SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

Toxicological Safety Assessment of: Super smoothie

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: C1008/03

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Composition of Formulation

CAS Number	INCI Name	Maximum Concentration %
90106-38-0 (Water)	Rosa Damascena Flower Distilate	54.3971
68650-44-2 / 72869-69-3	Prunus Armeniaca Kernel Oil	9.972801
84696-47-9	Rosa Canina Fruit Oil	9.972801
8012-89-3	Cera Alba	8.159565
59-02-9	Tocopherol	7.252947
61789-91-1	Simmondsia Chinensis (Jojoba) Seed Oil	6.527652
8001-31-8	Cocos Nucifera Oil	3.263826
122-99-6	Phenoxyethanol	0.2719855
1117-86-8	Caprylyl Glycol	0.1813237

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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/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 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 Super smoothie 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.

Super smoothie 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.

Super smoothie 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:	5
IFRA Category:	Face cream
Targeted Population:	Adults
Number of uses per day:	Once
Amount per Application/g:	1.54 g
Total amount applied per day/g:	1.54 g
Estimated daily exposure (Daily):	0.0252459 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:	10800 seconds
Exposure time dilute:	0 seconds

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Toxicological Summary

Super smoothie is a face cream for adult use. A small amount is applied to the skin of the face 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 1.54 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
Rosa Damascena Flower Distilate	1456.342	Safe
Prunus Armeniaca Kernel Oil	39718.42	Safe
Rosa Canina Fruit Oil	297.8881	Safe
Cera Alba	10679.84	Safe
Tocopherol	546.1282	Safe
Simmondsia Chinensis (Jojoba) Seed Oil	3034.046	Safe
Cocos Nucifera Oil	1990334	Safe
Geraniol	7281.71	Safe
Limonene	3640.855	Safe
Citronellol	2184.513	Safe
Phenoxyethanol	5461.282	Safe
Caprylyl Glycol	6553.538	Safe
Citral	20752.87	Safe
Farnesol	36408.55	Safe
Linalool	9102.137	Safe

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

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Effects of the finished product on specific organs and tissue types

Internal organs: Super smoothie is unlikely to cause damage to the internal organs following application.

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

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

Upper gastrointestinal: Super smoothie is likely to cause upper gastrointestinal irritation.

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

Super smoothie 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 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.

Super smoothie 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	0.1087942	0.3	Pass: Within limits
4602-84-0	0.1087942	0.6	Pass: Within limits
106-24-1	0.543971	2.8	Pass: Within limits
106-22-9	0.543971	7	Pass: Within limits

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

INCI Name	CAS	% Concentration of formulation
Citral	5392-40-5	0.1087942
Farnesol	4602-84-0	0.1087942
Geraniol	106-24-1	0.543971
Limonene	138-86-3	0.543971
Citronellol	106-22-9	0.543971
Linalool	78-70-6	0.1087942

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	0.1087942
Citronellol	106-22-9	1	0.543971
Farnesol	4602-84-0	0.2	0.1087942
Geraniol	106-24-1	1	0.543971
d-Limonene	5989-27-5	1	0.543971
Linalool	78-70-6	0.2	0.1087942

Conclusion

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

The finished product Super smoothie 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 Super smoothie 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: Rosa Damascena Flower Distilate, Prunus Armeniaca Kernel Oil, Rosa Canina Fruit Oil, Cera Alba, Tocopherol, Simmondsia Chinensis (Jojoba) Seed Oil, Cocos Nucifera Oil, Geraniol, Limonene, Citronellol, Phenoxyethanol, Caprylyl Glycol, Citral, Farnesol, Linalool

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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 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.

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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
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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, Perfuming
INCI Name	Rosa Damascena Flower Distilate
CAS	90106-38-0 (Water)
EINECS	290-260-3
SED(adult)	1.373304 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 factor	0.1
MoS(adult)	1456.342
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	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. 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 Super smoothie at this concentration and use as described, assuming the parameters stated.

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Chemical Name	Prunus Armeniaca Kernel Oil is the fixed oil expressed from the kernels of the Apricot, Prunus armeniaca L., Rosaceae
Function	Masking, Skin Conditioning
INCI Name	Prunus Armeniaca Kernel Oil
CAS	68650-44-2 / 72869-69-3
EINECS	272-046-1 / -
SED(adult)	0.02517724 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	0.01
MoS(adult)	39718.42
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	Care should be taken during procurement to ensure oil used has been refined to reduce Amygdalin concentrations. This process is found in apricot kernel oil for oral consumption. Amygdalin when consumed orally can be metabolised into cyanide compounds which can pose a risk to human health from inadvertent oral consumption. The risk of low amygdalin oils affecting health from topical use is considered very low, even when pessimistically assuming 100% amygdalin dermal penetration.

Type of test	Repeat feeding study
Route of exposure	Oral
Species observed	Rat
Dose	10 % of diet
Duration	13wk
Observations	No histological or gross abnormalities in any organs were identified.
Additional Notes	This study used kernel oil expressed from mild seed, and did not contain appreciable concentrations of amygdalin.

Type of test	Accute dermal toxicity
Route of exposure	Dermal
Species observed	Rabbit
Dose	7-10 mg.(kg bw)-1
Duration	
Observations	LD50 dermal = 7-10 mg.(kg bw)-1 in intact skin, and markedly higher in abraded skin.
Additional Notes	This study used cyanides in aqueous solutions. LD50 dermal for hydrogen cyanide is estimated to be 100 mg.(kg bw)-1 in humans.

Conclusion	It is believed that Prunus Armeniaca Kernel Oil is safe for use in Super smoothie at this concentration and use as described, assuming the parameters stated.

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Chemical Name	Rosa Canina Fruit Oil
Function	Emollient
INCI Name	Rosa Canina Fruit Oil
CAS	84696-47-9
EINECS	283-652-0
SED(adult)	2.517724 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	750 mg.(kg bw)-1.d-1
Dermal penetration factor	1
MoS(adult)	297.8881
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	A case study was reported in which a female subject had dermatitis around the eyes and earlobes, Patch testing with her sunscreen resulted in a positive result, Subsequent patch testing of the individual ingredients, a positive reaction to undiluted Rosa Canina Fruit Oil, but not the active ingredients was observed. Twenty control subjects were used, and reactions to Rosa Canina Fruit Oil were not seen.

Type of test	LD50
Route of exposure	Oral
Species observed	Rat
Dose	7910 mg/kg/bw/day
Duration	
Observations	
Additional Notes	None

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	Rat
Dose	83.426 mg/L/bw/day
Duration	
Observations	
Additional Notes	

Conclusion	It is believed that Rosa Canina Fruit Oil is safe for use in Super smoothie 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)	0.02059956 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 factor	0.01
MoS(adult)	10679.84
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
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 Super smoothie at this concentration and use as described, assuming the parameters stated.

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Chemical Name	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,[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)	1.831072 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)	546.1282
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	

Type of test	TDLo - Lowest published toxic dose
Route of exposure	Oral
Species observed	Rat
Dose	7500 mg.(kg bw)-1
Duration	1-20d 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 mmol.(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 Super smoothie at this concentration and use as described, assuming the parameters stated.

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Chemical Name	Simmondsia Chinensis(Jojoba) Seed Oil
Function	Emollient
INCI Name	Simmondsia Chinensis (Jojoba) Seed Oil
CAS	61789-91-1
EINECS	289-964-3
SED(adult)	1.647965 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	5000 mg.(kg bw)-1.d-1
Dermal penetration factor	1
MoS(adult)	3034.046
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	Reproductive Toxicity: Simmondsia Chinensis is not reported to produce reproductive toxicity in humans. Mutagenicity: Simmondsia Chinensis is not reported to produce mutagenic effects in humans. Embryotoxicity: Simmondsia Chinensis is not reported to produce embryotoxic effects in humans. Teratogenicity: Simmondsia Chinensis is not reported to produce teratogenic effects in humans. Reproductive Toxicity: Simmondsia Chinensis is not reported to produce reproductive effects in humans. Based on the large molecular weight of the components of the Jojoba Oil ingredients, the CIR Expert Panel concluded that they would not penetrate the skin. The CIR Expert Panel reviewed a number of studies that indicated low acute and subchronic toxicity of Simmondsia Chinensis (Jojoba) Seed Oil. Undiluted Simmondsia Chinensis (Jojoba) Seed Oil was not a skin irritant. In a maximization test, no sensitization reactions were observed with Jojoba Alcohol. Jojoba Alcohol and mixture of Jojoba Oil and Hydrogenated Jojoba Oil were not mutagenic in bacterial assays. Tests of topical products containing Simmondsia Chinensis (Jojoba) Seed Oil found them to be nonirritants and nonsensitizers to humans. Sensitization to undiluted Jojoba Oil was not observed. The use of Simmondsia Chinensis (Jojoba) Seed Oil, Simmondsia Chinensis (Jojoba) Seed Wax and the other Jojoba ingredients in cosmetic products in the European Union is allowed according to the general provisions of the Cosmetics Directive.

Type of test	Acute oral toxicity
Route of exposure	Oral
Species observed	Rat
Dose	750 mg.(kg bw)-1
Duration	
Observations	
Additional Notes	Ingestion of 750mg/kg isolated simmondsin for 14 weeks is sufficient to kill mice (5/8) with the remaining mice experiencing hepatotoxicity and intestinal hemorrhage. Oddly, no appetetite suppression nor toxicity was noted with injections, ingestion of 250mg/kg Simmondsin in rats for 5 days fails to find any toxicological signs in the pancreas, liver, intestines, testes, or kidneys.Simmondsin up to 0.5% of the diet in lean rats for 8 weeks failed to alter the weight of the liver, and caused a slight increase in percent of kidney weight relative to body weight (absolute kidney weight did not change, and this study did not weight loss due to food intake reduction); the same lack of organ weight changes were noted over 16 weeks in obese rats. Histological examination did not note any remarkable abnormalities

Type of test	Acute dermal toxicity
Route of exposure	Subcutanious
Species observed	Rabbit
Dose	1 mg.(kg bw)-1
Duration	
Observations	
Additional Notes	The subacute toxicity of jojoba wax (I) was determined following prolonged topical application (6 day/wk for 20 wk) to guinea pigs, and following daily SC injection of I, one ml/kg, to rats, to a total of 42 injections per animal. Results show normal growth and no histological changes in the internal organs of the guinea pigs. In the rats, no histopathological changes were observed, only a mild local granulomatous reaction. Results of blood and urine chemistry analyses and of the blood cell profile in the rats were similar to those in the control group. The small differences found in the monocyte and neutrophilic granulocyte counts of the peripheral blood of the treated animals and the controls were characteristic of a reaction to foreign material.

Type of test	Acute inhalation toxicity LD50
Route of exposure	Inhalation
Species observed	Rat
Dose	2000 mg.(kg bw)-1
Duration	
Observations	
Additional Notes	

Type of test	Ocular irritancy test
Route of exposure	Eye
Species observed	Rabbit
Dose	30 %ww
Duration	24hr
Observations	Mild to moderate irritation
Additional Notes	In the guideline study (OECD 405) the 80 % active spray dried substance was tested (Th. Goldschmidt AG, 1991b). The substance was irreversibly irritating. All other studies were performed according to the same protocol with slight variations: concentration of Cocamidopropyl Betaine used, reversibility testing and classification system (for details see tables 7 and 8). 30 % and 25 % Cocamidopropyl Betaine is an irreversibly irritating, or highly irritating substance 14 – 15 % solutions of Cocamidopropyl Betaine were highly irritating (Goldschmidt Chemical Corporation, 1993b, 1993c) and the results for the ≤ _10 % active compound varies between mildly and moderately eye irritating, reversible after 14 days Rinsing of the eyes after 30 seconds had no influence on the irritation effect but on the reversibility of the effects observed (US-EPA, 1991).

Type of test	Mutagenicity
Route of exposure	
Species observed	TA100 - AMES SALMONELLA TYPHIMURIUM
Dose	
Duration	
Observations	Negative
Additional Notes	The safety of jojoba-oil and jojoba-wax was assessed by the Cosmetic Ingredient Review Expert Panel. The physicochemical properties of both ingredients were summarized. Jojoba-oil is extracted from the seeds of the desert shrub Simmondsia-chinensis and consists of wax esters of monounsaturated straight chain acids and alcohols containing 16 to 26 carbon atoms. Jojoba-wax is completely hydrogenated jojoba-oil. Analytical methods for determination and uses of jojoba-oil and jojoba-wax were described. Jojoba-oil has been used as an occlusive skin conditioning agent and hair conditioner. Jojoba-wax has been used in exfoliating scrub products. The biological properties and toxicological properties of jojoba-oil and jojoba-wax were discussed. Jojoba-oil has shown only slight acute oral toxicity in experimental animals. The oral median lethal dose in rats was around 21.5 milliliters/kilogram. Jojoba-wax at 5.0 grams per kilogram was nontoxic in rats. Undiluted jojoba-oil caused a transient, mild conjunctival hyperemia in the eyes of rabbits. A lip balm product containing 20.0% jojoba-oil did not cause eye irritation in rabbits. Jojoba-oil did not induce skin irritation or sensitization in laboratory animals. Jojoba-oil and jojoba-wax were not mutagenic in the Amesalmonella assay. A topical product containing 0.5% jojoba-oil and a lip balm containing 20.0% jojoba-oil did not cause skin irritation or sensitization in human volunteers. Refined and crude jojoba-oil caused a low incidence of skin irritation in patients with histories of eczema or dermatitis. The Expert Panel concluded that jojoba-oil and jojoba-wax are safe as cosmetic ingredients as presently used. Final conclusion: Simmondsia Chinensis (Jojoba) Seed Oil is used in this formulation as a Emollient.

Type of test	Acute Oral Toxicity
Route of exposure	Oral
Species observed	Rat
Dose	5000 mg.(kg bw)-1
Duration	
Observations	LD50 oral > 5000 mg.(kg bw)-1
Additional Notes	

Conclusion	It is believed that Simmondsia Chinensis (Jojoba) Seed Oil is safe for use in Super smoothie 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)	0.008239823 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 factor	0.01
MoS(adult)	1990334
MoS(child)	N/A
MoS(baby)	N/A
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	

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 Super smoothie at this concentration and use as described, assuming the parameters stated.

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Chemical Name	2-Phenoxy-1-ethanol
Function	Preservative
INCI Name	Phenoxyethanol
CAS	122-99-6
EINECS	204-589-7
SED(adult)	0.06866519 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)	5461.282
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	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 2-phenoxyethanol 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 reproductivtity 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-fry 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 2-phenoxyethanol 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.

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

Conclusion	It is believed that Phenoxyethanol is safe for use in Super smoothie at this concentration and use as described, assuming the parameters stated.

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Chemical Name	Octane-1,2-diol
Function	Emollient
INCI Name	Caprylyl Glycol
CAS	1117-86-8
EINECS	214-254-7
SED(adult)	0.0457768 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)	6553.538
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 Super smoothie at this concentration and use as described, assuming the parameters stated.

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SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

Chemical Name	Citral
Function	Perfuming
INCI Name	Citral
CAS	5392-40-5
EINECS	226-394-6
SED(adult)	0.02746608 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)	20752.87
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	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. 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 Super smoothie at this concentration and use as described, assuming the parameters stated.
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Chemical Name	3,7-Dimethyloct-6-en-1-ol
Function	Perfuming
INCI Name	Citronellol
CAS	106-22-9
EINECS	203-375-0
SED(adult)	0.1373304 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)	2184.513
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	EU directive 2003/15/EC, requires that 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

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 observed	Rabbit
Dose	100%
Duration	24hr
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
Additional Notes	

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
Additional Notes	

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
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
Additional Notes	

Type of test	Repeat dose
Route of exposure	Oral
Species observed	Rat - Osborne-Mendel
Dose	55 550 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 Super smoothie 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-
Function	Perfuming
INCI Name	Farnesol
CAS	4602-84-0
EINECS	225-004-1
SED(adult)	0.02746608 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)	36408.55
MoS(child)	N/A
MoS(baby)	N/A
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	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 Super smoothie at this concentration and use as described, assuming the parameters stated.

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Chemical Name	2,6-Octadien-1-ol,3,7-dimethyl-, (2E)-
Function	Perfuming
INCI Name	Geraniol
CAS	106-24-1
EINECS	203-377-1
SED(adult)	0.1373304 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)	7281.71
MoS(child)	N/A
MoS(baby)	N/A
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 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 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	

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 Super smoothie at this concentration and use as described, assuming the parameters stated.
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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)	0.1373304 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
MoS(adult)	3640.855
MoS(child)	N/A
MoS(baby)	N/A
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	

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	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	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.

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 Super smoothie 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	Perfuming
INCI Name	Linalool
CAS	78-70-6
EINECS	201-134-4
SED(adult)	0.02746608 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)	9102.137
MoS(child)	N/A
MoS(baby)	N/A
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 Super smoothie at this concentration and use as described, assuming the parameters stated.
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