



**SUPER ACTIVE COSMETICS**  
THE FUTURE OF COSMETICS

Toxicological Safety Assessment of: Smooth num

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: C1008/02



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## Composition of Formulation

CAS Number	INCI Name	Maximum Concentration %
8001-31-8	Cocos Nucifera Oil	40.69176
91080-23-8	Butyrospermum Parkii Butter	40.69176
68650-44-2 / 72869-69-3	Prunus Armeniaca Kernel Oil	18.31129
84776-23-8 / 70892-20-5	Calendula Officinalis Flower Oil	0.2034588
8007-08-7	Zingiber Officinale Root Oil	0.1017294



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## Acronyms & Abbreviations used in this document

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



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## Microbiological Quality

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

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

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

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

**Category 2: other cosmetic product.**

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

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

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

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



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## **Purity of raw materials**

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

Smooth mum 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.

Smooth num 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

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



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## Toxicological Summary

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

The advised PAO for this type of product, with the advisable levels of preservative is 12 M.

INCI Name	MoS for adult	Conclusions
Cocos Nucifera Oil	122924.1	Safe
Butyrospermum Parkii Butter	37476.87	Safe
Prunus Armeniaca Kernel Oil	16656.39	Safe
Calendula Officinalis Flower Oil	22486.12	Safe
Zingiber Officinale Root Oil	14990.75	Safe
Limonene	749537.5	Safe
Citral	2441351	Safe
Linalool	1249229	Safe

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

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

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

Upper gastrointestinal: Smooth mum is likely to cause upper gastrointestinal irritation.

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

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



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## Fragrance Data

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

Smooth num contains fragrance allergens at concentrations exceeding the EU labelling threshold and therefore the following fragrance allergens need to be listed to the outer packaging: Limonene.

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	0.0007121058	0.6	Pass: Within limits

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

INCI Name	CAS	% Concentration of formulation
Citral	5392-40-5	0.0007121058
Limonene	138-86-3	0.002034588
Linalool	78-70-6	0.0006103764

**INCI Name:** Zingiber Officinale Root Oil

**CAS Number:** 8007-08-7

INCI Name	CAS	% Concentration of ingredient	% Concentration of formulation
Citral	5392-40-5	0.7	0.0007121058
Linalool	78-70-6	0.6	0.0006103764
d-Limonene	5989-27-5	2	0.002034588



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## Conclusion

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

The finished product Smooth mum 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 Smooth mum 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: Cocos Nucifera Oil, Butyrospermum Parkii Butter, Prunus Armeniaca Kernel Oil, Calendula Officinalis Flower Oil, Zingiber Officinale Root Oil, Limonene



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## **REACH**

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

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

Guardian Angel, 10 Pen Y Lan, Penclawdd, Swansea, SA4 3LL are committed to selling only safe products and work diligently to ensure that our formulations, packaging, and ancillary products meet the standards put forth by global governmental, regulatory, and scientific bodies, as well 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  
M66GD

Registered in England and Wales: 8564424



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<b>Chemical Name</b>	Cocos Nucifera Oil
<b>Function</b>	Emollient
<b>INCI Name</b>	Cocos Nucifera Oil
<b>CAS</b>	8001-31-8
<b>EINECS</b>	232-282-8
<b>SED(adult)</b>	0.1334156 mg.(kg bw)-1.d-1
<b>SED(child)</b>	N/A mg.(kg bw)-1.d-1
<b>SED(baby)</b>	N/A mg.(kg bw)-1.d-1
<b>NOAEL</b>	16400 mg.(kg bw)-1.d-1
<b>Dermal penetration factor</b>	0.01
<b>MoS(adult)</b>	122924.1
<b>MoS(child)</b>	N/A
<b>MoS(baby)</b>	N/A
<b>Additional Notes</b>	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
<b>Type of test</b>	Acute LD50
<b>Route of exposure</b>	Oral
<b>Species observed</b>	Rat
<b>Dose</b>	2000 mg/kg/bw/day
<b>Duration</b>	
<b>Observations</b>	
<b>Additional Notes</b>	
<b>Type of test</b>	LD50
<b>Route of exposure</b>	Dermal
<b>Species observed</b>	Rat
<b>Dose</b>	4000 mg/kg/bw/day
<b>Duration</b>	
<b>Observations</b>	
<b>Additional Notes</b>	
<b>Type of test</b>	LC50
<b>Route of exposure</b>	Inhalation
<b>Species observed</b>	Rat
<b>Dose</b>	57 ppm/24/H
<b>Duration</b>	
<b>Observations</b>	No conclusion
<b>Additional Notes</b>	
<b>Type of test</b>	Acute LD50
<b>Route of exposure</b>	Oral
<b>Species observed</b>	Rat
<b>Dose</b>	5000 mg/kg/bw/day
<b>Duration</b>	
<b>Observations</b>	
<b>Additional Notes</b>	



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

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

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

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<b>Chemical Name</b>	Butyrospermum Parkii Butter (shea butter)
<b>Function</b>	Emollient
<b>INCI Name</b>	Butyrospermum Parkii Butter
<b>CAS</b>	91080-23-8
<b>EINECS</b>	N/A
<b>SED(adult)</b>	0.1334156 mg.(kg bw)-1.d-1
<b>SED(child)</b>	N/A mg.(kg bw)-1.d-1
<b>SED(baby)</b>	N/A mg.(kg bw)-1.d-1
<b>NOAEL</b>	5000 mg.(kg bw)-1.d-1
<b>Dermal penetration factor</b>	0.01
<b>MoS(adult)</b>	37476.87
<b>MoS(child)</b>	N/A
<b>MoS(baby)</b>	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.

<b>Type of test</b>	LD50
<b>Route of exposure</b>	Oral
<b>Species observed</b>	Wistar rat
<b>Dose</b>	2000 mg/kg/bw/day
<b>Duration</b>	
<b>Observations</b>	
<b>Additional Notes</b>	

<b>Type of test</b>	LD50
<b>Route of exposure</b>	Dermal
<b>Species observed</b>	Rabbit
<b>Dose</b>	2951 mg/kg/bw/day
<b>Duration</b>	
<b>Observations</b>	
<b>Additional Notes</b>	

<b>Type of test</b>	LC50
<b>Route of exposure</b>	Inhalation
<b>Species observed</b>	Rat
<b>Dose</b>	142,500ppm/4/H
<b>Duration</b>	
<b>Observations</b>	
<b>Additional Notes</b>	

**Conclusion** It is believed that Butyrospermum Parkii Butter is safe for use in Smooth mum at this concentration and use as described, assuming the parameters stated.

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<b>Chemical Name</b>	Prunus Armeniaca Kernel Oil is the fixed oil expressed from the kernels of the Apricot, Prunus armeniaca L., Rosaceae
<b>Function</b>	Masking, Skin Conditioning
<b>INCI Name</b>	Prunus Armeniaca Kernel Oil
<b>CAS</b>	68650-44-2 / 72869-69-3
<b>EINECS</b>	272-046-1 / -
<b>SED(adult)</b>	0.06003702 mg.(kg bw)-1.d-1
<b>SED(child)</b>	N/A mg.(kg bw)-1.d-1
<b>SED(baby)</b>	N/A mg.(kg bw)-1.d-1
<b>NOAEL</b>	1000 mg.(kg bw)-1.d-1
<b>Dermal penetration factor</b>	0.01
<b>MoS(adult)</b>	16656.39
<b>MoS(child)</b>	N/A
<b>MoS(baby)</b>	N/A
<b>Additional Notes</b>	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.
<b>Type of test</b>	Repeat feeding study
<b>Route of exposure</b>	Oral
<b>Species observed</b>	Rat
<b>Dose</b>	10 % of diet
<b>Duration</b>	13wk
<b>Observations</b>	No histological or gross abnormalities in any organs were identified.
<b>Additional Notes</b>	This study used kernel oil expressed from mild seed, and did not contain appreciable concentrations of amygdalin.
<b>Type of test</b>	Accute dermal toxicity
<b>Route of exposure</b>	Dermal
<b>Species observed</b>	Rabbit
<b>Dose</b>	7-10 mg.(kg bw)-1
<b>Duration</b>	
<b>Observations</b>	LD50 dermal = 7-10 mg.(kg bw)-1 in intact skin, and markedly higher in abraded skin.
<b>Additional Notes</b>	This study used cyanides in aqueous solutions. LD50 dermal for hydrogen cyanide is estimated to be 100 mg.(kg bw)-1 in humans.
<b>Conclusion</b>	It is believed that Prunus Armeniaca Kernel Oil is safe for use in Smooth mum at this concentration and use as described, assuming the parameters stated.

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<b>Chemical Name</b>	Calendula Officinalis Flower Oil is the oil derived from the flowers of the Calendula, <i>Calendula officinalis</i> L., Compositae, extracted by infusion in sunflower seed oil
<b>Function</b>	Masking, Skin Conditioning, Perfuming
<b>INCI Name</b>	Calendula Officinalis Flower Oil
<b>CAS</b>	84776-23-8 / 70892-20-5
<b>EINECS</b>	283-949-5 / -
<b>SED(adult)</b>	0.00667078 mg.(kg bw)-1.d-1
<b>SED(child)</b>	N/A mg.(kg bw)-1.d-1
<b>SED(baby)</b>	N/A mg.(kg bw)-1.d-1
<b>NOAEL</b>	150 mg.(kg bw)-1.d-1
<b>Dermal penetration factor</b>	0.1
<b>MoS(adult)</b>	22486.12
<b>MoS(child)</b>	N/A
<b>MoS(baby)</b>	N/A

Constituents of *Calendulae flos* include flavonoids (0.3 to 0.8%) such as flavonols (isorhamnetin, quercetin) and flavonol glycosides including isoquercitrin, narcissin, neoliesperoside and rutin; volatile oil (0.2%) with sesquiterpenes, such as  $\alpha$ -cadinol (27% of the oil) and  $\delta$ -cadinol (13% of the oil) as main components and also containing menthone, isomenthone, caryophyllene, pedunculatine,  $\alpha$  and  $\beta$ -ionone, a  $\beta$ -ionone epoxide derivative, dihydroactinidiolide; triterpenoids, such as saponins with oleanolic acid as an aglycone (i.e. glycosides A to F, 2 to 10% of dry weight), and a large number of acylated pentacyclic mono-, di-, and tri-hydroxy-triterpenes derived from  $\Psi$ -taraxen, taraxen, lupen, oleanen and ursen, with the triterpene alcohols occur both in free form and as esters; sterols (0.06 to 0.08%), present as free alcohols, esters and glycosides; coumarins such as scopoletin, umbelliferon and aesculetin, carotenoids in form of a large number of carotene- and xanthophyll-derivatives, and polysaccharides, 14.8% water-soluble polysaccharides consisting of acidic, branched heteroglycans (rhamno-arabino-galactanes and arabino-galactanes). No further constituents have been reported for *Calendulae herba*.

**Additional Notes**

The acute and repeated dose toxicity of *Calendula* flower extracts is low. Reproduction toxicity studies are lacking. Six saponins from *Calendula* flower were non-mutagenic in the Ames test. Limited long-term carcinogenicity studies in rats and hamsters did not give evidence of a carcinogenic effect of *Calendula* flower extract. The sensitising potential of *Calendula* extract is low.

A European herbal medicine monograph specifies several established historical methods of preparation of *Calendula flos*, however with regard to topical administration of the infusion, "the use in children under 6 years of age is not recommended because there is no experience available".

There have been numerous studies using *Calendula flos* infused oils for the prevention of nappy rash / diaper dermatitis, and there is some evidence of success in this use. None of the studies raised any concerns about safety of toxicity.

<b>Type of test</b>	Acute toxicity
<b>Route of exposure</b>	Intravenous
<b>Species observed</b>	Mice
<b>Dose</b>	300 to 375 mg.(kg bw)-1
<b>Duration</b>	
<b>Observations</b>	LD50
<b>Additional Notes</b>	Used an aqueous flower extract

<b>Type of test</b>	Acute toxicity
<b>Route of exposure</b>	Intraperitoneal
<b>Species observed</b>	Mice
<b>Dose</b>	300 to 375 mg.(kg bw)-1
<b>Duration</b>	
<b>Observations</b>	LD50
<b>Additional Notes</b>	Used an aqueous flower extract



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**Type of test** Acute Toxicity  
**Route of exposure** Subcutaneous  
**Species observed** Mice  
**Dose** 45 mg.(kg bw)-1  
**Duration**  
**Observations** LD50  
**Additional Notes** Used an aqueous-ethanolic extract (30% ethanol) of the flowers.

**Type of test** Acute toxicity  
**Route of exposure** Intravenous  
**Species observed** Rat  
**Dose** 5260 mg.(kg bw)-1  
**Duration**  
**Observations** LD50  
**Additional Notes** Used an aqueous-ethanolic extract (30% ethanol) of the flowers.

**Type of test** Repeat dose oral toxicity  
**Route of exposure** Oral  
**Species observed** Hamster  
**Dose** 150 mg.(kg bw)-1.d-1  
**Duration** 18 months  
**Observations** NOAEL = 150 mg.(kg bw)-1.d-1  
**Additional Notes** Used an extract whose solvent was not specified.

**Conclusion** It is believed that Calendula Officinalis Flower Oil is safe for use in Smooth mum at this concentration and use as described, assuming the parameters stated.

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**SUPER ACTIVE COSMETICS**  
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**Chemical Name** Zingiber Officinale Oil is the volatile oil obtained from the dried rhizomes of the Ginger, Zingiber officinale L., Zingiberaceae  
**Function** Masking, Skin Conditioning, Tonic, Perfuming  
**INCI Name** Zingiber Officinale Root Oil  
**CAS** 8007-08-7  
**EINECS** N/A  
**SED(adult)** 0.0333539 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)** 14990.75  
**MoS(child)** N/A  
**MoS(baby)** N/A  
**Additional Notes**

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

**Type of test** LD50 - Lethal dose, 50 percent kill  
**Route of exposure** Oral  
**Species observed** Rodent - rat  
**Dose** >5 gm/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 - mouse  
**Dose** 3450 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** Intraperitoneal  
**Species observed** Rodent - mouse  
**Dose** 1230 mg/kg  
**Duration**  
**Observations** Details of toxic effects not reported other than lethal dose value  
**Additional Notes**





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**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**

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

**Type of test** Subchronic toxicity  
**Route of exposure** Oral  
**Species observed** Rat  
**Dose** 100 250 500 mg.(kg bw)-1.d-1  
**Duration** 13wk  
**Observations** NOAEL = 500 mg.(kg bw)-1.d-1  
**Additional Notes** There was no mortality and no decrease in body weight or food consumption as well as selective organ weights during the study period. Administration of ginger oil to rats did not produce any treatment-related changes in hematological parameters, hepatic, renal functions, serum electrolytes, or in histopathology of selected organs. The major component of ginger oil was found to be zingiberene (31.08%), and initial studies indicated the presence of zingiberene in the serum after oral dosing. These results confirmed that ginger oil is not toxic to male and female rats following subchronic oral administrations of up to 500 mg/kg per day (no observed adverse effect level [NOAEL]).

**Conclusion** It is believed that Zingiber Officinale Root Oil is safe for use in Smooth mum at this concentration and use as described, assuming the parameters stated.

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**SUPER ACTIVE COSMETICS**  
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<b>Chemical Name</b>	Citral
<b>Function</b>	Perfuming
<b>INCI Name</b>	Citral
<b>CAS</b>	5392-40-5
<b>EINECS</b>	226-394-6
<b>SED(adult)</b>	0.0002334773 mg.(kg bw)-1.d-1
<b>SED(child)</b>	N/A mg.(kg bw)-1.d-1
<b>SED(baby)</b>	N/A mg.(kg bw)-1.d-1
<b>NOAEL</b>	570 mg.(kg bw)-1.d-1
<b>Dermal penetration factor 1</b>	
<b>MoS(adult)</b>	2441351
<b>MoS(child)</b>	N/A
<b>MoS(baby)</b>	N/A
<b>Additional Notes</b>	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.
<b>Type of test</b>	Acute oral toxicity
<b>Route of exposure</b>	Oral
<b>Species observed</b>	Rat
<b>Dose</b>	4690 mg.(kg bw)-1
<b>Duration</b>	
<b>Observations</b>	LD50
<b>Additional Notes</b>	
<b>Type of test</b>	Acute dermal exposure
<b>Route of exposure</b>	Dermal
<b>Species observed</b>	Rat
<b>Dose</b>	2500 mg.(kg bw)-1
<b>Duration</b>	
<b>Observations</b>	LD50
<b>Additional Notes</b>	
<b>Type of test</b>	Acute inhalation toxicity
<b>Route of exposure</b>	Inhalation
<b>Species observed</b>	Rat
<b>Dose</b>	4.1 mg/L/96/H
<b>Duration</b>	
<b>Observations</b>	LC50
<b>Additional Notes</b>	
<b>Conclusion</b>	It is believed that Citral is safe for use in Smooth mum at this concentration and use as described, assuming the parameters stated. /



**SUPER ACTIVE COSMETICS**  
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**Chemical Name** 3,7-Dimethylocta-1,6-diene-3-ol  
**Function** Perfuming  
**INCI Name** Linalool  
**CAS** 78-70-6  
**EINECS** 201-134-4  
**SED(adult)** 0.0002001234 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)** 1249229  
**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 Smooth mum 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)** 0.000667078 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)** 749537.5  
**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**



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

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

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

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

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

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



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

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

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

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