SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

Toxicological Safety Assessment of: Golden Balm

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: C1008/04

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Composition of Formulation

CAS Number	INCI Name	Maximum Concentration %
8001-31-8	Cocos Nucifera Oil	47.44958
91080-23-8	Butyrospermum Parkii Butter	47.44958
1490-04-6	Menthol	4.313167
8001-21-6	Helianthus Annuus Seed Oil	0.4317912
68990-11-4 (extract)	Arnica montana extract	0.3558719

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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 Golden Balm 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.

Golden Balm 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.

Golden Balm 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:	Adults
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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Toxicological Summary

Golden Balm is a muscle rub moisturising balm 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	105417.2	Safe
Butyrospermum Parkii Butter	32139.38	Safe
Menthol	141.4274	Safe
Helianthus Annuus Seed Oil	1.200812e+007	Safe
Arnica montana extract	171.41	Safe

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

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

Ingestion: Golden Balm 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 Golden Balm 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: Golden Balm is likely to cause upper gastrointestinal irritation.

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

Golden Balm 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.

This formulation does not contain any fragrance allergens and therefore does not require listing or analysis of any fragrance allergens.

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Conclusion

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

The finished product Golden Balm 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 Golden Balm 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, Menthol, Helianthus Annuus Seed Oil , Arnica montana extract

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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
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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)	0.1555724 mg.(kg bw)-1.d-1
SED(child)	N/A mg.(kg bw)-1.d-1
SED(baby)	N/A mg.(kg bw)-1.d-1
NOAEL	16400 mg.(kg bw)-1.d-1
Dermal penetration factor	0.01
MoS(adult)	105417.2
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	Reproductive Toxicity: Cocos Nucifera Oil is not reported to produce reproductive toxicity in humans. Mutagenicity: Cocos Nucifera Oil is not reported to produce mutagenic effects in humans. Embryotoxicity: Cocos Nucifera Oil is not reported to produce embryotoxic effects in humans. Teratogenicity: Cocos Nucifera Oil is not reported to produce teratogenic effects in humans. Cocos Nucifera Oil was not an eye or skin irritant and it was not phototoxic. In genotoxicity /Mutagenic tests in bacteria, Cocos Nucifera Oil was not genotoxic /Mutagenic

Type of test	Acute LD50
Route of exposure	Oral
Species observed	Rat
Dose	2000 mg/kg/bw/day
Duration	
Observations	
Additional Notes	

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

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

Type of test	Acute LD50
Route of exposure	Oral
Species observed	Rat
Dose	5000 mg/kg/bw/day
Duration	
Observations	
Additional Notes	

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

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

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

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Chemical Name	Butyrospermum Parkii Butter (shea butter)
Function	Emollient
INCI Name	Butyrospermum Parkii Butter
CAS	91080-23-8
EINECS	N/A
SED(adult)	0.1555724 mg.(kg bw)-1.d-1
SED(child)	N/A mg.(kg bw)-1.d-1
SED(baby)	N/A mg.(kg bw)-1.d-1
NOAEL	5000 mg.(kg bw)-1.d-1
Dermal penetration factor	0.01
MoS(adult)	32139.38
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	Reproductive Toxicity: This product is not reported to produce reproductive toxicity in humans. Mutagenicity: This product is not reported to produce mutagenic effects in humans. Embryotoxicity: This product is not reported to produce embryotoxic effects in humans. Teratogenicity: This product is not reported to produce teratogenic effects in humans. Reproductive Toxicity: This product is not reported to produce reproductive effects in humans.

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

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

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

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

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Chemical Name	(1R,2S,5R)-2-isopropyl-5-methylcyclohexanol
Function	Perfuming
INCI Name	Menthol
CAS	1490-04-6
EINECS	216-074-4
SED(adult)	1.414153 mg.(kg bw)-1.d-1
SED(child)	N/A mg.(kg bw)-1.d-1
SED(baby)	N/A mg.(kg bw)-1.d-1
NOAEL	200 mg.(kg bw)-1.d-1
Dermal penetration factor	1
MoS(adult)	141.4274
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	Species Route LD50 (mg/kg bw) (-)-Menthol Rodent - Mouse Oral 4 380 Rodent - Rat Oral 940 Rodent - Cat Oral 800-1 000 Rodent - Mouse Subcutaneous 5 000-6 000 Rodent - Rat Subcutaneous 1 000-2 500 (±)-Menthol Rodent - Mouse Oral 3 100 Rodent - Rat Oral 2 900 Rodent - Mouse Subcutaneous 14 000-16 000 Biotransformation In rabbits, orally administered menthol is conjugated with glucuronic acid and eliminated in the urine. The maximum amount of menthol glucuronide excreted by a 2-kg rabbit was about 3 g after 10 h of feeding of 3.5 g menthol, resulting in a yield of 3/3.5 × 100% = 86% elimination by glucuronidation, even when this maximum toxic dose wasfed. After single daily doses of 2 g menthol for 24 days, 90% was excreted as menthol glucuronide within 6 h. In rats, the vast majority of orally administered menthol is elimiminated in the urine or faeces as the glucuronic acid conjugate or various oxidation products Observations in humans: Menthol has been tested in humans mainly for its potential pharmaceutical properties, such as enhancement of lung and airway volume. The usual human oral dose is 60-120 mg menthol per person. It can be estimated from unreferenced citations in pharmaceutical texts, that the lethal human dose is 50-500 mg/kg bw.

Type of test	Acute LD50
Route of exposure	Oral
Species observed	mice
Dose	2900 mg/kg
Duration	
Observations	No change in BW in males and significantly reduced BW in females. NOAEL determined at 560mg.(kg bw)-1.d-1
Additional Notes	Groups of six male mice were given (-)-menthol at doses of 2000,2500, 3200, 4000, or 5000 mg/kg bw by gavage for five days and examined for 14 days. Gross necropsy of animals that died or were killed at termination revealed no abnormal finding. The LD50 was calculated to be 2600 mg/kg bw. Groups of 10 male and 10 female B6C3F1 mice were maintained on diets containing (±)-menthol at concentrations of 0, 930, 1870, 3750,7500, or 15 000 mg/kg diet for 13 weeks, equivalent to 0, 140, 280,560, 1100, and 2300 mg/kg bw per day, respectively. Necropsies were preformed on all animals at the end of the study; histopathological examination was performed on tissues from the control animals and those at 2300 mg/kg bw per day and on selected tissues from animals at 1100 mg/kg bw per day. Six mice (sex not specified) died during the study, but the deaths could not be attributed to treatment. The final mean body weights of the treated mice were not statistically significantly different from those of the controls, except for females at the high dose, which had statistically significant decreased body weights. Slight increases in the incidences of perivascular lymphoid hyperplasia and interstitial nephritis were reported for female mice at the two highest doses. The NOEL was 560 mg/kg bw per day

Type of test	LD50
Route of exposure	Oral
Species observed	Rat
Dose	3100 mg/kg/bw/day
Duration	
Observations	
Additional Notes	

Type of test	Mutagenicity Studies:
Route of exposure	Dermal
Species observed	Rabbit
Dose	6.4-800 UG/PLATE (TEST MATERIAL SOLVENT: DMSO)
Duration	
Observations	
Additional Notes	

Type of test	Genotoxicity
Route of exposure	In Vitro
Species observed	AMES SALMONELLA TYPHIMURIUM
Dose	725 - 1450 mg/kg bw
Duration	
Observations	Negative
Additional Notes	Menthol was administered at 725 mg/kg bw or the maximum tolerated dose of 1450 mg/kg bw to male Fischer 344 rats and male B6C3F1 mice. Hepatocytes were removed at 24, 39, and 49 h, and replicative DNA synthesis was measured. Synthesis was increased in 6% of the rats and 1.7% of the mice. This assay indicates cell replication (i.e. mitogenesis), however, and not genotoxicity

Type of test	Developmental toxicity
Route of exposure	
Species observed	Rat/mice
Dose	0, 1.9, 8.6, 40, or 190 mg/kg bw at 6-15 of gestation
Duration	
Observations	Negative
Additional Notes	Control groups for each species were sham treated; positive control groups for each species were given 150 or 250 mg/kg bw per day aspirin. Body weight were recorded on three or four days during the gestation period. All animals were observed daily for appearance, behaviour, and food consumption. On the scheduled day, the fetuses were removed from all dams and dams and fetuses examined. One-third of the fetuses from each group underwent detailed visceral examination; the other two-thirds were examined for skeletal defects. There were no effects on nidation, maternal survival, fetal survival, or fetal abnormalities. The numbers of abnormalities seen in soft or skeletal tissues of treated animals did not differ from those occurring spontaneously in the sham-treated controls

Type of test	LC50
Route of exposure	Oral - Gavage
Species observed	mice
Dose	37.7 - 71 mg/l/24/H
Duration	
Observations	Negative
Additional Notes	

Type of test	
Route of exposure	Inhalation
Species observed	Rat
Dose	
Duration	
Observations	
Additional Notes	

Conclusion It is believed that Menthol is safe for use in Golden Balm at this concentration and use as described, assuming the parameters stated.
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Chemical Name	Helianthus Annuus Seed Oil (Sunflower seed oil)
Function	Emollient
INCI Name	Helianthus Annuus Seed Oil
CAS	8001-21-6
EINECS	232-273-9
SED(adult)	0.001415709 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	17000 mg.(kg bw)-1.d-1
Dermal penetration factor	0.01
MoS(adult)	1.200812e+007
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	Sunflower oil has an extensive history of safe use in foodstuffs and in cosmetic formulations. It is comprised of well characterised triglycerides and will be metabolised safely within the body. Vegetable oils form an occlusive layer and do not penetrate the stratum corneum.

Type of test	LD50
Route of exposure	Oral
Species observed	Rat
Dose	>4.0 g/kg/Bw/day
Duration	
Observations	
Additional Notes	None

Type of test	LD50
Route of exposure	Dermal
Species observed	Rabbit
Dose	3600 mg/kg/Bw/day
Duration	
Observations	
Additional Notes	None

Type of test	LC50
Route of exposure	Inhalation
Species observed	Rat
Dose	366 mg/L (96 h static)
Duration	
Observations	
Additional Notes	None

Conclusion	It is believed that Helianthus Annuus Seed Oil is safe for use in Golden Balm at this concentration and use as described, assuming the parameters stated.

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Chemical Name	Arnica Montana Flower extract is an extract of the flowers of arnica, Arnica montana L., Asteraceae
Function	Skin conditioning
INCI Name	Arnica montana extract
CAS	68990-11-4 (extract)
EINECS	273-579-2
SED(adult)	0.1166793 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	20 mg.(kg bw)-1.d-1
Dermal penetration factor	1
MoS(adult)	171.41
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	Prolonged use often causes edematous dermatitis with the formation of postules. Long use can also give rise to eczema. In treatment involving higher concentrations of the drug, primary toxic skin reactions with the formation of vesicles or even necroses may occur. Arnica flower extract has a sensitization capacity. Recommended that the product label states: discontinue use if adverse reaction occurs. A default NOAEL for botanical ingredients has been applied

Type of test	Dermal irritancy
Route of exposure	Dermal
Species observed	Mouse and Guinea pig
Dose	
Duration	
Observations	Not irritating or phototoxic
Additional Notes	

Type of test	Dermal Sensitization
Route of exposure	Dermal
Species observed	Guinea pig
Dose	
Duration	
Observations	Significant sensitization capacity
Additional Notes	Sensitising capacity is likely caused by the sesqutiterpene lactone helenalin. More than 100 cases of contact dermatitis caused by Arnica Montana are reported in the literature. In most cases, sensitisation was induced by self-treatment with tincture of Arnica (Council of Europe, 2008). Analysis of positive patch tests revealed an increasing incidence of contact allergy to Arnica.

Type of test	Acute dermal toxicity
Route of exposure	Dermal
Species observed	Rabbit
Dose	5000 mg.(kg bw)-1
Duration	
Observations	LD50
Additional Notes	

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

Type of test	Acute toxicity
Route of exposure	Intraperitoneal injection
Species observed	Mice
Dose	31 mg.(kg bw)-1
Duration	
Observations	LD50
Additional Notes	

Type of test	Repeated dose
Route of exposure	Oral
Species observed	Mouse
Dose	10, 20, 30 ml.(kg bw)-1
Duration	14d
Observations	LD50 >20ml.(kg bw)-1. One mouse of 30 ml.(kg bw)-1 group died.
Additional Notes	Mice were fed a mixture of Arnica Montana extract, butylene glycol and water (percentages not specified).

Type of test	Ames assay (with and without metabolic activation)
Route of exposure	
Species observed	S. Typhimurium TA-98, TA-100
Dose	10-400 mcl
Duration	
Observations	Mutagenic.
Additional Notes	An ethanolic extract of Arnica, 10-400 µl, was mutagenic in the Ames test with and without metabolic activation for the Salmonella typhimurium strain TA98 and for strain TA100 with metabolic activation (Göggelmann et al., 1986).

Type of test	Other toxicology - case study
Route of exposure	
Species observed	
Dose	
Duration	
Observations	
Additional Notes	Ingestion of helenalin, a constituent of the extract of Arnica Montana, can lead to severe intestinal upset, nervous disturbances, irregular heartbeat and collapse. Ingestion of 30 grams is reported to have caused severe illness, but not death. Helenanin has also been reported to be irritant to mucous membranes (Council of Europe, 2008). A person died after ingesting a 70 gram tincture of Arnica Montana. Arnica tincture has also been reported to caused oedema of eye lids and hyperaemia of the conjunctiva (Council of Europe, 2008).

Conclusion	It is believed that Arnica montana extract is safe for use in Golden Balm at this concentration and use as described, assuming the parameters stated.

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