzoate tr\2261.0%\r\na-Caryophyllene 0\2261.0%\r\nSafrrole 0\2260.04%\r\n[Source : Lawrence 1995 g p. 201; Tateo & Chizzini 1989; Kubeczka 2002]\r\n\r\nQuality assurance & Procurement\r\n\r\nCinnamon leaf oil is frequently adulterated with synthetic cinnamaldehyde and natural eugenol. Occasionally cassia oil or artificially reconstituted oils are sold as cinnamon leaf oil (Kubeczka 2002). Reconstitutions may include cinnamon leaf oil and synthetic cinnamaldehyde (Burfield 2000)\r\n\r\nThe is evidence of embryotoxicity resulting from Cinnamon leaf oil. As such it should not be used by pregnant or lactating women.\r\n\r\nCinnamon leaf oil carries a high risk of skin sensitization, and it is recommended that appropriate labeling is used.\r\n\r\nRecommended maximum dermal use level: 0.07%\r\nMaximum Oral daily dose: 200mg [Commission E monographs], based on cinnamaldehyde composition of 75.7% itself having a dermal use limit of 0.05% [IFRA 2009].\r\n\r\nNOAEL is nominal. In is expected that the cinnamaldehyde concentration is rate limiting, and the allergen profile should dictate the suitability of this product.
Type of test	Acute toxicity
Route of exposure	Oral
Species observed	Rats - Sprague Dawley
Dose	100 500 2000 mg.(kg bw)-1
Duration	
Observations	LOAEL = 500 mg.(kg bw)-1
Additional Notes	There were no statistically significant effects of all concentrations of CE on behaviour, mortality, water intake, food consumption, weight gain, internal organs weight (liver and kidney) and hematological parameters during treatment and post-treatment periods except 1) the slight decrease in kidney and liver weight of rats treated with 0.5g/kg and 2) slight decrease in liver weight of rats treated with 2.0g/kg, during post-treatment period. Hence, these toxicity studies suggest that the CE is low to moderate in toxicity and CE below 0.5 g/kg dose level is safe to be used in the efficacy study especially for diabetes treatment.
Type of test	Standard Draize test
Route of exposure	Administration onto the skin
Species observed	Rodent - rabbit
Dose	500 mg/24H
Duration	
Observations	Mild
Additional Notes	
Type of test	TDLo - Lowest published toxic dose
Route of exposure	Oral
Species observed	Human
Dose	29 mg/kg
Duration	
Observations	Behavioral - tremor Behavioral - convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - other changes
Additional Notes	



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Type of test LDLo - Lowest published lethal dose
Route of exposure Oral
Species observed Human - child
Dose 50 mg/kg
Duration
Observations Details of toxic effects not reported other than lethal dose value
Additional Notes

Type of test LD50 - Lethal dose, 50 percent kill
Route of exposure Oral
Species observed Rodent - rat
Dose 3730 mg/kg
Duration
Observations Details of toxic effects not reported other than lethal dose value
Additional Notes

Type of test LD50 - Lethal dose, 50 percent kill
Route of exposure Administration onto the skin
Species observed Rodent - rabbit
Dose >5 gm/kg
Duration
Observations Details of toxic effects not reported other than lethal dose value
Additional Notes

Conclusion It is believed that Cinnamomum Zeylanicum Leaf Oil is safe for use in Very Vapour at this concentration and use as described, assuming the parameters stated.

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SUPER ACTIVE COSMETICS
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Chemical Name 1-methyl-4-(1-methylethenyl)-cyclohexene
Function Perfuming
INCI Name d-Limonene
CAS 5989-27-5
EINECS 227-813-5
SED(adult) 0.01564983 mg.(kg bw)-1.d-1
SED(child) 0.05966496 mg.(kg bw)-1.d-1
SED(baby) 0.1618033 mg.(kg bw)-1.d-1
NOAEL 500 mg.(kg bw)-1.d-1

Dermal penetration factor 1

MoS(adult) 31949.24
MoS(child) 8380.128
MoS(baby) 3090.172

Additional Notes

The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)g when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products Peroxide value not to exceed less than 20 mmoles/L No information is available on the health effects of inhalation exposure to d-limonene in humans, and no long-term inhalation studies have been conducted in laboratory animals. NTP (1990) conducted a series of studies that investigated the toxicity of d-limonene (>99% pure) in both Fischer 344/N rats and B6C3F1 mice. In the first of the preliminary range-finding studies, doses ranging from 413-6600 mg/kg/day were administered by gavage in corn oil to five animals/species/sex/dose for 5 days/week for 16 days. All but 2/20 rats and 1/20 mice that were administered 3300 and 6600 mg/kg/day died. Body weight gain was reduced at 1650 mg/kg/day. No compound-related signs of toxicity were observed in those animals administered <1650 mg/kg/day. In the rabbit study, 10-18 pregnant Japanese white rabbits were administered 0, 250, 500, or 1000 mg/kg/day d-limonene by gavage on gestation days 6-18 (Kodama et al., 1977b). Exposure of does to 500 or 1000 mg/kg/day resulted in maternal toxicity. There were significant reductions in food consumption and body weight at both doses, and death also occurred in the 1000-mg/kg/day group. Developmental toxicity was not observed at any dose. This study is limited by the small sample size. No reproductive toxicity studies have been conducted on d-limonene. Igimi et al. (1974) studied the metabolism of d-limonene after oral administration and found that about 65% of the dose was recovered in urine, feces, and expired carbon dioxide, suggesting that the majority of an oral dose is absorbed. Although it is possible that an inhaled dose would also be largely absorbed, there is no information on inhalation exposures. Reproductive Toxicity: This product is not reported to produce reproductive toxicity in humans. Mutagenicity: This product is not reported to produce mutagenic effects in humans. Embryotoxicity: This product is not reported to produce embryotoxic effects in humans. Teratogenicity: This product is not reported to produce teratogenic effects in humans. Reproductive Toxicity: This product is not reported to produce reproductive effects in humans.

Type of test LD50
Route of exposure Oral
Species observed Rat
Dose 2790 mg/kg
Duration
Observations
Additional Notes

Type of test LD50
Route of exposure Dermal
Species observed Rabbit
Dose 5610 mg/kg
Duration
Observations
Additional Notes

Type of test LC50
Route of exposure Inhalation
Species observed Rat
Dose 295 mg/l/96H
Duration
Observations
Additional Notes



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Type of test LD50
Route of exposure Oral
Species observed Rat
Dose Application Volume: 5 ml
Duration
Observations 5600 mg/kg/bw/day
Additional Notes

Type of test LD50
Route of exposure Dermal
Species observed Rabbit
Dose 2000 mg/kg/bw/day
Duration
Observations
Additional Notes

Type of test LC50
Route of exposure Inhalation
Species observed
Dose 2.55 ppm/8 days
Duration
Observations
Additional Notes

Type of test OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents)
Route of exposure Oral
Species observed Mice - B6C3F1
Dose 0, 125, 250, 500, 1000 or 2000 mg.(kg bw)-1.d-1
Duration 90d
Observations NOEL = 500 mg.(kg bw)-1.d-1. LOAEL = 1000 mg.(kg bw)-1.d-1
Additional Notes MORTALITY: - 1/10 male and 2/10 females died at 2000 mg/kg bw/day - 1/10 female died at 500 mg/kg bw/day - Several animals in other groups died as a result of gavage error. CLINICAL SIGNS: - Rough hair coats and decreased activity were observed at 1000 and 2000 mg/kg bw/day. BODY WEIGHT AND WEIGHT GAIN - Final mean bodyweights of mice that received 1000 or 2000 mg/kg bw/day were 10% lower than that of the vehicle controls for males and 2% lower for females. HISTOPATHOLOGY - An alveolar cell adenoma was observed in the lung of 1/10 females that received 2000 mg/kg bw/day.

Type of test OECD Guideline 429 (Skin Sensitisation: Local Lymph Node Assay)
Route of exposure Dermal
Species observed Mouse - CBA/Ca
Dose 0, 10, 25, 50, 75 or 100% v/v in ethanol/diethyl phthalate (3:1 v/v)
Duration
Observations R43 May cause sensitisation by skin contact
Additional Notes

Type of test OECD Guideline 405 (Acute Eye Irritation / Corrosion)
Route of exposure Ocular
Species observed Rabbit - New Zealand White
Dose
Duration 7d post-exposure observation.
Observations None to minimal irritancy. Reversible.
Additional Notes Instillation of D-LIMONENE resulted in slight to moderate redness of conjunctivae associated with moderate chemosis in all treated animals after 1 hour of instillation. The irritation completely resolved within 7 days. Mean individual scores at 24, 48 and 72 hours after exposure for the 3 animals were 0, 0, 0 for cornea score; 0, 0, 0 for iris score; 0.3, 1, 1.3 for conjunctivae score and 1, 0.3, 1 for chemosis score.



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Type of test OECD Guideline 476 (In vitro Mammalian Cell Gene Mutation Test)
Route of exposure In vitro
Species observed mouse lymphoma L5178Y cells
Dose 100 mcg
Duration
Observations Non mutagenic with or without S9 activation under test conditions.
Additional Notes

Type of test Genotoxicity - Comet assay
Route of exposure Oral - gavage
Species observed Rat - Wistar
Dose 2000 mg.(kg bw)-1.d-1
Duration
Observations Non mutagenic.
Additional Notes

Conclusion It is believed that d-Limonene is safe for use in Very Vapour at this concentration and use as described, assuming the parameters stated.

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SUPER ACTIVE COSMETICS
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Chemical Name 3,7-Dimethylocta-1,6-diene-3-ol
Function Perfuming
INCI Name Linalool
CAS 78-70-6
EINECS 201-134-4
SED(adult) 0.002298462 mg.(kg bw)-1.d-1
SED(child) 0.008762888 mg.(kg bw)-1.d-1
SED(baby) 0.02376376 mg.(kg bw)-1.d-1
NOAEL 250 mg.(kg bw)-1.d-1

Dermal penetration factor 1

MoS(adult) 108768.4
MoS(child) 28529.41
MoS(baby) 10520.22

Additional Notes The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)g when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products Linalool was an irritant to the skin of various species of laboratory animal. In man, it has shown some ability to cause skin irritation and sensitization. It was of low acute toxicity by the oral route in rats and when applied to the skin of rabbits. Effects on the liver and its associated enzymes have been observed in rats given repeated oral doses. Linalool was not mutagenic in Ames bacterial tests but has demonstrated some activity in a test for DNA damage and in mammalian cells in culture. Reproductive Toxicity: This product is not reported to produce reproductive toxicity in humans. Mutagenicity: This product is not reported to produce mutagenic effects in humans. Embryotoxicity: This product is not reported to produce embryotoxic effects in humans. Teratogenicity: This product is not reported to produce teratogenic effects in humans. Reproductive Toxicity: This product is not reported to produce reproductive effects in humans.

Type of test LD50
Route of exposure Oral
Species observed Rat
Dose 2790 mg/kg
Duration
Observations
Additional Notes

Type of test LD50
Route of exposure Dermal
Species observed Rabbit
Dose 5610 mg/kg
Duration
Observations
Additional Notes

Type of test LC50
Route of exposure Inhalation
Species observed Rat
Dose 295 mg/l/96H
Duration
Observations
Additional Notes

Conclusion It is believed that Linalool is safe for use in Very Vapour at this concentration and use as described, assuming the parameters stated.
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SUPER ACTIVE COSMETICS
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Chemical Name Benzyl Benzoate
Function Perfuming
INCI Name Benzyl Benzoate
CAS 120-51-4
EINECS 204-402-9
SED(adult) 0.002028055 mg.(kg bw)-1.d-1
SED(child) 0.00773196 mg.(kg bw)-1.d-1
SED(baby) 0.02096803 mg.(kg bw)-1.d-1
NOAEL 500 mg.(kg bw)-1.d-1

Dermal penetration factor 1

MoS(adult) 246541.6
MoS(child) 64666.66
MoS(baby) 23845.83

The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)g when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products Benzyl benzoate is relatively nontoxic but may irritate the skin and eyes. Increased pruritus and irritation (manifested by burning and stinging, particularly of the genitalia and scalp) are common and may be severe in hot humid climates. This product is not reported to produce reproductive toxicity in humans. Mutagenicity: Benzyl Benzoate is not reported to produce mutagenic effects in humans. Embryotoxicity: Benzyl Benzoate is not reported to produce embryotoxic effects in humans. Teratogenicity: Benzyl Benzoate is not reported to produce teratogenic effects in humans. Reproductive Toxicity: Benzyl Benzoate is not reported to produce reproductive effects in humans.

Additional Notes

Use regulated by : 2003/15/EC III/1,85

Type of test Acute oral toxicity
Route of exposure Oral
Species observed Rat
Dose 2790 mg.(kg bw)-1
Duration
Observations LD50
Additional Notes

Type of test Acute dermal exposure
Route of exposure Dermal
Species observed Rat
Dose 5610 mg.(kg bw)-1
Duration
Observations LD50
Additional Notes

Type of test Acute inhalation toxicity
Route of exposure Inhalation
Species observed Rat
Dose 295 mg.L-1
Duration 96hr
Observations LC50
Additional Notes

Conclusion It is believed that Benzyl Benzoate is safe for use in Very Vapour at this concentration and use as described, assuming the parameters stated.

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SUPER ACTIVE COSMETICS
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Chemical Name 3-Phenylprop-2-enal
Function Perfuming
INCI Name Cinnamaldehyde
CAS 104-55-2
EINECS 203 - 213 - 9
SED(adult) 0.0009126249 mg.(kg bw)-1.d-1
SED(child) 0.003479382 mg.(kg bw)-1.d-1
SED(baby) 0.009435614 mg.(kg bw)-1.d-1
NOAEL 620 mg.(kg bw)-1.d-1

Dermal penetration factor 1

MoS(adult) 679359.1
MoS(child) 178192.5
MoS(baby) 65708.5

Additional Notes

Type of test Standard Draize test
Route of exposure Dermal
Species observed Human
Dose 40 mg
Duration 48 hours
Observations Severely irritating
Additional Notes

Type of test Acute oral toxicity
Route of exposure Oral
Species observed Rat
Dose 2220 mg.(kg bw)-1
Duration
Observations LD50 established at 2220 mg.(kg bw)-1
Additional Notes Toxic effects noted included: somnolence (general depressed activity) and gastrointestinal hypermotility and diarrhea.

Type of test Acute oral toxicity
Route of exposure Oral
Species observed Mouse
Dose 2225 mg.(kg bw)-1
Duration
Observations
Additional Notes Toxic effects observed include: convulsions or effect on seizure threshold, ataxia and respiratory stimulation

Type of test Acute toxicity LD50
Route of exposure Intraperitoneal
Species observed Mouse
Dose 200 mg.(kg bw)-1
Duration
Observations LD50 = 200 mg.(kg bw)-1
Additional Notes



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Type of test Acute toxicity LD50
Route of exposure Intravenous
Species observed Mouse
Dose 75 mg.(kg bw)-1
Duration
Observations LD50 = 75 mg.(kg bw)-1
Additional Notes

Type of test LDLo
Route of exposure Parenteral
Species observed Mouse
Dose 200 mg.(kg bw)-1
Duration
Observations LDLo = 200 mg.(kg bw)-1
Additional Notes

Type of test Acute oral toxicity
Route of exposure Oral
Species observed Guinea pig
Dose 1160 mg.(kg bw)-1
Duration
Observations Coma. LD50 = 1160 mg.(kg bw)-1
Additional Notes

Type of test TDLo
Route of exposure Oral
Species observed Rat
Dose 35 mg.(kg bw)-1.d-1
Duration 24wk
Observations
Additional Notes Changes in liver weight, hepatic microsomal mixed oxidase (dealkylation, hydroxylation,etc.), death

Type of test TDLo
Route of exposure Oral
Species observed Rat
Dose 8092 mg.(kg bw)-1
Duration 17wk
Observations Liver function tests impaired
Additional Notes

Type of test Reproductive toxicity TDLo
Route of exposure Oral
Species observed Rat
Dose 55 mg.(kg bw)-1
Duration 7-17d after conception in female
Observations Craniofacial anomalies including nose and tongue, in offspring. TDLo = 55mg.(kg bw)-1
Additional Notes



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Type of test Reproductive toxicity
Route of exposure Oral
Species observed Rat
Dose 275 mg.(kg bw)-1
Duration 7-17d after conception in female
Observations Abnormalities to the musculoskeletal system in rats
Additional Notes

Type of test Mutation in microorganisms
Route of exposure
Species observed Bacteria - Salmonella typhimurium
Dose 500 mcg.plate-1
Duration
Observations
Additional Notes

Type of test Mutagenicity - DNA repair
Route of exposure
Species observed Bacillus subtilis
Dose 10480 mcg.disc-1
Duration
Observations
Additional Notes

Conclusion It is believed that Cinnamaldehyde is safe for use in Very Vapour at this concentration and use as described, assuming the parameters stated.

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SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

Chemical Name Phenol,2-methoxy-4-(2-propenyl)
Function Perfuming
INCI Name Eugenol
CAS 97-53-0
EINECS 202-589-1
SED(adult) 0.05272944 mg.(kg bw)-1.d-1
SED(child) 0.201031 mg.(kg bw)-1.d-1
SED(baby) 0.5451688 mg.(kg bw)-1.d-1
NOAEL 300 mg.(kg bw)-1.d-1

Dermal penetration factor 1

MoS(adult) 5689.421
MoS(child) 1492.307
MoS(baby) 550.2883

Additional Notes The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)g when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products This product is not reported to produce reproductive toxicity in humans. Mutagenicity: This product is not reported to produce mutagenic effects in humans. Embryotoxicity: This product is not reported to produce embryotoxic effects in humans. Teratogenicity: This product is not reported to produce teratogenic effects in humans. Reproductive Toxicity: This product is not reported to produce reproductive effects in humans.

Type of test LD50
Route of exposure Oral
Species observed Rat
Dose 2130 mg/kg
Duration
Observations
Additional Notes

Type of test LD50
Route of exposure Dermal
Species observed Rabbit
Dose 2130 mg/kg
Duration
Observations
Additional Notes

Type of test LC50
Route of exposure Inhalation
Species observed Rat
Dose 2,580 mg/m³/4hr
Duration
Observations
Additional Notes

Conclusion It is believed that Eugenol is safe for use in Very Vapour at this concentration and use as described, assuming the parameters stated.

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