SUPER ACTIVE COSMETICS
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Toxicological Safety Assessment of: Healing Touch Ointment

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: C1008/01

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Composition of Formulation

CAS Number	INCI Name	Maximum Concentration %
8001-25-0	Olea Europaea Fruit Oil	74.51565
8012-89-3	Cera Alba	9.687034
8001-31-8	Cocos Nucifera Oil	8.941878
91080-23-8	Butyrospermum Parkii Butter	5.961252
84776-23-8 / 70892-20-5	Calendula Officinalis Flower Oil	0.7451565
8000-28-0 / 90063-37-9 (Essential Oils Direct)	Lavandula Angustifolia (Lavandula Officinalis) Oil	0.07451565
85085-48-9 (Essential Oils Direct)	Melaleuca Alternifolia Leaf Oil	0.07451565

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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 Healing Touch Ointment 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.

Healing Touch Ointment 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.

Healing Touch Ointment 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

Healing Touch Ointment 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
Olea Europaea Fruit Oil	8186.2	Safe
Cera Alba	6926.785	Safe
Cocos Nucifera Oil	559390.3	Safe
Butyrospermum Parkii Butter	255818.7	Safe
Calendula Officinalis Flower Oil	6139.65	Safe
Lavandula Angustifolia (Lavandula Officinalis) Oil	8186.2	Safe
Melaleuca Alternifolia Leaf Oil	49117.2	Safe
Linalool	22739.45	Safe
Limonene	409309.9	Safe
Geraniol	3721000	Safe

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

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

Ingestion: Healing Touch Ointment 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 Healing Touch Ointment 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: Healing Touch Ointment is likely to cause upper gastrointestinal irritation.

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

Healing Touch Ointment 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.

Healing Touch Ointment 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:

CAS Number	% Concentration of formulation	% Limit for this type of product	Conclusion
106-24-1	0.0008196722	5.3	Pass: Within limits

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

INCI Name	CAS	% Concentration of formulation
Geraniol	106-24-1	0.0008196722
Limonene	138-86-3	0.003725783
Linalool	78-70-6	0.03353204

INCI Name: Lavandula Angustifolia (Lavandula Officinalis) Oil **CAS Number:** 8000-28-0 / 90063-37-9 (Essential Oils Direct)

INCI Name	CAS	% Concentration of ingredient	% Concentration of formulation
Geraniol	106-24-1	1.1	0.0008196722
d-Limonene	5989-27-5	1	0.0007451565
Linalool	78-70-6	45	0.03353204

INCI Name: Melaleuca Alternifolia Leaf Oil **CAS Number:** 85085-48-9 (Essential Oils Direct)

INCI Name	CAS	% Concentration of ingredient	% Concentration of formulation
d-Limonene	5989-27-5	4	0.002980626

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Conclusion

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

The finished product Healing Touch Ointment 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 Healing Touch Ointment 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, Cera Alba, Cocos Nucifera Oil, Butyrospermum Parkii Butter, Calendula Officinalis Flower Oil, Lavandula Angustifolia (Lavandula Officinalis) Oil, Melaleuca Alternifolia Leaf Oil, Linalool, 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 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.

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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	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)	0.2443136 mg.(kg bw)-1.d-1
SED(child)	N/A mg.(kg bw)-1.d-1
SED(baby)	N/A mg.(kg bw)-1.d-1
NOAEL	2000 mg.(kg bw)-1.d-1
Dermal penetration factor	0.01
MoS(adult)	8186.2
MoS(child)	N/A
MoS(baby)	N/A
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 Healing Touch Ointment at this concentration and use as described, assuming the parameters stated.

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Chemical Name	Cera Alba
Function	Emollient
INCI Name	Cera Alba
CAS	8012-89-3
EINECS	232-383-7
SED(adult)	0.03176077 mg.(kg bw)-1.d-1
SED(child)	N/A mg.(kg bw)-1.d-1
SED(baby)	N/A mg.(kg bw)-1.d-1
NOAEL	220 mg.(kg bw)-1.d-1
Dermal penetration factor	0.01
MoS(adult)	6926.785
MoS(child)	N/A
MoS(baby)	N/A
	Reproductive Toxicity: This product is not reported to produce reproductive toxicity in humans. Mutagenicity: This product is not reported to produce mutagenic effects in humans. Embryotoxicity: This product is not reported to produce embryotoxic effects in humans. Teratogenicity: This product is not reported to produce teratogenic effects in humans. Reproductive Toxicity: This product is not reported to produce reproductive effects in humans.\n\n
Additional Notes	The NOAEL of beeswax was determined to be 22mg.(kg bw)-1.d-1 in humans by EFSA for the purpose of a glazing agent, based on typical exposures, however noted that the analysis of the chemical constituents would suggest a much higher NOAEL (10-50x higher). Furthermore the oral penetration of beeswax components are very low, and it is expected that the dermal penetration is even lower. Most of the constituents are known to metabolise to endogenous substrates in vivo. The applied NOAEL in this calculation has been modified (1%) to account for the low dermal penetration expected from beeswax.

Type of test	LD50
Route of exposure	Oral
Species observed	Rat
Dose	5000 mg/kg/Bw/day
Duration	
Observations	
Additional Notes	None

Type of test	LD50
Route of exposure	Dermal
Species observed	Rat
Dose	7960 mg/kg/Bw/day
Duration	
Observations	
Additional Notes	None

Type of test	LC50
Route of exposure	Inhalation
Species observed	Rabbit
Dose	10 ppm/8 days
Duration	
Observations	
Additional Notes	None

Conclusion	It is believed that Cera Alba is safe for use in Healing Touch Ointment at this concentration and use as described, assuming the parameters stated.

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Chemical Name	Cocos Nucifera Oil
Function	Emollient
INCI Name	Cocos Nucifera Oil
CAS	8001-31-8
EINECS	232-282-8
SED(adult)	0.02931763 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)	559390.3
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 Healing Touch Ointment 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)	0.01954509 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)	255818.7
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 Healing Touch Ointment at this concentration and use as described, assuming the parameters stated.

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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)	0.02443136 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	150 mg.(kg bw)-1.d-1
Dermal penetration factor	0.1
MoS(adult)	6139.65
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	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.

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 Healing Touch Ointment at this concentration and use as described, assuming the parameters stated.

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Chemical Name	Lavandula Angustifolia (Lavender) Oil
Function	Fragrance
INCI Name	Lavandula Angustifolia (Lavandula Officinalis) Oil
CAS	8000-28-0 / 90063-37-9 (Essential Oils Direct)
EINECS	N/A
SED(adult)	0.02443136 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)	8186.2
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	

Type of test	LD50
Route of exposure	Oral
Species observed	Rat
Dose	4200 mg.(kg bw)-1.d-1
Duration	
Observations	
Additional Notes	

Type of test	Acute dermal exposure
Route of exposure	Dermal
Species observed	Mouse
Dose	6500 mg.(kg bw)-1
Duration	
Observations	
Additional Notes	

Type of test	LC50
Route of exposure	Inhalation
Species observed	Rat
Dose	142500 ppm
Duration	4hr
Observations	
Additional Notes	

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

Type of test	Photosensitization
Route of exposure	Dermal
Species observed	Rabbit
Dose	
Duration	
Observations	
Additional Notes	Some evidence of farnesol and geraniol acting as photosensitizers from trace to <0.1% .

Type of test	Acute
Route of exposure	Mucous membrane
Species observed	Rabbit
Dose	
Duration	
Observations	Class C-D non irritant
Additional Notes	

Type of test	Repeat dose dermal toxicity
Route of exposure	Dermal
Species observed	Rats
Dose	250, 1000 and 4000 mg.(kg bw)-1.d-1
Duration	90d
Observations	Decreased activity and transient erythema. At 1000 mg.(kg bw)-1 weight gain and activity were reduced, and at the highest dose 11 of 20 animals died.
Additional Notes	Test substance was linalool. A consistuent of Lavandula Angistifolia Oil.

Type of test	Dermal irritancy
Route of exposure	Dermal
Species observed	Mice - hairless and pigs
Dose	
Duration	
Observations	Non irritant, except slight irritant on intact or abraded rabbit skin under occlusion for 24hr.
Additional Notes	

Conclusion	It is believed that Lavandula Angustifolia (Lavandula Officinalis) Oil is safe for use in Healing Touch Ointment at this concentration and use as described, assuming the parameters stated.

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Chemical Name	Melaleuca Alternifolia Leaf Oil
Function	Perfuming
INCI Name	Melaleuca Alternifolia Leaf Oil
CAS	85085-48-9 (Essential Oils Direct)
EINECS	285-377-1
SED(adult)	0.02443136 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	1200 mg.(kg bw)-1.d-1
Dermal penetration factor	1
MoS(adult)	49117.2
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	

Type of test	In-Vitro Dermal
Route of exposure	Dermal
Species observed	Human
Dose	2000 mg/24H
Duration	
Observations	
Additional Notes	

Type of test	LD50
Route of exposure	Dermal
Species observed	Rabbit
Dose	5610 mg/kg
Duration	
Observations	
Additional Notes	None

Type of test	Carcinogenety
Route of exposure	Dermal
Species observed	Mice
Dose	2000 mg/kg
Duration	
Observations	
Additional Notes	None

Conclusion	It is believed that Melaleuca Alternifolia Leaf Oil is safe for use in Healing Touch Ointment at this concentration and use as described, assuming the parameters stated.

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Chemical Name	2,6-Octadien-1-ol,3,7-dimethyl-, (2E)-
Function	Perfuming
INCI Name	Geraniol
CAS	106-24-1
EINECS	203-377-1
SED(adult)	0.000268745 mg.(kg bw)-1.d-1
SED(child)	N/A mg.(kg bw)-1.d-1
SED(baby)	N/A mg.(kg bw)-1.d-1
NOAEL	1000 mg.(kg bw)-1.d-1
Dermal penetration factor	1
MoS(adult)	3721000
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)g when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products Reproductive Toxicity: Geraniol is not reported to produce reproductive toxicity in humans. Mutagenicity: Geraniol is not reported to produce mutagenic effects in humans. Geraniol and other essential oils are currently under examination for genotoxic effects, until that point it can be assumed as same as long as kept with in current guidelines Embryotoxicity: Geraniol is not reported to produce embryotoxic effects in humans. Teratogenicity: Geraniol is not reported to produce teratogenic effects in humans. Reproductive Toxicity: Geraniol is not reported to produce reproductive effects in humans.

Type of test	LD50
Route of exposure	Acute Oral
Species observed	Rat
Dose	5000 mg/kg
Duration	
Observations	Duration of observation period following administration: 14 days - Other examinations performed: for mortality and toxic effects
Additional Notes	

Type of test	LD50
Route of exposure	Dermal
Species observed	Rabbit
Dose	5000 mg/kg
Duration	
Observations	
Additional Notes	

Type of test	LC50
Route of exposure	Inhalation
Species observed	Rat
Dose	93.19-150.0 ppm
Duration	
Observations	Name of test material (as cited in study report): Geraniol - Analytical purity: 99.4 %
Additional Notes	negative

Type of test	gene mutation
Route of exposure	bacterial reverse mutation assay (e.g. Ames test)
Species observed	S. typhimurium TA 1535, TA 1537, TA 98 and TA 100
Dose	Exposure duration: 48 h, 37°C
Duration	
Observations	Name of test material (as cited in study report): Geraniol - Analytical purity: 99.4 %
Additional Notes	The main findings of the present study can be summarized as follows: (1) Mortality: Through the whole experimental phase an increased mortality was observed in the males group treated with the highest test dose of 2000 mg/kg bw, indicating a cumulative toxicity of the test substance. In fact at 2000 mg/kg bw, 18/50 males survived versus 34/50 in the control group. At the low dose of 1000 mg/kg bw, survival of the males was 29/50. (2) Macroscopical findings: Retinopathy or cataracts were reported for the males of the high dose group and the females of the low dose group. In fact, it appeared that these findings were not related to the test substance but to the proximity of the rats to a source of fluorescent light. (3) Cancer findings: Two of the 50 males of the low dose group displayed kidney tubular cell adenomas. The incidence of kidney tumors in male rats within the vehicle control group of this study was similar to the historical incidence observed in the laboratory (0.4 %). Epidermal tumors were reported for the males of the low dose group (6/50, 12 %). The incidence of low dose males with epidermal tumors was increased compared to control (3/50, 6 %), but this increase was without statistical significance. In the high dose group, only one case was observed (1/50, 2 %). Under the conditions of the present study, the test substances Geraniol was not carcinogenic.

Type of test	Carcinogenicity
Route of exposure	Oral: Gavage
Species observed	Rat Fischer 344
Dose	1000, 2000 mg/kg bw/ 5 times a week / 103 weeks
Duration	
Observations	
Additional Notes	

Conclusion	It is believed that Geraniol is safe for use in Healing Touch Ointment 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)	0.001221568 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)	409309.9
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)g when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products Peroxide value not to exceed less than 20 mmoles/L No information is available on the health effects of inhalation exposure to d-limonene in humans, and no long-term inhalation studies have been conducted in laboratory animals. NTP (1990) conducted a series of studies that investigated the toxicity of d-limonene (>99% pure) in both Fischer 344/N rats and B6C3F1 mice. In the first of the preliminary range-finding studies, doses ranging from 413-6600 mg/kg/day were administered by gavage in corn oil to five animals/species/sex/dose for 5 days/week for 16 days. All but 2/20 rats and 1/20 mice that were administered 3300 and 6600 mg/kg/day died. Body weight gain was reduced at 1650 mg/kg/day. No compound-related signs of toxicity were observed in those animals administered <1650 mg/kg/day. In the rabbit study, 10-18 pregnant Japanese white rabbits were administered 0, 250, 500, or 1000 mg/kg/day d-limonene by gavage on gestation days 6-18 (Kodama et al., 1977b). Exposure of does to 500 or 1000 mg/kg/day resulted in maternal toxicity. There were significant reductions in food consumption and body weight at both doses, and death also occurred in the 1000-mg/kg/day group. Developmental toxicity was not observed at any dose. This study is limited by the small sample size. No reproductive toxicity studies have been conducted on d-limonene. Igimi et al. (1974) studied the metabolism of d-limonene after oral administration and found that about 65% of the dose was recovered in urine, feces, and expired carbon dioxide, suggesting that the majority of an oral dose is absorbed. Although it is possible that an inhaled dose would also be largely absorbed, there is no information on inhalation exposures. Reproductive Toxicity: This product is not reported to produce reproductive toxicity in humans. Mutagenicity: This product is not reported to produce mutagenic effects in humans. Embryotoxicity: This product is not reported to produce embryotoxic effects in humans. Teratogenicity: This product is not reported to produce teratogenic effects in humans. Reproductive Toxicity: This product is not reported to produce reproductive effects in humans.

Type of test	LD50
Route of exposure	Oral
Species observed	Rat
Dose	2790 mg/kg
Duration	
Observations	
Additional Notes	

Type of test	LD50
Route of exposure	Dermal
Species observed	Rabbit
Dose	5610 mg/kg
Duration	
Observations	
Additional Notes	

Type of test	LC50
Route of exposure	Inhalation
Species observed	Rat
Dose	295 mg/l/96H
Duration	
Observations	
Additional Notes	

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

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

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

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

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

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

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

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

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

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Chemical Name	3,7-Dimethylocta-1,6-diene-3-ol
Function	Perfuming
INCI Name	Linalool
CAS	78-70-6
EINECS	201-134-4
SED(adult)	0.01099411 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)	22739.45
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 Healing Touch Ointment at this concentration and use as described, assuming the parameters stated.

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