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COSMETIC PRODUCT SAFETY REPORT

In accordance with Annex I, EC 1223/2009 and The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019

Report Number	240050-7 (243864)	**Date:**	16 September 2024
Product type:	Melt and pour soap	**Responsible person details:**	Joe D'Arcy, 20 Heron Road, Bristol, BS5 0LU, United Kingdom
Product name/code:	Tea Tree & Eucalyptus with Activated Charcoal		
Product category:	Solid soap – Rinse off	**Email address:**	

SUMMARY

The product(s) have been reviewed and according to the information submitted in this report the product complies with EU Regulation (EC) No 1223/2009 and its subsequent amendments to date. The product(s) have been reviewed and according to the information submitted in this report the product complies with The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 and its subsequent amendments to date. The ingredients in this product are used at levels that are consistent with industry norms.

It is my opinion that these cosmetic formulation(s) are considered safe to use under normal or reasonably foreseeable conditions of use. The assessment is conditional on the items outlined in section B.

Signed:

Laura Turnham, ERT, RSB CBiol, MSc

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PART A COSMETIC PRODUCT SAFETY INFORMATION

1. Quantitative and qualitative composition of the cosmetic product(s)

Product name: Tea Tree & Eucalyptus with Activated Charcoal soap

Ingredients	
INCI names	**% INCI**
Sodium Palmate	51.548194
Aqua	16.022973
Sodium Palm Kernelate	16.022973
Glycerin	6.866989
Butyrospermum Parkii Butter	5.085733
Kaolin	1.015482
Melaleuca Alternifolia Leaf Oil	1.015482
**********	**********
Rosmarinus Officinalis Leaf Oil	0.507741
Eucalyptus Globulus Leaf Oil	0.507741
Sodium Chloride	0.091560
Charcoal Powder	0.307974
Tetrasodium Glutamate Diacetate	0.457799
Citric Acid	0.091560
Sodium Citrate	0.457799

Additional labeling requirements In accordance with article 19, paragraph 1, letter g, of Regulation (EC) No. 1223/2009

Labeling allergens	
INCI names	**% INCI**
Limonene	0.086316

Non-labeling allergens	
INCI names	**% INCI**
Geraniol	0.000508
Linalool	0.005585

Total %: 100.000000

Allergen declarations above are based on the information on the date of submission. It is the duty of the Responsible Person to ensure that the ingredient and allergen declarations are correct on the label.

For the EU:
Cosmetic products containing additional allergens listed in COMMISSION REGULATION (EU) 2023/1545 will need to be declared on the labelling, when its concentration exceeds:
— 0,001 % in leave-on products

— 0,01 % in rinse-off products.

Products that do not comply with the restriction(s) may be placed on the Union market until 31 July 2026 and made available on the Union market until 31 July 2028. It is the duty of the Responsible Person when placing a cosmetic on sale in the EU to comply with this requirement by the implementation date.

2. Physical/chemical characteristics and stability of the cosmetic product

A product specification was not provided.

Product name:	Description
Tea Tree & Eucalyptus with Activated Charcoal soap	Solid soap with a characteristic fragrance.

The product was tested for stability in an in-house method. Stability data was not provided.

The responsible person must ensure that the product is sold with an appropriate expiry date.

There is a long history of stability of vegetable derived cold processed soaps. Stability is not expected to be a safety concern, provided that there is no excess lye in the formulation, and that the product is cured for a suitable length of time, typically 4-6 weeks. Rancidification of cold process soaps can occur under certain conditions, but it is a quality and aesthetic concern, not a safety concern.

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3. Microbiological quality

The product(s) is a low risk for microbiological growth as the product is a soap-based formulation with low water availability. The product is likely to provide an environment that would deny microorganisms the physical and chemical requirements for growth and survival.

According to the principles outlined in ISO 29621:2017 this product would be considered a low microbiological risk and does not require a microbiological challenge test.

A microbiological specification was not provided. It is the duty of the responsible person to ensure that the product complies with the microbiological specifications outlined by SCCS/1628/21:

Types of microorganisms	**Products specifically intended for children under three years of age, the eye area or the mucous membranes**	**Other products**
Total Aerobic Mesophilic Microorganisms (Bacteria plus yeast and mould)	≤100 CFU / g or mL[a]	≤1000 CFU / g or mL[b]
Escherichia coli	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
Pseudomonas aeruginosa	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
Staphyloccocus aureus	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
Candida albicans	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml

Due to inherent variability of the plate count method, according to USP Chapter 61 or EP Chapter 2.6.12, Interpretation of results, results considered out of limit if
a > 200 CFU/g or ml, b > 2 000 CFU/g or ml.

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4. Impurities, traces, information about the packaging material quality

Toxicologically relevant impurities of the raw materials will be discussed in Annex I.

The product may be placed in the following primary packaging:
Food safe pouches/wrap
Food safe cellophane
Wax paper
Paper
Cardboard

The product may be placed in the following secondary packaging:
Paper
Cardboard
Cloth bags (for example: bamboo, cotton, sisal).

The responsible person must ensure that the packaging is food or cosmetic grade.

The responsible person must ensure that the packaging is compatible with the product.

It is not expected that heavy metal impurities will be present in the raw materials in significant amounts. Therefore, heavy metals are expected to be below acceptable limits. According to Health Canada guidance (2012) "technically unavoidable" limits for cosmetics are considered to be:

Lead:	10 ppm
Arsenic:	3 ppm
Cadmium	3 ppm
Mercury	1 ppm
Antimony	5 ppm

5. Normal and reasonably foreseeable use

It is expected that consumers will moisten the bar with water, bring to a lather and wash their body with the soap, followed by rinsing.

It is foreseeable that consumers may also apply the product to their face followed by rinsing.

Should the product enter the eyes it is expected that the product will cause irritation. It is expected that consumers will be aware of this risk and should rinse their eyes should this occur.

Ingestion would be considered misuse and will not be covered in this report.

The Responsible Person must ensure that the product does not mimic foodstuffs in order to ensure consumer safety and to comply with local and regional laws/ regulations.

Inhalation is not expected as the product is not expected to generate respirable particles during use.

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6. Exposure to the cosmetic product

Product type:	Solid soaps		
Use per day (g)	2.60	Source:	US EPA Exposure Factors Handbook, 2011
Retention factor:	0.01		
Site of application:	Total body area		
Skin exposure (cm^2)	17500.00	Source:	SCCS Notes of Guidance, 12th Revision
IFRA 49th Amendment Class	9		
IFRA 49th Amendment Consumer Exposure Level Estimate $\mu g/cm^2/day$	200		
Frequency of application	3.0/day (US EPA Exposure Factors Handbook, 2011)		
Calculated relative daily exposure (mg/kg bw/day)	43.33		
Body weight (kg)	60.00	Default value	
IFRA QRA2 Aggregate Adjustment Factor	0.5		

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7. Exposure to the substances

Product type:	Solid soaps	NESIL=No Expected Sensitization Induction Level
Product use per day (g):	2.6000	AEL-Acceptable Exposure Level
Retention factor:	0.0100	CEL=Consumer Exposure Level
Skin exposure (cm2)	17500.0000	
Body weight	60.0000	

INCI Name	Tea Tree & Eucalyptus with Activated Charcoal Soap (% w/w)	CAS Number	EC Number	Function(s)	Restrictions	Maximum Level Present in Product(s) (% w/w)	Systemic Exposure Dose (mg/kg bw/day)	Point of Departure (mg/kg bw/day)	Margin of Exposure	Apply skin penetration data? (Tick applies skin penetration data on all ingredients)	Skin penetration (%)	Dermal exposure ug/cm2	NESIL	Safety Factor	AEL/CEL	Acceptable Exposure Level ug/cm2
Aqua	16.0230	7732-18-5	231-791-2	Solvent	N/A	16.02297	0.06943	No Data			100	0.238	No Data	300		
Butyrospermum Parkii (Butter	5.0857	194043-92-0 - 91080-23-8	293-515-7	Skin Conditioning, Viscosity Controlling	N/A	5.08573	0.02204	No Data			100	0.076	No Data	300		
Charcoal Powder	0.3080	16291-96-6; 7440-44-0 (generic)	240-383-3; 231-153-3	Abrasive, Absorbent, Opacifying	N/A	0.30797	0.00133	4500	3371913		100	0.005	No Data	300		
Citric Acid	0.0916	77-92-9 / 5949-29-1	201-069-1	Buffering, Chelating, Masking	N/A	0.09156	0.00040	1200	3024498		100	0.001	No Data	300		
Eucalyptus Globulus Leaf Oil	0.5077	8000-48-4 / 84625-32-1	- / 283-406-2	Perfuming, Skin Conditioning	N/A	0.50774	0.00220	300	136351		100	0.008	No Data	300		
Glycerin	6.8670	56-81-5	200-289-5	Denaturant, Hair Conditioning, Humectant, Oral Care, Perfuming, Skin Protecting, Viscosity Controlling	N/A	6.86699	0.02976	10000	336056		100	0.102	No Data	300		
Kaolin	1.0155	1332-58-7	310-194-1	Abrasive, Absorbent, Anticaking, Bulking, Cosmetic Colorant, Opacifying	IV/119	1.01548	0.00440	10000	2272509		100	0.015	No Data	300		
Melaleuca Alternifolia Leaf Oil	1.0155	85085-48-9 / 8022-72-8 / 68647-73-4	285-377-1 / - / -	Antioxidant, Perfuming	N/A	1.01548	0.00440	117	26588		100	0.015	No Data	300		
Rosmarinus Officinalis Leaf Oil	0.5077	84604-14-8 / 8000-25-7	283-291-9	Masking, Skin Conditioning	N/A	0.50774	0.00220	230	104535		100	0.008	No Data	300		
Sodium Chloride	0.0916	7647-14-5	231-598-3	Bulking, Masking, Oral Care, Viscosity Controlling	N/A	0.09156	0.00001	50	4200692		3	0.001	No Data	300		
Sodium Citrate	0.4578	68-04-2 / 6132-04-3	200-675-3	Buffering, Chelating, Masking	N/A	0.45780	0.00198	No Data			100	0.007	No Data	300		
Sodium Palm Kernelate	16.0230	61789-89-7	263-097-0	Cleansing, Emulsifying, Surfactant, Viscosity Controlling	N/A	16.02297	0.06943	1000	14402		100	0.238	No Data	300		
Sodium Palmate	51.5482	61790-79-2	263-162-3	Cleansing, Emulsifying, Surfactant, Viscosity Controlling	N/A	51.54819	0.22338	1000	4477		100	0.766	No Data	300		
Tetrasodium Glutamate Diacetate	0.4578	51981-21-6	257-573-7	Chelating	N/A	0.45780	0.00198	300	151225		100	0.007	No Data	300		
Limonene	0.0863	138-86-3	205-341-0/931-893-3	Deodorant, Perfuming, Solvent	III/88 III/167 III/168	0.08632	0.00000	150	250644323		0.16	0.001	10000	300	12996	16.67
Geraniol	0.0005	106-24-1	203-377-1	Perfuming, Tonic	III/78	0.00051	0.00000	300	136281042		100	0.000	11800	300	2605744	19.67
Linalool	0.0056	78-70-6	201-134-4	Deodorant, Perfuming	III/84	0.00559	0.00000	117	2843751646		0.17	0.000	15000	300	301288	25.00

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8. Toxicological profile of the substances

The raw materials in this product were from recognised cosmetic, food or pharmaceutical grade ingredient suppliers. The responsible person is responsible for retaining all Certificates of Analysis (COAs), Technical documentation, MSDSs and retaining the information for the Product Information File (PIF). IFRA and allergen statements must be kept up to date and retained in the PIF file by the responsible person.

Toxicological profiles of ingredients found in Annex I of this document. Technically unavoidable traces of prohibited or restricted chemicals are also addressed in Annex I.

9. Undesirable effects and serious undesirable effects

No reports of undesirable or serious undesirable effects have been submitted. In the event that adverse reaction(s) occur the responsible person should inform the safety assessor so that the safety assessment can be updated and reviewed.

10. Additional information on the cosmetic product

The product must be manufactured according to the principles of GMP (Good Manufacturing Practice). It is recommended that the product is manufactured according to the principles outlined in ISO 22716: 2007.

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PART B – COSMETIC PRODUCT SAFETY ASSESSMENT

1. Assessment conclusion

This product has been reviewed and according to the information submitted in this report. The product complies with EU Regulation (EC) No 1223/2009 and its subsequent amendments to date. The product has been reviewed and according to the information submitted in this report the product complies with The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 and its subsequent amendments to date.

This report has reviewed the following;

- Microbiological safety, stability and physicochemical status of the product
- Packaging.
- Toxicological impurities in the packaging materials/raw materials.
- Systemic toxicity.
- Developmental/reproductive toxicity.
- Carcinogenicity/mutagenicity.
- Allergy (Type I, IV).
- Skin and eye irritancy.
- Photosensitivity and photosensitisation.

The product is considered safe and unlikely to cause an unreasonable level of adverse effects if used under normal and reasonably foreseeable conditions.

2. Labelled warnings and instructions of use

Mandatory label requirements: None.

Non mandatory but advisable warning statement:

"If product enters the eyes, rinse well with clean water."

"Keep out of reach of children."

Directions for use:
Directions for use were not provided for review.

Warnings:
Warnings were not provided for review.

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3. Reasoning

The product has been reviewed and according to the information submitted in this report the product complies with EU Regulation (EC) No 1223/2009 and its subsequent amendments to date. The product has been reviewed and according to the information submitted in this report the product complies with The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 and its subsequent amendments to date. The ingredients in this product are used at levels that are consistent with industry norms.

The Responsible Person must ensure that the purity/impurity criteria for ingredients outlined in Annex I are adhered to.

The Responsible Person must ensure that the product is manufactured in accordance with GMP.

The Responsible Person is responsible for the maintenance of the PIF (Product Information File).

The product is considered safe and unlikely to cause an unreasonable level of adverse effects if used under normal and reasonably foreseeable conditions.

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4. Assessor's credentials and approval of part B

The product has been reviewed and according to the information submitted in this report the product complies with EU Regulation (EC) No 1223/2009 and its subsequent amendments to date.

The product has been reviewed and according to the information submitted in this report the product complies with The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 and its subsequent amendments to date

The ingredients in this product are used at levels that are consistent with industry norms.

It is my opinion that this cosmetic formulation is considered safe to use under normal or reasonably foreseeable conditions of use. The assessment is conditional on the items outlined in section B.

Signed:

Laura Turnham, ERT, RSB CBiol, MSc

Qualifications:

Safety assessment of cosmetics in the EU, VUB (University of Brussels), 2015, Pass

MSc Molecular Pathology and Toxicology, Leicester University (UK), 2011. Distinction.

BSc Biochemistry (Toxicology), University of Surrey, 2008, 2:1 (Hons).

Eurotox registered toxicologist (ERT).

UK Registered Toxicologist (UKRT).

Chartered Biologist (CBiol RSB).

Member of the Royal Society of Biology (MRSB).

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Annex I – Toxicological Ingredient Profiles

Ingredient Profile: Butyrospermum Parkii (Shea) Butter

CAS number:	91080-23-8 / 194043-92-0	**EC number:**	293-515-7 (I)
INCI Name:	Butyrospermum Parkii Butter		
Pseudonyms:	Butyrospermum Parkii (Shea) Butter, Karite Butter.		
Structure:	N/A	**Image:**	
CLP Hazard classification(s):	Not classified		
REGULATION (EC) No 1223/2009	Not restricted.		
Other regulatory statuses:	N/A		

INCI Name	Tea Tree & Eucalyptus with Activated Charcoal Soap (% w/w)	CAS Number	EC Number	Function(s)	Restrictions	Maximum Level Present in Product(s) (% w/w)	Systemic Exposure Dose (mg/kg bw/day)	Point of Departure (mg/kg bw/day)	Margin of Exposure	Application penetration data? (Yes = applied for assessment, blank = not considered)	Skin penetration (%)	Dermal exposure (g/cm²)	NOEL	Safety Factor	AGL/CEL	Acceptable Exposure Level (g/cm²)
Butyrospermum Parkii Butter	5.0857	194043-92-0 - 91080-23-8	293-515-7	Skin Conditioning, Viscosity Controlling	N/A	5.0857%	0.07795	No Data			100	0.076	No Data	300		

Butyrospermum Parkii (Shea) Butter is a fat obtained from the fruit of Butyrospermum parkii. The accepted scientific name for Butyrospermum parkii is Vitellaria paradoxa. It is used as a skin conditioning agent, an occlusive agent and viscosity increasing agent in cosmetic products.

According to the CIR review[1], Butyrospermum Parkii (Shea) Butter typically contains; myristic acid (0.5%), palmitic acid (3-9%), stearic acid (30-50%), oleic acid (38-50%), linoleic acid (3-8%) linolenic acid (0.5%) and arachidic acid (2.5-3%). Butyrospermum Parkii (Shea) Butter is reported to be used at up to 60% in leave on products, up to 8% in products used in the eye area, up to 26% in products that may be ingested, up to 3% in products that may be inhaled, up to 15% in products that are dermally applied, up to 60% in products used on the nail area, and up to 5% in baby products[1].

In a HRIPT performed on 111 individuals with a body butter product containing 60% Butyrospermum Parkii (Shea) Butter. No irritation or sensitisation was reported. A body butter massage product containing 45% Butyrospermum Parkii (Shea) Butter was tested in 4 HRIPTs each tested on 109 individuals. No irritation or sensitisation was observed. On the basis of HRIPT and negative results *in vitro* skin irritation assays Butyrospermum Parkii (Shea) Butter is not expected to cause irritation or sensitisation. No reports of contact dermatitis exist in the literature. Protein content of shea butter is very low[2] (0.042%) and no reports of type I allergy exists in the literature. Phototoxicity is not expected.

Vegetable based fatty acids have a long history of safe use in the diet in edible oils, such as rapeseed oil, palm oil, olive oil and other vegetable-based oils. According to JECFA palmitic acid, stearic acid, lauric acid and oleic acid are do not have any safety concerns in the diet[3]. When applied topically fatty

acids have been shown to remain mainly on the outer layers of the stratum corneum with little penetration[4]. Therefore, systemic toxicity is not expected.

Summary:

The concentration and use of Butyrospermum Parkii (Shea) Butter is not restricted according to Regulation (EC) No 1223/2009. The concentration and usage of this ingredient is consistent with industry norms. Under normal conditions of use systemic toxicity is not expected. Local toxicity endpoints such as; skin and eye irritation, skin sensitization, and phototoxicity are not expected.

References:

1. IJT 36(Suppl. 3):51-129, 2017
2. Journal of Allergy and Clinical Immunology; 127, Iss. 3, (Mar 2011): 680-682
3. JECFA, WHO Food Additives Series No. 40, 1998.
4. Patzelt, A & Lademann, J & Richter, H & Darvin, Maxim & Schanzer, S & Thiede, Gisela & Sterry, Wolfram & Vergou, Theognosia & Hauser, Matthias. (2011). In vivo investigations on the penetration of various oils and their influence on the skin barrier. Skin research and technology : official journal of International Society for Bioengineering and the Skin (ISBS) [and] International Society for Digital Imaging of Skin (ISDIS) [and] International Society for Skin Imaging (ISSI). 18. 364-9. 10.1111/j.1600-0846.2011.00578.x.

Specification data:
No specification test data was provided the responsible person must ensure that the ingredient is food or cosmetic grade.

Supporting test data:

The data below is based on *in vivo* and *in vitro* data to support the safety assessment. Any animal testing data listed below has been obtained from publicly available literature sources. According to REGULATION (EC) No 1223/2009 and Council Directive 76/768/EEC animal testing is prohibited for cosmetic products and ingredient past the prescribed timescales.

Test type:	Guideline:	Result	Source
Skin irritation	OECD 404	Rabbit: Very slightly irritating at up to 100%	Secondary source: IJT 36(Suppl. 3):51-129, 2017Animal test date: 1999
Eye irritation	OECD 405	Rabbit: Non irritating at up to 100%	Secondary source: IJT 36(Suppl. 3):51-129, 2017Animal test date: 1985
Skin sensitisation	OECD 406	Negative in a Maximisation study at up to 75% (induction) and 20% (challenge)	Secondary source: IJT 36(Suppl. 3):51-129, 2017Animal test date: 1985
Repeated dose 90-day oral toxicity study in rodents	OECD 408	No toxicity observed in rats fed up to 20% in the diet.	Secondary source: JEPT 4(4):105-120, 1980 Animal test date: 1980

Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test	OECD 422	NOAEL rat: 7500 mg/kg bw/day	Secondary source: Safety Assessment of Butyrospermum parkii (Shea)- Derived Ingredients as Used in Cosmetics, 2017 Animal test date: 2002
***In vitro* 3T3 NRU phototoxicity test**	OECD 432	Not phototoxic	Secondary source: Safety Assessment of Butyrospermum parkii (Shea)- Derived Ingredients as Used in Cosmetics, 2017 Non animal test
Chronic toxicity studies	OECD 452	NOAEL rat: 7500 mg/kg bw/day	Secondary source: Safety Assessment of Butyrospermum parkii (Shea)- Derived Ingredients as Used in Cosmetics, 2017 Animal test date: 2001
***In vitro* skin irritation: reconstructed human epidermis test method**	OECD 439	Non irritating up to 67.3%	Secondary source: IJT 36(Suppl. 3):51-129, 2017 Non animal test data.
***In Chemico* skin sensitisation**	OECD 442c	Not a sensitiser.	Safety Assessment of Butyrospermum parkii (Shea)- Derived Ingredients as Used in Cosmetics, 2017 Non animal test data.
***In vitro* bacterial reverse mutation test**	OECD 471	Not mutagenic up to 5000 µg/plate ±S9	Secondary source: Safety Assessment of Butyrospermum parkii (Shea)- Derived Ingredients as Used in Cosmetics, 2017 Non animal test data.

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Ingredient Profile: Charcoal Powder

CAS number:	7440-44-0 (generic) / 16291-96-6	**EC number:**	231-153-3 (I) / 240-383-3 (I)
INCI Name:	Charcoal Powder		
Pseudonyms:			
Structure:	N/A	**Image:**	
CLP Hazard classification(s):	Not classified		
REGULATION (EC) No 1223/2009	Not restricted.		
Other regulatory statuses:	N/A		

INCI Name	Tea Tree & Eucalyptus with Activated Charcoal Soap (% w/w)	CAS Number	EC Number	Function(s)	Restrictions	Maximum Level Systemic Exposure Dose (mg/kg bw/day)	Point of Departure (mg/kg bw/day)	Margin of Exposure	Apply skin penetration data? Use to replace default skin penetration assumptions if data is of sufficient quality	Skin penetration (%)	Dermal exposure (ug/cm2)	NESIL	Safety Factor	AEL/CEL	Acceptable Exposure Level (ug/cm2)
Charcoal Powder	0.8080	16291 96 6; 7440 44 0 (generic)	240-383-3; 231-153-3	Abrasive, Absorbent, Opacifying	N/A	0.30797	0.00133	4500	3371.91		100	0.003	No Data	100	

Charcoal Powder is the dried, carbonaceous material obtained from the heating of organic substances. It is used as an abrasive agent, absorbent agent, colourant and opacifying agent in cosmetic products.

Charcoal powder (vegetable carbon), when used at food grade is an approved food additive in the EU (E153). Carbon black (not from vegetable origin) was not genotoxic *in vitro* and *in vivo* testing, some positive results were attributed to trace amounts polycyclic aromatic hydrocarbons (PAHs). Carbon black when levels of PAH are controlled did not cause carcinogenicity in rats and mice in carcinogenicity studies. The EFSA panel concluded that carbon black and vegetable carbon are not absorbed via the skin or gastro-intestinal tract, the level of PAHs in vegetable carbon and carbon black are lower than the dietary exposure from the diet[1].

Charcoal was a long history of use in the diet. Charcoal biscuits were introduced in the 19th Century as a remedy to stomach trouble[2]. Activated charcoal is used as a food supplement as a dietary aid at up to 1560 mg/day. Activated charcoal is also used for medical purposes to treat overdose and poisoning, it's absorptive properties can bind to toxins and drugs and reduce systemic exposure. For acute poisoning purposes doses of up to 100g are used[3].

Charcoal powder was not irritating to the eyes or skin in *in vitro* assays. Charcoal powder was not sensitising in a LLNA test at up to 10%. Systemic toxicity is not expected as the level of exposure from cosmetics is expected to be far lower than the exposure in the diet. Charcoal powder did not cause carcinogenicity in rats treated with up 4500 mg/kg bw/day.

Summary:

The concentration and use of Charcoal Powder is not restricted according to Regulation (EC) No 1223/2009. The concentration and usage of this ingredient is consistent with industry norms. Under normal conditions of use systemic toxicity is not expected. Local toxicity endpoints such as; skin and eye irritation, skin sensitization, and phototoxicity are not expected.

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References:

1. EFSA Journal 2012;10(4):2592
2. Rolland, Jacques L. (2006). The Food Encyclopedia: Over 8,000 Ingredients, Tools, Techniques and People. Robert Rose. p. 148.
3. Dtsch Arztebl Int. 2019 May; 116(18): 311–317.

Specification data:

No specification test data was provided the responsible person must ensure that the ingredient is food or cosmetic grade.

Supporting test data:

The data below is based on *in vivo* and *in vitro* data to support the safety assessment. Any animal testing data listed below has been obtained from publicly available literature sources. According to REGULATION (EC) No 1223/2009 and Council Directive 76/768/EEC animal testing is prohibited for cosmetic products and ingredient past the prescribed timescales.

Test type:	Guideline:	Result	Source
Skin absorption: *In vitro* method	ICCVAM recommended HET-CAM Method Protocol	Negative for irritation in a HET-CAM assay.	Secondary source: REACH dossier Non animal test data
Skin sensitisation: LLNA	OECD 429	Not sensitising at up to 10%	Secondary source: REACH dossier Animal test date: 2010
***In vitro* skin irritation: reconstructed human epidermis test method**	OECD 439	Not irritating in an EpiDerm skin assay.	Secondary source: REACH dossier Non animal test data
Carcinogenicity studies	OECD 451	Read across to carbon black: NOAEL rat 4500 mg/kg bw/day.	E Secondary source: FSA Journal 2012;10(4):2592 Animal test date: Prior to 2012.
***In vitro* bacterial reverse mutation test**	OECD 471	Not genotoxic 5000 µg/plate ±S9.	Secondary source: REACH dossier Non animal test data
***In Vitro* mammalian chromosome aberration test**	OECD 473	No chromosomal aberrations were observed in V79 cells	Secondary source: REACH dossier Non animal test data.

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Ingredient Profile: Citric Acid

CAS number: 5949-29-1 / 77-92-9 **EC number:** 201-069-1 (I)

INCI Name: Citric Acid

Pseudonyms: 2-Hydroxy-1,2,3-Propanetricarboxylic Acid, acidum citricum (EP).

Structure:

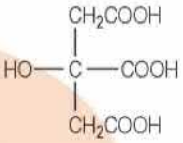

Image:

CLP Hazard classification(s): H319 Causes serious eye irritation

REGULATION (EC) No 1223/2009 Not restricted.

Other regulatory statuses: Food:
USFDA: GRAS, approved indirect and direct food addictive (21CFR178.1010, 21CFR184.1033).
JEFCA: Not restricted.
EU: Approved food additive.

Cosmetics:
Canada Hotlist: (AHAs)
FDA: AHAs
EU: Not restricted

INCI Name	Tea Tree & Eucalyptus with Activated Charcoal Soap (% w/w)	CAS Number	EC Number	Function(s)	Restriction	Maximum Level Present in Product(s) (% w/w)	Systemic Exposure Dose (mg/kg bw/day)	Point of Departure (mg/kg bw/day)	Margin of Exposure	Apply skin penetration data? (Yes = apply skin penetration data; No = assume 100% penetration)	Skin penetration (%)	Dermal exposure (ug/cm2	NOSIL	Safety Factor	ADI/DEL	Acceptable Exposure Level (ug/cm2
Citric Acid	0.0916	77 92 9 / 5949 29 1	201 069-1	Buffering, Chelating, Masking	N/A	0.09156	0.00040	1200	3014490		100	0.001	No Data	300		

Citric acid is an inorganic acid. It is naturally occurring in fruits with up to 8% of the dry weight of lemons and lime accounting for citric acid[1]. It is used as a chelating agent, fragrance ingredient and pH adjuster in cosmetic products.

Citric acid is an approved in direct and direct food additive by the USFDA (21CFR178.1010, 21CFR184.1033) and is considered to be Generally Recognised As Safe (GRAS). Citric acid was reviewed by JEFCA/WHO as a food additive and is not limited in foods. Citric acid is an approved food additive in the EU (E330).

According to the CIR review citric acid is used up to 35% in bath products (Such as bath salts/bath bombs), up to 10% in rinse off products and up to 4% in leave on products. It is used at up to 3% in products that may be ingested, up to 2% in products used in the eye area and 0.2% in baby products.

Citric acid when orally administered is well absorbed and metabolised. Citric acid is also produced endogenously as a part of normal metabolism, where is completes the breakdown of pyruvate produced from glucose metabolism. Approximately 2 Kg of citric acid is metabolised every day in humans. Citric acid is freely filterable in the kidney and 65-90% of citric acid is reabsorbed[2]. Therefore as citric acid is present in the diet naturally in addition to synthetic sources, coupled with endogenous

production of citric acid, systemic toxicity from cosmetic products containing citric acid is not expected.

Citric acid has a low acute oral toxicity. Citric acid can cause coughing in humans and in animal models when inhaled in high concentrations, the cough reflex is produced by irritation to the larynx and trachea[2]. In animal models citric acid is slightly irritating to the skin and severely irritating to the eyes. In a 48h patch test of 1% citric acid in 133 oral disease patients there were no reactions to citric acid[2]. however according to the OECD SIDS report[3] citric acid can cause a stinging sensation at 2% aqueous solutions. This effect was not related to irritation, therefore, although it is not necessarily a safety concern, it is recommended to limit the level of citric acid in aqueous cosmetics as high levels of citric acid topically is not always tolerated by the consumer.

Citric acid has been tested in a HRIPT test. Patches of a cuticle cream containing 4% citric acid were applied 3 times a week for 3 weeks followed by a rest period. There were no reports of irritation or sensitisation[2].

Citric acid is considered an alpha hydroxy acid by the USFDA and Health Canada, at high levels in leave on products it is recommended to place a suncare warning on the labelling.

Summary:

The concentration and use of citric acid is not restricted according to Regulation (EC) No 1223/2009. The concentration and usage of this ingredient is consistent with industry norms. Under normal conditions of use systemic toxicity is not expected. Local toxicity such as; skin and eye irritation, skin sensitization, and phototoxicity are not expected.

References:

1. Journal of Endourology. 22 (3): 567–570
2. IJT 33(Suppl.2):16-46, 2014
3. OECD SIDS Initial Assessment Report for 11th SIAM, Citric acid, 2001

Specification data:

No specification test data was provided the responsible person must ensure that the ingredient is food or cosmetic grade.

Recommended minimum specification:

Appearance:	White crystalline powder or crystals
Lead:	<0.5 mg/kg
Arsenic:	<3 mg/kg
Mercury:	<1 mg/kg

Supporting test data:

The data below is based on *in vivo* and *in vitro* data to support the safety assessment. Any animal testing data listed below has been obtained from publicly available literature sources. According to REGULATION (EC) No 1223/2009 and Council Directive 76/768/EEC animal testing is prohibited for cosmetic products and ingredient past the prescribed timescales.

Test type:	Guideline:	Result	Source

Acute oral toxicity	Not to GLP	Mouse LD_{50}: 5400 mg/kg	Secondary source: SIDS Initial Assessment Report for 11th SIAM, Citric acid, 2001 Animal test date: 1981
Dermal irritation	OECD 404, not to GLP	Rabbit: Slightly irritating	Secondary source: OECD SIDS Initial Assessment Report for 11th SIAM, Citric acid, 2001 Animal test date: 1991.
Eye irritation	Draize, not to GLP	Rabbit: At 10%, 30% citric acid was mildly to moderately irritating.	Secondary source: OECD SIDS Initial Assessment Report for 11th SIAM, Citric acid, 2001 Animal test date: 1984
Reproductive/developmental toxicity	Pre-guideline test data.	Rats NOAEL: 2500 mg/kg bw/day	Secondary source: OECD SIDS Initial Assessment Report for 11th SIAM, Citric acid, 2001 Animal test date: 1976.
***In vitro* Bacterial Reverse Mutation Test**	OECD 471	Not mutagenic up to 5000 µg/plate ±S9	Secondary source: OECD SIDS Initial Assessment Report for 11th SIAM, Citric acid, 2001 Animal test date: Non animal test method.
Chronic systemic toxicity	Pre-guideline test data.	NOAEL rat: 1200 mg/kg bw/day fed 3 and 5% citric acid in the diet for 2 years.	Secondary source: OECD SIDS Initial Assessment Report for 11th SIAM, Citric acid, 2001 Animal test date: 1957
Chronic systemic toxicity	Pre-guideline test data.	NOAEL dog: 1380 mg/kg bw/day fed in the diet for up to 120 days.	Secondary source: OECD SIDS Initial Assessment Report for 11th SIAM, Citric acid, 2001 Animal test date: 1946
Supporting data	N/A	In humans a 2% aqueous solution of citric acid can cause a stinging sensation that is not related to irritation.	SIDS Initial Assessment Report for 11th SIAM, 2001
Supporting data	N/A	HRIPT of 60 ezcema patients with 2.5% citric acid in petrolatum did not cause any irritant reactions	SIDS Initial Assessment Report for 11th SIAM, 2001

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Ingredient Profile: Eucalyptus Globulus Leaf Oil

CAS number:	8000-48-4	**EC number:**	N/A
INCI Name:	Eucalyptus Globulus Leaf Oil		
Pseudonyms:			
Structure:	N/A	**Image:**	
CLP Hazard classification(s):	Not classified		
REGULATION (EC) No 1223/2009	Not restricted.		
Other regulatory statuses:	Canada Hotlist: Maximum concentration 25%.		

INCI Name	Tea Tree & Eucalyptus with Activated Charcoal Soap (% w/w)	CAS Number	EC Number	Function(s)	Restrictions	Maximum Level Found in Product(s) (% w/w)	Systemic Exposure Dose (mg/kg bw/day)	Point of Departure (mg/kg bw/day)	Margin of Exposure	Apply skin penetration data? Use a read-across approach or assume 100% absorption	Skin penetration (%)	Dermal exposure (ug/cm2)	NOEL	Safety Factor	AEL/CEL	Acceptable Exposure Level (ug/cm2)
Eucalyptus Globulus Leaf Oil	0.5077	8000-48-4 / 84625-32-1	283-406-7	Perfuming, Skin Conditioning	N/A	0.5077	0.00770	800	136151		100	0.008	No Data	800		

Eucalyptus Globulus Leaf Oil is the volatile oil obtained from the leaves of Eucalyptus globulus and other species of Eucalyptus. It is used as a fragrance ingredient and skin conditioning agent in cosmetic products.

Eucalyptus Globulus Leaf Oil is approved for use as a direct food additive by the USFDA (21CFR172.510). It is also approved for use in OTC drugs (21CFR310.544, 21CFR310.545).

According to the CIR review[1] Eucalyptus Globulus Leaf Oil is used at levels of 0.4% in leave on products, up to 0.74% in rinse off products, up to 0.038% in products to be used on the eye area, up to 0.15% in nail products. According to the CIR review, skin sensitisation and should not be observed at levels of up to 1.4%, based on the results of LLNA data and Guinea pig data[1]. Eucalyptus Globulus Leaf Oil (10%) was not irritating or sensitising in a HRIPT performed on 25 individuals. Eucalyptus Globulus Leaf Oil was not genotoxic in *in vitro* testing.

According to the Tisserand the recommended topical dose is 20% and the recommended oral dose is 600 mg/day[3] equivalent to 10 mg/kg bw/day.

Eucalyptus oil is a schedule 6 poison in Australia, in the UK there are several case reports of acute toxicity in infants who accidentally ingested Eucalyptus oil. At the present and current practices of use in cosmetic products acute toxicity is not expected.

There is a long history of use of Eucalyptus oil for both internal and topical use in the EU as a Traditional Herbal Remedy. For oral use the daily dose can be as high as 1000 mg/day equivalent to 16.67 mg/kg bw/day[1].

Summary:

The concentration and use of Eucalyptus Globulus Leaf Oil is not restricted according to Regulation (EC) No 1223/2009. The concentration and usage of this ingredient is consistent with industry norms. Under normal conditions of use systemic toxicity is not expected. Local toxicity endpoints such as; skin and eye irritation, skin sensitization, and phototoxicity are not expected.

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References:

1. CIR, Safety Assessment of Eucalyptus globulus (Eucalyptus)-Derived Ingredients as Used in Cosmetics , 2018.
2. EMA/HMPC/307782/2012
3. Tisserand, Essential Oil Safety: A Guide for Health Care Professionals, 2nd Edition, 2013.

Specification data:

No specification test data was provided the responsible person must ensure that the ingredient is food or cosmetic grade.

Supporting test data:

The data below is based on *in vivo* and *in vitro* data to support the safety assessment. Any animal testing data listed below has been obtained from publicly available literature sources. According to REGULATION (EC) No 1223/2009 and Council Directive 76/768/EEC animal testing is prohibited for cosmetic products and ingredient past the prescribed timescales.

Test type:	Guideline:	Result	Source
Acute oral toxicity	OECD 401	Mice LD_{50}: >2000 mg/kg	Secondary source: REACH dossier Animal test date: Prior to 1984
Acute dermal toxicity	OECD 402	Rabbit LD_{50}: >5000 mg/kg	Secondary source: REACH dossier Animal test date: Prior to 1973
Reproduction/developmental toxicity screening test	OECD 421	NOAEL rat: 300 mg/kg bw/day based on decreased weight gain (maternal/foetal).	Secondary source: CIR, Safety Assessment of Eucalyptus globulus (Eucalyptus)-Derived Ingredients as Used in Cosmetics , 2018 Animal test date:
***In vitro* 3T3 NRU phototoxicity test**	OECD 432	Negative	Secondary source: CIR, Safety Assessment of Eucalyptus globulus (Eucalyptus)-Derived Ingredients as Used in Cosmetics , 2018 Non animal test data
***In vitro* bacterial reverse mutation test**	OECD 471	Not genotoxic 5000 µg/plate ±S9.	Secondary source: CIR, Safety Assessment of Eucalyptus globulus (Eucalyptus)-Derived Ingredients as Used in Cosmetics , 2018 Non animal test data.
***In Vitro* mammalian chromosome aberration test**	OECD 473	No chromosomal aberrations were observed in human lymphocytes.	Secondary source: CIR, Safety Assessment of Eucalyptus globulus (Eucalyptus)-Derived Ingredients as Used in Cosmetics , 2018 Non animal test data.

***In Vitro* mammalian cell gene mutation test**	OECD 476	Not genotoxic in L5178Y cells	Secondary source: CIR, Safety Assessment of Eucalyptus globulus (Eucalyptus)-Derived Ingredients as Used in Cosmetics, 2018 Non animal test data.

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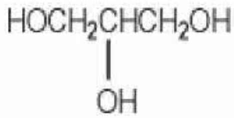
Ingredient Profile: Glycerin

CAS number:	56-81-5	**EC number:**	200-289-5 (I)
INCI Name:	Glycerin		
Pseudonyms:	Glycerine, Glycerol		
Structure:	$C_3H_8O_3$	**Image:**	
CLP Hazard classification(s):	N/A		
REGULATION (EC) No 1223/2009	Not restricted.		
Other regulatory statuses:	Cosmetics: Canada Hotlist. Food: Approved EU food additive - E422		

INCI Name	Tea Tree & Eucalyptus with Activated Charcoal Soap (% w/w)	CAS Number	EC Number	Function(s)	Restrictions	Maximum Level Present in Product(s) (% w/w)	Systemic Exposure Dose (mg/kg bw/day)	Point of Departure (mg/kg bw/day)	Margin of Exposure	Apply skin penetration data? [illegible]	Skin penetration (%)	Dermal exposure ug/cm2	NESIL	Safety Factor	AEL/CEL	Acceptable Exposure Level ug/cm2
Glycerin	6.8670	56-81-5	200-289-5	Denaturant, Hair Conditioning, Humectant, Oral Care, Perfuming, Skin Protecting, Viscosity Controlling	N/A	6.86699	0.07976	10000	[illegible]	[illegible]	100	0.107	No Data	300		

Glycerin is a polyhydric alcohol. Glycerin is classified as GRAS (Generally Recognised as Safe) by the USFDA (21CFR182.90). It is approved for use as an indirect and direct food additive by the USFDA (21CFR175.300, 21CFR172.866. According to the CIR (Cosmetic Ingredient Review Expert Panel) 2014 report glycerine is used at up to 79.2% in leave on products, up to 99.4% in rinse off products, up to 47.9% in products used in the eye area, and up to 68.6% in products which may incur incidental ingestion.

The U.S. Pharmacopeia-National Formulary (USP-NF) standards state that the amount of any individual impurity in glycerin cannot exceed 0.1%, and that the total for all impurities, including diethylene glycol and ethylene glycol, must not exceed 1%.

The technical data sheet for the raw material for this product indicates that the product is made to USP/EP standards.

Glycerin is rapidly absorbed in the intestine and stomach. Glycerol is phosphorylated to alpha-glycerophosphate by glycerol kinase predominantly in the liver (80-90%) and kidneys (10-20%) and incorporated in the standard metabolic pathways to form glucose and glycogen. Glycerin is also naturally occurring in all animals and plant matter as glycerides in fats and oils, or, in intracellular spaces as lipids[1].

According to the CIR glycerine has low acute oral and dermal toxicity (LD50 27,200 mg/kg and >18,700 mg/kg bw/day respectively) and undiluted glycerine is non irritating to the eyes and skin in testing performed on rabbits. Glycerin was negative for genotoxicity in a barrage of in vitro and in vivo toxicity tests. Natural and synthetic glycerine was non sensitising in tests performed in guinea pigs[1].

According to the OECD SIDS report for glycerol there was no concern for carcinogenicity in 2-year dietary studies (up to 20% glycerine in diet) equivalent to 10,000 mg/kg bw/day. This was determined

to be the NOAEL by the OECD report. Glycerin was tested in a developmental toxicity test in rats, mice and rabbits. The NOAEL was >2000 mg/kg bw/day the highest dose tested[2].

The CIR panel concluded that glycerin is safe when used at present practices of use and concentration. Glycerin not restricted according to Regulation (EC) No. 1223/2009. The use of glycerin is acceptable in this product type and application.

References:

1. CIR, Safety Assessment of Glycerin as Used in Cosmetics, 2015
2. SIDS Initial Assessment Report For SIAM 14 Paris, France, 26-28 March 2002

Specification data:

No specification test data was provided the responsible person must ensure that the ingredient is food or cosmetic grade.

Supporting test data:

The data below is based on *in vivo* and *in vitro* data to support the safety assessment. Any animal testing data listed below has been obtained from publicly available literature sources. According to REGULATION (EC) No 1223/2009 and Council Directive 76/768/EEC animal testing is prohibited for cosmetic products and ingredient past the prescribed timescales.

Test type:	Guideline:	Result	Source
Acute oral toxicity	OECD 401	Rat LD_{50}: >27,200 mg/kg	Secondary source: SIDS Initial Assessment Report For SIAM 14 Paris, France, 26-28 March 2002 Animal test date: Prior to 1953
Acute dermal toxicity	OECD 402	Rat LD_{50}: >18,700 mg/kg	Secondary source: SIDS Initial Assessment Report For SIAM 14 Paris, France, 26-28 March 2002 Animal test date: Prior to 1953
Skin irritation	OECD 404	Rabbit: Undiluted non irritating	Secondary source: SIDS Initial Assessment Report For SIAM 14 Paris, France, 26-28 March 2002 Animal test date: Prior to 1971
Eye irritation	OECD 405	Rabbit: Undiluted non irritating	Secondary source: SIDS Initial Assessment Report For SIAM 14 Paris, France, 26-28 March 2002 Animal test date: Prior to 1953
Two-Generation Reproduction Toxicity Study	OECD 416	NOAEL maternal & foetal rat: >2000 mg/kg bw/day	Secondary source: SIDS Initial Assessment Report For SIAM 14 Paris, France, 26-28 March 2002 Animal test date: Prior to 1953
Carcinogenicity	Non guideline study	NOAEL rat: >10,000 in the diet. 2 year study.	Secondary source: SIDS Initial Assessment Report

			For SIAM 14 Paris, France, 26-28 March 2002 Animal test date: Prior to 2002
Bacterial mutagenicity	OECD 471	Not mutagenic ±S9	Secondary source: SIDS Initial Assessment Report For SIAM 14 Paris, France, 26-28 March 2002 Animal test date: Non animal test method
In Vitro Mammalian Mutagenicity Test	OECD 476	Negative up to cytotoxic dose levels.	Secondary source: SIDS Initial Assessment Report For SIAM 14 Paris, France, 26-28 March 2002 Animal test date: Non animal test method
Mammalian Bone Marrow Chromosome Aberration Test	OECD 475	Negative up to cytotoxic dose levels.	Secondary source: SIDS Initial Assessment Report For SIAM 14 Paris, France, 26-28 March 2002 Animal test date: Non animal test method

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Ingredient Profile: Kaolin

CAS number:	1332-58-7	**EC number:**	N/A
INCI Name:	1332-58-7		
Pseudonyms:	China Clay, CI 77004		
Structure:	$Al_2Si_2O_5(OH)_4$	**Image:**	
CLP Hazard classification(s):	H373 – May cause damage to organs (lungs) through prolonged or repeated exposure		
REGULATION (EC) No 1223/2009	IV/119		
Other regulatory statuses:	Food: USFDA: GRAS, approved direct food addictive (21CFR184.1077). JEFCA: ADI not restricted EU food additive E559		

INCI Name	Tea Tree & Eucalyptus with Activated Charcoal Soap (% w/w)	CAS Number	EC Number	Function(s)	Restrictions	Maximum Level Present in Product(s) (% w/w)	Systemic Exposure Dose (mg/kg bw/day)	Point of Departure (mg/kg bw/day)	Margin of Exposure	Apply skin potentiation data? (Yes applies the assessment factor as per ingredient)	Skin penetration (%)	Dermal exposure (µg/cm2)	NOEL	Safety Factor	ADI/OEL	Acceptable Exposure Level (µg/cm2
Kaolin	1.0155	1332 58 7	310 194 1	Abrasive, Absorbent, Anticaking, Bulking, Cosmetic Colorant, Opacifying	IV/119	1.01548	0.00440	10000	2272509		100	0.015	No Data	300		

Kaolin is a native hydrated aluminium silicate. Kaolin is a natural component of the soil and occurs widely in ambient air. Kaolin mining and refining involve considerable exposure, and significant exposure is also expected in paper, rubber, and plastic production.

Kaolin is used as an absorbent agent, anticaking agent, bulking agent, opacifying agents, skin protectants, and slip modifiers.

Kaolin is an approved indirect food additive by the USFDA (21CFR186.125) and is considered to be Generally Recognised As Safe (GRAS). Kaolin is approved as an OTC ingredient as a digestive aid, antidiarrheal aid (21CFR310.545, 21CFR335.10).

Kaolin may cause mechanical irritation to the eyes and skin. In animal models kaolin was not irritating to the skin[1].

According to the CIR review kaolin is used at levels of up to 84% in face masks, up to 36% in foundations, up to 30% in lipsticks, up to 25% in moisturizers and up to 25% in suntan gels/creams. The CIR concluded that there is a concern regarding occupational exposure to kaolin via inhalation which has been related to case reports of fibrosis and silicosis in humans. However, in cosmetic preparations inhalation is not expected. It concluded that kaolin was safe as currently used in cosmetics[1].

Skin sensitisation has not been reported to kaolin despite widespread use in medicines, cosmetics and food/food contact materials. According to suppliers MSDSs skin sensitisation was not observed in LLNA testing (details not provided). Skin sensitisation is not expected.

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Orally kaolin is considered to be relatively inert, the only toxicological effects appear to derive from its adsorptive abilities. The lethal dose for humans is considered to be >15 g/kg[3]. Kaolin was well tolerated in a 90 day oral study up to 20% in the diet (~10,000 mg/kg bw/day)[1]. Systemic toxicity is not expected in the current application.

Regarding inhalation risk, it is well established that clay minerals may cause long term lung damage, usually observed with occupational exposure. According to a WHO report, kaolin inhalation may lead to a relatively benign form of pneumoconiosis, known as kaolinosis. Based on occupational exposure from china clay workers in the UK it has been estimated that "kaolin is at least an order of magnitude less potent than quartz".

In the proposed usage it is not anticipated that consumers will be exposed to respirable particles, therefore lung toxicity is not expected.

Summary:

The concentration and use of kaolin is not restricted according to Regulation (EC) No 1223/2009. The concentration and usage of this ingredient is consistent with industry norms. Under normal conditions of use systemic toxicity is not expected. Local toxicity such as; skin and eye irritation, skin sensitization, and phototoxicity are not expected.

References:

1. IJT 22(Suppl. 1):37-102, 2003
2. Environmental Health Criteria 231, BENTONITE, KAOLIN, AND SELECTED CLAY MINERALS, World Health Organization Geneva, 2005 https://www.who.int/ipcs/publications/ehc/ehc_231.pdf
3. CFNP TAP Review for Kaolin Pectin, 2002

Supporting test data:

The data below is based on *in vivo* and *in vitro* data to support the safety assessment. Any animal testing data listed below has been obtained from publicly available literature sources. According to REGULATION (EC) No 1223/2009 and Council Directive 76/768/EEC animal testing is prohibited for cosmetic products and ingredient past the prescribed timescales.

Test type:	Guideline:	Result	Source
Acute oral toxicity	Not to guideline	Rat LD_{50}: 149 g /kg	Secondary source: 1.IJT 22(Suppl. 1):37-102, 2003 Animal test date: 1977
Acute dermal toxicity		Rat LD_{50}: >5000 mg/kg	Secondary source: HSDB database Animal test date:
Dermal irritation	OECD 404	Rabbit: Not irritating	Secondary source: REACH Dossier Animal test date: 2000.
Acute eye irritation	OECD 405	Rabbit: causes mechanical irritation. Moderate eye irritant	Secondary source: HSDB database Animal test date: 2007
Sensitization: Local Lymph Node Assay	OECD 429	Not sensitising	Secondary source: Suppliers MSDS Animal test date: Prior to 2013

3 month inhalation study	Not to guideline	Rats administered 50 mg/rat displayed pulmonary toxicity signs of fibrogenesis	Secondary source: I.IJT 22(Suppl. 1):37-102, 2003 Animal test date: 1975
90 day oral study	Not to guideline	Rats fed either a 20% kaolin diet which was either iron supplemented or kaolin alone. There was a significant reduction in haemoglobin, hemaocrit and RBC numbers. This was not seen in the iron supplemented diet, suggesting toxicity was related to adsorption.	Secondary source: I.IJT 22(Suppl. 1):37-102, 2003 Animal test date: 1977
Supporting data	ADI	Not restricted	Joint FAO/WHO Expert Committee on Food Additives which met in Geneva, 25 June - 4 July 1973

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Ingredient Profile: Melaleuca Alternifolia (Tea Tree) Leaf Oil

CAS number:	68647-73-4 / 8022-72-8	**EC number:**	N/A
INCI Name:	Melaleuca Alternifolia Leaf Oil		
Pseudonyms:	Melaleuca Alternifolia (Tea Tree) Leaf Oil, Tea Tree Oil		
Structure:	N/A	**Image:**	
CLP Hazard classification(s):	Not classified		
REGULATION (EC) No 1223/2009	Not restricted.		
Other regulatory statuses:	BfR: Limited to 1% in cosmetic products.		

INCI Name	Tea Tree & Eucalyptus with Activated Charcoal Soap (% w/w)	CAS Number	EC Number	Function(s)	Restrictions	Maximum Level Present in Product(s) (% w/w)	Systemic Exposure Dose (mg/kg bw/day)	Point of Departure (mg/kg bw/day)	Margin of Exposure	Apply skin penetration data? [illegible]	Skin penetration (%)	Dermal exposure ug/cm2	NESIL	Safety Factor	AEL/OEL	Acceptable Exposure Level ug/cm2
Melaleuca Alternifolia Leaf Oil	1.0155	85085-48-9 / 8022-72-8 / 68647-73-4	285-377-1 / /	Antioxidant, Perfuming	N/A	1.01540	0.00440	117	26588	[illegible]	100	0.015	No Data	300		

Melaleuca Alternifolia (Tea Tree) Leaf Oil is the oil distilled from the leaves of the Melaleuca alternifolia. It is used as an antioxidant and fragrance ingredient in cosmetic products.

According to the SCCP/1155/08 report on tea tree oil, it is typically used at up to 1.25% in leave on products, up to 2% in rinse off products, up to 2% in deodorant products and up to 0.5% in oral hygiene products. In single insult patch tests 5% tea tree oil was not irritating in 311 volunteers. In a separate study a product containing 5% tea tree oil caused irritation in 20.3% of 217 patients. According to the SCCP the NOAEL was 117 mg/kg bw/day, based on the systemic toxicity of its constituents. Tea tree oil was not mutagenic or clastogenic in *in vitro* and *in vivo* testing. The SCCP commented that methyl eugenol should be minimised in tea tree products and prevented from oxidation. According to Tisserand, tea tree oil can remain unoxidized and undegraded for as long as 3-10 years if sealed adequately. Tea tree oil contains natural antioxidants, which oxidise into p-cymene. Therefore excessive p-cymene content is an indicator of the oxidative degradation[2].

The specification for this raw material states that methyl eugenol is not present.

Summary:

The concentration and use of Melaleuca Alternifolia (Tea Tree) Leaf Oil is not restricted according to Regulation (EC) No 1223/2009. The concentration and usage of this ingredient is consistent with industry norms. Under normal conditions of use systemic toxicity is not expected. Local toxicity endpoints such as; skin and eye irritation, skin sensitization, and phototoxicity are not expected.

References:

1. SCCP/1155/08

2. Tisserand, Essential Oil Safety, A Guide for Health Care Professionals, 2014

Specification data:

No specification test data was provided the responsible person must ensure that the ingredient is food or cosmetic grade.

Supporting test data:

The data below is based on *in vivo* and *in vitro* data to support the safety assessment. Any animal testing data listed below has been obtained from publicly available literature sources. According to REGULATION (EC) No 1223/2009 and Council Directive 76/768/EEC animal testing is prohibited for cosmetic products and ingredient past the prescribed timescales.

Test type:	Guideline:	Result	Source
Acute oral toxicity	OECD 401	Rat LD_{50}: >2300 mg/kg	Secondary source: SCCP/0843/04 Animal test date: Prior to 1989
Acute dermal toxicity	OECD 402	Rabbit LD_{50}: 5000 mg/kg	Secondary source: SCCP/0843/04 Animal test date: Prior to 1995
Skin irritation	OECD 404	Rabbit: Severe irritant at up to 100%. Minor irritation at 25%	Secondary source: SCCP/0843/04 Animal test date: 1998
Eye irritation	OECD 405	Rabbit: Up to 5% was minimally irritating.	Secondary source: SCCP/0843/04 Animal test date: 1998
Skin sensitisation	OECD 406	Not sensitising to guinea pigs	Secondary source: Tisserand, Essential Oil Safety, A Guide for Health Care Professionals, 2014 Animal test date: 1990
Skin sensitisation: LLNA	OECD 429	EC3 value was 8.3% (moderate sensitiser).	Secondary source: SCCP/0843/04 Animal test date: 2007
***In vitro* bacterial reverse mutation test**	OECD 471	Not mutagenic at up to 1500 µg/plate.	Secondary source: SCCP/0843/04 Non animal test data.
***In vivo* mammalian erythrocyte micronucleus test**	OECD 474	Non clastogenic in mice fed 0, 1000, 1350 and 1750 mg/kg bw tea tree oil	Secondary source: SCCP/0843/04 Animal test date: 2005

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Ingredient Profile: Rosmarinus Officinalis (Rosemary) Leaf Oil

CAS number:	8000-25-7	**EC number:**	N/A
INCI Name:	Rosmarinus Officinalis Leaf Oil		
Pseudonyms:	Rosmarinus Officinalis (Rosemary) Leaf Oil, Rosemary Oil		
Structure:	N/A	**Image:**	
CLP Hazard classification(s):	Not classified		
REGULATION (EC) No 1223/2009	Not restricted.		
Other regulatory statuses:	N/A		

INCI Name	Tea Tree & Eucalyptus with Activated Charcoal Soap (% w/w)	CAS Number	EC Number	Function(s)	Restrictions	Maximum Level Present in Product(s) (% w/w)	Systemic Exposure Dose (mg/kg bw/day)	Point of Departure (mg/kg bw/day)	Margin of Exposure	Apply skin penetration data?	Skin penetration (%)	Dermal exposure (μg/cm2)	NESIL	Safety Factor	AEL/CEL	Acceptable Exposure Level μg/cm2
Rosmarinus Officinalis Leaf Oil	0.5077	84604-14-8 / 8000-25-7	283-291-9	Masking, Skin Conditioning	N/A	0.50774	0.00770	230	[illegible]		100	0.008	No Data	300		

Rosmarinus Officinalis (Rosemary) Leaf Oil is the essential oil obtained from the flowering tops and leaves of Rosmarinus officinalis. The accepted scientific name for Rosmarinus officinalis is Salvia rosmarinus. It is used as a fragrance ingredient, skin conditioning agent and solvent in cosmetic products.

Rosmarinus Officinalis (Rosemary) Leaf Oil is considered to be Generally Recognised As Safe for human consumption by the USFDA (21CFR182.20).

Rosemary Oil has a long history of use as a Traditional Herbal Remedy in the EU. It is used orally to at 3-4 drops 3-4 times per day. Dermal applications include; rosemary oil is added to baths to improve skin function at up to 5g, up to 6% in ointments for the treatment of muscle and joint pain and up to 2% as a topical antiseptic[1].

According to the CIR review[2] Rosmarinus Officinalis (Rosemary) Leaf Oil is used at up to 1.5% in leave on products, up to 0.12% in rinse off products, up to 1.5% in products that may be sprayed, and up to 0.97% in products that may be applied to the mucous membrane[2]. In a 3 week oral study rats fed up to 1,500 mg/kg bw/day the NOAEL was 1500 mg/kg bw/day. However, the lowest NOAEL for Rosmarinus Officinalis (Rosemary) Leaf Extract was 230 mg/kg bw/day from 90-day oral studies in rats, taking a precautionary approach, this NOAEL was selected for Margin of Exposure calculations.

In a HRIPT of 104 volunteers a massage oil containing 1.5% Rosmarinus Officinalis (Rosemary) Leaf Oil was not irritating or sensitising[2]. In a HRIPT performed on 25 volunteers 10% Rosmarinus Officinalis (Rosemary) Leaf Oil was not a sensitizer[2]. In a patch testing of 200 contact dermatitis patients Rosmarinus Officinalis (Rosemary) Leaf Oil (2%) there were no positive reactions[3]. There are contact dermatitis reports for rosemary, however given the widespread exposure from cooking, gardening/occupational exposure, aromatherapy, herbal medicines and cosmetics allergies are relatively rare[2].

Rosmarinus Officinalis (Rosemary) Leaf Oil has low acute oral toxicity, is not likely to cause irritation at the levels and practices of use in cosmetic products. Rosmarinus Officinalis (Rosemary) Leaf Oil is

reported to be a moderate eye irritant (details not provided)[2]. Rosmarinus Officinalis (Rosemary) Leaf Oil was not genotoxic *in vitro* or *in vivo*.

Summary:
The concentration and use of Rosmarinus Officinalis (Rosemary) Leaf Oil is not restricted according to Regulation (EC) No 1223/2009. The concentration and usage of this ingredient is consistent with industry norms. Under normal conditions of use systemic toxicity is not expected. Local toxicity endpoints such as; skin and eye irritation, skin sensitization, and phototoxicity are not expected.
References:

1. EMA/HMPC/13631/2009
2. IJT 37(Suppl 3):12-50, 2018
3. Essential Oil Safety: A Guide for Health Care Professionals, 2nd Edition, 2013.
4. CIR, Amended Safety Assessment of Triglycerides as Used in Cosmetics, 2017
5. JEPT 4(4):105-120, 1980

Specification data:
No specification test data was provided the responsible person must ensure that the ingredient is food or cosmetic grade.

Supporting test data:
The data below is based on *in vivo* and *in vitro* data to support the safety assessment. Any animal testing data listed below has been obtained from publicly available literature sources. According to REGULATION (EC) No 1223/2009 and Council Directive 76/768/EEC animal testing is prohibited for cosmetic products and ingredient past the prescribed timescales.

Test type:	**Guideline:**	**Result**	**Source**
Acute oral toxicity	OECD 401	Rat LD_{50}: >10g mg/kg	Secondary source: IJT 37(Suppl 3):12-50, 2018 Animal test date: Prior to 1974
Skin irritation	OECD 404	Rabbit: Non irritating at up to 40% Moderately irritating at 100%.	Secondary source: IJT 37(Suppl 3):12-50, 2018 Animal test date: 1999
***In vitro* bacterial reverse mutation test**	OECD 471	Not genotoxic 5000 µg/plate ±S9.	Secondary source: IJT 37(Suppl 3):12-50, 2018 Non animal test data.
***In vivo* mammalian erythrocyte micronucleus test**	OECD 474	No genotoxicity observed at up to 1500 mg/kg bw/day.	Secondary source: IJT 37(Suppl 3):12-50, 2018 Animal test date: 1999

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Ingredient Profile: Sodium Chloride

CAS number:	7647-14-5	**EC number:**	231-598-3 (I)
INCI Name:	Sodium Chloride		
Pseudonyms:	Salt, rock salt		
Structure:	NaCl	**Image:**	
CLP Hazard classification(s):	N/A		
REGULATION (EC) No 1223/2009	Not restricted		
Other regulatory statuses:	N/A		

INCI Name	Tea Tree & Eucalyptus with Activated Charcoal Soap (% w/w)	CAS Number	EC Number	Function(s)	Restrictions	Maximum Level Present in Product(s) (% w/w)	Systemic Exposure Dose (mg/kg bw/day)	Point of Departure (mg/kg bw/day)	Margin of Exposure	Apply skin penetration data? (Yes = skin penetration data will be applied to calculate systemic exposure)	Skin penetration (%)	Dermal exposure ug/cm2	NESIL	Safety Factor	AEL/DEL	Acceptable Exposure Level ug/cm2
Sodium Chloride	0.0916	7647 14 5	231 598 3	Bulking, Masking, Oral Care, Viscosity Controlling	N/A	0.09156	0.00001	50	4200692		3	0.001	No Data	300		

Sodium Chloride an inorganic salt. Sodium chloride is the major salt responsible for the salinity of sea water. It is used as a flavouring agent, condiment and food preservative in foods. It is used as a flavouring agent, oral care agent and viscosity increasing agent in cosmetic products.

Sodium chloride is consumed at ~10g/day in Western countries, with the majority of salt coming from processed food and restaurant food. Due to the concern regarding sodium consumption and increased risk of cardiovascular diseases it is recommended to limit salt to less than 3 g/day[1].

Sodium chloride is not expected to cause irritation to the skin at concentrations of less than 10% according to testing on rabbits, sodium chloride may cause transient eye irritation at similar concentrations. Sodium chloride was not genotoxic in *in vitro* assays

Summary:

The concentration and use of sodium chloride is not restricted according to Regulation (EC) No 1223/2009. The concentration and usage of this ingredient is consistent with industry norms. Systemic toxicity is not expected at the proposed level and usage. Local toxicity endpoints such as skin and eye irritation, sensitisation is not expected at the proposed level and usage. There are no toxicological concerns with the proposed application under normal usage scenarios.

References:

1. He Feng J, Li Jiafu, MacGregor Graham A. Effect of longer term modest salt reduction on blood pressure: Cochrane systematic review and meta-analysis of randomised trials BMJ 2013; 346 :f1325

Specification data:

No specification test data was provided the responsible person must ensure that the ingredient is food or cosmetic grade.

Supporting test data:

The data below is based on *in vivo* and *in vitro* data to support the safety assessment. Any animal testing data listed below has been obtained from publicly available literature sources. According to REGULATION (EC) No 1223/2009 and Council Directive 76/768/EEC animal testing is prohibited for cosmetic products and ingredient past the prescribed timescales.

Test type:	Guideline:	Result	Source
Acute Oral Toxicity	OECD 401	Rat LD50: 3550 mg/kg	Secondary source: REACH dossier Animal test date: Not declared.
Acute Dermal Toxicity	OECD 402	Rat LD50: >10,000 mg/kg	Secondary source: REACH dossier Animal test date: Not declared.
Dermal Irritation	OECD 404	In contact with intact skin, sodium chloride causes no irritation, however on abraded skin 20% solutions can cause scab and scarring, at 10% slight irritation is observed.	Secondary source: REACH dossier Animal test date: 1954
***In Vitro* Bacterial Genotoxicity Assay**	OECD 471	Negative ±S9	Secondary source: REACH dossier Animal test date: Non animal test method
In vitro Mammalian Cell Micronucleus Test	OECD 487	Negative	Secondary source: REACH dossier Animal test date: Non animal test data

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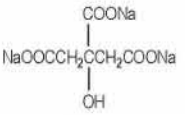
Ingredient Profile: Sodium Citrate

CAS number:	994-36-5 / 6132-04-3 (dihydrate) / 68-04-2 (anhydrous)	**EC number:**	213-618-2 (I) / 200-675-3 (I)
INCI Name:	Sodium Citrate		
Pseudonyms:	Citric Acid, Trisodium Salt		
Structure:	$C_6H_5O_7 \cdot 3Na$	**Image:**	
CLP Hazard classification(s):	Not classified		
REGULATION (EC) No 1223/2009	Not restricted.		
Other regulatory statuses:	N/A		

INCI Name	Tea Tree & Eucalyptus with Activated Charcoal Soap (% w/w)	CAS Number	EC Number	Function(s)	Restrictions	Maximum Level Present in Product(s) (% w/w)	Systemic Exposure Dose (mg/kg bw/day)	Point of Departure (mg/kg bw/day)	Margin of Exposure	Apply skin penetration data? Use a read-across analogue? Additional comments	Skin penetration (%)	Dermal exposure ug/cm2	NESIL	Safety Factor	AEL/CEL	Acceptable Exposure Level ug/cm2
Sodium Citrate	0.45/98	68-04-2 / 6132-04-3	200-675-3	Buffering, Chelating, Masking	N/A	0.45/980	0.001988	No Data			100	0.007	No Data	300		

Sodium Citrate is the sodium salt of citric acid. Sodium Citrate is used as a buffering agent, chelating agent, pH adjuster and fragrance ingredients in cosmetic products.

According to the CIR review[1] Sodium Citrate is typically used at up to 10% in leave on products and up to 10% in rinse off products, up to 2% in products used in the eye area, up to 0.4% in products which may be ingested, up to 4% in hair products, up to 0.5% in nail products and up to 1% in products which may be used on the mucous membrane. In a human irritation study Sodium Citrate was not irritating to the skin at 10%[1]. Citric acid and its salts have not reported to be a sensitiser in human studies[1]. Sodium Citrate was not genotoxic in an *in vitro* Ames study.

Upon ingestion it is expected that Sodium Citrate will dissociate into Citric acid and sodium. When orally administered is well absorbed and metabolised. Citric acid is also produced endogenously as a part of normal metabolism, where is completes the breakdown of pyruvate produced from glucose metabolism. Approximately 2 Kg of citric acid is metabolised every day in humans. Citric acid is freely filterable in the kidney and 65-90% of citric acid is reabsorbed[2]. Therefore, as citric acid is present in the diet naturally in addition to synthetic sources, coupled with endogenous production of citric acid, systemic toxicity from cosmetic products containing citric acid/ sodium citrate is not expected.

Summary:

The concentration and use of Sodium Citrate is not restricted according to Regulation (EC) No 1223/2009. The concentration and usage of this ingredient is consistent with industry norms. Under normal conditions of use systemic toxicity is not expected. Local toxicity endpoints such as; skin and eye irritation, skin sensitization, and phototoxicity are not expected.

References:

1. IJT 33(Suppl.2):16-46, 2014

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Specification data:

No specification test data was provided the responsible person must ensure that the ingredient is food or cosmetic grade.

Supporting test data:

The data below is based on *in vivo* and *in vitro* data to support the safety assessment. Any animal testing data listed below has been obtained from publicly available literature sources. According to REGULATION (EC) No 1223/2009 and Council Directive 76/768/EEC animal testing is prohibited for cosmetic products and ingredient past the prescribed timescales.

Test type:	Guideline:	Result	Source
***In vitro* bacterial reverse mutation test**	OECD 471	Not genotoxic 5000 µg/plate ±S9.	Secondary source: IJT 33(Suppl.2):16-46, 2014 Non animal test data.

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Ingredient Profile: Sodium Palm Kernelate

CAS number:	61789-89-7	**EC number:**	263-097-0 (I)
INCI Name:	Sodium Palm Kernelate		
Pseudonyms:	Palm Kernel Acids, Sodium Salt		
Structure:	N/A	**Image:**	N/A
CLP Hazard classification(s):	Not classified		
REGULATION (EC) No 1223/2009	Not restricted.		
Other regulatory statuses:	N/A		

INCI Name	Tea Tree & Eucalyptus with Activated Charcoal Soap (% w/w)	CAS Number	EC Number	Function(s)	Restrictions	Maximum Level Present in Product(s) (% w/w)	Systemic Exposure Dose (mg/kg bw/day)	Point of Departure (mg/kg bw/day)	Margin of Exposure	Apply skin penetration data? (Yes = apply the relevant skin penetration data as % of ingredient)	Skin penetration (%)	Dermal exposure (ug/cm2)	NOEL	Safety Factor	ADI/OEL	Acceptable Exposure Level (ug/cm2)
Sodium Palm Kernelate	16.0730	61789-89-7	263-097-0	Cleansing, Emollying, Surfactant, Viscosity Controlling	N/A	16.00737	0.06914	1000	14470		100	0.7387	No Data	300		

Sodium Palm Kernelate is the sodium salt of the acids derived from palm kernel oil.

In soap making; oils such as palm oil are saponified with lye (sodium hydroxide) to make the sodium fatty acid salt and glycerin.

The earliest evidence of soap making comes from soap deposits found in Egypt dated to ~2800 BC, inscriptions state the fats were boiled with ashes. There is evidence from 1500 BC that soaps were used for washing and treating skin diseases[1]. Soaps made with vegetable oils or animals fats have a long history of safe use for skin cleansing purposes.

Sodium Palm Kernelate is used as a surfactant and cleansing agent in cosmetic products. Elaeis Guineensis (Palm) Oil consists of[2]; up to 44% palmitic acid, up to 0.1% % palmitoleic acid, up to 4.5% stearic acid, up to 39.2% oleic acid, up to 10.1% linoleic acid and up to 0.4% linolenic acid. Saponification of olive oil with lye would create sodium palmitate, sodium stearate and their respective sodium salts of the fatty acids. Depending on the superfatting level there may be some unreacted fatty acids.

The CIR review[2] determined that Sodium Laurate/Linoleate/Oleate/Palmitate (major constituents of Sodium Palm Kernelate)[3] is used at up to 84.7% in rinse off products, up to 74.5% in leave on products, up to 74.5% in baby products and up to 84.7% in products applied to the mucous membranes.

Vegetable based fatty acids have a long history of safe use in the diet in edible oils, such as rapeseed oil, palm oil, olive oil and other vegetable-based oils. According to JECFA palmitic acid, stearic acid, lauric acid and oleic acid are do not have any safety concerns in the diet[4]. When applied topically fatty acids have been shown to remain mainly on the outer layers of the stratum corneum with little penetration[5]. Therefore, any unreacted fatty acids are not likely to cause systemic toxicity.

The salts of fatty acids are all approved food additives in the US and EU[6,7]. Upon ingestion these sodium salts are expected to dissociate in the gastric tract to fatty acid carboxylates and sodium salts. Sodium stearate has demonstrated the ability to penetrate the skin[7], it is expected that other sodium fatty acid salts may also penetrate the skin.

For the purposes of margin of safety calculations, a group read across assessment of various fatty acid salts was used. The lowest NOAEL was 1000 mg/kg bw/day and should be suitably conservative for margin of exposure calculations.

Summary:

The concentration and use of Sodium Palm Kernelate is not restricted according to Regulation (EC) No 1223/2009. The concentration and usage of this ingredient is consistent with industry norms. Under normal conditions of use systemic toxicity is not expected. Local toxicity endpoints such as; skin and eye irritation, skin sensitization, and phototoxicity are not expected.

References:

1. Nanoscale Assembly: Chemical Techniques Nanostructure Science and Technology Editor Wilhelm T.S. Huck, Springer Science & Business Media, 2006
2. CIR, Safety Assessment of Plant Derived Fatty Acid Oils, 2017.
3. CIR, Safety Assessment of Fatty Acids & Fatty Acid Salts as Used in Cosmetics, 2019
4. JECFA, WHO Food Additives Series No. 40, 1998.
5. Patzelt, A & Lademann, J & Richter, H & Darvin, Maxim & Schanzer, S & Thiede, Gisela & Sterry, Wolfram & Vergou, Theognosia & Hauser, Matthias. (2011). In vivo investigations on the penetration of various oils and their influence on the skin barrier. Skin research and technology : official journal of International Society for Bioengineering and the Skin (ISBS) [and] International Society for Digital Imaging of Skin (ISDIS) [and] International Society for Skin Imaging (ISSI). 18. 364-9. 10.1111/j.1600-0846.2011.00578.x.
6. 21CFR172.863
7. Re-evaluation of sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) as food additives, 2018.

Specification data:

No specification test data was provided the responsible person must ensure that the ingredient is food or cosmetic grade.

Supporting test data:

The data below is based on *in vivo* and *in vitro* data to support the safety assessment. Any animal testing data listed below has been obtained from publicly available literature sources. According to REGULATION (EC) No 1223/2009 and Council Directive 76/768/EEC animal testing is prohibited for cosmetic products and ingredient past the prescribed timescales.

Test type:	Guideline:	Result	Source
Acute oral toxicity	OECD 401	Read across: Calcium stearate. Rat LD_{50}: >2000 mg/kg	Secondary source: Safety Assessment of Fatty Acids & Soaps as Used in Cosmetics Animal test date: Prior to 2013
Acute dermal toxicity	OECD 402	Read across: Lithium stearate. Rat LD_{50}: >2000 mg/kg	Secondary source: Safety Assessment of Fatty Acids & Soaps as Used in Cosmetics Animal test date: Prior to 2013

Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test	OECD 422	Read across: Calcium stearate NOAEL >1000 mg/kg bw/day systemic effects. NOAEL 100 mg/kg bw/day for local effects of ulceration and inflammation of the skin. Lithium stearate >1000 mg/kg bw/day. No reproductive toxicity observed in either study.	Secondary source: Safety Assessment of Fatty Acids & Soaps as Used in Cosmetics Animal test date: Prior to 2013.

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Ingredient Profile: Sodium Palmate

CAS number:	61790-79-2	**EC number:**	263-162-3 (I)
INCI Name:	Sodium Palmate		
Pseudonyms:			
Structure:	N/A	**Image:**	N/A
CLP Hazard classification(s):	Not classified		
REGULATION (EC) No 1223/2009	Not restricted.		
Other regulatory statuses:	N/A		

INCI Name	Tea Tree & Eucalyptus with Activated Charcoal Soap (% w/w)	CAS Number	EC Number	Function(s)	Restrictions	Maximum Level Present in Product(s) (% w/w)	Systemic Exposure Dose (mg/kg bw/day)	Point of Departure (mg/kg bw/day)	Margin of Exposure	Apply skin penetration data? [illegible]	Skin penetration (%)	Dermal exposure ug/cm2	NESIL	Safety Factor	AEL/CEL	Acceptable Exposure Level ug/cm2
Sodium Palmate	51.5480	61790-79-2	263-162-3	Cleansing, Emulsifying, Surfactant, Viscosity Controlling	N/A	51.54819	0.77338	1000	[illegible]		100	0.766	No Data	300		

Sodium Palmate is the sodium salt of the acids derived from Elaeis Guineensis (Palm) Oil.

It is used as a soap, surfactant and emulsifying agent in cosmetic products. In soap making; oils such as palm oil are saponified with lye (sodium hydroxide) to make the sodium fatty acid salt and glycerin.

The earliest evidence of soap making comes from soap deposits found in Egypt dated to ~2800 BC, inscriptions state the fats were boiled with ashes. There is evidence from 1500 BC that soaps were used for washing and treating skin diseases[1]. Soaps made with vegetable oils or animals fats have a long history of safe use for skin cleansing purposes.

Sodium Palmate is approved as indirect food additive by the USFDA (21CFR175.105, and 21CFR176.170).

Sodium Palmate is used as a surfactant and cleansing agent in cosmetic products. Elaeis Guineensis (Palm) Oil consists of[2]; up to 44% palmitic acid, up to 0.1% % palmitoleic acid, up to 4.5% stearic acid, up to 39.2% oleic acid, up to 10.1% linoleic acid and up to 0.4% linolenic acid. Saponification of olive oil with lye would create sodium palmitate, sodium stearate and their respective sodium salts of the fatty acids. Depending on the superfatting level there may be some unreacted fatty acids.

The CIR review[2] determined that Sodium Laurate/Linoleate/Oleate/Palmitate (major constituents of sodium palmate)[3] is used at up to 84.7% in rinse off products, up to 74.5% in leave on products, up to 74.5% in baby products and up to 84.7% in products applied to the mucous membranes.

Vegetable based fatty acids have a long history of safe use in the diet in edible oils, such as rapeseed oil, palm oil, olive oil and other vegetable-based oils. According to JECFA palmitic acid, stearic acid, lauric acid and oleic acid are do not have any safety concerns in the diet[4]. When applied topically fatty acids have been shown to remain mainly on the outer layers of the stratum corneum with little penetration[5]. Therefore, any unreacted fatty acids are not likely to cause systemic toxicity.

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The salts of fatty acids are all approved food additives in the US and EU[6,7]. Upon ingestion these sodium salts are expected to dissociate in the gastric tract to fatty acid carboxylates and sodium salts. Sodium stearate has demonstrated the ability to penetrate the skin[7], it is expected that other sodium fatty acid salts may also penetrate the skin.

For the purposes of margin of safety calculations, a group read across assessment of various fatty acid salts was used. The lowest NOAEL was 1000 mg/kg bw/day and should be suitably conservative for margin of exposure calculations.

Summary:

The concentration and use of Sodium Palmate is not restricted according to Regulation (EC) No 1223/2009. The concentration and usage of this ingredient is consistent with industry norms. Under normal conditions of use systemic toxicity is not expected. Local toxicity endpoints such as; skin and eye irritation, skin sensitization, and phototoxicity are not expected.

References:

1. Nanoscale Assembly: Chemical Techniques Nanostructure Science and Technology Editor Wilhelm T.S. Huck, Springer Science & Business Media, 2006
2. CIR, Safety Assessment of Plant Derived Fatty Acid Oils, 2017.
3. CIR, Safety Assessment of Fatty Acids & Fatty Acid Salts as Used in Cosmetics, 2019
4. JECFA, WHO Food Additives Series No. 40, 1998.
5. Patzelt, A & Lademann, J & Richter, H & Darvin, Maxim & Schanzer, S & Thiede, Gisela & Sterry, Wolfram & Vergou, Theognosia & Hauser, Matthias. (2011). In vivo investigations on the penetration of various oils and their influence on the skin barrier. Skin research and technology : official journal of International Society for Bioengineering and the Skin (ISBS) [and] International Society for Digital Imaging of Skin (ISDIS) [and] International Society for Skin Imaging (ISSI). 18. 364-9. 10.1111/j.1600-0846.2011.00578.x.
6. 21CFR172.863
7. Re-evaluation of sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) as food additives, 2018.

Specification data:

No specification test data was provided the responsible person must ensure that the ingredient is food or cosmetic grade.

Supporting test data:

The data below is based on *in vivo* and *in vitro* data to support the safety assessment. Any animal testing data listed below has been obtained from publicly available literature sources. According to REGULATION (EC) No 1223/2009 and Council Directive 76/768/EEC animal testing is prohibited for cosmetic products and ingredient past the prescribed timescales.

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Test type:	Guideline:	Result	Source
Acute oral toxicity	OECD 401	Read across: Calcium stearate. Rat LD_{50}: >2000 mg/kg	Secondary source: Safety Assessment of Fatty Acids & Soaps as Used in Cosmetics Animal test date: Prior to 2013
Acute dermal toxicity	OECD 402	Read across: Lithium stearate. Rat LD_{50}: >2000 mg/kg	Secondary source: Safety Assessment of Fatty Acids & Soaps as Used in Cosmetics Animal test date: Prior to 2013
Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test	OECD 422	Read across: Calcium stearate NOAEL >1000 mg/kg bw/day systemic effects. NOAEL 100 mg/kg bw/day for local effects of ulceration and inflammation of the skin. Lithium stearate >1000 mg/kg bw/day. No reproductive toxicity observed in either study.	Secondary source: Safety Assessment of Fatty Acids & Soaps as Used in Cosmetics Animal test date: Prior to 2013.

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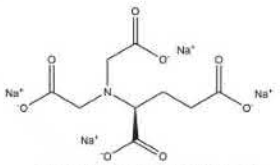
Ingredient Profile: Tetrasodium Glutamate Diacetate

CAS number:	51981-21-6	**EC number:**	257-573-7
INCI Name:	Tetrasodium Glutamate Diacetate		
Pseudonyms:	Tetrasodium N,N-bis(carboxylatomethyl)-L-glutamate		
Structure:	$C_9H_9NO_8Na_4$	**Image:**	



Tetrasodium Glutamate Diacetate

CLP Hazard classification(s):	Not classified
REGULATION (EC) No 1223/2009	Not restricted.
Other regulatory statuses:	N/A

INCI Name	Tea Tree & Eucalyptus with Activated Charcoal Soap (% w/w)	CAS Number	EC Number	Function(s)	Restrictions	Maximum Level Present in Product(s) (% w/w)	Systemic Exposure Dose (mg/kg bw/day)	Point of Departure (mg/kg bw/day)	Margin of Exposure	Apply skin penetration data? If not, apply default skin penetration assumptions	Skin penetration (%)	Dermal exposure (ug/cm2	NESIL	Safety Factor	AEL/ADI	Acceptable Exposure Level (ug/cm2
Tetrasodium Glutamate Diacetate	0.4578	51981 21 6	257 573 7	Chelating	N/A	0.45780	0.00198	300	151,225		100	0.007	No Data	300		

Tetrasodium Glutamate Diacetate is used as a chelating agent in cosmetic products.

Tetrasodium Glutamate Diacetate has low acute oral toxicity. Tetrasodium Glutamate Diacetate is not irritating to the skin or eye in animal models when applied undiluted. Tetrasodium Glutamate Diacetate is not a skin sensitiser in a guinea pig maximisation assay when tested at up to 50% concentrations. Tetrasodium Glutamate Diacetate is not genotoxic *in vitro* or *in vivo*. Tetrasodium Glutamate Diacetate was tested in a 90 oral toxicity test in rats, the NOAEL was 300 mg/kg bw/day.

Summary:

The concentration and use of Tetrasodium Glutamate Diacetate is not restricted according to Regulation (EC) No 1223/2009. The concentration and usage of this ingredient is consistent with industry norms. Under normal conditions of use systemic toxicity is not expected. Local toxicity endpoints such as; skin and eye irritation, skin sensitization, and phototoxicity are not expected.

References:

1. Cosmetic Ingredient Review Expert Panel, Scientific Literature Review for Public Comment, Safety Assessment of Beta-Alanine Diacetic Acid and Tetrasodium Glutamate Diacetateas Used in Cosmetics, 2019.

Specification data:

No specification test data was provided the responsible person must ensure that the ingredient is food or cosmetic grade.

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Supporting test data:

The data below is based on *in vivo* and *in vitro* data to support the safety assessment. Any animal testing data listed below has been obtained from publicly available literature sources. According to REGULATION (EC) No 1223/2009 and Council Directive 76/768/EEC animal testing is prohibited for cosmetic products and ingredient past the prescribed timescales.

Test type:	Guideline:	Result	Source
Acute oral toxicity	OECD 401	Rat LD_{50}: >5000 mg/kg	Secondary source: ECHA Dossier for Tetrasodium N,N-bis(carboxylatomethyl)-L-glutamate Animal test date: Prior to 1994
Skin irritation	OECD 404	Rabbit: Non irritating at up to 100%	Secondary source: ECHA Dossier for Tetrasodium N,N-bis(carboxylatomethyl)-L-glutamate Animal test date: Prior to 1994
Eye irritation	OECD 405	Rabbit: Non irritating at up to 100%	Secondary source: ECHA Dossier for Tetrasodium N,N-bis(carboxylatomethyl)-L-glutamate Animal test date: Prior to 1994
Skin sensitisation	OECD 406	Not sensitising at up to 50% in guinea pigs	Secondary source: ECHA Dossier for Tetrasodium N,N-bis(carboxylatomethyl)-L-glutamate Animal test date: Prior to 1995
Repeated dose 90-day oral toxicity study in rodents	OECD 408	Rats rat 0, 100, 300 and 1000 mg/kg bw/day. NOAEL 300 mg/kg bw/day	Secondary source: ECHA Dossier for Tetrasodium N,N-bis(carboxylatomethyl)-L-glutamate Animal test date: Prior to 2007
***In vitro* bacterial reverse mutation test**	OECD 471	Not genotoxic 5000 µg/plate ±S9.	Secondary source: ECHA Dossier for Tetrasodium N,N-bis(carboxylatomethyl)-L-glutamate Non animal test data.
***In vivo* mammalian erythrocyte micronucleus test**	OECD 474	Not genotoxic at 400 mg/kg	Secondary source: ECHA Dossier for Tetrasodium N,N-bis(carboxylatomethyl)-L-glutamate Animal test date: Prior to 1995

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Annex II – Fragrance Information

The product contains the following essential oils:

Common name	INCI name	Supplier(s)	Restrictions
Eucalyptus Essential Oil	Eucalyptus Globulus Leaf Oil	The Soapery	N/A
Tea Tree Essential Oil	Melaleuca Alternifolia Leaf Oil	The Soapery	N/A
Rosemary Essential Oil	Rosmarinus Officinalis Leaf Oil	The Soapery	N/A

Substitution of essential oil suppliers not named above must be substituted with similar grades and the INCI name must not change. The Responsible Person must comply with restrictions listed above.

Allergen declarations in this report are based on the information on the date of submission. It is the duty of the Responsible Person to ensure that the ingredient and allergen declarations are correct on the label. It is the duty of the Responsible Person to check raw material information for changes and update labelling accordingly.

For the EU:
Cosmetic products containing additional allergens listed in COMMISSION REGULATION (EU) 2023/1545 will need to be declared on the labelling, when its concentration exceeds:
— 0,001 % in leave-on products

— 0,01 % in rinse-off products.

Products that do not comply with the restriction(s) may be placed on the Union market until 31 July 2026 and made available on the Union market until 31 July 2028. It is the duty of the Responsible Person when placing a cosmetic on sale in the EU to comply with this requirement by the implementation date.

Annex III

This report is only valid for the formulation(s) submitted herein, should re-formulation occur re-assessment will be necessary.

This report does not cover food imitation, which is prohibited for cosmetic products. This report does not cover medical claims which are prohibited for cosmetic products.

This report covers the Regulation (EC) No. 2009/1223, if the product is marketed in a way is out of scope of the Cosmetic Regulations, for example but not limited to; Biocides (Regulation (EU) No 528/2012), detergents Regulation (EU) 648/2004 or as a toy and relevant safety requirements Regulation (EU) 2009/48/EC The Responsible Person accepts all liability and responsibility for ensuring that their products comply with all of the relevant regulations that apply to their product(s).

The Responsible Person is responsible for ensuring that other elements of the Regulation (EC) No. 2009/1223 such as but not limited to; manufacture to GMP, maintenance/update of the Product Information File, reporting of Serious Undesirable Effects and labelling requirements.

Swift Fox Ltd is not liable for any damage or injury resulting from use of this product.

The validity of the report depends on the disclosure by the manufacturers of the raw materials, packaging and the manufacturer of the finished products.