SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

Toxicological Safety Assessment of: Charcoal Detox Soap

Client Name: Veronika O'Connor, Mind beauty and soul, 50 auburn road, Doncaster, DN12 1DP

Responsible Person: Veronika O'Connor, Mind beauty and soul, 50 auburn road, Doncaster, DN12 1DP

REF: C1280/14

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Composition of Formulation

CAS Number	INCI Name	Maximum Concentration %
90063-37-9 (Whole)	Lavandula Angustifolia Flower	2
7732-18-5	Aqua (Water)	23.6825
56-81-5	Glycerin	23.6825
8001-31-8 (sodium saponified)	Sodium Cocoate	12.3149
50-70-4	Sorbitol	12.3149
57-11-4 (sodium saponified)	Sodium Stearate	6.6311
61789-40-0	Cocamidopropyl Betaine	4.7365
7647-14-5	Sodium Chloride	4.7365
68-04-2	Sodium citrate	4.7365
8016-24-8	Cannabis Sativa (hemp) Seed Oil	1
7440-44-0	Activated charcoal	1
85085-48-9 (Biorigins)	Melaleuca Alternifolia Leaf Oil	0.85
8001-31-8	Cocos Nucifera Oil	0.57365
9007-48-1 / 71012-10-7	Polyglyceryl-4 Oleate	0.47365
13419-59-5	Trisodium Sulfosuccinate	0.47365
77-92-9	Citric Acid	0.47365
8006-90-4 (Biorigins)	Mentha Piperita Oil	0.3
13956-29-1	Cannabidiol	0.02

Ingredients whose concentration is a trace, are denoted with concentrations of 0.

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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 Charcoal Detox Soap 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 Veronika O'Connor, Mind beauty and soul, 50 auburn road, Doncaster, DN12 1DP, 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.

Charcoal Detox Soap 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.

Charcoal Detox Soap 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:	9a
IFRA Category:	Soap
Targeted Population:	Adults
Number of uses per day:	Twice
Amount per Application/g:	0.8 g
Total amount applied per day/g:	1.6 g
Estimated daily exposure (Daily):	0.008655738 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:	0.33
Exposure time neat:	0 seconds
Exposure time dilute:	60 seconds

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Toxicological Summary

Charcoal Detox Soap is a soap bar intended for the adult population. The skin is wetted prior to use and apply the product to the area. After application rinse off. It has been estimated that the product will be applied Twice a day totalling 1.6 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
Aqua (Water)	878093.7	Safe
Glycerin	9756.597	Safe
Sodium Cocoate	15385.4	Safe
Sorbitol	7036.007	Safe
Sodium Stearate	1742.249	Safe
Cocamidopropyl Betaine	731744.8	Safe
Sodium Chloride	24391.49	Safe
Sodium citrate	2439.149	Safe
Lavandula Angustifolia Flower	11553.03	Safe
Cannabis Sativa (hemp) Seed Oil	57765.15	Safe
Activated charcoal	11553.03	Safe
Melaleuca Alternifolia Leaf Oil	16310.16	Safe
Cocos Nucifera Oil	3.30288e+007	Safe
Polyglyceryl-4 Oleate	7317.448	Safe
Trisodium Sulfosuccinate	9756.597	Safe
Citric Acid	29269.79	Safe
Mentha Piperita Oil	11553.03	Safe
Cannabidiol	57765.15	Safe
Limonene	341704.5	Safe
Linalool	9383553	Safe

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

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

Ingestion: Charcoal Detox Soap poses low risk from ingestion if used as directed. If swallowed the ingredients do not pose a significant acute hazard, although regular ingestion maybe harmful. Upper GI Irritation such as nausea and vomiting and diarrhoea can be expected. If large amounts of Charcoal Detox Soap 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: Charcoal Detox Soap is likely to cause upper gastrointestinal irritation.

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

Charcoal Detox Soap 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.

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

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

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	0.016905
Linalool	78-70-6	0.00171

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

INCI Name	CAS	% Concentration of ingredient	% Concentration of formulation
d-Limonene	5989-27-5	0.93	0.007905
Linalool	78-70-6	0.06	0.00051

INCI Name: Mentha Piperita Oil **CAS Number:** 8006-90-4 (Biorigins)

INCI Name	CAS	% Concentration of ingredient	% Concentration of formulation
d-Limonene	5989-27-5	3	0.009
Linalool	78-70-6	0.4	0.0012

Conclusion

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

The finished product Charcoal Detox Soap 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 Charcoal Detox Soap can be considered as SAFE.

Labelling requirements

The product label must state:

- 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.
- Do not use if you are sensitive or allergic to any of the ingredients.
- Expected date of minimum durability from date of manufacture: + 12 M

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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 Veronika O'Connor, Mind beauty and soul, 50 auburn road, Doncaster, DN12 1DP and subsequent PIF (Public Information File) and therefore is compliment with REACH.

Veronika O'Connor, Mind beauty and soul, 50 auburn road, Doncaster, DN12 1DP 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: 20/04/2019

Safety Administrator on behalf of
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Chemical Name	Lavandula Angustifolia Flower are the dried flowers of the Lavender, Lavandula angustifolia, Labiatae
Function	Decoration
INCI Name	Lavandula Angustifolia Flower
CAS	90063-37-9 (Whole)
EINECS	289-995-2
SED(adult)	0.001731148 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	0.01
MoS(adult)	11553.03
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	The chemical constituents of the flower is not expected to diffuse in any appreciable manner into the finished product prior to use. Lavandula angustifolia flowers have a history of safe use in foodstuff, that exceed concentrations found in this product. Incidental oral consumption is unlikely to produce any serious adverse acute effects.
Conclusion	It is believed that Lavandula Angustifolia Flower is safe for use in Charcoal Detox Soap at this concentration and use as described, assuming the parameters stated.

Chemical Name	Water
Function	Solvent
INCI Name	Aqua (Water)
CAS	7732-18-5
EINECS	231-791-2
SED(adult)	0.02049895 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	18000 mg.(kg bw)-1.d-1
Dermal penetration factor	0.01
MoS(adult)	878093.7
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	

Type of test	LD50
Route of exposure	Oral
Species observed	Rat
Dose	90 mg/kg/bw/day
Duration	
Observations	
Additional Notes	

Type of test	LD50
Route of exposure	Dermal
Species observed	Rat
Dose	3400 mg/kg/bw/day
Duration	
Observations	
Additional Notes	

Type of test	Mutagenicity Studies
Route of exposure	Rec-assay, spot test, DNA effects (bacterial DNA repair)
Species observed	Bacillus subtilis (H17 vs M45)
Dose	90 mg/kg/bw/day
Duration	
Observations	No conclusion
Additional Notes	

Type of test	Mutagenicity Studies
Route of exposure	Rec-assay, spot test, DNA effects (bacterial DNA repair)
Species observed	Bacillus subtilis (H17 vs M45)
Dose	90 mg/kg/bw/day
Duration	
Observations	No conclusion
Additional Notes	

Conclusion	It is believed that Aqua (Water) is safe for use in Charcoal Detox Soap at this concentration and use as described, assuming the parameters stated.

Chemical Name	1,2,3-Propanetriol
Function	Humectant
INCI Name	Glycerin
CAS	56-81-5
EINECS	200-289-5
SED(adult)	2.049895 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	20000 mg.(kg bw)-1.d-1
Dermal penetration factor	1
MoS(adult)	9756.597
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	The NOAEL used in the calculation of MoS has been increased by a factor of 10 to account for the NOAEL oral study having been conducted in humans and therefore the MoS does not have to account for the interspecies difference.

Type of test	LD50
Route of exposure	Oral
Species observed	Rabbit
Dose	10.000 mg/kg
Duration	
Observations	Lungs, Thorax, or Respiration: Chronic pulmonary edema.
Additional Notes	

Type of test	Standard Draize
Route of exposure	Ocular
Species observed	Rabbit
Dose	1.0-8.5% 1,24,72/H
Duration	
Observations	Mildly irritating
Additional Notes	Acute Exposure/ 0.1 mL undiluted glycerol was instilled in the eyes of 6 rabbit) caused no evidence of irritation after 1, 24 and 72 hours and after 7 days. The overall irritation score using the Draize system was 0-2 on a scale up to a maximum of 110. In another study of similar design, using 4 rabbits, irritation of unspecified severity observed at 1 hr after instillation of glycerol was absent after 24 hr. Another test with a similar design on a glycerol/water mixture (not further specified) gave a similar result and reactions, which were reversible within 24 hr. ... it is apparent from these studies that glycerol has a very low potential to irritate the eyes

Type of test	Carcinogenicity
Route of exposure	Oral
Species observed	Mice
Dose	0,0.5/1% v/v/ 1 Year
Duration	
Observations	
Additional Notes	

Type of test	Repeat dose
Route of exposure	Dermal
Species observed	Rabbit
Dose	0.5 to 4 ml at 100%
Duration	45wk
Observations	No treatment effects observed.
Additional Notes	Exposed skin surface area: 30% of the body surfaces.

Type of test	Repeat dose
Route of exposure	Dermal
Species observed	Rabbit
Dose	0.5 to 4 ml at 100%
Duration	45wk
Observations	No treatment effects observed.
Additional Notes	Exposed skin surface area: 30% of the body surfaces.

Type of test	Repeat dose
Route of exposure	Oral
Species observed	Rat
Dose	5 and 10 %
Duration	2yr
Observations	Feed consumption increased, and no treatment related effects on organ weight nor gross pathology.
Additional Notes	

Type of test	Repeat dose
Route of exposure	Oral
Species observed	Human
Dose	1300 to 2200 mg.(kg bw)-1.d-1
Duration	50d
Observations	NOAEL > 2200 mg.(kg bw)-1.d-1
Additional Notes	

Type of test	Repeat dose
Route of exposure	Oral
Species observed	Human - 14 subjects
Dose	90 ml.d-1
Duration	50d
Observations	No adverse effects noted.
Additional Notes	

Type of test	Repeat dose
Route of exposure	Inhalation
Species observed	Rats - Sprague Dawley
Dose	
Duration	6hr.d-1 for 5d.wk-1 for 2wk
Observations	LOAEL = 1000 mg.L-1
Additional Notes	Route of administration: Nose only. Localised symptoms of toxicity were observed in the epithelium of the upper respiratory tract.

Type of test	Repeat dose
Route of exposure	Inhalation
Species observed	Rats - Sprague Dawley
Dose	
Duration	5hr.d-1 for 5d.wk-1 fpr 13wk
Observations	NOAEL inhalation = 0.167 mg.L-1
Additional Notes	Minimal squamous metaplasia of the epiglottis.

Type of test	Reproductive and developmental toxicity (three generation)
Route of exposure	Oral - drinking water
Species observed	Rat
Dose	0.20% = c 2000 mg.(kg bw)-1.d-1
Duration	8wk prior to mating, until weaning of pups.
Observations	No adverse effects on fertility, growth or reproductive performance, histological changes, estrus cycle, litter size nor microscopic evaluation of endocrine organs.
Additional Notes	

Type of test	Genotoxicity - Ames Test
Route of exposure	In vitro
Species observed	Salmonella typhimurium
Dose	upto 50 mg.plate-1
Duration	
Observations	Non genotoxic
Additional Notes	

Type of test	OECD Guideline 473 (In vitro Mammalian Chromosome Aberration Test)
Route of exposure	Oral and Intraperitoneal
Species observed	Rat
Dose	1000 mg.(kg bw)-1
Duration	
Observations	Negative.
Additional Notes	

Type of test	Irritation - EPA OPPTS 870.2400 (Acute Eye Irritation)
Route of exposure	Ocular
Species observed	Rabbit
Dose	100%
Duration	
Observations	Non irritant
Additional Notes	

Type of test	Guinea pig maximisation test - OECD Guideline 406 (Skin Sensitisation)
Route of exposure	intradermal and epicutaneous
Species observed	Guinea pig
Dose	Induction: 10 injections of 0.1mL of 0.1% solution every other day. Challenge: 0.05mL of the 0.1% solution after a 2wk cessation.
Duration	
Observations	Non sensitizing.
Additional Notes	

Conclusion	It is believed that Glycerin is safe for use in Charcoal Detox Soap at this concentration and use as described, assuming the parameters stated.

Chemical Name	Sodium Cocoate is the sodium salt of saponified Cocos Nucifera Oil
Function	Cleansing, Emulsifier, Surfactant
INCI Name	Sodium Cocoate
CAS	8001-31-8 (sodium saponified)
EINECS	232-282-8
SED(adult)	1.065945 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	1
MoS(adult)	15385.4
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	As with similar saponified salts of plant derived fatty acids, this component is expected to be a strong ocular irritant, and maybe a mild dermal irritant. Avoid contact with eyes.

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 Sodium Cocoate is safe for use in Charcoal Detox Soap at this concentration and use as described, assuming the parameters stated.

Chemical Name	D-Glucitol
Function	Humectant, Skin Conditioning
INCI Name	Sorbitol
CAS	50-70-4
EINECS	200-061-5
SED(adult)	1.065945 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	7500 mg.(kg bw)-1.d-1
Dermal penetration factor	1
MoS(adult)	7036.007
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	LogKow (QSAR) = 3.1 & LogKow (HSDB) = 2.2.

Type of test	Reprotoxicity
Route of exposure	Oral
Species observed	Rat
Dose	7500 mg.(kg bw)-1.d-1
Duration	17mn
Observations	NOAEL = 7500 mg.(kg bw)-1.d-1
Additional Notes	

Type of test	Subchronic toxicity
Route of exposure	Oral
Species observed	Rat
Dose	7500 mg.(kg bw)-1.d-1
Duration	90d
Observations	NOAEL = 7500 mg.(kg bw)-1.d-1
Additional Notes	

Conclusion	It is believed that Sorbitol is safe for use in Charcoal Detox Soap at this concentration and use as described, assuming the parameters stated.

Chemical Name	Sodium Stearate is the sodium salt of saponified stearic acid
Function	Surfactant
INCI Name	Sodium Stearate
CAS	57-11-4 (sodium saponified)
EINECS	200-313-4
SED(adult)	0.5739706 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)	1742.249
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	Mutagenicity: Stearic Acid is not reported to produce mutagenic effects in humans. Embryotoxicity: Stearic Acid is not reported to produce embryotoxic effects in humans. Teratogenicity: Stearic Acid is not reported to produce teratogenic effects in humans. Reproductive Toxicity: Stearic Acid is not reported to produce reproductive effects in humans.

Type of test	LD50
Route of exposure	Oral
Species observed	Wistar rat
Dose	10000 mg/kg/bw/day
Duration	
Observations	
Additional Notes	

Type of test	LD50
Route of exposure	Dermal
Species observed	Rabbit
Dose	4600 mg/kg/bw/day
Duration	
Observations	
Additional Notes	

Type of test	LC50
Route of exposure	Inhalation
Species observed	Rat
Dose	45 mg/
Duration	
Observations	
Additional Notes	

Type of test	LD50
Route of exposure	Oral
Species observed	Wistar rat
Dose	10000 mg/kg/bw/day
Duration	
Observations	
Additional Notes	

Type of test	LD50
Route of exposure	Dermal
Species observed	Rabbit
Dose	4600 mg/kg/bw/day
Duration	
Observations	
Additional Notes	

Type of test	LC50
Route of exposure	Inhalation
Species observed	Rat
Dose	45 mg/
Duration	
Observations	
Additional Notes	

Conclusion	It is believed that Sodium Stearate is safe for use in Charcoal Detox Soap at this concentration and use as described, assuming the parameters stated.

Chemical Name	1-Propanaminium,3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-coco acyl derivs.,hydroxides, inner salts
Function	Surfactant
INCI Name	Cocamidopropyl Betaine
CAS	61789-40-0
EINECS	263-058-8
SED(adult)	0.000409979 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	300 mg.(kg bw)-1.d-1
Dermal penetration factor	0.001
MoS(adult)	731744.8
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	Studies in Humans: Human patch tests show, that impurities - most likely amidoamine - are responsible for the irritating properties of Cocamidopropyl Betaine. Tests have been carried out with different batches and concentrations (0.15 to 3 % w/v) of Cocamidopropyl Betaine for 2 days under occlusive conditions in 39 - 67 patients. Additionally, several non-invasive investigations - transepidermal water loss, cutaneous blood flow and critical micelle concentration - were performed. For all batches slight irritating reactions were recorded after patch testing (score 0.21 -0.79 of maximum 4 scores, score 1 indicates erythema). Cocamidopropyl Betaine with the highest amidoamine concentrations showed the highest mean irritation score. The results of the non-invasive investigations confirmed this resul). In this investigation the irritant potency did not increase at higher concentration of the Cocamidopropyl betaine. Weak irritating effects (slight erythema) have been observed also in patch tests for investigation of sensitizing properties. Occlusive exposure for two days to 1 % dilutions of Cocamidopropyl Betaine caused erythema in 15 of 1200 patients analyzed

Type of test	Acute toxicity LD50
Route of exposure	Oral
Species observed	Rat
Dose	≥ _4900 (mg/kg bw)
Duration	
Observations	
Additional Notes	In each of the studies Cocamidopropyl Betaine was administered undiluted (circa 30 % active solution) via gavage. The post-dose observation period was 2 weeks in each of the investigations. Slightly decreased body weights were seen in one study in 4/10 males and 3/10 females after Observed clinical signs were: diarrhea, nasal hemorrhage, salivation, decreased motor activity, coordination disturbance and abnormal body posture The only necropsy findings recorded were: redness of intestinal mucous membranes and blood-like viscous liquid in the intestines, stomach and gastrointestinal tract

Type of test	Acute toxicity LD50
Route of exposure	Dermal
Species observed	Rabbit
Dose	2000 (mg/kg bw)
Duration	
Observations	
Additional Notes	One acute dermal toxicity study with CD rats (OECD guideline 402) with cocamidopropyl betaine (31 % active content) is available (Kao Corporation, 1987a). 10 male and female rats were administered 1.92 ml cocamidopropyl betaine/kg bw (corresponding to 2000 mg/kg bw 31 % active substance) for 24 h under occlusive conditions. 10 % of the total body surface was covered. No deaths occurred during 14 days post-dose observation period. The only findings were slightly lower body weights in 3/5 females. The acute dermal toxicity (LD50) is > 2000 mg/kg bw for the 31 % active substance.

Type of test	LC50
Route of exposure	Inhalation
Species observed	Rat
Dose	≥ 4900 (mg/kg bw)
Duration	
Observations	No conclusion
Additional Notes	

Type of test	Draize Test
Route of exposure	Ocular
Species observed	Rabbit
Dose	30%w/w 24H
Duration	
Observations	Mild to moderate irritant
Additional Notes	In the guideline study (OECD 405) the 80 % active spray dried substance was tested (Th. Goldschmidt AG, 1991b). The substance was irreversibly irritating. All other studies were performed according to the same protocol with slight variations: concentration of cocamidopropyl betaine used, reversibility testing and classification system (for details see tables 7 and 8). 30 % and 25 % cocamidopropyl betaine is an irreversibly irritating, or highly irritating substance (Th. 14 - 15 % solutions of cocamidopropyl betaine were highly irritating (Goldschmidt Chemical Corporation, 1993b, 1993c) and the results for the ≤ _10 % active compound varies between mildly and moderately eye irritating, reversible after 14 days ,Rinsing of the eyes after 30 seconds had no influence on the irritation effect but on the reversibility of the effects observed (US-EPA, 1991).

Type of test	
Route of exposure	
Species observed	
Dose	1-10000 UG/PLATE
Duration	
Observations	
Additional Notes	

Type of test	OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents)
Route of exposure	Oral - gavage
Species observed	Rat - Sprague-Dawley
Dose	250 500 1000 mg.(kg bw)-1.d-1
Duration	90 days
Observations	NOAEL systemic = 300 mg.(kg bw)-1.d-1 ; NOAEL local = 150 mg.(kg bw)-1.d-1
Additional Notes	other: local irritative effects at the side of application (forestomach gastritis), judged as not relevant to humans due to significant different anatomic situation and exposure probability in humans Test substance : 30% concentration

Type of test	OECD Guideline 428 (Skin Absorption: in vitro Method)
Route of exposure	
Species observed	Human - female - skin sample
Dose	
Duration	48 hr
Observations	1 mg.cm-2 ; Mean Penetration = 0.1% ; Permeation Papp = 0%
Additional Notes	

Conclusion	It is believed that Cocamidopropyl Betaine is safe for use in Charcoal Detox Soap at this concentration and use as described, assuming the parameters stated.

Chemical Name	Sodium Chloride
Function	Viscosity Modifier, Abrasive
INCI Name	Sodium Chloride
CAS	7647-14-5
EINECS	231-598-3
SED(adult)	0.409979 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	10000 mg.(kg bw)-1.d-1
Dermal penetration factor	1
MoS(adult)	24391.49
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	None

Type of test	LD50
Route of exposure	Oral
Species observed	Mouse
Dose	Acute: 3000 (mg/kg bw)
Duration	
Observations	
Additional Notes	

Type of test	LD50
Route of exposure	Dermal
Species observed	Rabbit
Dose	Acute: 1000 (mg/kg bw)
Duration	
Observations	
Additional Notes	

Type of test	LC50
Route of exposure	Inhalation
Species observed	Rat
Dose	>42 gm/m3/hour
Duration	
Observations	
Additional Notes	

Type of test	LD50
Route of exposure	Oral
Species observed	Mouse
Dose	Acute: 3000 (mg/kg bw)
Duration	
Observations	
Additional Notes	

Type of test	LD50
Route of exposure	Dermal
Species observed	Rabbit
Dose	Acute: 1000 (mg/kg bw)
Duration	
Observations	
Additional Notes	

Type of test	LC50
Route of exposure	Inhalation
Species observed	Rat
Dose	>42 gm/m3/1H
Duration	
Observations	
Additional Notes	

Type of test	Acute Toxicity
Route of exposure	Dermal
Species observed	Rabbits
Dose	10000 mg.(kg bw)-1
Duration	
Observations	LD50 > 10000 mg.(kg bw)-1
Additional Notes	

Conclusion	It is believed that Sodium Chloride is safe for use in Charcoal Detox Soap at this concentration and use as described, assuming the parameters stated.

Chemical Name	Trisodium citrate
Function	Buffering, Chelating
INCI Name	Sodium citrate
CAS	68-04-2
EINECS	200-675-3
SED(adult)	0.409979 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)	2439.149
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	Citrate salts are hydrolysed in vivo into citrate and their counterpart ion. NOAEL is nominal, as repeat dose studies are unjustified considering citrate is a natually occuring metabolic intermediate in the TCA cycle.
Conclusion	It is believed that Sodium citrate is safe for use in Charcoal Detox Soap at this concentration and use as described, assuming the parameters stated.

SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

Chemical Name	Cannabis Sativa (hemp) Seed Oil
Function	Emolient, skin conditioning
INCI Name	Cannabis Sativa (hemp) Seed Oil
CAS	8016-24-8
EINECS	289-644-3
SED(adult)	0.08655738 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	1
MoS(adult)	57765.15
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	Hempseed oil is a fixed oil from the cannabis cultivated and processed to ensure it's THC is below permissible limits. The oil has an extensive history of safe use in foodstuffs spanning many centuries. No toxicological studies have been identified in the literature, other than those for its constituent fatty acids.
Conclusion	It is believed that Cannabis Sativa (hemp) Seed Oil is safe for use in Charcoal Detox Soap at this concentration and use as described, assuming the parameters stated.

Chemical Name	Activated charcoal
Function	Absorbant
INCI Name	Activated charcoal
CAS	7440-44-0
EINECS	931-328-0
SED(adult)	0.08655738 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)	11553.03
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	The responsible person must ensure compliance during procurement that EU purity criteria are met.

Type of test	OECD Guideline 423 (Acute Oral toxicity - Acute Toxic Class Method)
Route of exposure	Oral - gavage
Species observed	Rats - Wistar
Dose	2000 mg.(kg bw)-1
Duration	
Observations	LD50 > 2000 mg.(kg bw)-1. No deaths occured. Some reversible signs were observed including hunched posture and ruffled fur.
Additional Notes	

Type of test	OECD Guideline 404 (Acute Dermal Irritation / Corrosion)
Route of exposure	Dermal
Species observed	Rabbit - New Zealand White
Dose	500mg mg.(kg bw)-1
Duration	4hr with 72hr post-exposure observation
Observations	No signs of toxicity, dermal irritancy or corrosion occured.
Additional Notes	

Type of test	OECD Guideline 405 (Acute Eye Irritation / Corrosion) 2002
Route of exposure	Ocular
Species observed	Rabbit - New Zealand White
Dose	100 mg
Duration	24hr with 72hr post exposure observation
Observations	Non irritating
Additional Notes	The primary eye irritation potential of Steam Activated Carbon was investigated according to OECD test guideline no. 405. The test item was applied by instillation of 0.1 g into the left eye of each of 3 young adult New Zealand White rabbits. Scoring of irritation effects was performed approximately 1, 24, 48 and 72 hours after test item instillation. The mean score was calculated across 3 scoring times (24, 48 and 72 hours after instillation) for each animal for corneal opacity, iris, redness and chemosis of the conjunctivae, separately. The individual mean scores for corneal opacity and iris light reflex were 0.00 for all three animals. The individual mean scores for the conjunctivae were 0.67, 0.67 and 0.67 for reddening and 0.33, 0.00 and 0.33 for chemosis. The instillation of Steam Activated Carbon into the eye resulted in mild, early-onset and transient ocular changes, such as reddening of the conjunctivae and sclerae, chemosis of the conjunctivae and ocular discharge. These effects were reversible and were no longer evident 72 hours after treatment, the end of the observation period for all animals. No abnormal findings were observed in the cornea or for the iris light reflex of any animals at any of the examinations. No corrosion was observed at any of the measuring intervals. No staining of the treated eyes by the test item was observed and no clinical signs were observed. Thus, the test item did not induce significant or irreversible damage to the rabbit eye.

Type of test	OECD Guideline 429 (Skin Sensitisation: Local Lymph Node Assay)
Route of exposure	Dermal
Species observed	Mouse
Dose	0, 5, 10, 25 %
Duration	
Observations	Non sensitizing
Additional Notes	

Conclusion	It is believed that Activated charcoal is safe for use in Charcoal Detox Soap at this concentration and use as described, assuming the parameters stated.

Chemical Name	Melaleuca Alternifolia Leaf Oil
Function	Perfuming
INCI Name	Melaleuca Alternifolia Leaf Oil
CAS	85085-48-9 (Biorigins)
EINECS	285-377-1
SED(adult)	0.07357377 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)	16310.16
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

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

Type of test	TDLo
Route of exposure	Oral
Species observed	Human - child
Dose	500 uL/kg
Duration	
Observations	Hallucinations, distorted perceptions & ataxia
Additional Notes	

Type of test	Dermal irritancy
Route of exposure	Dermal
Species observed	Rabbit - New Zealand White
Dose	0.5 ml
Duration	
Observations	Draize Irritation Index = 5.0. Severe irritant
Additional Notes	

Type of test	Dermal irritancy
Route of exposure	Dermal
Species observed	Rabbit
Dose	25 % in paraffin oil
Duration	30d
Observations	Minor irritations declined. Some histopathological changes observed.
Additional Notes	

Type of test	OECD Guideline 404 (Acute Dermal Irritation / Corrosion)
Route of exposure	Dermal - semiocclusive
Species observed	Rabbit
Dose	
Duration	
Observations	12.5% and 25% tea tree oil was not irritating. 50% was minimally irritating. 75% was slightly irritating. 100% triggered irritation within 24hr.
Additional Notes	

Type of test	Dermal irritation - patch test
Route of exposure	Dermal - Occlusive
Species observed	Human - 25 volunteers
Dose	0 3.8 8 12 16 19.9 24 and 28.1 % in soft white paraffin
Duration	21d
Observations	No skin irritation observed. 3/28 exhibited an allergic response.
Additional Notes	

Type of test	Eye Irritancy Potential - HET-CAM Assay
Route of exposure	In vitro
Species observed	Hen - Chorioallantoic membrane
Dose	100 mg.egg-1
Duration	
Observations	Mean irritation index = 16.1. Severely irritating.
Additional Notes	

Type of test	Dermal sensitization
Route of exposure	Dermal
Species observed	Human - 151 subjects
Dose	
Duration	
Observations	3/150 subjects showed sensitization to tea tree oil
Additional Notes	On day 1, 100 µl of the respective product was placed in Finn chambers onto the upper arm or the back. After 48 h the chambers were removed and the skin was assessed. If needed, the volunteers returned 48 h later for a further assessment. Skin reaction was assessed on a 5-graded scale. The test products were applied to the skin 9 times over a 3 week period and any response for irritancy was recorded (induction). After a 2 week rest phase the products were applied on a new site (challenge). 2 days later and - if necessary - again after 4 days the skin reaction was assessed. Any doubtful results were repeated 2 weeks later.

Conclusion

It is believed that Melaleuca Alternifolia Leaf Oil is safe for use in Charcoal Detox Soap at this concentration and use as described, assuming the parameters stated.

Chemical Name	Cocos Nucifera Oil
Function	Emollient
INCI Name	Cocos Nucifera Oil
CAS	8001-31-8
EINECS	232-282-8
SED(adult)	0.0004965364 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)	3.30288e+007
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 Charcoal Detox Soap at this concentration and use as described, assuming the parameters stated.

Chemical Name	1,2,3-Propanetriol, homopolymer, (Z)-, 9-octadecenoate
Function	Emulsifying
INCI Name	Polyglyceryl-4 Oleate
CAS	9007-48-1 / 71012-10-7
EINECS	N/A
SED(adult)	0.0409979 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	300 mg.(kg bw)-1.d-1
Dermal penetration factor	1.0
MoS(adult)	7317.448
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	The toxicological profile was obtained from a category read across from similar Polyglyceryl-4 esters.

Type of test	OECD Guideline 422 (Combined repeated dose toxicity with the reproduction/developmental screening test)
Route of exposure	Oral - gavage
Species observed	Rat - Wistar
Dose	0 100 300 1000 mg.(kg bw)-1.d-1
Duration	
Observations	NOAEL male = 300 mg.(kg bw)-1.d-1 ; NOAEL females = 1000 mg.(kg bw)-1.d-1
Additional Notes	Test substance: 1,2,3-propanetriol, homopolymer, diisooctadecanoate in corn oil. Initially, the groups consisted of 12 males and 12 females. However, because a disturbance of the light/dark cycle was believed to cause a reduction in mating rate of the females of the first delivery, additional male and female rats were added in a second delivery for breeding in order to meet guideline requirements concerning number of gravid females per group. The additional animals were used in the whole study as the animals from the first delivery, with the exception that the males went to necropsy on day 24 after mating, and not on day 16 of mating as the males of the first delivery. Therefore, Polyglyceryl-3 Diisostearate was administered to male rats for up to 28 days (first delivery) and up to 41 days (second delivery) and to female rats for 14 days prior to mating, through the mating and gestation periods, and until the F1 generation reached day 4 post-partum. Because an impact cause by the light/dark cycle disturbance could not be excluded (i.e., a prolonged duration of gestation and an increased post-implantation loss in the high dose), the study was repeated with a third delivery with control and high-dose groups under proper light conditions. The test article was administered to 12 male rats/group for 33 days and to 12 female rats/group for 14 days prior to mating, through the mating and gestation, and until day 4 post-partum. No adverse effects on body weights and body weight gains, feed consumption, hematology, clinical chemistry, neurobehavior, or gross or microscopic lesions were observed. Statistically significantly increases in absolute and relative liver and kidney weights in males and females of the 1000 mg/kg bw/day, were not considered adverse effects because there was no evidence for an impairment of organ function by clinical pathology and histopathology. Additionally, increases in the absolute and relative heart weights in high-dose females were without histopathological correlation and considered to be incidental.

Type of test	Genotoxicity - Review
Route of exposure	In vitro
Species observed	S Typhimurium - TA98 TA100 TA102 TA1535 TA1537 ; V79
Dose	
Duration	
Observations	Unlikely to be genotoxic
Additional Notes	Test substances: Polyglyceryl-2 Oleate, Polyglyceryl-2 Diisostearate, and 1,2,3-propanetriol, homopolymer, diisooctadecanoate were not genotoxic in Ames, mammalian cell gene mutation assay, or chromosomal aberration assay, with or without metabolic activation. Polyglyceryl-10 Laurate (~60% pure) gave equivocal results in the absence and positive results in the presence of metabolic activation when tested at concentrations up to 125 and 2250 µg/ml, respectively, in a chromosomal aberration assay using Chinese hamster V79 cells, but was not clastogenic in a chromosomal aberration assay in human peripheral lymphocytes, with or without activation.

Type of test	Genotoxicity - Predictive
Route of exposure	In silico
Species observed	
Dose	
Duration	
Observations	EFSA opinion that the impurities of polyglycerol fatty acid esters, i.e. free fatty acids and their esters, have no structural alerts for genotoxicity.
Additional Notes	

Type of test	OECD Guideline 453 (Combined Chronic Toxicity/Carcinogenicity Studies)
Route of exposure	Oral - diet
Species observed	Rat
Dose	5 % of diet
Duration	2 years
Observations	No evidence of carcinogenic risk from the test substance
Additional Notes	Test substance: polyglycerol ester No adverse effects on body weight, feed consumption, hematology values, or survival rate were noted. Liver function tests and renal function tests performed at 59 and 104 weeks were comparable between the test group and a control group fed 5% ground nut oil. The carcass fat contained no polyglycerol, and the levels of free fatty acid, unsaponifiable residue and fatty acid composition of carcass fat were not different from the controls. Organ weights, tumor incidence and tumor distribution ware similar in control and test groups. A complete histological examination of major organs showed nothing remarkable.

Type of test	Sensitization - Buehler test
Route of exposure	Intradermal induction ; Epicutaneous challenge (occlusive)
Species observed	Guinea pig
Dose	100% induction ; 20% challenge
Duration	
Observations	Non sensitizing. Non to slightly irritating.
Additional Notes	In rabbits, undiluted Polyglyceryl-3 Diisostearate and 1,2,3-propanetriol, homopolymer, diisooctadecanoate were not irritating to skin, and Polyglyceryl-2 Diisostearate was slightly irritating. Test substance: Polyglyceryl-2 Diisostearate

Type of test	Eye irritation - HET CAM - Read Across
Route of exposure	In vitro
Species observed	Hen - chorioallantoic membrane
Dose	30-40%
Duration	
Observations	Non irritating.
Additional Notes	Test substance: polyglyceryl-4 Laurate and Polyglyceryl-2 Dioleate emulsions.
Conclusion	It is believed that Polyglyceryl-4 Oleate is safe for use in Charcoal Detox Soap at this concentration and use as described, assuming the parameters stated.

Chemical Name	Butanedioic Acid, Sulfo-, Trisodium Salt
Function	Buffering, Chelating, Hydrotrope, Surfactant
INCI Name	Trisodium Sulfosuccinate
CAS	13419-59-5
EINECS	236-524-3
SED(adult)	0.0409979 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	400 mg.(kg bw)-1.d-1
Dermal penetration factor	1.0
MoS(adult)	9756.597
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	The toxicological profile of this was category read across from diethylhexyl sodium sulfosuccinate and other monoester sulfosuccinates found by CIR to be comparable in structure and function. Contact with eyes should be avoided.

Type of test	Acute Oral Toxicity
Route of exposure	Oral
Species observed	Mice - ARS/ICR
Dose	2640 mg.(kg bw)-1
Duration	
Observations	LD50 oral
Additional Notes	

Type of test	Acute Oral Toxicity
Route of exposure	Oral
Species observed	Guinea pig
Dose	650 mg.(kg bw)-1
Duration	
Observations	LD50 oral
Additional Notes	

Type of test	Acute Dermal Toxicity (Occluded)
Route of exposure	Dermal
Species observed	Rabbit - New Zealand White
Dose	10000 mg.(kg bw)-1
Duration	
Observations	LD50 > 10g.(kg bw)-1
Additional Notes	

Type of test	Repeat dose toxicity
Route of exposure	Oral - diet
Species observed	Rat - Wistar Albino
Dose	1 % diet
Duration	90d
Observations	No evidence of toxicity
Additional Notes	

Type of test	Repeat dose toxicity
Route of exposure	Oral - diet
Species observed	Rat
Dose	0, 0.5, 1.04, or 1.5 % diet
Duration	26wk
Observations	One third of the 1.5% group died, two from hemoragic gastroenteritis. NOAEL = 0.5% diet. LOAEL = 1.04%
Additional Notes	

Type of test	Repeat dose toxicity
Route of exposure	Oral
Species observed	Dog - Beagle
Dose	30 mg.(kg bw)-1.d-1
Duration	1yr
Observations	No adverse effects were observed. NOAEL > 30 mg.(kg bw)-1.d-1
Additional Notes	

Type of test	Irritancy
Route of exposure	Ocular
Species observed	Rabbit
Dose	100 mg
Duration	24, 48, and 72hr observations.
Observations	Scored at 11.66, 12.50, and 4.16 after 24, 48 and 72hr respectively. No distructive or irreversible changes observed.
Additional Notes	

Type of test	Irritancy
Route of exposure	Ocular
Species observed	Rabbit
Dose	10 %
Duration	2 seconds
Observations	Severe irritation, including perforation damage.
Additional Notes	

Type of test	Reproductive toxicity
Route of exposure	Oral - gavage
Species observed	Mice and Rats
Dose	0, 16, 80, 400 mg.(kg bw)-1 of 0.4% w/v
Duration	dosed d6-15 of gestation
Observations	NOAEL maternal and developmental = 400 mg.(kg bw)-1 of 0.4% w/v
Additional Notes	

Type of test	Skin sensitization
Route of exposure	Dermal
Species observed	Human (100 subjects)
Dose	0.3g of 2.5%
Duration	
Observations	Irritant but not a sensitizer.
Additional Notes	The following observations were made: Mild erythema in 11 subjects on days 3-10 and in 1 subject on days 3-7; mild erythema on all days except day 7 and intense erythema on day 7 in one subject; mild erythema on days 3-6/7 followed by intense erythema on days 6/7-10 in 6 subjects. No reactions were observed at challenge.

Conclusion	It is believed that Trisodium Sulfosuccinate is safe for use in Charcoal Detox Soap at this concentration and use as described, assuming the parameters stated.

Chemical Name	2-hydroxypropane-1,2,3-tricarboxylicacid
Function	p H Adjusting
INCI Name	Citric Acid
CAS	77-92-9
EINECS	201-069-1
SED(adult)	0.0409979 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)	29269.79
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	

Type of test	Chronic oral toxicity
Route of exposure	Oral
Species observed	Rats
Dose	1200 mg/kg bw/day
Duration	
Observations	Changes in blood chemistry parameters and metal absorption / excretion kinetics were the primary toxicodynamic mechanisms identified.
Additional Notes	

Type of test	Reprotoxicity : 2 generational
Route of exposure	Oral
Species observed	Rats
Dose	1.2% dietary citric acid over 90 weeks.
Duration	
Observations	No harmful effects identified other than slight maternal dental attrition.
Additional Notes	

Type of test	Developmental
Route of exposure	Oral
Species observed	Rats
Dose	241 mg/kg bw/day from day 6-25 of pregnancy
Duration	
Observations	No adverse effects
Additional Notes	

Type of test Genotoxicity : Bacterial
Route of exposure
Species observed Salmonella typhimurium
Dose
Duration
Observations Non mutagenic in 4 strains with and without metabolic activation
Additional Notes

Type of test Genotoxicity : Mammalian In Vivo
Route of exposure Oral
Species observed Rats
Dose 3g/kg bw/day
Duration
Observations
Additional Notes

Type of test Sensitization
Route of exposure
Species observed Humans
Dose
Duration
Observations Low sensitizing potential
Additional Notes

Type of test Skin irritation
Route of exposure Topical
Species observed Rabbit
Dose 0.5ml 30% aq solution for 4hr under occlusive patch
Duration
Observations No irritation in intact skin, well defined effects in abraded skin.
Additional Notes

Type of test Standard Draize
Route of exposure Ocular
Species observed Rabbits
Dose 500mg/24hr
Duration
Observations Mild irritation
Additional Notes

Type of test	Standard Draize
Route of exposure	Ocular
Species observed	Rabbits
Dose	30 minute irrigation with 0.5% aq solution caused irreversible cloudiness and opacification
Duration	
Observations	Mild irritation
Additional Notes	
Conclusion	It is believed that Citric Acid is safe for use in Charcoal Detox Soap at this concentration and use as described, assuming the parameters stated.

Chemical Name	Mentha Piperita Oil
Function	Perfuming
INCI Name	Mentha Piperita Oil
CAS	8006-90-4 (Biorigins)
EINECS	282-015-4
SED(adult)	0.02596721 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	300 mg.(kg bw)-1.d-1
Dermal penetration factor	1
MoS(adult)	11553.03
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	Peppermint Oil is used at a concentration of < or = 3% in rinse-off formulations and < or = 0.2% in leave on formulations. Peppermint Oil is composed primarily of menthol and menthone. Other possible constituents include pulegone, menthofuran, and limone. Most of the safety test data concern Peppermint Oil. The oil is considered to present the "worst case scenario" because of its many constituents, so data on the oil were considered relevant to the entire group of ingredients. Peppermint Oil was minimally toxic in acute oral studies. Short-term and sub-chronic oral studies reported cystlike lesions in the cerebellum in rats that were given doses of Peppermint Oil containing pulegone, pulegone alone, or large amounts (>200 mg/kg/day) of menthone. Pulegone is also a recognized hepatotoxin. Repeated intradermal dosing with Peppermint Oil produced moderate and severe reactions in rabbits, although Peppermint Oil did not appear to be phototoxic. Peppermint Oil was negative in the Ames test and a mouse lymphomamutagenesis assay but gave equivocal results in a Chinese hamster fibroblast cell chromosome aberration assay. In a carcinogenicity study of toothpaste and its components, no apparent differences were noted between mice treated with Peppermint Oil and those treated with the toothpaste base. Isolated clinical cases of irritation and/or sensitization to Peppermint Oil and/or its constituents have been reported, but Peppermint Oil (8%) was not a sensitizer when tested using a maximization protocol. It was expected that dermal absorption of Peppermint Oil would be rapid, following that of menthol, a major component, but in no case would be greater than absorption through the gastrointestinal tract. Because of the toxicity of pulegone, the safe concentration of this constituent was limited to < or = 1%. This concentration was achievable both by controlling the time of harvest and processing technique. There is evidence that menthol can enhance penetration of other agents. Formulators were cautioned that this enhanced penetration can affect the use of other ingredients whose safety assessment was based on their lack of absorption. With the limitation that the concentration of pulegone in these ingredients should not exceed 1%, it was concluded that Mentha Piperita (Peppermint) Oil, Mentha Piperita (Peppermint) Extract, Mentha Piperita (Peppermint) Leaves, Mentha Piperita (Peppermint) Water are safe as used in cosmetic formulations.

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

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

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

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

Type of test	OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents)
Route of exposure	Oral
Species observed	Rat
Dose	0, 10, 40, and 100 mg.(kg bw)-1.d-1
Duration	90 day
Observations	NOAEL oral = 40 mg.(kg bw)-1.d-1
Additional Notes	At the highest dose histopathological changes consisting of cyst-like spaces scattered in the white matter of cerebellum were seen. No other signs of encephalopathy were observed. Nephropathy was seen in the male rats in the highest dose group. A no-observed-adverse-effect level of 40 mg/kg body wt. per day was determined.

Type of test	Repeat dose
Route of exposure	Oral
Species observed	Rat
Dose	80 160 mg.(kg bw)-1.d-1
Duration	28 days
Observations	
Additional Notes	Test substance: Pulegone Atonia, weight loss, decreased blood creatinine, content, and histopathological changes in the liver and the white matter of the cerebellum.

Type of test	Dermal irritation and sensitization - Single insult patch test
Route of exposure	Dermal ; Occluded
Species observed	Human - 380 eczema patients
Dose	1 %
Duration	48hr exposure
Observations	No adverse effects observed
Additional Notes	

Type of test	Mucous membrane sensitivity
Route of exposure	
Species observed	
Dose	
Duration	
Observations	
Additional Notes	Occasional reports of oral mucous membrane sensitivity to peppermint oil and menthol either on contact (Morton et al 1995) or after excessive prolonged use (Rogers & Pahor 1995; Fleming & Forsyth 1998). In each case, a burning sensation, ulceration and inflammation were the result. These reactions are excessively rare given peppermint's widespread use in dental hygiene products.

Type of test	Phototoxicity & Photosensitization
Route of exposure	Dermal
Species observed	Mice - Hairless & Swine - Miniture
Dose	100 %
Duration	96hr post irradiation observation
Observations	No treatment related adverse effects noted.
Additional Notes	Test substance: Undiluted Peppermint Oil Irradiation intensity: 60min with integrated UVA of 3 W/m2, or 40 minutes with light from a Xenon Lamp at a weighted erythema energy of 0.1667 W/m2.

Type of test	OECD Guideline 476 (Mouse Lymphoma)
Route of exposure	In vitro
Species observed	Mice - L5178Y lymphoma cell
Dose	150 mcg.ml-1
Duration	
Observations	Negative for genotoxicity.
Additional Notes	

Type of test	OECD Guideline 482 (Unscheduled DNA Synthesis in Mammalian Cells in vitro)
Route of exposure	In vitro
Species observed	Rat - hepatocyte
Dose	155 mcg
Duration	
Observations	Negative for genotoxicity.
Additional Notes	

Conclusion	It is believed that Mentha Piperita Oil is safe for use in Charcoal Detox Soap at this concentration and use as described, assuming the parameters stated.

Chemical Name	1,3-Benzenediol, 2-[(1R,6R)-3-methyl-6-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-
Function	Antioxidant, Skin conditioning
INCI Name	Cannabidiol
CAS	13956-29-1
EINECS	N/A
SED(adult)	0.001731148 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	100 mg.(kg bw)-1.d-1
Dermal penetration factor	1.0
MoS(adult)	57765.15
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	The use of this component is not subject to Annex II/306 (Narcotics, natural and synthetic: All substances listed in Tables I and II of the single Convention on narcotic drugs signed in New York on 30 March 1961) as it is not listed in the convention. No evidence of any adverse localised (dermal nor ocular) reactions were identified in the literature. This component is present in existing topical formulations on the market, and has been present in foodstuffs that were on sale within the EU. The responsible person must ensure this components purity during procurement and manufacture, and ensure compliance with Annex II/306. The extreme hydrophobicity of the cannabinoids make crossing the aqueous layer of the skin's viable tissue the rate-limiting step in the diffusion process (Scheuplein & Blank 1973; Challapalli & Stinchcomb 2002).

Type of test	Mutagenicity
Route of exposure	Intraperitoneal
Species observed	Rat - Wistar Kyoto
Dose	120 mg.(kg bw)-1
Duration	
Observations	No mutagenicity and genotoxicity observed.
Additional Notes	

Type of test	Repeat dose
Route of exposure	Oral
Species observed	Human - children - 25 subjects
Dose	5-25 mg.(kg bw)-1.d-1
Duration	8 weeks
Observations	
Additional Notes	An 8-week-long clinical study, including 13 children who were treated for epilepsy with clobazam (initial average dose of 1 mg/kg b.w.) and CBD (oral; starting dose of 5 mg/kg b.w. raised to maximum of 25 mg/kg b.w.). Side effects observed in 77% of subjects, but were alleviated with clobazam dose reduction.

Type of test	Repeat dose
Route of exposure	Oral
Species observed	Human - adults
Dose	1280 mg.d-1
Duration	28 days
Observations	NOAEL = 20 mg.(kg bw)-1.d-1. No side effects noted.
Additional Notes	

Type of test	Genotoxicity
Route of exposure	
Species observed	
Dose	
Duration	
Observations	
Additional Notes	This cannabinoid was studied for their DNA-damaging properties in human-derived cell lines under conditions which reflect the exposure of consumers. Both compounds induced DNA damage in single cell gel electrophoresis (SCGE) experiments in a human liver cell line (HepG2) and in buccal-derived cells (TR146) at low levels (≥ 0.2 µM). Results of micronucleus (MN) cytome assays showed that the damage leads to formation of MNi which reflect chromosomal aberrations and leads to nuclear buds and bridges which are a consequence of gene amplifications and dicentric chromosomes. Additional experiments indicate that these effects are caused by oxidative base damage and that liver enzymes (S9) increase the genotoxic activity of both compounds. Our findings show that low concentrations of CBD and CBDV cause damage of the genetic material in human-derived cells. Furthermore, earlier studies showed that they cause chromosomal aberrations and MN in bone marrow of mice. Fixation of damage of the DNA in the form of chromosomal damage is generally considered to be essential in the multistep process of malignancy, therefore the currently available data are indicative for potential carcinogenic properties of the cannabinoids.

Type of test	Repeat dose (Pre OECD)
Route of exposure	Oral - gavage
Species observed	Monkey - Rhesus
Dose	30 100 300 mg.(kg bw)-1.d-1
Duration	90 days
Observations	No clear dose-dependent toxicologically relevant changes, except for significantly lower relative testicular-to-brain weights in the high-dose group and inhibition of spermatogenesis in all treated male monkeys.
Additional Notes	90-day repeated-dose study conducted by Rosenkrantz et al. (1981) in Rhesus monkeys [15]. This study was conducted prior to the adoption of Organisation of Economic Cooperation and Development (OECD) guidelines for 90-day repeated dose oral toxicity studies (1981) and OECD Good Laboratory Practice (GLP) standards (1992). Four monkeys/sex/group received nearly pure CBD by gavage at doses of 30, 100, and 300 mg/kg bw/day for 90 days. The study results showed no clear dose-dependent toxicologically relevant changes, except for significantly lower relative testicular-to-brain weights in the high-dose group and inhibition of spermatogenesis in all treated male monkeys. Limitations of the study include the involvement of male monkeys at various stages of sexual maturity and unreported ages of the animals.

Type of test	OECD Guideline 473 (In Vitro Mammalian Chromosome Aberration Test)
Route of exposure	In vitro
Species observed	Chinese Hamster Lung V79
Dose	50 70 90 and 10 20 30 (with and without activation respectivly) mcg.ml-1
Duration	
Observations	The test article did not induce an increase in the number of cells with aberrations or rates of polyploidy or endoreduplicated metaphases at concentrations ranging from 10 to 90 µg/mL. There were no statistically significant differences between treatment and the solvent control groups, and no dose-response relationships were noted
Additional Notes	Test substance : O2 supercritical extract

Type of test	OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test)
Route of exposure	Oral - gavage
Species observed	Mice - Crl:NMRI BR - Male
Dose	500 1000 2000 mg.(kg bw)-1
Duration	
Observations	
Additional Notes	Adverse reactions to treatment were not observed in the positive controls, in negative controls, or in the 500 mg/kg bw group. A moderate decrease in activity, moderate restlessness, and slight/moderate irritability were observed in the 10 male mice treated with 1000 and 2000 mg/kg bw of the test article on the day of treatment. The mice did not exhibit any symptoms 24 and 48 hours after treatment. Because there was no mortality, bone marrow slides were not prepared on the two extra animals included in the high-dose group. No significant differences were observed in frequency of MPCEs between the three dose groups compared to the negative control, and all results were within the laboratory's historical control range (see Table 4). Compared to the negative control group, the numbers of PCEs at 24- and 48-hour sampling times in the 500 and 1000 mg/kg bw groups were similar. In the 2000 mg/kg bw dose group, the number of PCEs was slightly decreased compared to the negative control group at the 24- and 48-hour sampling time points. The effect was not biologically significant but demonstrated exposure of the bone marrow to the test article. A large, statistically significant increase in MPCE frequency was observed in the positive control group compared to negative control. The cyclophosphamide-treated mice had MPCE counts that were slightly higher (61.40/2000 PCE) than historical controls (54.03/2000 PCE) but this deviation did not influence the quality or integrity of the study

Type of test	OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents)
Route of exposure	Oral - gavage
Species observed	Rat - Hsd.Han Wistar - Male
Dose	0, 100, 360, and 720 mg.(kg bw)-1.d-1
Duration	90 days
Observations	
Additional Notes	No deaths occurred in any dose groups throughout the main study period (0, 100, 360, and 720 mg/kg bw/day) or during the satellite groups recovery period (0 and 720 mg/kg bw/day (high dose)). No abnormal clinical signs were seen in either sex of the control group or in males of the 100 mg/kg bw/day group. In one female at 100 mg/kg bw/day, sanguineous fur around the eyes was detected between days 39 and 42. Clinical signs were observed in all animals in the 360 and 720 mg/kg bw/day groups. Nuzzling up the bedding material occurred in the 360 mg/kg bw/day group from day 20 or 21 up to the end of the treatment period. In the 720 mg/kg bw/day groups, nuzzling up the bedding material and restlessness were observed throughout the study. Salivation occurred in males (= 7) and females (= 4) of the 720 mg/kg bw/day shortly after administration of the test article during the first four weeks of the study. No further signs were found in detailed clinical observations in any dose group. No alterations in behavior or in reactions to various stimuli were noted in the FOB (data not shown). No clinical signs were observed in the satellite groups during the recovery period. Significant decreases in body weight were detected in males in the 360 and 720 mg/kg bw/day groups and in females in the 720 mg/kg bw/day group as compared to controls (see Table 7). In the high-dose satellite group, these differences did not return to normal during the recovery period, although mean body weight gain was higher than controls in males from day 96 to the end of the recovery period with statistical significance between days 96–103 and days 110–117 (see Table 8). Body weight gain was not significantly affected in animals in the 100 mg/kg bw/day group, with the exception of a lower mean body weight gain in male animals between days 70 and 77, which did not correlate with a difference in mean body weight on day 77. However, similar to body weight, body weight gain was significantly lower with respect to the control group in males of the 360 mg/kg bw/day group and males and females in the 720 mg/kg bw/day group, although the mean body weight gain of females in the 720 mg/kg bw/day slightly exceeded control values between days 17 and 21. Food consumption was significantly decreased compared to controls in males and females in the 360 and 720 mg/kg bw/day treatment groups from week 1 until the end of the treatment period, correlating with body weight differences (see Table 9). These differences also did not fully return to normal in the high-dose satellite group during the recovery period. Lower mean food consumption compared to controls was noted sporadically in males and females in the 100 mg/kg bw/day group. Statistically significant lower mean food consumption compared to controls was also noted in high-dose satellite animals in recovery week 1 (male) and in recovery weeks 1 and 4 (females). Slight, sporadic, yet statistically significant differences were noted in feed efficiency in all treatment groups (data not shown). Upon necropsy, enlarged and pale adrenal glands were noted in male (5/10) and female (7/10) animals in the 720 mg/kg bw/day group. Mottled surface of the kidneys was also noted in one male (1/10) in the 100 mg/kg bw/day group and in two females (1/10 in the 100 mg/kg bw/day group and 1/10 in the 360 mg/kg bw/day group). Slight or moderate hydrometra of the uterus was observed in some females (4/10 in the control group, 2/10 in the 100 mg/kg bw/day group, and 2/10 in the 720 mg/kg bw/day group). At the end of the recovery period, no macroscopic findings were noted in satellite group males. In satellite group females, slight or moderate hydrometra was observed in both control and high-dose groups (3/5 and 1/5, resp.). Total sperm count, sperm morphology, and percentage of motile and immotile sperm cells were similar in the control and 720 mg/kg bw/day groups at the end of the treatment period. Therefore, no sperm examinations were conducted during the recovery period. Histopathological examination revealed mild-to-moderate diffuse cytoplasmic vacuolation of the cortical cells of the adrenal glands (involving the zona fasciculata and zona reticularis) in male (6/10) and female (8/10) animals of the 720 mg/kg bw/day group, although these lesions were not detected in satellite groups at the end of the recovery period

SUPER ACTIVE COSMETICS
THE FUTURE OF COSMETICS

Type of test	ADME - Dermal penetration
Route of exposure	In vitro
Species observed	Human - skin sample
Dose	
Duration	
Observations	
Additional Notes	Mean flux [nmol.cm-2] = 1.40 Permeability [x10-5 cm.hr-1] = 24 Skin conc. [mmol.(g skin)-1] = 19.4
Conclusion	It is believed that Cannabidiol is safe for use in Charcoal Detox Soap 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)	0.001463252 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)	341704.5
MoS(child)	N/A
MoS(baby)	N/A
Additional Notes	The presence of the substance must be indicated in the list of ingredients referred to in Article 6(1)g when its concentration exceeds: - 0.001% in leave-on products - 0.01% in rinse-off products Peroxide value not to exceed less than 20 mmoles/L No information is available on the health effects of inhalation exposure to d-limonene in humans, and no long-term inhalation studies have been conducted in laboratory animals. NTP (1990) conducted a series of studies that investigated the toxicity of d-limonene (>99% pure) in both Fischer 344/N rats and B6C3F1 mice. In the first of the preliminary range-finding studies, doses ranging from 413-6600 mg/kg/day were administered by gavage in corn oil to five animals/species/sex/dose for 5 days/week for 16 days. All but 2/20 rats and 1/20 mice that were administered 3300 and 6600 mg/kg/day died. Body weight gain was reduced at 1650 mg/kg/day. No compound-related signs of toxicity were observed in those animals administered <1650 mg/kg/day. In the rabbit study, 10-18 pregnant Japanese white rabbits were administered 0, 250, 500, or 1000 mg/kg/day d-limonene by gavage on gestation days 6-18 (Kodama et al., 1977b). Exposure of does to 500 or 1000 mg/kg/day resulted in maternal toxicity. There were significant reductions in food consumption and body weight at both doses, and death also occurred in the 1000-mg/kg/day group. Developmental toxicity was not observed at any dose. This study is limited by the small sample size. No reproductive toxicity studies have been conducted on d-limonene. Igimi et al. (1974) studied the metabolism of d-limonene after oral administration and found that about 65% of the dose was recovered in urine, feces, and expired carbon dioxide, suggesting that the majority of an oral dose is absorbed. Although it is possible that an inhaled dose would also be largely absorbed, there is no information on inhalation exposures. Reproductive Toxicity: This product is not reported to produce reproductive toxicity in humans. Mutagenicity: This product is not reported to produce mutagenic effects in humans. Embryotoxicity: This product is not reported to produce embryotoxic effects in humans. Teratogenicity: This product is not reported to produce teratogenic effects in humans. Reproductive Toxicity: This product is not reported to produce reproductive effects in humans.

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

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

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

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 Charcoal Detox Soap at this concentration and use as described, assuming the parameters stated.

Chemical Name	3,7-Dimethylocta-1,6-diene-3-ol ; Linalool
Function	Perfuming
INCI Name	Linalool
CAS	78-70-6
EINECS	201-134-4
SED(adult)	2.131389e-005 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	0.144
MoS(adult)	9383553
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. Dermal penetration is reported by RIFM as 14.4% of the applied dose.

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	OECD Guideline 471 (Bacterial Reverse Mutaton Test)
Route of exposure	In vitro
Species observed	S Typhimurium - TA98 TA100 TA102 TA1535 TA1537 TA1538
Dose	
Duration	
Observations	Negative for genotoxicityq
Additional Notes	

Type of test	OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test)
Route of exposure	In vitro
Species observed	Rat
Dose	
Duration	
Observations	Negative for genotoxicityq
Additional Notes	

Type of test	Subchronic toxicity
Route of exposure	Dermal
Species observed	Rat
Dose	250 mg.(kg bw)-1.d-1
Duration	90 day
Observations	NOAEL dermal = 250 mg.(kg bw)-1.d-1. Reduced bodyweights observed at higher doses.
Additional Notes	

Type of test	Developmental toxicity
Route of exposure	Oral - gavage
Species observed	Rat - Sprague-Dawley
Dose	0, 250, 500, or 1000 mg.(kg bw)-1.d-1
Duration	Days 7-17 of gestation
Observations	NOAEL maternal = 500 mg.(kg bw)-1.d-1 ; NOAEL developmental > 1000 mg.(kg bw)-1.d-1
Additional Notes	There were no maternal deaths, clinical signs, or gross lesions that were considered related to linalool. During the dosage period, mean relative feed consumption was significantly reduced by 7% and mean body weight gains were reduced by 11% at 1000 mg/kg/day. During the postdosage period, feed consumption values at 1000 mg/kg/day were significantly higher than vehicle control values, which corresponded to the increase in body weight gains during this period. Caesarean section and litter parameters, as well as fetal alterations, were not affected by linalool at any of the three dosages tested. On the basis of these data, the maternal no observed adverse effect level (NOAEL) of linalool is 500 mg/kg/day, whereas the developmental NOAEL is > or = 1000 mg/kg/day. It is concluded that linalool is not a developmental toxicant in rats at maternal doses of up to 1000 mg/kg/day.

Type of test	Reproductive (Read Across: Dihydrolinalool)
Route of exposure	Oral - gavage
Species observed	Rat
Dose	750 mg.(kg bw)-1.d-1
Duration	
Observations	NOAEL reproduction males = 700 mg.(kg bw)-1.d-1 ; NOAEL reproduction females = 200 mg.(kg bw)-1.d-1
Additional Notes	Based on maternal clinical signs, decreased live birth index and viability.

Type of test	Dermal sensitization - Predictive
Route of exposure	
Species observed	
Dose	
Duration	
Observations	Linalool is not predicted to be directly reactive to skin proteins, however undergos auto-oxidation to products that are reactive.
Additional Notes	

Type of test	Dermal irritation and sensitization - Human Repeat Insult Patch Test
Route of exposure	Dermal ; Occluded
Species observed	Human
Dose	12.7 %
Duration	
Observations	No evidence of sensitization at maximum tested dose.
Additional Notes	

Type of test	Phototoxicity - predictive
Route of exposure	
Species observed	
Dose	
Duration	
Observations	Based on the UV/Vis spectra, linalool is not expected to be a phototoxicant
Additional Notes	
Conclusion	It is believed that Linalool is safe for use in Charcoal Detox Soap at this concentration and use as described, assuming the parameters stated.