

Toxicological Safety Assessment of: Marble Smooth

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: C1008/06



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Composition of Formulation

CAS Number	INCI Name	Maximum Concentration %
8001-25-0	Olea Europaea Fruit Oil	34.45306
90106-38-0 (Water)	Rosa Damascena Flower Distilate	34.45306
8001-31-8	Cocos Nucifera Oil	17.22653
8012-89-3	Cera Alba	8.613264
59-02-9	Tocopherol	4.306632
122-99-6	Phenoxyethanol	0.2583979
1117-86-8	Caprylyl Glycol	0.1722653
8000-28-0 / 90063-37-9 (Essential Oils Direct)	Lavandula Angustifolia (Lavandula Officinalis) Oil	0.129199
89957-98-2 / 8050-07-5 (Essential Oils Direct)	Boswellia Carteri Extract	0.129199
90082-51-2 / 8000-46-2 (Essential Oils Direct)	Pelargonium Graveolens Flower Oil	0.129199
90045-43-5 / 8016-20-4 (Essential Oils Direct 26/05/2015)	Citrus Grandis Peel Oil	0.129199



Acronyms & Abbreviations used in this document

Expanded form Acronym

CAS Number Chemical Abstracts Service Number

bw Body Weight

cfu Colony Forming Units

EINECS European Inventory of Existing Commercial chemical Substances

Grams

GI Gastrointestinal

INCI International Nomenclature of Cosmetic Ingredients

Kg LD50 Kilograms

Lethal Dose 50 (Toxicology protocol)

mcg Micrograms Milligrams mg Millilitres ml MoS Margin of Safety Not Applicable N/A N/K Not Known

NOAEL No Observed Adverse Effect Level

PPM Parts Per Million

Quantity Sufficient qs

SCCS Scientific Committee on Consumer Safety

SED Systemic Exposure Dose TVC Total Viable Count



Microbiological Quality

To comply with the guidelines on the microbiology quality (ssnfp/0004/98), 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 critical

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.



Purity of raw materials

It is assumed that all raw materials used in Marble Smooth 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.



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.

Marble Smooth has proven to be inert when in contact with the final packaging



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.



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.

Marble Smooth 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.



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



Consumer Exposure and Toxicological and Regulatory Review Summary

Product Class: 4c

IFRA Category:

Targeted Population:
Number of uses per day:
Amount per Application/g:

Total amount applied per day/g:

Body creams
Adults
Once
2 g
2 g

Estimated daily exposure (Daily): 0.03278689 g(kg bw)-1.day-1

0 seconds

Average mean weight of Adult:
Average mean weight of Child:
Average mean weight of Child:
Average mean weight of Baby:
S.9 Kg
Retention factor:
Exposure time neat:
3600 seconds

Exposure time dilute:



Toxicological Summary

Marble Smooth is a body cream for adult use. 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.

INCI Name	MoS for adult	Conclusions
Olea Europaea Fruit Oil	17705.25	Safe
Rosa Damascena Flower Distilate	1770.525	Safe
Cocos Nucifera Oil	290366.1	Safe
Cera Alba	7790.31	Safe
Tocopherol	708.21	Safe
Limonene	3082.927	Safe
Citronellol	2419.852	Safe
Geraniol	8200.671	Safe
Phenoxyethanol	4426.313	Safe
Caprylyl Glycol	5311.575	Safe
Linalool	5383.169	Safe
Lavandula Angustifolia (Lavandula Officinalis) Oil	4721.399	Safe
Boswellia Carteri Extract	28328.39	Safe
Pelargonium Graveolens Flower Oil	28328.39	Safe
Citrus Grandis Peel Oil	2950.874	Safe
Citral	24450.62	Safe
Farnesol	44263.12	Safe

Therefore with the MoS of each raw material being above 100, Marble Smooth is very unlikely to produce any long-term adverse effects.



Effects of the finished product on specific organs and tissue types

Internal organs: Marble Smooth is unlikely to cause damage to the internal organs following application.

Ocular area: Marble Smooth may cause irritation to the eye area; instructions following eye irritation are printed on the packaging

Ingestion: Marble Smooth poses low risk from ingestion if used as directed. If swallowed the ingredients do not pose a significan 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 Marble Smooth 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: Marble Smooth is likely to cause upper gastrointestinal irritation.

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

Marble Smooth 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.



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 permissable 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.

Marble Smooth contains fragrance allergens at concentrations exceeding the EU labelling threshold and therefore the following fragrance allergens need to be listed to the outer packaging Citral, Farnesol, Geraniol, Limonene, Citronellol, Linalool.

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

CAS Number	% Concentration of formulation	% Limit for this type of product	Conclusion
5392-40-5	0.0711025	0.6	Pass: Within limits
4602-84-0	0.06890612	1.2	Pass: Within limits
106-24-1	0.3719208	5.3	Pass: Within limits
106-22-9	0.3781223	13.3	Pass: Within limits

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

INCI Name	CAS	% Concentration of formulation
Citral	5392-40-5	0.0711025
Farnesol	4602-84-0	0.06890612
Geraniol	106-24-1	0.3719208
Limonene	138-86-3	0.4946598
Citronellol	106-22-9	0.3781223
Linalool	78-70-6	0.1416452

INCI Name: Rosa Damascena Flower Distilate CAS Number: 90106-38-0 (Water)

INCI Name	CAS	% Concentration of ingredient	% Concentration of formulation
Citral	5392-40-5	0.2	0.06890612
Citronellol	106-22-9	1	0.3445306
Farnesol	4602-84-0	0.2	0.06890612
Geraniol	106-24-1	1	0.3445306
d-Limonene	5989-27-5	1	0.3445306
Linalool	78-70-6	0.2	0.06890612

INCI Name: Lavandula Angustifolia (Lavandula Officinalis) Oil CAS Number: 8000-28-0 / 90063-37-9 (Essential Oils Direct)

INCI Name	CAS	% Concentration of ingredient	% Concentration of formulation
Geraniol	106-24-1	1.1	0.001421189
d-Limonene	5989-27-5	1	0.00129199
Linalool	78-70-6	45	0.05813955

INCI Name: Boswellia Carteri Extract CAS Number: 89957-98-2 / 8050-07-5 (Essential Oils Direct)

INCI Name	CAS	% Concentration of ingredient	% Concentration of formulation
		0 4 " 0 " 1 1 1	



Citral	5392-40-5	0.1	0.000129199
d-Limonene	5989-27-5	18.2	0.02351422
Linalool	78-70-6	0.1	0.000129199

INCI Name: Pelargonium Graveolens Flower Oil CAS Number: 90082-51-2 / 8000-46-2 (Essential Oils Direct)

INCI Name	CAS	% Concentration of ingredient	% Concentration of formulation
Citral	5392-40-5	1.5	0.001937985
Citronellol	106-22-9	26	0.03359174
Geraniol	106-24-1	20	0.0258398
d-Limonene	5989-27-5	1	0.00129199
Linalool	78-70-6	11	0.01421189

INCI Name: Citrus Grandis Peel Oil CAS Number: 90045-43-5 / 8016-20-4 (Essential Oils Direct 26/05/2015)

INCI Name	CAS	% Concentration of ingredient	% Concentration of formulation
Citral	5392-40-5	0.1	0.000129199
Geraniol	106-24-1	0.1	0.000129199
d-Limonene	5989-27-5	96	0.124031
Linalool	78-70-6	0.2	0.000258398



Conclusion

Marble Smooth 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, Marble Smooth is not expected to pose a risk to the health of the majority of consumers through any path of irritation.

The finished product Marble Smooth 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 Marble Smooth 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.

- Ingredients: Olea Europaea Fruit Oil, Rosa Damascena Flower Distilate, Cocos Nucifera Oil, Cera Alba, Tocopherol, Limonene, Citronellol, Geraniol, Phenoxyethanol, Caprylyl Glycol, Linalool, Lavandula Angustifolia (Lavandula Officinalis) Oil, Boswellia Carteri Extract, Pelargonium Graveolens Flower Oil, Citrus Grandis Peel Oil, Citral, Farnesol



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 compliment 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 there here own exceedingly high quality assurance standards.



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.

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- 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		



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)
 0.1129609 mg.(kg bw)-1.d-1

 SED(child)
 N/A mg.(kg bw)-1.d-1

 SED(baby)
 N/A mg.(kg bw)-1.d-1

 NOAEL
 2000 mg.(kg bw)-1.d-1

Dermal penetration factor0.01MoS(adult)17705.25MoS(child)N/AMoS(baby)N/A

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



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

Conclusion

Observations Mild irritant especially under occlusion

Additional Notes

It is believed that Olea Europaea Fruit Oil is safe for use in Marble Smooth at this concentration and use as described, assuming the

parameters stated.

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Chemical Name

Rosa Damascena Flower Distilate is an aqueous distillate of the flowers of Damask Rose, Rosa damascena, Rosaceae, Rose Water

Function Masking, Tonic, Perfilming
INCI Name Rosa Damascena Flower Distilate

CAS 90106-38-0 (Water)

EINECS 290-260-3

 SED(adult)
 1.129609 mg.(kg bw)-1.d-1

 SED(child)
 N/A mg.(kg bw)-1.d-1

 SED(baby)
 N/A mg.(kg bw)-1.d-1

 NOAEL
 2000 mg.(kg bw)-1.d-1

N/A

Dermal penetration factor 0.1 MoS(adult) 1770.525 MoS(child) N/A

Rose water has an extensive history of safe use in foodstuffs as a flavouring, and in perfumery.

The NOAEL has been assumed and is based on the extent of rose water oral consumption in many parts of the world, with no reports

of adverse effects identified.

Additional Notes

MoS(baby)

Care should be taken by the responsible person, for assurance regarding the composition of the rose water used, as some rose water products may contain additional excipients, and their composition may vary considerably from that investigated at time of assessment.

The dermal penetration is likely to be quite low, due to rose water being mainly water with rose oil in a distinct phase ie non-emulsified.

Conclusion It is believed that Rosa Damascena Flower Distilate is safe for use in Marble Smooth at this concentration and use as described,

assuming the parameters stated.

/



Chemical Name Cocos Nucifera Oil

Function Emollient

 INCI Name
 Cocos Nucifera Oil

 CAS
 8001-31-8

 EINECS
 232-282-8

 SED(adult)
 0.05648043 mg.(kg bw)-1.d-1

 SED(child)
 N/A mg.(kg bw)-1.d-1

 SED(baby)
 N/A mg.(kg bw)-1.d-1

 NOAEL
 16400 mg.(kg bw)-1.d-1

Dermal penetration factor0.01**MoS(adult)**290366.1**MoS(child)**N/A**MoS(baby)**N/A

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

Additional Notes 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



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

It is believed that Cocos Nucifera Oil is safe for use in Marble Smooth at this concentration and use as described, assuming the Conclusion

parameters stated.

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Chemical NameCera AlbaFunctionEmollientINCI NameCera AlbaCAS8012-89-3EINECS232-383-7

 SED(adult)
 0.02824021 mg(kg bw)-1.d-1

 SED(child)
 N/A mg (kg bw)-1.d-1

 SED(baby)
 N/A mg (kg bw)-1.d-1

 NOAEL
 220 mg (kg bw)-1.d-1

Dermal penetration factor0.01**MoS(adult)**7790.31**MoS(child)**N/A**MoS(baby)**N/A

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

not reported to produce reproductive en

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

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 Marble Smooth at this concentration and use as described, assuming the parameters

stated.

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Tocopherol; Vitamin E;(All-R)- α -Tocopherol; (2R,4'R,8'R)- α -Tocopherol;D- α -tocopherol; Almefrol; Antisterility vitamin; Denamone;Emipherol; Endo E; Eprolin; Eprolin S; Epsilan; Esorb; Etamican;Etavit; Evion; Evitaminum; Ilitia; Phytogermine; Profecundin;Spavit E; Syntopherol; Tokopharm; Vascuals; Verrol; Vi-E; Vitaplex E; Vitayonon; Viteolin; 5,7,8-Trimethyltocol; Aquasol E; Lan-E;Med-E; Vita E; Covi-ox; Spavit; (R,R,R)- α -Tocopherol;(+)- α -Tocopherol;[2R-2R*(4R*,8R*)]-3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-1-benzopyran-6-ol;3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-1-benzopyran-6-ol;3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-1-benzopyran-6-ol;3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-1-benzopyran-6-ol;3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-1-benzopyran-6-ol;3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-1-benzopyran-6-ol;3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-1-benzopyran-6-ol;3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-1-benzopyran-6-ol;3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-1-benzopyran-6-ol;3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-1-benzopyran-6-ol;3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-1-benzopyran-6-ol;3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-1-benzopyran-6-ol;3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-1-benzopyran-6-ol;3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-1-benzopyran-6-ol;3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-1-benzopyran-6-ol;3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-1-benzopyran-6-ol;3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-1-benzopyran-6-ol;3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-1-benzopyran-6-ol;3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-1-benzopyran-6-ol;3,4-Di

2H-1-benzopyran-6-ol.[2R-[2R*(4R*,8R*)]]-; Covitol F 1300; E-vimin; Viprimol;(2R)-3,4-Dihydro-2,5,7,8-tetramethyl-2-[(4R,8R)-4,8,12-trimethyltridecyl]-2H-1-benzopyran-6-ol;E-Oil 1000; Tenox GT 1; Rhenogran Ronotec 50; Covitol F 1000;α-Vitamin E; α-D-Tocopherol;2,5,7,8-Tetramethyl-2-(4,8,12-trimethyltridecyl)-6-chromanol;E-toplex; Epsilan-m; Evipherol;

Tocopherex

Function Antioxidant; Masking, Skin Conditioning

 INCI Name
 Tocopherol

 CAS
 59-02-9

 EINECS
 200-412-2

 SED(adult)
 1.41201 mg (kg bw)-1.d-1

 SED(child)
 N/A mg (kg bw)-1.d-1

 SED(baby)
 N/A mg (kg bw)-1.d-1

 NOAEL
 1000 mg (kg bw)-1.d-1

Mos(adult)708.21Mos(child)N/AMos(baby)N/A

Additional Notes

Chemical Name

Type of test TDLo - Lowest published toxic dose

Route of exposure Oral Species observed Rat

Dose7500 mg (kg bw)-1Duration1-20d after conception

Observations Reproductive - Fertility - other measures of fertility

Additional Notes

Type of test DNA adduct
Route of exposure Intravenous
Species observed Rat

Dose 27 nmol.(kg bw)-1

Duration Observations Additional Notes

Type of test DNA inhibition

Route of exposure

Species observed Rodent - Rat Liver
Dose 100 mcmol.L-1

Duration
Observations
Additional Notes

Conclusion It is believed that Tocopherol is safe for use in Marble Smooth at this concentration and use as described, assuming the parameters

stated.



Chemical Name 2-Phenoxy-1-ethanol

Function Preservative
INCI Name Phenoxyethanol
CAS 122-99-6
EINECS 204-589-7

 SED(adult)
 0.08472062 mg (kg bw)-1.d-1

 SED(child)
 N/A mg (kg bw)-1.d-1

 SED(baby)
 N/A mg (kg bw)-1.d-1

 NOAEL
 375 mg (kg bw)-1.d-1

Dermal penetration factor 1

 MoS(adult)
 4426,313

 MoS(child)
 N/A

 MoS(baby)
 N/A

Ethylene glycol ethers (EGEs) are a class of chemicals used extensively in the manufacture of a wide range of domestic and industrial products, which may result in human exposure and toxicity. Hematologic and reproductive toxicity of EGEs are well known whereas their action on neuronal cell viability has not been studied so far. In the present study, we investigated the effects of some EGEs on cell viability and on the hydrogen peroxide-induced damage in the human neuroblastoma (SH-SY5Y) cells. It has been found that 2phenoxyethanol in a concentration-dependent manner (5-25 mM, 24 hr) increased the basal and H(2)O(2)-induced lactate dehydrogenase (LDH) release and 3-[4,5-dimethylthiazol-2-yl]2,5-diphenyl tetrazolium bromide (MTT) reduction. 2-Butoxyethanol given alone did not affect LDH release and MTT reduction but concentration-dependently enhanced the cytotoxic effect of H(2)O(2). 2-Isopropoxyethanol significantly and concentration-dependently (1-25 mM) increased the basal LDH release and attenuated MTT reduction, but did not potentiate the cytotoxic effect of H(2)O(2). Contrary to this, 2-methoxyethanol did not show a cytotoxic effect while 2-ethoxyethanol at high concentrations intensified the hydrogen peroxide action. This study demonstrated that among the EGEs studied, 2-phenoxyethanol showed the most consistent cytotoxic effect on neurons in in vitro conditions and enhanced the hydrogen peroxide action. 2-Isopropoxyethanol had also a potent cytotoxic effect, but it did not enhance the hydrogen peroxide action, whereas 2-butoxyethanol only potentiated cytotoxic effect of H(2)O(2). It is concluded that the results of the present study should be confirmed in in vivo conditions and that some EGEs, especially 2-phenoxyethanol, 2-butoxyethanol and 2-isopropoxyethanol, may be responsible for initiation or exacerbation of neuronal cell damage. Reproductive Toxicity: Phenoxyethanol is not reported to effect reproductivity in humans when used at the upper limit of 1.0% w/w Mutagenicity. Phenoxyethanol is not reported to produce mutagenic effects in humans. Embryotoxicity: Acute toxicity tests were performed on aquarium fish Danio rerio, which is considered to be one of the model organisms most commonly used in toxicity testing. The semi-static method according to OECD No. 203 (Fish acute toxicity test) was used for testing juvenile fish. Embryo toxicity tests were performed in zebrafish embryos (D. rerio) in compliance with the OECD No. 212 methodology (Fish, short-term toxicity test on embryo and sac-fiv stages). The results obtained (the number of dead individuals at particular test concentrations) were subjected to a probit analysis using the EKO-TOX 5.2 programme in order to determine LC50 clove oil and 2-phenoxyethanol values. The statistical significance of the difference between LC50 values in juvenile and embryonic stages of D. rerio was tested using the Mann-Whitney non-parametric test implemented in the Unistat 5.1 programme. The LC50 clove oil mean value was 18.8 +/- 5.52 mg/per/ L in juvenile D. rerio, and 15.64 +/- 3.30 mg/per/ L in embryonic stages of D. rerio. The LC50 2-phenoxyethanol mean value was 338.22 +/- 15.22 mg/per/ L in juvenile D. rerio, whereas in embryonic stages of D. rerio it was 486.35 +/- 25.53 mg/per/ L. The study proved statistically significantly higher (p<0.01) sensitivity in juvenile fish to 2phenoxyethanol compared to the embryonic stages. Acute toxicity values of clove oil for juvenile and embryonic stages were comparable.. Developmental or Reproductive Toxicity Pregnant New Zealand white rabbits were treated dermally with 300, 600, or 1000 mg/kg/day of undiluted 2-phenoxyethanol on days 6 thru 18 of gestation (25 animals per dose group). 2-Phenoxyethanol was

toxic to the dams (maternal death) at the 600 and 1000 mg/kg doses. No adverse effects on pregnancy rate, resorptions, or fetal body measurements were observed at any dose. 2-Phenoxyethanol did not cause malformations in the fetuses as compared with controls.

Reproductive Toxicity: Phenoxyethanol is not reported to produce reproductive effects in humans.

Additional Notes

Type of test Acute oral toxicity

Route of exposure Oral Species observed Mouse

Dose 1260 mg.(kg bw)-1.d-1

Duration Observations Additional Notes



Type of test Acute dermal toxicity

Route of exposure Dermal Species observed Rabbit

Dose 14422 mg.(kg bw)-1.d-1

Duration Observations Additional Notes

Type of test Ocular irritancy test

Route of exposure Eye
Species observed Rabbit
Dose Neat

Duration

Observations Mild irritation

Additional Notes

he major hazards encountered in the use and handling of 2-phenoxyethanol stem from its toxicological properties. Toxic by all routes (inhalation, ingestion, and dermal contact), exposure to this faintly aromatic, colorless, oily liquid may occur from its use as a fixative for cosmetics, perfumes, and soaps; as a bactericide and insect repellant; as a solvent for cellulose acetate, dyes, stamp pad, ball point, and specialty inks; as a chemical intermediate for carboxylic acid esters (eg., acrylate, maleate) and polymers (eg., formaldehyde, melamine); and as a preservative for human specimen used for dissection and demonstrations in anatomical studies. Effects from exposure may include eye irritation, headache, tremors, and CNS depression. If contact should occur, irrigate exposed eyes with copious amounts of tepid water for at least 15 minutes, and wash exposed skin thoroughly with soap and water. Phenoxyethanol is aromatic ether, which is used in cosmetics as a preservative at concentrations below 1% and as a fixative for perfumes. According to the classification scheme of Hodge and Sterner, (1) Phenoxyethanol is practically nontoxic when administered orally or dermally to rats. In a subchronic oral toxicity study in rats of Phenoxyethanol, signs of toxicity included reduced body weights and an impaired ability to utilize feed. Increased liver, kidney, and thyroid weights were noted at necropsy in surviving rats. Undiluted Phenoxyethanol was a strong eye irritant, but was nonirritating when tested at 2.2%. Phenoxyethanol at 2.0% was a slight irritant to rabbit skin, but was neither an irritant nor sensitizer to guinea pig skin. In dermal treatment studies, Phenoxyethanol was neither teratogenic, embryotoxic, or fetotoxic at doses which were maternally toxic. Phenoxyethanol was nonmutagenic in the Ames test, with and without metabolic activation, and in the mouse micronucleus test. In clinical studies, Phenoxyethanol was neither a primary irritant nor sensitizer. Phenoxyethanol was not phototoxic in clinical studies. It is concluded that Phenoxyethanol is safe as a cosmetic ingredient in the present practices of use and concentration Final conclusion: With a MoS of 1.016667e+008, Phenoxyethanol is at safe toxicological levels used in this formulation as a preservative. The exposure limit being under 1 minute and the Partition coefficient is 0.10. At the level used in this formulation 0.8 in formulation and a daily exposure amount of 0.024g, Its very unlikely to be irritating to skin, But in some sensitive individuals they might get dermal irritation, this can be counteracted by washing the affected area with fragrance free soap and water

Type of test Reproductive toxicity

Route of exposure Oral - diet
Species observed Mice - CD1

Dose 375 1875 3700 mg,(kg bw)-1.d-1

Duration

Conclusion

Observations NOAEL parental and offspring = 375 mg.(kg bw)-1.d-1

Additional Notes

It is believed that Phenoxyethanol is safe for use in Marble Smooth at this concentration and use as described, assuming the parameters

stated.

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Chemical NameOctane-1,2-diolFunctionEmollientINCI NameCaprylyl GlycolCAS1117-86-8EINECS214-254-7

 SED(adult)
 0.05648043 mg(kg bw)-1.d-1

 SED(child)
 N/A mg (kg bw)-1.d-1

 SED(baby)
 N/A mg (kg bw)-1.d-1

 NOAEL
 300 mg (kg bw)-1.d-1

Dermal penetration factor 1

 MoS(adult)
 5311.575

 MoS(child)
 N/A

 MoS(baby)
 N/A

Additional Notes

No evidence of reproductive or teratogenic toxicity, nor carcinogenicity was identified in the literature. Due to the structure of the 1,2

glycols, phototoxicity is not expected.

Type of test LD50
Route of exposure Oral
Species observed Rat

Dose 2500 mg/kg/bw/day

Duration
Observations

Additional Notes None

Type of test LD50
Route of exposure Dermal
Species observed Rabbit

Dose 1300 mg/kg/bw/day

Duration Observations Additional Notes

Type of test LC50
Route of exposure Inhalation
Species observed Rat

Dose 13 ppm 8 hours

Duration Observations Additional Notes

Type of test Repeat dose
Route of exposure Oral
Species observed Rat - Wistar

Dose 50 300 1000 mg.(kg bw)-1.d-1

Duration 28d

Observations NOAEL oral = 300 mg.(kg bw)-1.d-1

Additional Notes No mortalities. Slightly reduced locomotor activity and elevated kidney weights at highest dose. Systemic effects not observed upto

300mg (kg bw)-1.d-1 dose group. Slight irritation observed at 300 dose group around pars nonglandularis and limiting ridge of the

stomach (no analogous structures in humans).



Type of test Eye Irritancy Potential - HET-CAM Assay

Route of exposure In vitro

Species observed Hen - Chorioallantoic membrane

Dose 1 3 %

Duration

Observations Non irritant

Additional Notes

Type of test OECD Guideline 404 (Acute Dermal Irritation / Corrosion) - read across

Route of exposure Dermal Species observed Rabbit Dose 100 %

Duration

 Observations
 PII = 3.2. Moderate irritation

 Additional Notes
 Test substance: decylene glycol

Type of test Guinea pig maximisation test - OECD Guideline 406 (Skin Sensitisation)

Route of exposure intradermal and epicutaneous

Species observed Guinea pig

Dose 5 & 50 % induction; 50% challenge

Duration

Observations Non sensitizing.

Additional Notes

Conclusion It is believed that Caprylyl Glycol is safe for use in Marble Smooth at this concentration and use as described, assuming the parameters

stated.

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Chemical Name Lavandula Angustifolia (Lavender) Oil

Function Fragrance

INCI Name Lavandula Angustifolia (Lavandula Officinalis) Oil CAS 8000-28-0 / 90063-37-9 (Essential Oils Direct)

EINECS N/A

 SED(adult)
 0.04236033 mg(kg bw)-1.d-1

 SED(child)
 N/A mg (kg bw)-1.d-1

 SED(baby)
 N/A mg.(kg bw)-1.d-1

 NOAEL
 200 mg.(kg bw)-1.d-1

Dermal penetration factor 1

 MoS(adult)
 4721.399

 MoS(child)
 N/A

 MoS(baby)
 N/A

Additional Notes

Type of test LD50
Route of exposure Oral
Species observed Rat

Dose 4200 mg.(kg bw)-1.d-1

Duration Observations Additional Notes

Type of test Acute dermal exposure

Route of exposure Dermal Species observed Mouse

Dose 6500 mg.(kg bw)-1

Duration Observations Additional Notes

Type of test LC50
Route of exposure Inhalation
Species observed Rat
Dose 142500 ppm
Duration 4hr

Observations Additional Notes

Type of test Acute dermal exposure

Route of exposure Dermal Species observed Rabbit

Dose 5000 mg.(kg bw)-1

Duration

Observations Class C dermal irritation



Type of test Photosensitization

Route of exposure Dermal Species observed Rabbit

Dose Duration

 Observations
 Additional Notes
 Some evidence of farmesol and geraniol acting as photosensitizers from trace to <0.1%.

Type of test Acute

Route of exposure Mucous membrane

Species observed Rabbit

Dose

Duration

Observations Class C-D non irritant

Additional Notes

Type of test Repeat dose dermal toxicity

Route of exposure Dermal Species observed Rats

Dose 250, 1000 and 4000 mg.(kg bw)-1.d-1

Duration 90d

Observations Decreased activity and transient erythema. At 1000 mg (kg bw)-1 weight gain and activity were reduced, and at the highest dose 11 of

20 animals died.

Additional Notes Test substance was linalool. A consistuent of Lavandula Angistifolia Oil.

Type of test Dermal irritancy
Route of exposure Dermal

Species observed Mice - hairless and pigs

Dose

Duration

Observations Non irritant, except slight irritant on intact or abraded rabbit skin under occlusion for 24hr.

Additional Notes

Conclusion It is believed that Lavandula Angustifolia (Lavandula Officinalis) Oil is safe for use in Marble Smooth at this concentration and use as

described, assuming the parameters stated.

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Chemical Name Boswellia Carteri (Frankincense) Oil

Function Fragrance

INCI Name Boswellia Carteri Extract

CAS 89957-98-2 / 8050-07-5 (Essential Oils Direct)

EINECS 289-620-2

 SED(adult)
 0.04236033 mg(kg bw)-1.d-1

 SED(child)
 N/A mg (kg bw)-1.d-1

 SED(baby)
 N/A mg (kg bw)-1.d-1

 NOAEL
 1200 mg (kg bw)-1.d-1

Dermal penetration factor 1

 MoS(adult)
 28328.39

 MoS(child)
 N/A

 MoS(baby)
 N/A

Additional Notes

Type of test Acute oral toxicity

Route of exposure Oral Species observed Rat

Dose 5000 mg.(kg bw)-1

Duration

Observations LD50

Additional Notes

Type of test Acute dermal exposure

Route of exposure Dermal Species observed Rat

Dose 5000 mg.(kg bw)-1

Duration

Observations LD50 greater than 5g.(kg bw).d-1

Additional Notes

Type of test Acute dermal irritation

Route of exposure Dermal Species observed Rabbit Dose 8 %

Duration

Observations No irritation at <8%

Additional Notes

Type of test Dermal sensitization

Route of exposureDermalSpecies observedRabbitDose8 %

Duration

Observations No sensitisation observed at 8%

Additional Notes

Conclusion It is believed that Boswellia Carteri Extract is safe for use in Marble Smooth at this concentration and use as described, assuming the

parameters stated.

/



Chemical Name Pelargonium Graveolens (Geranium) Flower Oil

Function Perfuming

INCI Name Pelargonium Graveolens Flower Oil

CAS 90082-51-2 / 8000-46-2 (Essential Oils Direct)

EINECS 90082-46-5

 SED(adult)
 0.04236033 mg(kg bw)-1.d-1

 SED(child)
 N/A mg (kg bw)-1.d-1

 SED(baby)
 N/A mg (kg bw)-1.d-1

 NOAEL
 1200 mg (kg bw)-1.d-1

Dermal penetration factor 1

 MoS(adult)
 28328.39

 MoS(child)
 N/A

 MoS(baby)
 N/A

Reproductive Toxicity: Pelargonium Graveolens Flower Oil is not reported to produce reproductive toxicity in humans.

Mutagenicity: Pelargonium Graveolens Flower Oil is not reported to produce mutagenic effects in humans.

Additional Notes

Embryotoxicity: Pelargonium Graveolens Flower Oil is not reported to produce embryotoxic effects in humans.

Teratogenicity: Pelargonium Graveolens Flower Oil is not reported to produce teratogenic effects in humans.

Reproductive Toxicity: Pelargonium Graveolens Flower Oil is not reported to produce reproductive effects in humans.

Pelargonium Graveolens Flower Oil is Not found to be a sensitizer not found to be phototoxic;

Type of test Acute oral toxicity

Route of exposure Oral Species observed Rat

Dose 5000 mg.(kg bw)-1

Duration

Observations LD50 = 5000 mg.(kg bw)-1

Additional Notes

Type of test Acute inhalation toxicity

Route of exposure Inhalation
Species observed Rabbit

Dose 2500 mg.L-1.(4H)-1

Duration
Observations
Additional Notes

Type of test Acute dermal exposure

Route of exposure Dermal Species observed Rabbit

Dose 5000 mg.(kg bw)-1

Duration

Observations LD50 dermal > 5000 mg.(kg bw)-1

Additional Notes

Type of test Acute oral toxicity

Route of exposure Oral Species observed Rat

Dose 5000 mg.(kg bw)-1

Duration

Observations LD50 = 5000 mg.(kg bw)-1



Type of test Acute inhalation toxicity

Route of exposure Inhalation
Species observed Rabbit

Dose 2500 mg.L-1.(4H)-1

Duration Observations Additional Notes

Type of test Acute dermal exposure

Route of exposure Dermal Species observed Rabbit

Dose 5000 mg.(kg bw)-1

Duration

Observations LD50 dermal \geq 5000 mg.(kg bw)-1

Additional Notes

Conclusion It is believed that Pelargonium Graveolens Flower Oil is safe for use in Marble Smooth at this concentration and use as described,

assuming the parameters stated.

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

Function Perfuming

INCI Name Citrus Grandis Peel Oil

CAS 90045-43-5 / 8016-20-4 (Essential Oils Direct 26/05/2015)

EINECS 289-904-6

SED(adult) 0.04236033 mg.(kg bw)-1.d-1 SED(child) N/A mg.(kg bw)-1.d-1 SED(baby) N/A mg.(kg bw)-1.d-1 **NOAEL** 125 mg.(kg bw)-1.d-1

Dermal penetration factor 1

MoS(adult) 2950.874 MoS(child) N/A N/A MoS(baby)

Grapefruit oil expressed at high concentrations will cause photo-irritation.

Additional Notes

Subject to: Annex II 358 - Furocoumarines.

Type of test LD50 Route of exposure Oral Species observed

Dose Application Volume: 5 ml

Duration

Observations 14400-5100 mg/kg/bw/day

Additional Notes

LD50 Type of test Route of exposure Dermal Rabbit Species observed

5000 mg/kg/bw/day Dose

Duration Observations **Additional Notes**

Semiocclusive Type of test Dermal Irritation Route of exposure Species observed Human 10%/24H Dose

Duration

Observations tested at 10% in petrolatum.../produced/ no irritation after 48-hr closed-patch test in 24 human subjects. A patch test using full strength

grapefruit oil for 24 hr produced no reactions in 26 subjects

Additional Notes Mild irritation

LC50 Type of test Inhalation Route of exposure Species observed Rat

10.3 mg/dm3 Dose Duration

Observations Additional Notes

It is believed that Citrus Grandis Peel Oil is safe for use in Marble Smooth at this concentration and use as described, assuming the Conclusion

parameters stated.



Chemical NameCitralFunctionPerfumingINCI NameCitralCAS5392-40-5EINECS226-394-6

 SED(adult)
 0.0233123 mg (kg bw)-1.d-1

 SED(child)
 N/A mg (kg bw)-1.d-1

 SED(baby)
 N/A mg (kg bw)-1.d-1

 NOAEL
 570 mg (kg bw)-1.d-1

Dermal penetration factor 1

 MoS(adult)
 24450.62

 MoS(child)
 N/A

 MoS(baby)
 N/A

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.

Additional Notes Teratogenicity: 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.

Citral is highly irritating to the eyes and mucous membranes and maybe irritating to the skin of some sensitive individuals.

Type of test Acute oral toxicity

Route of exposure Oral Species observed Rat

Dose 4690 mg.(kg bw)-1

Duration

Observations LD50

Additional Notes

Type of test Acute dermal exposure

Route of exposure Dermal Species observed Rat

Dose 2500 mg.(kg bw)-1

Duration

Observations LD50

Additional Notes

Type of test Acute inhalation toxicity

Route of exposure Inhalation Species observed Rat

Dose 4.1 mg/L/96/H

Duration

Observations LC50

Additional Notes

Conclusion It is believed that Citral is safe for use in Marble Smooth at this concentration and use as described, assuming the parameters stated.

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Chemical Name 3,7-Dimethyloct-6-en-1-ol

FunctionPerfuningINCI NameCitronellolCAS106-22-9EINECS203-375-0

 SED(adult)
 0.1239745 mg.(kg bw)-1.d-1

 SED(child)
 N/A mg.(kg bw)-1.d-1

 SED(baby)
 N/A mg.(kg bw)-1.d-1

 NOAEL
 300 mg.(kg bw)-1.d-1

Dermal penetration factor 1

 MoS(adult)
 2419.852

 MoS(child)
 N/A

 MoS(baby)
 N/A

EU directive 2003/15/EC, requires that the presence of the substance must be indicated in the list of ingredients referred to in Article

Additional Notes 6(1)g when its concentration exceeds:

0.001% in leave-on products0.01% in rinse-off products

Type of test Acute oral toxicity

Route of exposure Oral Species observed Rat

Dose 3450 mg.(kg bw)-1

Duration

Observations LD50

Additional Notes

Type of test Acute dermal exposure

Route of exposure Dermal Species observed Rabbit

Dose 2650 mg.(kg bw)-1

Duration

Observations LD50

Additional Notes

Type of test Irritation

Route of exposure Dermal (abraded skin)

Species observedRabbitDose100%Duration24hr

Observations Moderate irritation.

Additional Notes Test performed under occlusive patch.

Type of test Dermal irritancy
Route of exposure Shaved skin
Species observed albino angora rabbits
Dose 0.1 ml; 32% in acetone
Duration 24 and 48 hours
Observations severely irritating



Type of test Dermal irritancy

Route of exposure Occluded shaved dorsal skin

Species observed Pitman-Moore Improved miniature swine

Dose 0.05 ml; 32% in acetone

Duration 48 hours **Observations** not irritating

Additional Notes

Type of test Subchronic oral toxicity

Route of exposure oral Species observed Rats

Dose 50 mg.(kg bw)-1.d-1

Duration 12wk

Observations No adverse effects

Additional Notes

Type of test Draize
Route of exposure Dermal
Species observed Human
Dose 16 mg
Duration 48hr

Observations Moderate irritation

Additional Notes

Type of test Draize
Route of exposure Dermal
Species observed Rabbit
Dose 100 mg
Duration 24hr

Observations severely irritating

Additional Notes

Type of test Draize
Route of exposure Dermal
Species observed Guinea pig
Dose 100 mg
Duration 24hr

Observations severely irritating

Additional Notes

Type of test Acute oral toxicity

Route of exposure Oral Species observed Rat

Dose 3450 mg.(kg bw)-1

Duration

Observations LD50



Type of test Acute subcutaneous toxicity

Route of exposure Subcutaneous **Species observed** Mouse

Dose 880 mg.(kg bw)-1

Duration

Observations Peripheral Nerve and Sensation - spastic paralysis with or without sensory change

Additional Notes

Type of test Acute intramuscular toxicity

Route of exposure Intramuscular Species observed Mouse

Dose 4000 mg.(kg bw)-1

Duration

Observations LD50

Additional Notes

Type of test Acute dermal exposure

Route of exposure Dermal Species observed Rabbit

Dose 2650 mg.(kg bw)-1

Duration

Observations LD50

Additional Notes

Type of test Repeat dose
Route of exposure Oral
Species observed Rat

Dose 51 and 56 mg.(kg bw)-1.d-1 (male and femail respectively)

Duration 90d **Observations** NOAEL

Additional Notes

Type of test Repeat dose
Route of exposure Oral
Species observed Mice - B6C3F1

species observed Mice - BoC3F1

Dose 125, 250, 500, 1000, 2000 mg.(kg bw)-1.d-1

Duration 13wk

Observations NOAEL = 1000 mg.(kg bw)-1.d-1

Additional Notes

Type of test Repeat dose Route of exposure Oral

Species observed Rat - Fischer 344

Dose 250, 500, 1000, 2000, 4000 mg.(kg bw)-1.d-1

Duration 13wk

Observations NOAEL = 2000 mg.(kg bw)-1.d-1



Type of test Repeat dose **Route of exposure** Oral

Species observedRat - Osborne-MendelDose55 550 mg.(kg bw)-1.d-1

Duration 112d

Observations NOAEL > 550 mg.(kg bw)-1.d-1

Additional Notes

Type of test OECD Guideline 421 (Reproduction / Developmental Toxicity Screening Test)

Route of exposure Dermal Species observed Rat

Dose 50 150 300 450 mg,(kg bw)-1.d-1

Duration

Observations Parental NOAEL of 300 mg.(kg bw)-1.d-1. NOAEL offspring = 300 mg.(kg bw)-1.d-1. Massive irritation occured in the 450 mg.(kg

bw)-1.d-1 group.

Additional Notes Exposure - Preparation frequency: The preparations were prepared at intervals for which the stability is guaranteed (7 days). -

Application area: Intact clipped skin of the back (dorsal and dorsolateral areas of the trunk; not less than 10% of the body surface); the first clipping was carried out at least 24 hours before the randomization. The rats were reclipped at least once a week (depending on the hair growth). - Type of application: Dermal application of the test-substance preparations to the clipped intact dorsal skin by means was carried out with 3-mL syringes (3CC Syringe, supplied by Becton, Dickinson & Co., Franklin Lakes, U.S.A.) and a semiocclusive dressing (4 layers of absorbent gauze) and stretch bandage)). The test-substance preparation was applied to the dorsal skin with the syringe in each case. After removal of the dressing, the application area was washed with lukewarm water. - Volume to

be applied: 4 mL/kg body weight (related to the body weight determined most recently in each case).

Conclusion It is believed that Citronellol is safe for use in Marble Smooth at this concentration and use as described, assuming the parameters

stated.

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Chemical Name 2,6,10-Dodecatrien-1-ol,3,7,11-trimethyl-

FunctionPerfuringINCI NameFamesolCAS4602-84-0EINECS225-004-1

 SED(adult)
 0.02259217 mg(kg bw)-1.d-1

 SED(child)
 N/A mg (kg bw)-1.d-1

 SED(baby)
 N/A mg (kg bw)-1.d-1

 NOAEL
 1000 mg (kg bw)-1.d-1

Dermal penetration factor 1

 MoS(adult)
 44263.12

 MoS(child)
 N/A

 MoS(baby)
 N/A

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.

Additional Notes 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 Rabbit

Dose 1745 mg/kg/bw/dat

Duration Observations Additional Notes

Type of test LD50
Route of exposure Dermal
Species observed Rat

Dose 5000 mg/kg/bw/day

Duration
Observations
Additional Notes

Type of test LC50
Route of exposure Inhalation
Species observed Rat
Dose 13.0 ppm

Duration Observations Additional Notes

Conclusion It is believed that Farnesol is safe for use in Marble Smooth at this concentration and use as described, assuming the parameters stated.



Chemical Name 2,6-Octadien-1-ol,3,7-dimethyl-, (2E)-

FunctionPerfuringINCI NameGeraniolCAS106-24-1EINECS203-377-1

 SED(adult)
 0.1219412 mg.(kg bw)-1.d-1

 SED(child)
 N/A mg.(kg bw)-1.d-1

 SED(baby)
 N/A mg.(kg bw)-1.d-1

 NOAEL
 1000 mg.(kg bw)-1.d-1

Dermal penetration factor 1

 MoS(adult)
 8200.671

 MoS(child)
 N/A

 MoS(baby)
 N/A

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 Reproductive Toxicity: Geraniol is not reported to produce reproductive

toxicity in humans. Mutagenicity: Geraniol is not reported to produce mutagenic effects in humans. Geraniol and other essential oils are currently under examination for genotoxic effects, until that point it can be assumed as same as long as kept with in current quidelines.

currently under examination for genotoxic effects, until that point it can be assumed as same as long as kept with in current guidelines Embryotoxicity: Geraniol is not reported to produce embryotoxic effects in humans. Teratogenicity: Geraniol is not reported to produce

teratogenic effects in humans. Reproductive Toxicity: Geraniol is not reported to produce reproductive effects in humans.

Type of test LD50
Route of exposure Acute Oral
Species observed Rat
Dose 5000 mg/kg

Duration

Observations Duration of observation period following administration: 14 days - Other examinations performed: for mortality and toxic effects

Additional Notes

Additional Notes

Type of test LD50
Route of exposure Dermal
Species observed Rabbit
Dose 5000 mg/kg

Duration
Observations
Additional Notes

Type of test LC50
Route of exposure Inhalation
Species observed Rat

Dose 93.19-150.0 ppm

Duration

Observations Name of test material (as cited in study report): Geraniol - Analytical purity: 99.4 %

Additional Notes negative



Type of test gene mutation

Route of exposure bacterial reverse mutation assay (e.g. Ames test) **Species observed** S. typhimurium TA 1535, TA 1537, TA 98 and TA 100

Dose Exposure duration: 48 h, 37°C

Duration

Observations Name of test material (as cited in study report): Geraniol - Analytical purity: 99.4 %

Additional Notes The main findings of the present study can be summarized as follows: (1) Mortality: Through the whole experimental phase an increased

mortality was observed in the males group treated with the highest test dose of 2000 mg/kg bw, indicating a cumulative toxicity of the test substance. In fact at 2000 mg/kg bw, 18/50 males survived versus 34/50 in the control group. At the low dose of 1000 mg/kg bw, survival of the males was 29/50. (2) Macroscopical findings: Retinopathy or cataracts were reported for the males of the high dose group and the females of the low dose group. In fact, it appeared that these findings were not related to the test substance but to the proximity of the rats to a source of fluorescent light. (3) Cancer findings: Two of the 50 males of the low dose group displayed kidney tubular cell adenomas. The incidence of kidney tumors in male rats within the vehicle control group of this study was similar to the historical incidence observed in the laboratory (0.4 %). Epidermal tumors were reported for the males of the low dose group (6/50, 12 %). The incidence of low dose males with epidermal tumors was increased compared to control (3/50, 6 %), but this increase was without statistical significance. In the high dose group, only one case was observed (1/50, 2 %). Under the conditions of the present

study, the test substances Geraniol was not carcinogenic.

Type of test Carcinogenicity
Route of exposure Oral: Gavage
Species observed Rat Fischer 344

Dose 1000, 2000 mg/kg bw/ 5 times a week / 103 weeks

Duration Observations Additional Notes

Conclusion It is believed that Geraniol is safe for use in Marble Smooth at this concentration and use as described, assuming the parameters stated.



Chemical Name 1-methyl-4-(1-methylethenyl)-cyclohexene

Function Perfuming **INCI** Name d-Limonene CAS 5989-27-5 **EINECS** 227-813-5

SED(adult) 0.1621835 mg.(kg bw)-1.d-1 SED(child) N/A mg.(kg bw)-1.d-1 SED(baby) N/A mg.(kg bw)-1.d-1 NOAEL 500 mg.(kg bw)-1.d-1

Dermal penetration factor 1

3082.927 MoS(adult) MoS(child) N/A MoS(baby) N/A

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).

Additional Notes

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.

LD50 Type of test Oral Route of exposure Species observed Rat Dose 2790 mg/kg

Duration

Observations Additional Notes

LD50 Type of test Route of exposure Dermal Species observed Rabbit Dose 5610 mg/kg

Duration Observations **Additional Notes**

LC50 Type of test Route of exposure Inhalation Species observed Rat

Duration Observations Additional Notes

295 mg/l/96H Dose



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 testLD50Route of exposureDermalSpecies observedRabbit

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 NOEAL = 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 Derma

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

Duration7d post-exposure observation.ObservationsNone 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

animals after 1 hour of instillation. The irritation completely resolved within 7 days. Mean individual scores at 24, 48 and 72 hours aft 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.



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

Conclusion

Observations Non mutagenic.

Additional Notes

It is believed that d-Limonene is safe for use in Marble Smooth at this concentration and use as described, assuming the parameters

stated.

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Chemical Name 3,7-Dimethylocta-1,6-diene-3-ol

Function Perfuring
INCI Name Linalool
CAS 78-70-6
EINECS 201-134-4

 SED(adult)
 0.04644105 mg (kg bw)-1.d-1

 SED(child)
 N/A mg (kg bw)-1.d-1

 SED(baby)
 N/A mg (kg bw)-1.d-1

 NOAEL
 250 mg (kg bw)-1.d-1

Dermal penetration factor 1

 MoS(adult)
 5383.169

 MoS(child)
 N/A

 MoS(baby)
 N/A

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.

Additional Notes

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 is not reported to produce 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

Type of test LD50
Route of exposure Dermal
Species observed Rabbit
Dose 5610 mg/kg

Duration Observations Additional Notes

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 Marble Smooth at this concentration and use as described, assuming the parameters stated.

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