SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

Toxicological Safety Assessment of: Sniffles

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: C1008/07

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Composition of Formulation

CAS Number	INCI Name	Maximum Concentration %
8001-25-0	Olea Europaea Fruit Oil	41.40787
8001-31-8	Cocos Nucifera Oil	41.40787
8012-89-3	Cera Alba	16.56315
8006-90-4 (Essential Oils Direct)	Mentha Piperita Oil	0.2070393
84625-32-1 (Essential Oils Direct)	Eucalyptus Globulus Leaf Oil	0.2070393
84604-14-8 (Leaf Oil) (Essential Oils Direct)	Rosmarinus Officinalis Leaf Oil	0.1035197
84649-98-9 (Essential Oils Direct)	Cinnamomum Zeylanicum Leaf Oil	0.1035197

Super Active Cosmetics Ltd
Registered in England and Wales: 8564424
31 Brindle Heath Road, Salford, Greater Manchester, M6 6GD, United Kingdom
Info@superactivecosmetics.co.uk
0787 3546 489

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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 Sniffles 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.

Sniffles 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.

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

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

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

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General Manufacturing Procedure

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

General Procedures

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

Personal Hygiene, Health and Safety

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

Storage of Ingredients and Finished cosmetics

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

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Consumer Exposure and Toxicological and Regulatory Review Summary

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

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Margin of Safety, Percutaneous Permutation and Potential Systemic Exposure in Infants

Nappy area and broken skin

The skin structure and barrier function of full-term neonates/newborns and early infants is similar to that of adult skin and the general absorption is generally comparable.

However distinction should be made between the skin of the nappy zone and the rest of the baby skin, due to breaches in barrier function such as from irritation from urine and faecal material. Consideration of incidental contact with partially disrupted barrier function has been considered independent of the systemic risk for this group. Cosmetic product should not be used on broken skin unless directed to do so under medical direction.

Label must specify: Not to be used on broken skin.

Toxicokinetic deviations in neonates.

Existing interspecies factor in the margin of safety for systemic toxicity is greater than the variation in toxicokinetic differences between adults and children unless specific evidence is identified that suggest a greater risk, in which case further analysis is required.

INCI Name	NOAEL	Predicted Systemic Exposure in Neonates	Evidence of toxicokinetic deviations
Cocos Nucifera Oil	16400	1.847319	Negative
Butyrospermum Parkii Butter	5000	0.9236597	Negative
Maranta Arundinacea Root Powder	160	0.6003786	Negative
Calendula Officinalis Flower Oil	150	0.09236597	Negative
Chamomilla Recutita Extract	400	0.9236597	Negative
Linalool	250	0.004849214	Negative
Limonene	500	0.003463722	Negative

Permeation deviation in neonates

Consideration is also given to components that may act as penetration enhancers, thus reducing barrier function.

INCI Name	Percutaneus Permeation %	Evidence of percutaneus permeation enhancement in neonates
Olea Europaea Fruit Oil	1	Negative
Cocos Nucifera Oil	1	Negative
Cera Alba	1	Negative
Mentha Piperita Oil	100	Negative
Eucalyptus Globulus Leaf Oil	100	Negative
Rosmarinus Officinalis Leaf Oil	100	Negative
Cinnamomum Zeylanicum Leaf Oil	100	Negative
Eugenol	100	Negative

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Limonene	100	Negative
Linalool	100	Negative
Benzyl Benzoate	100	Negative
Cinnamaldehyde	100	Negative

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Toxicological Summary

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

INCI Name	MoS for adult	Conclusions
Olea Europaea Fruit Oil	14731.5	Safe
Cocos Nucifera Oil	120798.3	Safe
Cera Alba	4051.162	Safe
Mentha Piperita Oil	4419.451	Safe
Eucalyptus Globulus Leaf Oil	4419.451	Safe
Rosmarinus Officinalis Leaf Oil	11785.2	Safe
Cinnamomum Zeylanicum Leaf Oil	2946.299	Safe
Eugenol	11331.92	Safe
Limonene	51329.28	Safe
Linalool	204604.1	Safe
Benzyl Benzoate	491049.9	Safe
Cinnamaldehyde	1353115	Safe

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

INCI Name	MoS for child	Conclusions
Olea Europaea Fruit Oil	3864	Safe
Cocos Nucifera Oil	31684.8	Safe
Cera Alba	1062.6	Safe
Mentha Piperita Oil	1159.2	Safe
Eucalyptus Globulus Leaf Oil	1159.2	Safe
Rosmarinus Officinalis Leaf Oil	3091.199	Safe
Cinnamomum Zeylanicum Leaf Oil	772.7998	Safe
Eugenol	2972.307	Safe
Limonene	13463.42	Safe
Linalool	53666.65	Safe
Benzyl Benzoate	128800	Safe
Cinnamaldehyde	354915.4	Safe

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

INCI Name	MoS for baby	Conclusions
Olea Europaea Fruit Oil	1424.85	Safe
Cocos Nucifera Oil	11683.77	Safe
Cera Alba	391.8337	Safe
Mentha Piperita Oil	427.4551	Safe
Eucalyptus Globulus Leaf Oil	427.4551	Safe
Rosmarinus Officinalis Leaf Oil	1139.88	Safe
Cinnamomum Zeylanicum Leaf Oil	284.9699	Safe
Eugenol	1096.038	Safe
Limonene	4964.635	Safe
Linalool	19789.58	Safe
Benzyl Benzoate	47494.99	Safe
Cinnamaldehyde	130875.1	Safe

Therefore with the MoS of each raw material being above 100, Sniffles 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: Sniffles is unlikely to cause damage to the internal organs following application.

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

Ingestion: Sniffles 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 Sniffles 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: Sniffles is likely to cause upper gastrointestinal irritation.

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

Sniffles 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.

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

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

CAS Number	% Concentration of formulation	% Limit for this type of product	Conclusion
120-51-4	0.003105591	26.7	Pass: Within limits
104-55-2	0.001397516	0.05	Pass: Within limits
97-53-0	0.08074537	0.5	Pass: Within limits

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

INCI Name	CAS	% Concentration of formulation
Benzyl Benzoate	120-51-4	0.003105591
Cinnamaldehyde	104-55-2	0.001397516
Eugenol	97-53-0	0.08074537
Limonene	138-86-3	0.02971014
Linalool	78-70-6	0.003726709

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

INCI Name	CAS	% Concentration of ingredient	% Concentration of formulation
d-Limonene	5989-27-5	3	0.006211179
Linalool	78-70-6	0.4	0.0008281572

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

INCI Name	CAS	% Concentration of ingredient	% Concentration of formulation
d-Limonene	5989-27-5	8.1	0.01677018

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

INCI Name	CAS	% Concentration of ingredient	% Concentration of formulation
d-Limonene	5989-27-5	6	0.006211182
Linalool	78-70-6	0.8	0.0008281576

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

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INCI Name	CAS	% Concentration of ingredient	% Concentration of formulation
Benzyl Benzoate	120-51-4	3	0.003105591
Cinnamaldehyde	104-55-2	1.35	0.001397516
Eugenol	97-53-0	78	0.08074537
d-Limonene	5989-27-5	0.5	0.0005175985
Linalool	78-70-6	2	0.002070394

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Conclusion

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

The finished product Sniffles 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 Sniffles can be considered as SAFE.

Labelling requirements

The product label must state:

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

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REACH

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

It is important to note that all substances used in cosmetics are already regulated for human health by the European Union Cosmetics Directive, Therefore all of our formulations, packaging and transportation is covered by Guardian Angel, 10 Pen Y Lan, Penclawdd, Swansea, SA4 3LL and subsequent PIF (Public Information File) and therefore is 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
Super Active Cosmetics Ltd
31 Brindle Heath Road
Salford
Greater Manchester
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Chemical Name	Olea Europaea Fruit Oil is the oil expressed from the fruit of the olive
Function	Emollient
INCI Name	Olea Europaea Fruit Oil
CAS	8001-25-0
EINECS	232-277-0
SED(adult)	0.1357635 mg.(kg bw)-1.d-1
SED(child)	0.5175984 mg.(kg bw)-1.d-1
SED(baby)	1.403657 mg.(kg bw)-1.d-1
NOAEL	2000 mg.(kg bw)-1.d-1
Dermal penetration factor	0.01
MoS(adult)	14731.5
MoS(child)	3864
MoS(baby)	1424.85
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	
Observations	Mild irritant especially under occlusion
Additional Notes	

Conclusion	It is believed that Olea Europaea Fruit Oil is safe for use in Sniffles 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)	0.1357635 mg.(kg bw)-1.d-1
SED(child)	0.5175984 mg.(kg bw)-1.d-1
SED(baby)	1.403657 mg.(kg bw)-1.d-1
NOAEL	16400 mg.(kg bw)-1.d-1
Dermal penetration factor	0.01
MoS(adult)	120798.3
MoS(child)	31684.8
MoS(baby)	11683.77
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 Sniffles 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)	0.05430541 mg.(kg bw)-1.d-1
SED(child)	0.2070394 mg.(kg bw)-1.d-1
SED(baby)	0.5614627 mg.(kg bw)-1.d-1
NOAEL	220 mg.(kg bw)-1.d-1
Dermal penetration factor	0.01
MoS(adult)	4051.162
MoS(child)	1062.6
MoS(baby)	391.8337
	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 Sniffles at this concentration and use as described, assuming the parameters stated.

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Chemical Name	Mentha Piperita Oil
Function	Perfuming
INCI Name	Mentha Piperita Oil
CAS	8006-90-4 (Essential Oils Direct)
EINECS	282-015-4
SED(adult)	0.06788174 mg.(kg bw)-1.d-1
SED(child)	0.2587991 mg.(kg bw)-1.d-1
SED(baby)	0.7018281 mg.(kg bw)-1.d-1
NOAEL	300 mg.(kg bw)-1.d-1
Dermal penetration factor	1
MoS(adult)	4419.451
MoS(child)	1159.2
MoS(baby)	427.4551
Additional Notes	Peppermint Oil is used at a concentration of < or = 3% in rinse-off formulations and < or = 0.2% in leave on formulations. Peppermint Oil is composed primarily of menthol and menthone. Other possible constituents include pulegone, menthofuran, and limone. Most of the safety test data concern Peppermint Oil. The oil is considered to present the "worst case scenario" because of its many constituents, so data on the oil were considered relevant to the entire group of ingredients. Peppermint Oil was minimally toxic in acute oral studies. Short-term and sub-chronic oral studies reported cystlike lesions in the cerebellum in rats that were given doses of Peppermint Oil containing pulegone, pulegone alone, or large amounts (>200 mg/kg/day) of menthone. Pulegone is also a recognized hepatotoxin. Repeated intradermal dosing with Peppermint Oil produced moderate and severe reactions in rabbits, although Peppermint Oil did not appear to be phototoxic. Peppermint Oil was negative in the Ames test and a mouse lymphomamutagenesis assay but gave equivocal results in a Chinese hamster fibroblast cell chromosome aberration assay. In a carcinogenicity study of toothpaste and its components, no apparent differences were noted between mice treated with Peppermint Oil and those treated with the toothpaste base. Isolated clinical cases of irritation and/or sensitization to Peppermint Oil and/or its constituents have been reported, but Peppermint Oil (8%) was not a sensitizer when tested using a maximization protocol. It was expected that dermal absorption of Peppermint Oil would be rapid, following that of menthol, a major component, but in no case would be greater than absorption through the gastrointestinal tract. Because of the toxicity of pulegone, the safe concentration of this constituent was limited to < or = 1%. This concentration was achievable both by controlling the time of harvest and processing technique. There is evidence that menthol can enhance penetration of other agents. Formulators were cautioned that this enhanced penetration can affect the use of other ingredients whose safety assessment was based on their lack of absorption. With the limitation that the concentration of pulegone in these ingredients should not exceed 1%, it was concluded that Mentha Piperita (Peppermint) Oil, Mentha Piperita (Peppermint) Extract, Mentha Piperita (Peppermint) Leaves, Mentha Piperita (Peppermint) Water are safe as used in cosmetic formulations.

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

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

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

Type of test	Mutagenicity - DNA repair
Route of exposure	
Species observed	Bacteria - Bacillus subtilis
Dose	5 mcL/disc
Duration	
Observations	
Additional Notes	
Conclusion	It is believed that Mentha Piperita Oil is safe for use in Sniffles at this concentration and use as described, assuming the parameters stated.

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Chemical Name	Eucalyptus Globulus Leaf Oil is the volatile oil obtained from the fresh leaves of the Eucaluptus, Eucalyptus globulus and other species of Eucalyptus, Myrtaceae. Syn. Yuukari Yu (Japanese)
Function	Perfuming
INCI Name	Eucalyptus Globulus Leaf Oil
CAS	84625-32-1 (Essential Oils Direct)
EINECS	283-406-2
SED(adult)	0.06788174 mg.(kg bw)-1.d-1
SED(child)	0.2587991 mg.(kg bw)-1.d-1
SED(baby)	0.7018281 mg.(kg bw)-1.d-1
NOAEL	300 mg.(kg bw)-1.d-1
Dermal penetration factor	1
MoS(adult)	4419.451
MoS(child)	1159.2
MoS(baby)	427.4551
Additional Notes	Eucalyptus Globulus essential oil was evaluated for its fetotoxic potential on Mice. Pregnant dams were injected S.C. (135 mg essential oil kg body weight) on days 6 to 15 of gestation. In this study, neither embryotoxicity nor fetotoxicity were observed.

Type of test	In-Vitro Dermal
Route of exposure	Oral
Species observed	Human
Dose	4400 mg/ Bw/Day
Duration	
Observations	
Additional Notes	

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

Type of test	LC50
Route of exposure	Inhalation
Species observed	Rat
Dose	0.216 l/cm2
Duration	
Observations	
Additional Notes	

Type of test	Dermal irritancy
Route of exposure	Dermal
Species observed	Rabbit
Dose	5000 mg.(kg bw)-1
Duration	14d observation
Observations	Dermal reactions noted were slight redness (5/10 rabbits), moderate redness (3/10 rabbits) and moderate oedema (10/10 rabbits) at the site of application. Irritant.
Additional Notes	

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

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

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

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Chemical Name	Rosmarinus Officinalis Leaf Oil is the oil expressed from the leaves of the rosemary plant Rosmarinus Officinalis.
Function	Perfuming
INCI Name	Rosmarinus Officinalis Leaf Oil
CAS	84604-14-8 (Leaf Oil) (Essential Oils Direct)
EINECS	283-291-9
SED(adult)	0.03394089 mg.(kg bw)-1.d-1
SED(child)	0.1293996 mg.(kg bw)-1.d-1
SED(baby)	0.3509142 mg.(kg bw)-1.d-1
NOAEL	400 mg.(kg bw)-1.d-1
Dermal penetration factor	1
MoS(adult)	11785.2
MoS(child)	3091.199
MoS(baby)	1139.88
Additional Notes	Reproductive Toxicity: Rosmarinus Officinalis Oil is not reported to produce reproductive toxicity in humans. Mutagenicity: Rosmarinus Officinalis Oil is not reported to produce mutagenic effects in humans. Embryotoxicity: Rosmarinus Officinalis Oil is not reported to produce embryotoxic effects in humans. Teratogenicity: Rosmarinus Officinalis Oil is not reported to produce teratogenic effects in humans. Reproductive Toxicity: Rosmarinus Officinalis Oil is not reported to produce reproductive effects in humans.

Type of test	Chronic oral toxicity
Route of exposure	Oral
Species observed	Rat
Dose	3 months
Duration	
Observations	NOAEL of 180 to 400 mg/kg bw/day
Additional Notes	Absence of any notable effect on reprotductive organs.

Type of test	Acute LD50
Route of exposure	Oral
Species observed	Rabbit
Dose	3600 mg/kg/bw/day
Duration	
Observations	
Additional Notes	

Type of test	LD50
Route of exposure	Dermal
Species observed	Rabbit
Dose	10000 mg/kg/24H
Duration	
Observations	
Additional Notes	

Type of test	LC50
Route of exposure	Inhalation
Species observed	Rat
Dose	297.9 µl/L air
Duration	
Observations	
Additional Notes	

Conclusion	It is believed that Rosmarinus Officinalis Leaf Oil is safe for use in Sniffles at this concentration and use as described, assuming the parameters stated.

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Chemical Name	Cinnamomum Zeylanicum Leaf Oil is the volatile oil expressed from the leaf of the Ceylon Cinnamon, Cinnamomum
Function	Perfuming, masking, tonic
INCI Name	Cinnamomum Zeylanicum Leaf Oil
CAS	84649-98-9 (Essential Oils Direct)
EINECS	283-479-0
SED(adult)	0.03394089 mg.(kg bw)-1.d-1
SED(child)	0.1293996 mg.(kg bw)-1.d-1
SED(baby)	0.3509142 mg.(kg bw)-1.d-1
NOAEL	100 mg.(kg bw)-1.d-1
Dermal penetration factor	1
MoS(adult)	2946.299
MoS(child)	772.7998
MoS(baby)	284.9699
Additional Notes	Typically the key constituents of the oil are:(E)-Cinnamaldehyde 63.1\22675.7%\r\nEugenol 2.0\22613.3%\r\n(E)-Cinnamyl acetate 0.3\22610.6%\r\nLinalool 0.2\2267.0%\r\nb-Caryophyllene 1.3\2265.8%\r\np-Cymene 1.7\2262.5%\r\n1,8-Cineole 0.4\2262.3%\r\nBenzaldehyde tr\2262.2%\r\nb-Phellandrene <1.5%\r\na-Terpineol 0.4\2261.4%\r\nCamphor tr\2261.4%\r\nTerpinen-4-ol 0.4\2261.1%\r\nBenzyl benzoate tr\2261.0%\r\na-Caryophyllene 0\2261.0%\r\nSafrole 0\2260.04%\r\n[Source : Lawrence 1995 g p. 201; Tateo & Chizzini 1989; Kubeczka 2002]\r\n\r\nQuality assurance & Procurement\r\n\r\nCinnamon leaf oil is frequently adulteratedwith synthetic cinnamaldehyde and natural eugenol. Occasionally cassia oil or artificially reconstituted oils are sold as cinnamon leaf oil (Kubeczka 2002). Reconstitutions may include cinnamon leaf oil and synthetic cinnamaldehyde (Burfield 2000)\r\n\r\nThe is evidence of embryotoxicity resulting from Cinnamon leaf oil. As such it should not be used by pregnant or lactating women.\r\n\r\nCinnamon leaf oil carries a high risk of skin sensitization, and it is recommended that appropriate labeling is used.\r\n\r\nRecommended maximum dermal use level: 0.07%\r\nMaximum Oral daily dose: 200mg [Commission E monographs], based on cinnamaldehyde composition of 75.7% itself having a dermal use limit of 0.05% [IFRA 2009].\r\n\r\nNOAEL is nominal. In is expected that the cinnamaldehyde concentration is rate limiting, and the allergen profile should dictate the suitability of this product.

Type of test	Acute toxicity
Route of exposure	Oral
Species observed	Rats - Sprague Dawley
Dose	100 500 2000 mg.(kg bw)-1
Duration	
Observations	LOAEL = 500 mg.(kg bw)-1
Additional Notes	There were no statistically significant effects of all concentrations of CE on behaviour, mortality, water intake, food consumption, weight gain, internal organs weight (liver and kidney) and heamatological parameters during treatment and post-treatment periods except 1) the slight decrease in kidney and liver weight of rats treated with 0.5g/kg and 2) slight decrease in liver weight of rats treated with 2.0g/kg, during post-treatment period. Hence, these toxicity studies suggest that the CE is low to moderate in toxicity and CE below 0.5 g/kg dose level is safe to be used in the efficacy study especially for diabetes treatment.

Type of test	Standard Draize test
Route of exposure	Administration onto the skin
Species observed	Rodent - rabbit
Dose	500 mg/24H
Duration	
Observations	Mild
Additional Notes	

Type of test	TDLo - Lowest published toxic dose
Route of exposure	Oral
Species observed	Human
Dose	29 mg/kg
Duration	
Observations	Behavioral - tremor Behavioral - convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - other changes
Additional Notes	

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

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

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

Conclusion	It is believed that Cinnamomum Zeylanicum Leaf Oil is safe for use in Sniffles 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)	0.00974103 mg.(kg bw)-1.d-1
SED(child)	0.03713768 mg.(kg bw)-1.d-1
SED(baby)	0.1007123 mg.(kg bw)-1.d-1
NOAEL	500 mg.(kg bw)-1.d-1
Dermal penetration factor	1
MoS(adult)	51329.28
MoS(child)	13463.42
MoS(baby)	4964.635
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 Sniffles 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)	0.001221872 mg.(kg bw)-1.d-1
SED(child)	0.004658386 mg.(kg bw)-1.d-1
SED(baby)	0.01263291 mg.(kg bw)-1.d-1
NOAEL	250 mg.(kg bw)-1.d-1
Dermal penetration factor	1
MoS(adult)	204604.1
MoS(child)	53666.65
MoS(baby)	19789.58
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 Sniffles at this concentration and use as described, assuming the parameters stated.

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SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

Chemical Name	Benzyl Benzoate
Function	Perfuming
INCI Name	Benzyl Benzoate
CAS	120-51-4
EINECS	204-402-9
SED(adult)	0.001018227 mg.(kg bw)-1.d-1
SED(child)	0.003881989 mg.(kg bw)-1.d-1
SED(baby)	0.01052743 mg.(kg bw)-1.d-1
NOAEL	500 mg.(kg bw)-1.d-1
Dermal penetration factor	1
MoS(adult)	491049.9
MoS(child)	128800
MoS(baby)	47494.99
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 Benzyl benzoate is relatively nontoxic but may irritate the skin and eyes. Increased pruritus and irritation (manifested by burning and stinging, particularly of the genitalia and scalp) are common and may be severe in hot humid climates. This product is not reported to produce reproductive toxicity in humans. Mutagenicity: Benzyl Benzoate is not reported to produce mutagenic effects in humans. Embryotoxicity: Benzyl Benzoate is not reported to produce embryotoxic effects in humans. Teratogenicity: Benzyl Benzoate is not reported to produce teratogenic effects in humans. Reproductive Toxicity: Benzyl Benzoate is not reported to produce reproductive effects in humans. Use regulated by : 2003/15/EC III/1,85

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

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

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

Conclusion It is believed that Benzyl Benzoate is safe for use in Sniffles at this concentration and use as described, assuming the parameters stated.
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Chemical Name	3-Phenylprop-2-enal
Function	Perfuming
INCI Name	Cinnamaldehyde
CAS	104-55-2
EINECS	203 - 213 - 9
SED(adult)	0.000458202 mg.(kg bw)-1.d-1
SED(child)	0.001746895 mg.(kg bw)-1.d-1
SED(baby)	0.004737342 mg.(kg bw)-1.d-1
NOAEL	620 mg.(kg bw)-1.d-1
Dermal penetration factor	1
MoS(adult)	1353115
MoS(child)	354915.4
MoS(baby)	130875.1
Additional Notes	

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

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

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

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

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

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

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

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

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

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

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

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

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

Conclusion It is believed that Cinnamaldehyde is safe for use in Sniffles at this concentration and use as described, assuming the parameters stated.
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Chemical Name	Phenol,2-methoxy-4-(2-propenyl)
Function	Perfuming
INCI Name	Eugenol
CAS	97-53-0
EINECS	202-589-1
SED(adult)	0.02647389 mg.(kg bw)-1.d-1
SED(child)	0.1009317 mg.(kg bw)-1.d-1
SED(baby)	0.2737131 mg.(kg bw)-1.d-1
NOAEL	300 mg.(kg bw)-1.d-1
Dermal penetration factor	1
MoS(adult)	11331.92
MoS(child)	2972.307
MoS(baby)	1096.038
Additional Notes	The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)g when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products This product is not reported to produce reproductive toxicity in humans. Mutagenicity: This product is not reported to produce mutagenic effects in humans. Embryotoxicity: This product is not reported to produce embryotoxic effects in humans. Teratogenicity: This product is not reported to produce teratogenic effects in humans. Reproductive Toxicity: This product is not reported to produce reproductive effects in humans.

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

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

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

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

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