SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

Toxicological Safety Assessment of: Giggly Goo

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: C1008/09

SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

Table Of Content

Part A

Part B

SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

Composition of Formulation

CAS Number	INCI Name	Maximum Concentration %
8001-25-0	Olea Europaea Fruit Oil	66.22517
68650-44-2 / 72869-69-3	Prunus Armeniaca Kernel Oil	33.11258
84776-23-8 / 70892-20-5	Calendula Officinalis Flower Oil	0.3311258
84082-60-0 (flower oil extract)	Chamomilla Recutita Extract	0.3311258

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

SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

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

SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

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.

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

SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

Purity of raw materials

It is assumed that all raw materials used in Giggly Goo 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.

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

SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

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.

Giggly Goo has proven to be inert when in contact with the final packaging

SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

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.

SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

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.

Giggly Goo 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.

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

SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

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

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

SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

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

SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

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
Prunus Armeniaca Kernel Oil	1	Negative
Calendula Officinalis Flower Oil	10	Negative
Chamomilla Recutita Extract	100	Negative
Linalool	100	Negative
Limonene	100	Negative

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

SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

Toxicological Summary

Giggly Goo is a oil cream for use on babies. 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	9210.999	Safe
Prunus Armeniaca Kernel Oil	9211.001	Safe
Calendula Officinalis Flower Oil	13816.5	Safe
Chamomilla Recutita Extract	3684.4	Safe
Linalool	438619.2	Safe
Limonene	1228133	Safe

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

INCI Name	MoS for child	Conclusions
Olea Europaea Fruit Oil	2416	Safe
Prunus Armeniaca Kernel Oil	2416	Safe
Calendula Officinalis Flower Oil	3624	Safe
Chamomilla Recutita Extract	966.4001	Safe
Linalool	115047.7	Safe
Limonene	322133.3	Safe

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

INCI Name	MoS for baby	Conclusions
Olea Europaea Fruit Oil	890.8999	Safe
Prunus Armeniaca Kernel Oil	890.9001	Safe
Calendula Officinalis Flower Oil	1336.35	Safe
Chamomilla Recutita Extract	356.36	Safe
Linalool	42423.82	Safe
Limonene	118786.7	Safe

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

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

SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

Effects of the finished product on specific organs and tissue types

Internal organs: Giggly Goo is unlikely to cause damage to the internal organs following application.

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

Ingestion: Giggly Goo 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 Giggly Goo 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: Giggly Goo is likely to cause upper gastrointestinal irritation.

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

Giggly Goo 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.

SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

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.

Giggly Goo 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, Linalool.

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

There are no IFRA concentration restrictions on any allergens contained within this formulation.

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

INCI Name	CAS	% Concentration of formulation
Limonene	138-86-3	0.001241722
Linalool	78-70-6	0.00173841

INCI Name: Chamomilla Recutita Extract **CAS Number:** 84082-60-0 (flower oil extract)

INCI Name	CAS	% Concentration of ingredient	% Concentration of formulation
d-Limonene	5989-27-5	0.375	0.001241722
Linalool	78-70-6	0.525	0.00173841

Conclusion

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

The finished product Giggly Goo 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 Giggly Goo 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, Prunus Armeniaca Kernel Oil, Calendula Officinalis Flower Oil, Chamomilla Recutita Extract, Linalool, Limonene

SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

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.

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

SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

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

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)	0.2171317 mg.(kg bw)-1.d-1
SED(child)	0.8278146 mg.(kg bw)-1.d-1
SED(baby)	2.244921 mg.(kg bw)-1.d-1
NOAEL	2000 mg.(kg bw)-1.d-1
Dermal penetration factor	0.01
MoS(adult)	9210.999
MoS(child)	2416
MoS(baby)	890.8999
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 Giggly Goo at this concentration and use as described, assuming the parameters stated.

/

Chemical Name	Prunus Armeniaca Kernel Oil is the fixed oil expressed from the kernels of the Apricot, Prunus armeniaca L., Rosaceae
Function	Masking, Skin Conditioning
INCI Name	Prunus Armeniaca Kernel Oil
CAS	68650-44-2 / 72869-69-3
EINECS	272-046-1 / -
SED(adult)	0.1085658 mg.(kg bw)-1.d-1
SED(child)	0.4139073 mg.(kg bw)-1.d-1
SED(baby)	1.12246 mg.(kg bw)-1.d-1
NOAEL	1000 mg.(kg bw)-1.d-1
Dermal penetration factor	0.01
MoS(adult)	9211.001
MoS(child)	2416
MoS(baby)	890.9001
Additional Notes	Care should be taken during procurement to ensure oil used has been refined to reduce Amygdalin concentrations. This process is found in apricot kernel oil for oral consumption. Amygdalin when consumed orally can be metabolised into cyanide compounds which can pose a risk to human health from inadvertent oral consumption. The risk of low amygdalin oils affecting health from topical use is considered very low, even when pessimistically assuming 100% amygdalin dermal penetration.

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

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

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

/

Chemical Name	Calendula Officinalis Flower Oil is the oil derived from the flowers of the Calendula, Calendula officinalis L., Compositae, extracted by infusion in sunflower seed oil
Function	Masking, Skin Conditioning, Perfuming
INCI Name	Calendula Officinalis Flower Oil
CAS	84776-23-8 / 70892-20-5
EINECS	283-949-5 / -
SED(adult)	0.01085658 mg.(kg bw)-1.d-1
SED(child)	0.04139073 mg.(kg bw)-1.d-1
SED(baby)	0.112246 mg.(kg bw)-1.d-1
NOAEL	150 mg.(kg bw)-1.d-1
Dermal penetration factor	0.1
MoS(adult)	13816.5
MoS(child)	3624
MoS(baby)	1336.35
	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 α-cadinol (27% of the oil) and δ-cadinol (13% of the oil) as main components and also containing menthone, isomenthone, caryophyllene, pedunculatine, α and β -ionone, a β-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 Ψ-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 xantophyll-derivatives, and polysaccharides, 14.8% water-soluble polysaccharides consisting of acidic, branched heteroglycanes (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 ith 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.

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

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

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 Giggly Goo at this concentration and use as described, assuming the parameters stated.

/

Chemical Name	Chamomilla Recutita (camomile) Extract is an oil phase extraction of the flowers of the plant chamomilla recutita
Function	Skin conditioning
INCI Name	Chamomilla Recutita Extract
CAS	84082-60-0 (flower oil extract)
EINECS	282-006-5
SED(adult)	0.1085658 mg.(kg bw)-1.d-1
SED(child)	0.4139073 mg.(kg bw)-1.d-1
SED(baby)	1.12246 mg.(kg bw)-1.d-1
NOAEL	400 mg.(kg bw)-1.d-1
Dermal penetration factor	1
MoS(adult)	3684.4
MoS(child)	966.4001
MoS(baby)	356.36
Additional Notes	The oil soluble extract can contain upto 50% of the essential oil. The yield of essential oil from chamomile is typically less than 2%. Pessimistic assumptions have been used in assessing allergen concentrations of this component. The toxicological studies listed below relate to the essential oil itself.

Type of test	Acute oral toxicity
Route of exposure	Oral
Species observed	Mouse - Swiss NOS
Dose	1440 mg.(kg bw)-1
Duration	
Observations	None of the animals died, and there was no evidence of acute toxicity.
Additional Notes	Dried extract from an aqueous infusion.

Type of test	Acute oral toxicity
Route of exposure	Oral
Species observed	Rat
Dose	5000 mg.(kg bw)-1
Duration	
Observations	None of the animals died, and an LD50 of > 5g/kg was reported.
Additional Notes	Observed for 14d post exposure.

Type of test	Acute dermal toxicity
Route of exposure	Dermal
Species observed	Rabbit
Dose	>5000 mg.(kg bw)-1
Duration	
Observations	No deaths observed at 5000mg.(kg bw)-1
Additional Notes	Used the flower oil extract

Type of test	Repeated dose toxicity
Route of exposure	Oral
Species observed	Rat
Dose	2 % w/v
Duration	4wk
Observations	No gross changes to organs, No changes to bodyweight, liver weight, or body part ratios.
Additional Notes	Used a flower infusion extract.

Type of test	Repeated dose
Route of exposure	Oral
Species observed	Human
Dose	200 ml.d-1
Duration	2wk
Observations	Decreased creatinine and elevated hippurate and glycine observed.
Additional Notes	

Type of test	Repeat dose - TDLo
Route of exposure	Oral
Species observed	Rat - SD
Dose	4000 mg.(kg bw)-1.d-1
Duration	14d
Observations	TDLo
Additional Notes	Used flower extract.

Conclusion	It is believed that Chamomilla Recutita Extract is safe for use in Giggly Goo at this concentration and use as described, assuming the parameters stated.

/

Chemical Name	1-methyl-4-(1-methylethenyl)-cyclohexene
Function	Perfuming
INCI Name	d-Limonene
CAS	5989-27-5
EINECS	227-813-5
SED(adult)	0.000407122 mg.(kg bw)-1.d-1
SED(child)	0.001552153 mg.(kg bw)-1.d-1
SED(baby)	0.004209227 mg.(kg bw)-1.d-1
NOAEL	500 mg.(kg bw)-1.d-1
Dermal penetration factor	1
MoS(adult)	1228133
MoS(child)	322133.3
MoS(baby)	118786.7
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 Giggly Goo at this concentration and use as described, assuming the parameters stated.
/

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)	0.0005699705 mg.(kg bw)-1.d-1
SED(child)	0.002173012 mg.(kg bw)-1.d-1
SED(baby)	0.005892915 mg.(kg bw)-1.d-1
NOAEL	250 mg.(kg bw)-1.d-1
Dermal penetration factor	1
MoS(adult)	438619.2
MoS(child)	115047.7
MoS(baby)	42423.82
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 Giggly Goo at this concentration and use as described, assuming the parameters stated.
/