

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	240050-3 (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:	Ginger & Lime with Pumice		
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

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

Product name: Ginger & Lime with Pumice soap

Ingredients	
INCI names	% INCI
Sodium Palmate	51.651376
Aqua	16.055046
Sodium Palm Kernelate	16.055046
Glycerin	6.880734
Mangifera Indica Seed Butter	5.087573
Kaolin	1.000834

Rosmarinus Officinalis Leaf Oil	0.583820
Curcuma Longa Root Powder	0.166806
Zingiber Officinale Root Oil	0.667223
Citrus Aurantifolia Oil	0.667223
Sodium Chloride	0.091743
Pumice	0.083403
Tetrasodium Glutamate Diacetate	0.458716
Citric Acid	0.091743
Sodium Citrate	0.458716

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

Labeling allergens	
INCI names	% INCI
Limonene	0.348624

Non-labeling allergens	
INCI names	% INCI
Linalool	0.005838

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
Ginger & Lime with Pumice 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.

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
<i>Escherichia coli</i>	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
<i>Pseudomonas aeruginosa</i>	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
<i>Staphylococcus aureus</i>	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
<i>Candida albicans</i>	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.

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.

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 µg/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	

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	Ginger & Lime with Pumice 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 applied skin penetration data on all ingredients)	Skin penetration (%)	Dermal exposure ug/cm2	NESIL	Safety Factor	AEL/CEL	Acceptable Exposure Level ug/cm2
Aqua	16.0550	7732-18-5	231-791-2	Solvent	N/A	16.05505	0.06957	No Data			100	0.239	No Data	300		
Citric Acid	0.0917	77-92-9 / 5949-29-1	201-069-1	Buffering, Chelating, Masking	N/A	0.09174	0.00040	1200	3018465		100	0.001	No Data	300		
Citrus Aurantifolia Oil	0.6672	8008-26-2 / 90063-52-8	- / 290-010-3	Cleansing, Hair Conditioning, Masking, Perfuming, Skin Conditioning, Tonic	II/358 RI	0.66722	0.00289	No Data			100	0.010	No Data	300		
Curcuma Longa Root Powder	0.1668	84775-52-0	283-882-1	Skin Conditioning	N/A	0.16681	0.00072	200	276692		100	0.002	No Data	300		
Glycerin	6.8807	56-81-5	200-289-5	Denaturant, Hair Conditioning, Humectant, Oral Care, Perfuming, Skin Protecting, Viscosity Controlling	N/A	6.88073	0.02982	10000	335385		100	0.102	No Data	300		
Kaolin	1.0008	1332-58-7	310-194-1	Abrasive, Absorbent, Anticaking, Bulking, Cosmetic Colorant, Opacifying	IV/119	1.00083	0.00434	10000	2305769		100	0.015	No Data	300		
Mangifera Indica Seed Butter	5.0876	90063-86-8	290-045-4	Skin Conditioning	N/A	5.08757	0.02205	No Data			100	0.076	No Data	300		
Pumice	0.0834	1332-09-8	-	Abrasive, Bulking, Viscosity Controlling	N/A	0.08340	0.00036	No Data			100	0.001	No Data	300		
Rosmarinus Officinalis Leaf Oil	0.5838	84604-14-8 / 8000-25-7	283-291-9	Masking, Skin Conditioning	N/A	0.58382	0.00253	230	90913		100	0.009	No Data	300		
Sodium Chloride	0.0917	7647-14-5	231-598-3	Bulking, Masking, Oral Care, Viscosity Controlling	N/A	0.09174	0.00001	50	4192313		3	0.001	No Data	300		
Sodium Citrate	0.4587	68-04-2 / 6132-04-3	200-675-3	Buffering, Chelating, Masking	N/A	0.45872	0.00199	No Data			100	0.007	No Data	300		
Sodium Palm Kernelate	16.0550	61789-89-7	263-097-0	Cleansing, Emulsifying, Surfactant, Viscosity Controlling	N/A	16.05505	0.06957	1000	14374		100	0.239	No Data	300		
Sodium Palmate	51.6514	61790-79-2	263-162-3	Cleansing, Emulsifying, Surfactant, Viscosity Controlling	N/A	51.65138	0.22382	1000	4468		100	0.767	No Data	300		
Tetrasodium Glutamate Diacetate	0.4587	51981-21-6	257-573-7	Chelating	N/A	0.45872	0.00199	300	150923		100	0.007	No Data	300		
Zingiber Officinale Root Oil	0.6672	2230756	-	Masking, Perfuming, Skin Conditioning, Tonic	N/A	0.66722	0.00289	500	172933		100	0.010	No Data	300		
Limonene	0.3486	138-86-3	205-341-0/931-893-3	Deodorant, Perfuming, Solvent	III/88 III/167 III/168	0.34862	0.00000	150	62057160		0.16	0.005	10000	300	3218	16.67
Linalool	0.0058	78-70-6	201-134-4	Deodorant, Perfuming	III/84	0.00584	0.00000	117	2720512665		0.17	0.000	15000	300	288231	25.00

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.

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.

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.

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).

Annex I – Toxicological Ingredient Profiles

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:

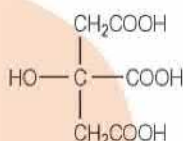


Image:



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 additive (21CFR178.1010, 21CFR184.1033).
JEFCA: Not restricted.
EU: Approved food additive.

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

INCI Name	Other Names	CAS Number	EC Number	Function(s)	Restrictions	Maximum Level Systemic Exposure (mg/kg bw/day)	Point of Exposure (mg/kg bw/day)	Weight of Exposure (kg)	Apply when potential risk is significant	Safe concentration (%)	Dermal exposure (mg/cm ²)	NIEL	Safety Factor	AE/CEL	Acceptable Exposure Level (mg/kg bw/day)
Citric Acid	Ginger & Lime with Rumice Soap (% w/w)	77-92-9 / 5949-29-1	201-069-1	Buffering, Chelating, Masking	N/A	0.09174	0.00040	1200	3018465	100	0.001	No Data	300	AE/CEL	Level 1 mg/kg bw/day

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 acid¹. It is used as a chelating agent, fragrance ingredient and pH adjuster in cosmetic products.

Citric acid is an approved indirect 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 it 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 reabsorbed². 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 trachea². 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 acid², however according to the OECD SIDS report³ 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 sensitisation².

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
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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	HRIFT of 60 eczema patients with 2.5% citric acid in petrolatum did not cause any irritant reactions	SIDS Initial Assessment Report for 11th SIAM, 2001

Ingredient Profile: Citrus Aurantifolia (Lime) Oil

CAS number:	8008-26-2	EC number:	N/A
INCI Name:	Citrus Aurantifolia Oil		
Pseudonyms:	Lime Oil		
Structure:	N/A	Image:	

CLP Hazard classification(s): Not classified

REGULATION (EC) No 1223/2009 II/358: Furocoumarines (e.g. trioxysalen (INN), 8-methoxypsoralen, 5-methoxypsoralen), except for normal content in natural essences used. In sun protection and in bronzing products, furocoumarines shall be below 1 mg/kg.

Other regulatory statuses: N/A

INCI Name	Ingredient & Limit with Purities (if any)	CAS Number	SC Number	Function(s)	Restrictions	Maximum Limit Systemic Exposure Product(s) (% dose (mg/kg bodyweight))	Point of Departure (mg/kg bodyweight)	Margin of Exposure	Apply oral assessment only (yes/no/unknown)	Skin penetration (%)	Dermal exposure (mg/cm ²)	MSL	Safety Factor	Acceptable Exposure Level (mg/kg)
Citrus Aurantifolia Oil	0.66/77	8008-26-2 / 90063-07-8	- / 799-010-1	Cleaning, Hair Conditioning, Perfuming, Skin Conditioning, Tonic	II/358 RI	0.66/77	0.00089	No Data	0	100	0.010	No Data	300	

Citrus Aurantifolia (Lime) Oil is the volatile oil obtained from the whole plant, Citrus aurantifolia. The accepted scientific name for Citrus aurantifolia is Citrus x aurantiifolia. It is used as a skin conditioning agent and fragrance agent in cosmetic products.

It is considered to be suitable for human consumption by the USFDA (21CFR182.20), who have also granted it GRAS status (Generally Recognised As Safe). Citrus essential oils are also used as flavouring agents in pharmaceutical products.

The SCCNFP¹ expressed concern regarding the potential for furocoumarins in citrus oils, such as lime oil to cause phototoxicity and photomutagenicity. For sun protection products furocoumarins must be kept below 1 mg/kg. Citrus Aurantifolia (Lime) Oil may contain natural sources of furocoumarines which are restricted by Regulation (EC) No 1223/2009. Furocoumarines (e. g. trioxysalen (INN), 8-methoxypsoralen, 5-methoxypsoralen) except for normal content in natural essences used. In sun protection and in bronzing products, furocoumarines shall be below 1 mg/kg. In sun protection products total furocoumarines must be kept below 1 mg/kg. As this is a natural content in a natural essential oil Citrus Aurantifolia (Lime) Oil complies with Annex II/358.

The essential oil is steam distilled therefore, furocoumarines content should be reduced significantly. Phototoxicity is not expected. This product is a rinse off product, therefore, exposure to residual furocoumarins following rinsing to the sun is expected to be limited. Phototoxicity is not expected.

According to the CIR review, lime oil is used at levels of 0.36% in leave on products, up to 0.17% in rinse off products, up to 0.36% in products which may be ingested, up to 0.17% in dermally applied products, and up to 0.12% in products which may be sprayed². The CIR concluded that lime oil is safe at present practices of use and concentration when formulated to be non-irritating and sensitising.

According to Tisserand³, lime oil has low acute oral and dermal toxicity (LD₅₀: >5000 mg/kg). Undiluted lime oil was irritating to the skin of rabbits. Undiluted lime oil was slightly irritating to the skin of rabbits. Lime oil tested on 25 volunteers at 25% was non irritating and sensitising. Genotoxicity was not observed in *in vitro*.

As lime oil has a long history of safe use as a food flavouring agent, systemic toxicity is not expected.

Summary:

The concentration and use of Citrus Aurantifolia (Lime) Oil is restricted according to Regulation (EC) No 1223/2009. Furocoumarines (e.g. trioxysalan (INN), 8-methoxypsoralen, 5-methoxypsoralen), except for normal content in natural essences used. In sun protection and in bronzing products, furocoumarines shall be below 1 mg/kg. This ingredient may contain naturally occurring furocoumarines. 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.

EU only:

Citrus Aurantifolia (Lime) Oil has been identified as a cosmetic allergen. Therefore, The presence of the substance or the substances shall be indicated in the list of ingredients referred to in Article 19(1), point (g), when the concentration of the substance or the substances exceeds:

— 0,001 % in leave-on products

— 0,01 % in rinse-off products.

Cosmetic products containing this substance 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**.

References:

1. SCCP/0942/05
2. CIR, Safety Assessment of Citrus Plant- and Seed-Derived Ingredients as Used in Cosmetics, 2017
3. 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
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Acute oral toxicity	OECD 401	Rat LD ₅₀ : >5000 mg/kg	Secondary source: Tisserand, Essential Oil Safety, A Guide for Health Care Professionals, 2014 Animal test date: Prior to 1974
Acute dermal toxicity	OECD 402	Rabbit LD ₅₀ : >5000 mg/kg	Secondary source: Tisserand, Essential Oil Safety, A Guide for Health Care Professionals, 2014 Animal test date: Prior to 1974
Skin irritation	OECD 404	Rabbit: Slightly irritating at up to 100%	Secondary source: Tisserand, Essential Oil Safety, A Guide for Health Care Professionals, 2014 Animal test date: Prior to 1974
In vitro bacterial reverse mutation test	OECD 471	Not mutagenic	Secondary source: Tisserand, Essential Oil Safety, A Guide for Health Care Professionals, 2014 Non animal test data.
In Vitro mammalian chromosome aberration test	OECD 473	No chromosomal aberrations were observed in CHO cells.	Secondary source: Tisserand, Essential Oil Safety, A Guide for Health Care Professionals, 2014 Non animal test data.

Ingredient Profile: Curcuma Longa (Turmeric) Root Powder

CAS number: N/A **EC number:** N/A
INCI Name: Curcuma Longa Root Powder
Pseudonyms: Curcuma Longa (Turmeric) Root Powder, Turmeric powder
Structure: N/A **Image:**



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

INCI Name	Origin & Limit with Pesticide Stop (% w/w)	CAS Number	EC Number	Function(s)	Restrictions	Maximum Local Systemic Protein in Product(s) (% w/w max) view	Systemic Exposure (% w/w max) view	Point of Exposure (mg/kg bodyweight)	Margin of Exposure	Apply skin penetration data (yes/no) or systemic exposure data (yes/no)	Systemic Exposure (%)	Dermal Exposure (mg/kg)	MSL	Safety Factor	ASL/CEL	Acceptable Exposure Level (mg/kg)
Curcuma Longa Root	0.1668	84775-57-0	783-882-1	Skin Conditioning	N/A	0.1668	0.0007	700	2.663	Yes	100	0.007 (No Data)	300			

Curcuma Longa (Turmeric) Root Powder is a powder obtained from the dried, ground rhizomes of Curcuma longa. Curcuma Longa (Turmeric) Root Powder is used as a exfoliant in cosmetic products.

Curcuma Longa (Turmeric) Root Powder is used as a spice, and is a major constituent in curry powder. Turmeric powder consists of approximately 3% curcumin, the chemical responsible for its distinctive yellow colour¹. It is estimated that up to 0.87g/day/person of turmeric is consumed in India².

Curcuma Longa (Turmeric) Root Powder is approved for use in as a colourant in foods by the USFDA and is exempt from certification (21CFR73.600). Curcuma Longa (Turmeric) Root Powder is considered to be Generally Recognised As Safe by the USFDA as a spice in foods (21CFR182.10).

Curcuma Longa (Turmeric) Root Powder has a long history of use as a Traditional Herbal Remedy in Chinese and Ayurvedic medicine systems³. In a clinical study of 120 subjects with arthritis Curcuma Longa (Turmeric) Root Powder was administered at 1000mg/day for 42 days was equally as effective as ibuprofen but with fewer side effects. The only symptoms reported was mild intestinal symptoms³. In other clinical trials there were no dose limiting adverse effects at up to 12g/day⁴. Turmeric may be ingested as a food supplement in the EU at up to 1200 mg/day with few reported adverse effects.

Given the widespread use of Curcuma Longa (Turmeric) Root Powder in foods, and the high doses tolerated in human clinical studies and as a food supplement, systemic toxicity is not expected.

Curcuma Longa (Turmeric) Root Powder has a long history of use as a cosmetic in India⁴ where it is applied to the skin as a paste. Topical curcumin and turmeric have been reported to reduce skin healing times and improve out comes in clinical case reports⁵. Allergic contact dermatitis has been reported for Curcuma Longa (Turmeric) Root Powder, but are generally rare⁶.

Summary:

The concentration and use of Curcuma Longa (Turmeric) Root 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.

References:

1. Reema F. Tayyem, Dennis D. Heath, Wael K. Al-Delaimy & Cheryl L. Rock (2006) Curcumin Content of Turmeric and Curry Powders, Nutrition and Cancer, 55:2, 126-131, DOI: 10.1207/s15327914nc5502_2.
2. Siruguri, V., Bhat, R.V. Assessing intake of spices by pattern of spice use, frequency of consumption and portion size of spices consumed from routinely prepared dishes in southern India. Nutr J 14, 7 (2015). <https://doi.org/10.1186/1475-2891-14-7>.
3. Daily JW, Yang M, Park S. Efficacy of Turmeric Extracts and Curcumin for Alleviating the Symptoms of Joint Arthritis: A Systematic Review and Meta-Analysis of Randomized Clinical Trials. J Med Food. 2016.
4. Gopinath H, Karthikeyan K. Turmeric: A condiment, cosmetic and cure. Indian J Dermatol Venereol Leprol 2018;84:16-21.
5. Heng MCY (2017) Topical Curcumin: A Review of Mechanisms and uses in Dermatology. Int J Dermatol Clin Res 3(1):010-017.
6. Assessment report on Curcuma longa L., rhizome, EMA/HMPC/329745/2017.

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
Carcinogenicity studies	OECD 451	In 103 week studies performed in rats and mice no carcinogenicity was observed at 50,000 mg/kg turmeric oleoresin.	Secondary source: Assessment report on Curcuma longa L., rhizoma EMA/HMPC/329745/2017 Animal test date: 1993
In vitro bacterial reverse mutation test	OECD 471	Not genotoxic 5000 µg/plate ±S9.	Secondary source: National Toxicology Program Non animal test data.

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:** $HOCH_2CH(OH)CH_2OH$

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	Group & Limit (if any)	CAS Number	EC Number	Function(s)	Restrictions	Maximum Limit: Systemic: Present in Product (by wt%)	Exposure: (% Dose (mg/kg bodyweight))	Point of Departure (mg/kg bodyweight)	Margin of Exposure	Apply skin permeation data (if available) Systemic Exposure (mg/kg body weight)	Skin penetration (%)	Dermal exposure (mg/cm ²)	MSL	Safety Factor	ADL/CEL Level (mg/kg)	Acceptable Exposure Level (mg/kg)
Glycerin	6.880/	56-81-5	700-289-5	Densitiser, Hair Conditioning, Moisturiser, Oral Care, Perfuming, Skin Protecting, Viscosity Controller	N/A	6.880/1	0.07962	10000	70.325	20	100	0.102 (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 lipids¹.

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 pigs¹.

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 tested².

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 \pm 59	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

Ingredient Profile: Kaolin

CAS number: 1332-58-7 **EC number:** N/A
INCI Name: 1332-58-7
Pseudonyms: China Clay, CI 77004
Structure: $\text{Al}_2\text{Si}_2\text{O}_5(\text{OH})_4$ **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 additive (21CFR184.1077).
JEFCA: ADI not restricted
EU food additive E559

INCI Name	Group A Limit with Parent Soap (%) value	CAS Number	EC Number	Function(s)	Restrictions	Maximum Allowable Systemic Exposure to Systemic Parent(s) (% Daily Intake)	Route of Exposure (mg/kg/day)	Margin of Exposure	Apply when potential for systemic exposure is identified	Skin protection (mg/cm²)	Dermal exposure (mg/cm²)	NIEL	Safety Factor	ADL/CEL	Acceptable Exposure Level against
Kaolin	1.0000	1332-58-7	316-194-1	Abrasive, Absorbent, Anticaking, Bulking, Cosmetic Colorant, Opacifying	IV/119	1.00007	0.00434	10000	2305767	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 skin¹.

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 cosmetics¹.

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.

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 $>15 \text{ g/kg}^3$. Kaolin was well tolerated in a 90 day oral study up to 20% in the diet ($\sim 10,000 \text{ mg/kg bw/day}$)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: I.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.JT 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.JT 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

Ingredient Profile: Mangifera Indica (Mango) Seed Butter

CAS number: 90063-86-8 (generic) **EC number:** 290-045-4 (I)
INCI Name: Mangifera Indica Seed Butter
Pseudonyms: Mangifera Indica (Mango) Seed 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	Origin & Use with Purposes (N/A)	CAS Number	EC Number	Function(s)	Restrictions	Maximum Level System: Product in (N/A)	Exposure (N/A)	Point of Application (N/A)	Material of Construction (N/A)	Apply after preparation (N/A)	Stability (N/A)	Detected (N/A)	MSL	Safety Factor	ASL/CEL	Acceptable: Reasonable Level (N/A)
Mangifera Indica Seed Butter	5,08/76	90063-86-8	290-045-4	Skin Conditioning	N/A	5,08/76	0,03705: No Data				100	0,0376: No Data	100			

Mangifera Indica (Mango) Seed Butter is the fat obtained from the seeds of Mangifera indica. It is used as a skin conditioning agent in cosmetic products. Mangifera Indica (Mango) Seed Butter is used as a substitute in foods for cocoa butter.

Mangifera Indica (Mango) Seed Butter typically has the following composition¹:

Fatty acids	Percentage (%)	Fatty acids	Percentage (%)
Caproic Acid (C6)	N/A	Linoleic Acid (C18:2)	Up to 5%
Caprylic Acid (C8)	N/A	Linolenic Acid (C18:3)	N/A
Capric Acid (C10)	N/A	Arachidic Acid (C20)	N/A
Lauric Acid (C12)	N/A	Eicosenoic Acid (C20:1)	N/A
Myristic (C14)	N/A	Eicosadienoic Acid (C20:2)	N/A
Myristoleic Acid (C14:1)	N/A	Arachidonic Acid (C20:4)	<1
Palmitic Acid (C16)	Up to 15%	Behenic Acid (C22)	N/A
Palmitoleic Acid *C16:1)	N/A	Erucic Acid	N/A
Heptadecanoic Acid (C17:0)	N/A	Docosadienoic Acid (C22:2)	N/A
Stearic Acid (C18)	Up to 35%	Docosahexaenoic Acid (C22:6)	N/A
Oleic Acid (C18:1)	Up to 65%	Lignoceric Acid (C24)	N/A

According to the CIR review² Mangifera Indica (Mango) Seed Butter is used in leave on products at up to 5%, in rinse off products at up to 0.5%, up to 5% in products that may be ingested and up to 0.02% in products which may be used in the eye area. A product containing 9% Mangifera Indica (Mango) Seed Butter was tested in a HRIPT in 102 individuals it was concluded that it was not a sensitizer. A product containing 1% Mangifera Indica (Mango) Seed Butter was tested in a HRIPT in 100 individuals, no signs of irritation or sensitisation were observed in the study².

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 diet³. When applied topically fatty acids have been shown to remain mainly on the outer layers of the stratum corneum with little penetration⁴. Therefore, the fatty acids contained in Mangifera Indica Seed Butter are not likely to cause systemic toxicity. As Mangifera Indica Seed Butter is used as a cocoa butter substitute in the diet, systemic toxicity is not expected.

Summary:

The concentration and use of Mangifera Indica (Mango) Seed 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. Sci Rep. 2016; 6: 32050.
2. IJT 36(Suppl. 3):51-129, 2017
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.

Ingredient Profile: Pumice

CAS number: 1332-09-8 **EC number:** N/A
INCI Name: Pumice
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	Ginger & Lime with Pomegranate Soap (N. wine)	CAS Number	EC Number	Presidential	Restrictions	Maximum Level System Present in Product (N. wine)	Spencer (% Done (mg/kg bodyweight))	Power of Separation (mg/kg bodyweight)	Margin of Exposure	Apply skin penetration data (N. wine)	Site	Dermal exposure (g/kg bodyweight)	PERL	Safety Factor	Acceptable Exposure Level (g/kg bodyweight)
Pumice	0.0014	1332-09-8		Abrasive, Bulking, Viscosity Controlling	N/A	0.00140	0.00036	No Data			100	0.001	No Data	300	

Pumice is a substance of volcanic origin consisting chiefly of complex silicates of aluminum and alkali metals. Pumice is used as an exfoliating ingredient and bulking agent in cosmetic products.

Pumice is a light weight and porous volcanic rock that has a long history of use as a traditional herbal remedy in China for over 2000 years pumice was added to teas. Western medicine pumice has been employed as cleansers for ulcers and in eye ointments¹. Pumice is not likely to penetrate the skin given the large molecular size of the silicates and poor absorption of inorganic materials. Coupled with the long history of use of pumice being used as an exfoliating agent systemic toxicity is not expected.

Pumice may cause skin and eye irritation by mechanical means, but the irritation is expected to be transient.

Summary:

The concentration and use of Pumice 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. History of the pharmaceutical use of pumice, Geological Society, London, Special Publications, 375, 157-169

Specification data:

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

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
Other regulatory statuses: Not restricted.
N/A

INCI Name	Other Names (if any)	CAS Number	EC Number	Function(s)	Maximum Level Systemic Exposure (% Rosemary Leaf Oil)	Margin of Exposure (mg/kg bw/day)	Margin of Exposure (mg/kg bw/day)	Apply skin penetration data (1) to calculate potential systemic exposure (2)	Systemic exposure (mg/kg bw/day)	Systemic exposure (mg/kg bw/day)	Systemic exposure (mg/kg bw/day)	Systemic exposure (mg/kg bw/day)	Systemic exposure (mg/kg bw/day)	Systemic exposure (mg/kg bw/day)
Rosmarinus Officinalis Leaf Oil		8000-25-7	283 291 9	Masking, Skin Conditioning	N/A	0.50302	0.00253	230	999 (1)	100	0.009 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 antiseptic¹.

According to the CIR review² 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 membrane². 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 sensitising². In a HRIPT performed on 25 volunteers 10% Rosmarinus Officinalis (Rosemary) Leaf Oil was not a sensitizer². In a patch testing of 200 contact dermatitis patients Rosmarinus Officinalis (Rosemary) Leaf Oil (2%) there were no positive reactions³. 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 rare².

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
<i>In vitro</i> 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.
<i>In vivo</i> 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

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	Single & Limit with Percent Soap (% w/w)	CAS Number	EC Number	Functions	Restrictions	Maximum Level Systemic Present in Products (%) (B-Base (mg/kg body weight))	Potential of Irritation (mg/kg body weight)	Marginal Exposure	Apply when product is used in cosmetics (mg/kg body weight)	Systemic exposure (mg/kg body weight)	Dermal exposure (mg/kg body weight)	NESTL	Safety Factor	ASUSEL	Acute/Chronic Exposure Level (mg/kg body weight)
Sodium Chloride	0.0917	7647-14-5	231-598-3	Bulking, Moistening, Oral Care, Viscosity Controlling	N/A	0.09174	0.00001	50	4192313	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/day¹.

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

Ingredient Profile: Sodium Citrate

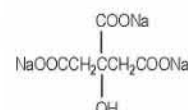
CAS number: 994-36-5 / 6132-04-3 **EC number:** 213-618-2 (I) / 200-675-3 (I)
(dihydrate) / 68-04-2
(anhydrous)

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	Quar & Limb with Preservative Sys (% info)	CAS Number	EC Number	Classification	Restrictions	Maximum Lotion Systems Preservative Product (%)	Exposure (% dose mg/kg body)	Point of Departure (mg/kg body)	Margin of Safety	Apply non preservative data (10% max concn in product)	Skin penetration (%)	Dermal exposure region1	MSGL	Safety Phrase	ADL/CCL	Accumulative Exposure Level region2
Sodium Citrate	0.0367	68-04-2 / 6132-04-3	700-675-3	Buffering, Chelating, Preserving	N/A	0.15877	0.00199	No Data			100	0.0077 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 review¹ 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 sensitizer in human studies¹. 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 it 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 reabsorbed². 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

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
<i>In vitro</i> 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.

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	Group & Limit with Permitted Use (if any)	CAS Number	EC Number	Function(s)	Restrictions	Maximum Level Systemic Product(s) (%)	Exposure (% dose (mg/kg body weight))	Point of Exposure (mg/kg body weight)	Margin of Exposure	Apply skin penetration data (if available) or use of skin penetration data (if available)	Sub population (if any)	Permitted exposure (if any)	REACH	Substance	AGL/CEL	Accumulate Exposure Limit (if any)
Sodium Palm Kernelate	16.05.00	61789-89-7	263-097-0	Cleansing, Presilifying, Surfactant, Visibly Controlling	N/A	16.05.00	0.0895/	1000	143/4	100	0.739	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 diseases¹. 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 of²; 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 review² 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 diet⁴. When applied topically fatty acids have been shown to remain mainly on the outer layers of the stratum corneum with little penetration⁵. 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 skin⁷; 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.

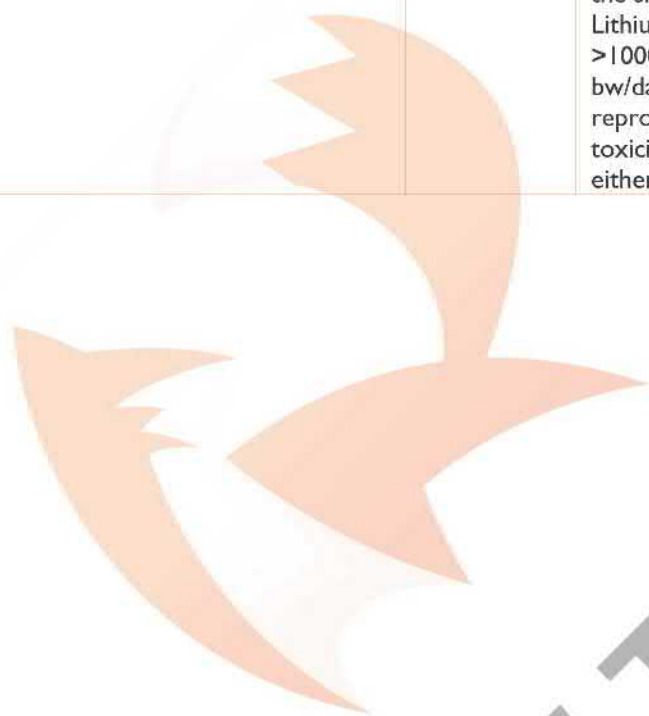
Supporting test data:

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



<p>Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test</p>	<p>OECD 422</p>	<p>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.</p>	<p>Secondary source: Safety Assessment of Fatty Acids & Soaps as Used in Cosmetics</p> <p>Animal test date: Prior to 2013.</p>
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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	Quaternary & Ammonium Salts (Cationic)	CAS Number	EC Number	Classification	Restrictions	Maximum Lead Exposure: Product or Productivity (% dose mg/kg body weight)	Exposure: (% dose mg/kg body weight)	Point of Departure (mg/kg body weight)	Marginal Exposure	Applicable to: Cosmetic, Food, Industrial, Pharmaceutical, Veterinary	Safe penetration (% dose)	Dermal exposure (mg/kg body weight)	MSDS	Safety Phrase	ADL/CLL	Accumulative Exposure Limit (mg/kg body weight)
Sodium Palmate	3 (L&T)	61790-79-2	763-162-3	Cleansing, Preserving, Surfactant, Visually Cleansing	N/A	51.63188	0.73862	1000	1460		100	0.767 (No Data)	000			

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 diseases¹. 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 of²; 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 review² 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 diet⁴. When applied topically fatty acids have been shown to remain mainly on the outer layers of the stratum corneum with little penetration⁵. 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 skin⁷; 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.

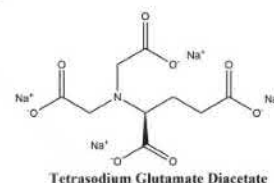
Supporting test data:

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.

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.

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:**



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

INCI Name	Slings & Limb with Benzene Soap (% w/w)	CAS Number	EC Number	Pseudonym	Restrictions	Maximum Level Systemic Exposure (by dose mg/kg bw/day)	Potential of Systemic Exposure (mg/kg bw/day)	Margin of Exposure	Apply skin penetration data risk assessment	Skin penetration (S)	Dermal exposure (mg/cm²)	NETS	Safety Factor	ASUSEL	Acute/Chronic Exposure Level (mg/kg)
Tetrasodium Glutamate Diacetate	0.4507	51981-21-6	257-573-7	Chelating	N/A	0.45872	0.00199	300	150723	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 Diacetate 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.

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
<i>In vitro</i> 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.
<i>In vivo</i> 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

Ingredient Profile: Zingiber Officinale (Ginger) Root Oil

CAS number: 8007-08-7 **EC number:** N/A
INCI Name: Zingiber Officinale Root Oil
Pseudonyms: Zingiber Officinale (Ginger) Root Oil, Ginger 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	Gliger A Line with Purified Soap (1:100)	CAS Number	EC Number	Function(s)	Risk factors	Maximum Level Systemic Exposure (mg/kg bw/day)	Value of Exposure (mg/kg bw/day)	Margin of Exposure	Apply skin penetration data (1:100) or use data with skin penetration	Skin penetration (%)	Dermal exposure (mg/cm ² /day)	NIEL	Safety Factor	ADL/CEL	Acceptable Exposure Level (mg/kg bw/day)
Zingiber Officinale Root Oil	0.6672	2230756		Masking, Perfuming, Skin Conditioning, Tonic	N/A	0.66722	0.00309	500	17213	100	0.010	No Data	300		

Zingiber Officinale (Ginger) Root Oil is obtained from the dried rhizomes of Zingiber officinal. It is used as a flavouring agent, skin conditioning agent and fragrance ingredient in cosmetic products.

Zingiber Officinale (Ginger) Root Oil is considered to be Generally Recognised As Safe (GRAS by the USFDA for human consumption (21CFR182.20).

Zingiber Officinale (Ginger) Root Oil was not irritating in an *in vitro* EpiSkin assay. Zingiber Officinale (Ginger) Root Oil was not irritating or sensitising at 4% in 25 individuals¹. Zingiber Officinale (Ginger) Root Oil was not genotoxic in *in vitro* studies.

In a 90-day study performed on rats 0, 100, 250 and 500 mg/kg bw/day. No toxicity was observed at any dose.

Summary:

The concentration and use of Zingiber Officinale (Ginger) Root 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. 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	Rat LD ₅₀ : >5000 mg/kg	Secondary source: Tisserand, Essential Oil Safety, 2013 Animal test date: Prior to 1974
Acute dermal toxicity	OECD 402	Rat LD ₅₀ : >5000 mg/kg	Secondary source: Tisserand, Essential Oil Safety, 2013 Animal test date: Prior to 1974
Repeated dose 90-day oral toxicity study in rodents	OECD 408	NOAEL: >500 mg/kg bw/day, highest dose tested.	Secondary source: Tisserand, Essential Oil Safety, 2013 Animal test date: Prior to 1974
<i>In vitro</i> skin irritation: reconstructed human epidermis test method	OECD 439	Ginger oil was not cytotoxic to cells, with a mean viability of 91.9% of treated controls. It was concluded that the substance is non-irritating.	Secondary source: REACH dossier Non animal test data
Extended one-generation reproductive toxicity study	OECD 443	Negative up to 1000 µg/plate, ±S9	Secondary source: REACH dossier Non animal test data
<i>In vitro</i> bacterial reverse mutation test	OECD 471	Negative up to 1000 µg/plate, ±S9	Secondary source: REACH dossier Non animal test data
<i>In Vitro</i> mammalian chromosome aberration test	OECD 473	No chromosomal aberrations were observed in CHL cells	Secondary source: Tisserand, Essential Oil Safety, 2013 Non animal test data.

Annex II – Fragrance Information

The product contains the following essential oils:

Common name	INCI name	Supplier(s)	Restrictions
Ginger Essential Oil	Zingiber Officinale Root Oil	Bay House	N/A
Lime Essential Oil	Citrus Aurantifolia Oil	The Soapery	N/A
Rosemary Essential Oil	Rosmarinus Officinalis Leaf Oil	The Soapery	

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.