DWECK DATA

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Consultant on Natural Products to the Cosmetic and Toiletry industry

SAFETY ASSESSMENT FOR A COSMETIC PRODUCT

PRODUCT SAFETY REPORT

Statement No:	30072014/1
Date of Issue:	30th July 2014
Client name:	Your company name
Product name:	Your Product name
Formula ref:	Your reference

I, Anthony C. Dweck, am a Chartered Chemist duly authorised according to the Regulation of the European Parliament and of the Council on cosmetic products (recast) 2008/0035 (COD) dated 10 November 2009 (finally as 1223/2009 on 30 November 2009) and all subsequent additions which replace all other regulations.

We have taken into consideration the general toxicological profile of each ingredient used, the chemical structure, the CIR panel evaluation where available, the level of exposure (full technical data and/or toxicology files are held for each ingredient) and a total daily exposure has been calculated along with the margins of safety for each ingredient. As a result of our evaluation the product has been classified as: **SAFE**.

We have independently assessed the product declared above and confirm that a PIF (Product Information File formerly PIP) has been completed and is summarised in the attached PIF (Excel) booklet by the parties involved. A full evaluation of the product has been compiled that includes stability testing, microbiological testing and pack compatibility testing and as a result this product safety report has been issued. The product fully complies with the legislation listed above and complies with the various Annexes relating to banned, CMRs, and restricted ingredients; colours, preservatives and sunscreens. The product has been produced by a company certified to have good proven GMP and tested to ensure good microbiological quality. There are no impurities or trace materials in the raw materials or packaging that would give any rise for concern. All the documentation relating to these tests can be made available from the supplier upon request. Where specific tests have been conducted these will be listed separately.

Signature of safety assessor: ……..

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CPNP Download Information
Cosmetic Products Notification Portal

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CAS	Ingredients	%w/w
	Product reference	
7732-18-5	Aqua (Water)	80.8671%
1335-72-4	Sodium Laureth Sulfate	7.5600%
7647-14-5	Sodium Chloride	3.4550%
61789-40-0	Cocamidopropyl Betaine	2.4375%
8000-48-4	Eucalyptus Globulus Leaf Oil	2.0000%
89-78-1	Menthol	1.0000%
0	Parfum (Fragrance)	0.6000%
58846-77-8	Decyl Glucoside	0.5500%
9005-64-5	Polysorbate 20	0.5000%
515861-29-7	Sodium Sheabutteramphoacetate	0.3000%
71329-50-5	Hydroxypropyl Guar Hydroxypropyltrimonium Chloride	0.2000%
9010-92-8	Sodium Styrene/Acrylates Copolymer	0.1900%
131-57-7	Benzophenone-3	0.1500%
139-33-3	Disodium EDTA	0.0990%
77-92-9	Citric Acid	0.0390%
112-27-6	Triethylene Glycol	0.0250%
57-55-6	Propylene Glycol	0.0150%
151-21-3	Sodium Lauryl Sulfate	0.0045%
64-17-5	Alcohol Denat.	0.0033%
8028-89-5	Caramel	0.0021%
10377-60-3	Magnesium Nitrate	0.0009%
26172-55-4	Methylchloroisothiazolinone	0.0006%
7786-30-3	Magnesium Chloride	0.0005%
2682-20-4	Methylisothiazolinone	0.0002%
1310-73-2	Sodium Hydroxide	0.0001%
2783-94-0	CI 15985 (Yellow 6)	0.0002%
122-40-7	Amyl Cinnamal	0.0000%
118-58-1	Benzyl Salicylate	0.0000%
101-86-0	Hexyl Cinnamal	0.0000%
80-54-6	Butylphenyl Methylpropional	0.0000%
5989-27-5	Limonene	0.0000%

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Client name: Your company name
Product name: Your Product name
Formula ref: Your reference

Ingredients
Product reference
Aqua (Water)
Sodium Laureth Sulfate
Sodium Chloride
Cocamidopropyl Betaine
Eucalyptus Globulus Leaf Oil
Menthol
Parfum (Fragrance)
Decyl Glucoside
Polysorbate 20
Sodium Sheabutteramphoacetate
Hydroxypropyl Guar Hydroxypropyltrimonium Chloride
Sodium Styrene/Acrylates Copolymer
Benzophenone-3
Disodium EDTA
Citric Acid
Triethylene Glycol
Propylene Glycol
Sodium Lauryl Sulfate
Alcohol Denat.
Caramel
Magnesium Nitrate
Methylchloroisothiazolinone
Magnesium Chloride
Methylisothiazolinone
Sodium Hydroxide
CI 15985 (Yellow 6)
Amyl Cinnamal
Benzyl Salicylate
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CAS	Ingredients	
	Product reference	Banding
7732-18-5	Aqua (Water)	75-100
1335-72-4	Sodium Laureth Sulfate	5-10
7647-14-5	Sodium Chloride	1-5
61789-40-0	Cocamidopropyl Betaine	1-5
8000-48-4	Eucalyptus Globulus Leaf Oil	1-5
89-78-1	Menthol	0.1-1.0
0	Parfum (Fragrance)	0.1-1.0
58846-77-8	Decyl Glucoside	0.1-1.0
9005-64-5	Polysorbate 20	0.1-1.0
515861-29-7	Sodium Sheabutteramphoacetate	0.1-1.0
71329-50-5	Hydroxypropyl Guar Hydroxypropyltrimonium Chloride	0.1-1.0
9010-92-8	Sodium Styrene/Acrylates Copolymer	0.1-1.0
131-57-7	Benzophenone-3	0.1-1.0
139-33-3	Disodium EDTA	<0.1
77-92-9	Citric Acid	<0.1
112-27-6	Triethylene Glycol	<0.1
57-55-6	Propylene Glycol	<0.1
151-21-3	Sodium Lauryl Sulfate	<0.1
64-17-5	Alcohol Denat.	<0.1
8028-89-5	Caramel	<0.1
10377-60-3	Magnesium Nitrate	<0.1
26172-55-4	Methylchloroisothiazolinone	<0.1
7786-30-3	Magnesium Chloride	<0.1
2682-20-4	Methylisothiazolinone	<0.1
1310-73-2	Sodium Hydroxide	<0.1
2783-94-0	CI 15985 (Yellow 6)	<0.1
122-40-7	Amyl Cinnamal	<0.1
118-58-1	Benzyl Salicylate	<0.1
101-86-0	Hexyl Cinnamal	<0.1
80-54-6	Butylphenyl Methylpropional	<0.1
5989-27-5	Limonene	<0.1

HELPFUL DATA
Date: 30/07/2014
Customer: Company name
Formula code: Product reference
Product type: Shower Gel
Exposure mg/day: 10000
Surface Area cm2: 16900
Applications/day: 2
mg/cm2/day: 0.015
Dilution value: 100
IFRA Category: 9
PAO months: 12
Frame formulation number: 2,10
Nanomaterials: 0
Carcinogenic, mutagenic or toxic for reproduction CMR 1A or 1B: 0
Total level of VOCs 0.17134

The Product Information File contains numerous documents that are summarised as follows:

- This product is a detergent based product and has passed a challenge test 7
- The packaging is suitable for cosmetic use without migration of harmful substances or presence of impurities.
- The raw materials are of Cosmetic or Pharmaceutical grade and are low in impurities.
- The Cosmetic Ingredient Review panel opinion on raw materials can be seen on the USA legal tab in the PIP Booklet.
- The ingredients are legally permitted according to the Health Canada's List of Prohibited and Restricted Cosmetic Ingredients (The Cosmetic Ingredient "Hotlist") 2005 as amended. See USA tab in the PIP Booklet.
- The status of raw materials according to AICS can be seen on the Australia tab in the PIP booklet.
- The method of manufacture is in the PIF file and available on request.
- The specification of the product is in the PIF file and available on request.
- The product has been stability tested and a report is available on request.
- The California Proposition P65 is on Toxicology and USA tab (beta trial at moment). #N/A

CPNP Rule 17. Camphor, menthol, cineole (eucalyptol) total present **2.6000**

- Camphor 0.0000
- Menthol 1.0000
- Cineole 1.6000

Ingredients Toxicology comments
Product reference

Aqua (Water) The quality of water used in the production of cosmetics and personal care products, called process water, is monitored according to Good Manufacturing Practices outlined in FDA's Guidance on Cosmetic Manufacturing Practice Guidelines, and in international guidelines on Good Manufacturing Practices known as ISO 22716. Some companies may also comply with the U.S. Pharmacopeia (USP) standards for the purity of water used in drugs, devices and diagnostics published in the Purified Water monograph. USP Purified Water is prepared from water complying with the regulations of the U.S. Environmental Protection Agency (EPA) with respect

to drinking water. It contains no intentionally added substances. . Oral Rat LD50 = >90 mL/kg

Sodium Laureth Sulfate Both SLS and SLES are safe for use in cosmetic products. Both ingredients were reviewed in 1983 and re-reviewed in 2002 by the Cosmetic Ingredient Review (CIR) Expert Panel and found to be safe for use in cosmetic and personal care products. SLS and SLES can cause skin irritation in some persons, which is one reason why it is important to follow the label instructions when using a cosmetic product. Complete reports on both ingredients are available from CIR. Substances known to be carcinogenic have been classified and registered by several international organizations, such as the World Health Organization or the International Agency for the Research of Cancer as well as the US Environment Protection Agency and the European Union. None of these organizations have classified SLES and SLS as carcinogens. There is no direct or circumstantial evidence that these two ingredients have any carcinogenic potential. The studies that have been conducted on SLS and SLES indicate that both are safe under proper conditions of use.

Sodium Chloride The Food and Drug Administration (FDA) reviewed the safety of Sodium Chloride and approved its use as an active ingredient in Over-The-Counter (OTC) drug products for the eyes at concentrations of 2 to 5%. In addition to being an important component of food, FDA includes Sodium Chloride on its list of substances considered Generally Recognized as Safe (GRAS) as a substance migrating to food from packaging. The FDA also regulates labeling of table salt, and regulates labeling statements on food regarding levels of Sodium Chloride the food product contains. Cosmetic Ingredient Review (CIR) has deferred evaluation of this ingredient because the safety has been assessed by FDA. This deferral of review is according to the provisions of the CIR Procedures.

Cocamidopropyl Betaine Cocamidopropyl betaine (CAPB) is a mild surfactant used in shampoos, conditioners, body washes, and other personal-care products. Several recently published case reports have suggested that CAPB may be a skin sensitizer. A 6-wk product-use study was conducted to determine whether subjects with previous positive patch tests to CAPB could use personal-care products (prototype hair shampoo, liquid handsoap, and body wash) with this surfactant without problems. Post-study patch testing suggested that amidoamine, a material used in the synthesis of CAPB and a contaminant of CAPB preparations, is a likely sensitizer. However, patch testing did not rule out the possibility that CAPB itself may be an allergen to a small number of presensitized individuals. It is recommended that CAPB with minimal levels of contamination be used for the formulation of personal-care products.

Eucalyptus Globulus Leaf Oil Characteristic aromatic camphoraceous odour and a pungent camphoraceous cooling taste. Eucalyptus oil taken by mouth for catarrh and used as an inhalation often in combination with other volatile substances. Eucalyptus oil has also been applied as a rubefacient. Has local antiseptic, expectorant, deodorant and refreshing effects. Eucalyptus oil was at most only slightly irritant to human skin, but has provoked sensitization reactions after skin application, ingestion or inhalation. There have been many cases of human poisoning with single oral doses causing cardiovascular, central nervous system, respiratory, gastro-intestinal and (occasionally) urinary effects, and some deaths. Damage to the stomach, respiratory tract and kidney, and fluid in the chest and abdominal cavities, have been evident in a few individuals on autopsy. Eucalyptus oil was of low acute oral toxicity in rats and of

low acute dermal toxicity in rabbits. It appeared to have a weak tumour-promoting action on mouse skin. Cineols 80.00%, Limonene 8.00%, Pinenes 3.00%, gamma-Terpinene 3.00%, para-Cymene 1.00%.

Menthol Menthol (2-isopropyl-5-methylcyclohexan-1-ol) is a naturally occurring cyclic terpene alcohol of plant origin, obtained from cornmint, peppermint or other mintoils. Menthol has been used since antiquity for medicinal purposes (Patel et al., 2007). Its use in dermatology is ubiquitous, where it is frequently part of topical antipruritic, antiseptic, analgesic, and cooling formulations. Menthol was reported to be a mild skin irritant in man, but caused more severe damage to the mucous membranes. In rabbits, menthol was a mild skin irritant but severely irritated the eyes. It was of low acute toxicity in experimental animals treated by the oral and dermal routes, causing central nervous system effects. Liver and kidney changes have been seen in a number of studies in laboratory animals, involving oral and inhalation administration. Inhalation of menthol produced respiratory tract injury in rats and rabbits. In oral studies, there was no convincing evidence of carcinogenicity in rats and mice or of reproductive effects in mice, rats, rabbits and hamsters. No chromosome damage occurred in rats treated orally, although there were some indications of weak activity in mammalian cells in culture. Ames bacterial tests have, in general, given no evidence of mutagenicity but other assays in microorganisms have provided some suggestion of genotoxicity. Recessive lethal mutations were not induced in fruit flies.Respiratory Distress in Infants Exposed to Menthol. A number of reports have appeared suggesting toxicity to menthol in small infants. Because of respiratory tract infections of unknown severity these patients received home treatments which included menthol containing ointments (Meyler, 1996; Martindale The Extra Pharmacopoeia, 1993; Leung and Foster, 1996, PDR for Herbal Medicne, 2000). The infants reportedly developed severe respiratory distress in most cases and cyanosis in a few. Symptoms persisted for one of more days in many infants and was thought to be due to the inhalation of menthol (Larkin and Castellano, 1967). The contraindications for some menthol-containing products caution against use in infants and young children specifying that menthol containing preparations should not be used on areas of the face, especially the nose (Herbal Medicine, 2000). Similar approvals for food uses by other authoritative bodies are extant (Council of CD Europe: CE No. 63, Category A- Approved; IOFI: Nature Identical). The Joint FAO/WHO Expert Committee on Food Additives [JECFA] has specified an acceptable daily dietary intake (A.D.I.) of 0-4 mg/kg bw/day for menthol (JECFA, 1998) on the basis of an Gvi available chronic feeding study that demonstrated a NOEL of >375 mg/kg bw/day (NCI, 1979). A recent comparison of this experimental NOEL to an estimated maximum US/European per capita daily intake of 3.05 x 10-l mg/kg/day indicates a 1,229-fold margin of safety for oral intake of menthol (Munro and Kennepohl, 2001). Sensitivity reactions associated with the use of mentholated products (including cigarettes) have been reported. Treatment of infants with mentholated nasal drops has evidently caused isolated cases of spasm of the larynx, and a few cases of nervous or digestive system disturbance have been associated with excessive inhalation or oral exposure to mentholated products. Menthol was reported to be a mild skin irritant in man, but caused more severe damage to the mucous membranes. In rabbits, menthol was a mild skin irritant but severely irritated the eyes. It was of low acute toxicity in experimental animals treated by the oral and dermal routes, causing central nervous system effects. Liver and kidney changes have been seen in a number of studies in laboratory animals, involving oral and inhalation administration. Inhalation of menthol produced respiratory tract injury in rats and rabbits. In oral studies, there was no convincing evidence of carcinogenicity in rats

and mice or of reproductive effects in mice, rats, rabbits and hamsters. No chromosome damage occurred in rats treated orally, although there were some indications of weak activity in mammalian cells in culture. Ames bacterial tests have, in general, given no evidence of mutagenicity but other assays in microorganisms have provided some suggestion of genotoxicity. Recessive lethal mutations were not induced in fruit flies. The NOEL in 13-week studies of toxicity with D/L-menthol in the diet was 560 mg/kg per day in mice and 750 mg/kg bw per day in rats on the basis of slightly increased incidences of interstitial nephritis at the next highest dose (US National Cancer Institute, 1979). The only effect seen in mice of both sexes was a reduction in body weight gain in the highest dose group. The NOAELs derived from these studies were 937 mg/kg/day for the male rat, 998 mg/kg/day for the female rat, 1956 mg/kg/day for the male and 2386 mg/kg/day for the female mouse. Even the highest dose of D/L-menthol tested in the long-term studies in mice and rats had no specific toxic effect. As the survival of mice was reduced at the high dose of 600 mg/kg per day, the Committee allocated an ADI in the range of 0 - 4 mg/kg (IPCS, 1999). Menthol topical should not be used in or near the eyes or other mucous membranes. Menthol topical should not be applied to wounds or damaged skin. Following application tight bandages and/or heat should not be applied to the treatment area. Safety and effectiveness of menthol topical 6% spray have not been established in pediatric patients less than 13 years of age. Safety and effectiveness of menthol topical 1.4% pad, 1.25% pad, and menthol 7% topical gel have not been established in pediatric patients less than 12 years of age. Safety and effectiveness of menthol topical 5% pad have not been established in pediatric patients less than 10 years of age. Safety and effectiveness of menthol topical oral lozenge have not been established in pediatric patients less than 4 years of age. Safety and effectiveness of menthol 2% topical gel, menthol 0.15% topical lotion, or menthol 0.5% topical lotion have not been established in pediatric patients less than 2 years of age. A client tested 5% menthol in an aqueous cream (Aqua (Water), Petrolatum, Cetearyl Alcohol, Paraffinum Liquidum (Mineral Oil), Menthol, Phenoxyethanol, Sodium Lauryl Sulfate 0.23% and no scores were seen for irritation.

Parfum (Fragrance) Fragrance allergens have been calculated on the INCI tab of the PIP Booklet and have been compared to the limits imposed by the IFRA QRA category for the product. All values have fallen below the IFRA limit.

Decyl Glucoside Surfactant; foaming agent, cosurfactant for industrial prods., cosmetics, and dermopharmaceuticals; degreaser; emulsifier; dispersant; wetting agent. Decyl glucoside is a beneficial ingredient in many types of skin and hair care products, including cleansers, shampoos and body washes. Considered relatively new for use in the beauty industry, decyl glucoside's benefits have led to its ever-increasing popularity for inclusion in products. The ingredient may also be referred to as d-glucoside decyl, decyl-b-d-glucopyranoside or b-d-glucopyranoside. Research into the effects of decyl glucoside has found that the ingredient is far less likely to cause skin irritation than other types of surfactants. In fact, in one clinical study, decyl glucoside was found to cause no adverse effects when placed on normal, healthy skin for as long a period as 24 hours. The ingredient is used in products for all hair and skin types, including in products designed for use by children and those with sensitive skin.

Polysorbate 20 Polysorbate 20 was a skin irritant in dermatitis patients but was reported not to induce irritant responses when applied to the intact skin of health volunteers. It produced, at worst, minimal irritation in the eyes of rabbits. Only a small number of cases of skin sensitization have been reported in humans, although a moderate to strong sensitizing potential was seen in guinea-pigs treated by intradermal

injection. A low acute oral toxicity was demonstrated in laboratory animals. In rats and hamsters, repeated oral exposure to polysorbate 20 produced damage at a range of sites including the gastro-intestinal tract, liver and kidneys. In preliminary studies, reproductive toxicity induced in rats and mice by intraperitoneal injections during pregnancy was not seen in rats given the polysorbate 20 either orally or dermally. Polysorbate 20 probably induced a skin tumour in a mouse treated dermally. In oral studies in rats and skin-painting studies in mice, it increased the yield of tumours induced by established carcinogens. Polysorbate 20 was a skin irritant in dermatitis patients but was reported not to induce irritant responses when applied to the intact skin of health volunteers. It produced, at worst, minimal irritation in the eyes of rabbits. Only a small number of cases of skin sensitization have been reported in humans, although a moderate to strong sensitizing potential was seen in guinea-pigs treated by intradermal injection. A low acute oral toxicity was demonstrated in laboratory animals. On repeated intravenous administration, effects on the liver, spleen and kidneys were seen in premature babies exposed to polysorbate 80:polysorbate 20 mixture and some fatalities occurred. In rats and hamsters, repeated oral exposure to polysorbate 20 produced damage at a range of sites including the gastro-intestinal tract, liver and kidneys. In preliminary studies, reproductive toxicity induced in rats and mice by intraperitoneal injections during pregnancy was not seen in rats given the polysorbate 20 either orally or dermally. Polysorbate 20 probably induced a skin tumour in a mouse treated dermally. In oral studies in rats and skin-painting studies in mice, it increased the yield of tumours induced by established carcinogens. The acute oral toxicity in the mouse, rat and hamster was shown to be extremely low (Eagle & Poling, 1956; Hopper et al., 1949). Polyoxyethylene (20) sorbitan monolaurate has an LD50 of 3.75 g/kg bw when injected i.v. into mice (Hopper al., 1949). The accidental administration of a dose of 19.2 g of polyoxyethylene (20) sorbitan monooleate per kg bw on two successive days to an infant was followed by no ill effects, apart from purgation (Chusid & Diamond, 1955). Oral LD50 (Rat) >39,000 mg/kg. A range of polyethylene sorbitan esters of fatty acids ("Tween 20, 21, 40, 60, 61, 65, 80, 81, 85") failed to produce reactions on patch testing of each in 50 subjects. On instillation in the rabbit conjunctival sac, most failed to produce a reaction even when the eye was not subsequently washed and did not produce reaction when the eye was washed (Treon et al., 1967). 4.5-6 g of polyoxyethylene (20) sorbitan monooleate were taken daily by 100 adults - 10 for three to four years, 17 for two to three years, 19 for one to two years, 54 for less than one year. No deleterious effects could be demonstrated (Krantz, 1951).

Sodium Sheabutteramphoacetate Amides, shea-oil, N-[2-[N-(2-hydroxyethyl)-N-(carboxymethyl)amino]ethyl]-, sodium salt.

Hydroxypropyl Guar Hydroxypropyltrimonium Chloride Guar Gum is a Natural Hydrocolloid obtained from the ground endosperm of the guar plant, Cyanmopsis tetragonolobus belonging to the family Leguminosae. Guar is mainly grown in India and Pakistan from July to December. This is a modified Cationic Guar used in cosmetics and personal care formulations as thickener and conditioner.

Sodium Styrene/Acrylates Copolymer Sodium Styrene/Acrylates Copolymer is a sodium salt of a polymer of styrene and amonomer consisting of acrylic acid, methacrylic acid or one of their simple esters. Film forming, opacifying.

Benzophenone-3 The Food and Drug Administration (FDA) has approved the use of Benzophenone-3 and Benzophenone-4 as safe and effective, over-the-counter (OTC) sunscreen ingredients. When used as a sunscreen ingredient in the United

States, Benzophenone-3 is called Oxybenzone, and may be used at concentrations up to 6%, and Benzophenone-4 is called Sulisobenzone, and may be used at concentrations up to 10%. The safety of Benzophenone-3 and related ingredients has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Benzophenone-1, -3, -4, -5, -9 and -11 were safe for use in cosmetics and personal care products. In 2002, the CIR Expert Panel considered available new data on these Benzophenone ingredients and reaffirmed the above conclusion.

Disodium EDTA The Food and Drug Administration (FDA) reviewed the safety of Disodium EDTA and Calcium Disodium EDTA and approved the use of these ingredients as food preservatives for direct addition to food. The safety of Disodium EDTA, Calcium Disodium EDTA, Diammonium EDTA, Dipotassium EDTA, EDTA, HEDTA, TEA-EDTA, Tetrasodium EDTA, Tripotassium EDTA and Trisodium HEDTA was assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Disodium EDTA and related ingredients were safe as used in cosmetics and personal care products.

Citric Acid Citric acid caused severe eye damage in man and rabbits, and irritated the skin of rabbits. Consumption of large amounts by man may cause tooth erosion and other local effects including mouth ulceration. One study has reported adverse reactions (including asthma) in an individual after the ingestion of foods containing citric acid. The acid and its sodium salt were of low acute oral toxicity in laboratory animals. Repeated oral administration of citric acid has caused slight degeneration of the spleen and thymus gland in rats. No adverse effects on reproduction or foetal development were seen in laboratory animals fed citric acid. A limited feeding study with citric acid revealed no evidence of carcinogenicity in rats, but its sodium salt, when given orally, enhanced the activity of known carcinogens. Citric acid and its sodium and potassium salts gave no convincing evidence of activity in a variety of genotoxicity screening assays. The citrate ion occurs naturally in the diet and enters normal metabolic pathways. Oral Mouse LD50 = 7280 mg/kg. Oral Rat LD50 = 3 gm/kg

Triethylene Glycol The Food and Drug Administration (FDA) permits the use of Polyethylene Glycol (PEG) as direct and indirect food additives. The safety of Triethylene Glycol and PEG-4 (Polyethylene Glycol) have been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Triethylene Glycol and PEG-4 were safe as cosmetic ingredients.

Propylene Glycol In man, propylene glycol has caused skin and mucous membrane irritation. It has produced skin sensitization reactions in several individuals and when taken orally can also induce skin rashes. Administration by the oral or injection routes was associated with severe effects on the central nervous system and metabolic disruptions. The glycol was minimally irritating to the eyes of rabbits. A low acute toxicity has been demonstrated in laboratory animals treated orally. The blood was the main site of injury in cats and dogs given multiple oral doses, with evidence of red blood cell damage being noted. Effects on the blood, liver, kidney and caecum of rats were reported in studies involving repeated oral administration. At high and maternally toxic dietary concentrations, propylene glycol induced reproductive effects in rats. No malformations were seen in a range of species when pregnant animals were treated orally. There was no evidence of carcinogenicity in rats treated by repeated oral administration, and more limited skin-painting studies in mice

and rabbits also failed to detect carcinogenic potential. Propylene glycol was not mutagenic in Ames bacterial assays.

Sodium Lauryl Sulfate The OECD report (1997) concluded that, “The human health hazard assessment for SLS shows that at present the substance is of no concern for the general public (consumers) and for workers” and similarly the CIR report (1983) concluded, “SLS [and ALS] appear to be safe in [cosmetic] formulations designed for discontinuous, brief use followed by thorough rinsing from the surface of the skin. In products intended for prolonged contact with skin, concentrations should not exceed 1%.” The CIR report (2005) has confirmed these findings.

Alcohol Denat. Ethanol is used in cleansing products as a solvent to keep in solution some ingredients. It is a clear, colorless alcohol, produced by fermentation of sugars when used for alcoholic beverage. Ethanol is not harmful to aquatic organisms. Acute toxicity (i.e., L(E)C50) for several algae, invertebrates and fish species tested was greater than approximately 1,000 mg/l. Chronic toxicity (i.e., NOEC) for algae, invertebrates and fish was greater than 280 mg/l. Ethanol is widely recognized as being readily biodegradable in the environment as it is both a metabolite of and nutrient for microbes. There are no persistent metabolites formed during biodegradation. Ethanol does not pose a threat when applied topically. Coming in contact with the skin will do nothing but dry it out and sterilize it. Spilt on a cut, it will hurt, but it will also prevent infection. Transient smarting is sometimes experienced in high alcohol content products but this is not of concern.

Caramel The Food and Drug Administration (FDA) includes Caramel on its list of substances considered Generally Recognized As Safe (GRAS) as a multipurpose food substances. FDA also lists Caramel as a color additive exempt from certification. Caramel is determined to be safe for use in coloring cosmetics and personal care products, including products applied to the lips and area of the eye. The Cosmetic Ingredient Review (CIR) has deferred evaluation of this ingredient because the safety has been assessed by FDA. This deferral of review is according to the provisions of the CIR Procedures.

Magnesium Nitrate Magnesium nitrate poses no unusual hazards. Magnesium nitrate is a hygroscopic salt with the formula Mg(NO3)2. In air, it quickly forms the hexahydrate with the formula Mg(NO3)2·6H2O (and molar weight of 256.41 g/mol). It is very soluble in both water and ethanol. Draize test, rabbit, eye: 500 mg/24H Mild; Draize test, rabbit, skin: 500 mg/24H Mild; Oral, rat: LD50 = 5440 mg/kg. Carcinogenicity: Magnesium nitrate Not listed as a carcinogen by ACGIH, IARC, NTP, or CA Prop 65. Magnesium nitrate hexahydrate Not listed as a carcinogen by ACGIH, IARC, NTP, or CA Prop 65. Used as a filler in certain preservative blends.

Methylchloroisothiazolinone The mixture of MCI/MI is water soluble and controls both Gram positive and Gram negative bacteria, yeasts and moulds at very low levels. It is stable up to 60oCand a pH of 9, except when in the presence of amines, such as coco-DEA, which cause rapid degradation of the MCI if they are in contact above a pH of 7. As these compounds are very often found in washes and shampoo, the pH of 7 is often the maximum that can be tolerated. It is stable in the presence of anionic, cationic and nonionic surfactants but the MCI is degraded by free pyrithione so is not recommended for use in antidandruff shampoos containing high levels of zinc pyrithione. For 15% active: Oral LD50 (rat) 252mg/kg. Dermal LD50 (Rabbit) >214mg/kg. Inhalation LC50 (rat, male): 1.4mg/kg/4h. Inhalation LC50 (rat, female): 1.5-2.0mg/kg/4h. The mixture of MCI/MI is water soluble and controls both Gram

positive and Gram negative bacteria, yeasts and moulds at very low levels. It is stable up to 60oCand a pH of 9, except when in the presence of amines, such as coco-DEA, which cause rapid degradation of the MCI if they are in contact above a pH of 7. As these compounds are very often found in washes and shampoo, the pH of 7 is often the maximum that can be tolerated. It is stable in the presence of anionic, cationic and nonionic surfactants but the MCI is degraded by free pyrithione so is not recommended for use in antidandruff shampoos containing high levels of zinc pyrithione.

Magnesium Chloride Magnesium chloride poses no unusual hazards. Toxicity data. ORL-RAT LD50 8100 mg kg-1. ORL-MUS LD50 7600 mg kg-1. IPR-MUS LD50 775 mg kg-1. Magnesium chloride (E511[8]) is an important coagulant used in the preparation of tofu from soy milk. In Japan it is sold as nigari (にがり, derived from the Japanese word for "bitter"), a white powder produced from seawater after the sodium chloride has been removed, and the water evaporated. In China it is called lushui (卤水). Nigari or lushui consists mostly of magnesium chloride, with some magnesium sulfate and other trace elements. It is also an ingredient in baby formula milk. Magnesium ions are bitter-tasting, and magnesium chloride solutions are bitter in varying degrees, depending on the concentration of magnesium. Magnesium toxicity from magnesium salts is rare in healthy individuals with a normal diet, because excess magnesium is readily excreted in urine by the kidneys. A few cases of oral magnesium toxicity have been described in persons with normal renal function ingesting large amounts of magnesium salts, but it is rare. If a large amount of magnesium chloride is eaten, it will have effects similar to magnesium sulfate, causing diarrhoea, although the sulfate also contributes to the laxative effect in magnesium sulfate, so the effect from the chloride is not as severe. Topically at the levels employed no adverse effects are expected.

MethylisothiazolinoneMI was previously only produced in combination with MCI but is now available as a single compound. MI has to be used at a higher concentration than the mixture of MCI/MI due to the lower activity of MI. [Technical Editor: The maximum permitted level is 0.01%.] It shows activity against Gram positive and Gram negative bacteria but is poor against fungi. However, it has a much lower sensitisation potential then the chlorinated compound MCI, making it safer to use. MI is an effective replacement for the formaldehyde donors; it is equally effective for leave on or rinse off products and has a good toxicological and environmental profile. MI is significantly more stable then MCI but the poor antifungal activity requires that it is used in combination with other actives to give complete protection. It may be combined with parabens or specific fungicides such as IPBC or chlorphenesin. The combination of MI with 1, 2 alkanediols, such as caprylyl glycol and decylene glycol also shows good broad spectrum protection. 12/12/13 stop presss. Cosmetics Europe, the personal care association, is today issuing an industry-wide recommendation to discontinue the use of the preservative Methylisothiazolinone (MIT) in leave-on skin cosmetics and personal care products. The recommendation is made in the interests of consumer health and in response to recent clinical data which shows an increase in adverse skin reactions to this ingredient. Cosmetics Europe, following discussions with the European Society of Contact Dermatitis (ESCD), recommends that the use of Methylisothiazolinone (MIT) in leave-on skin products including cosmetic wet wipes is discontinued. This action is recommended in the interests of consumer safety in relation to adverse skin reactions. It is recommended that companies do not wait for regulatory intervention under the Cosmetics Regulation but implement this recommendation as soon as feasible.

Sodium Hydroxide The Food and Drug Administration (FDA) includes Sodium Hydroxide, Magnesium Hydroxide and Potassium Hydroxide on its list of substances affirmed as Generally Recognized as Safe (GRAS) for direct addition to food. All three ingredients, as well as Calcium Hydroxide are also approved as indirect food additives for use as defoaming agents in the manufacture of paper and paperboard used as food packaging. Sodium and Potassium Hydroxide can be used for the production of cacao products. The FDA has approved Magnesium Hydroxide for use in Over-the-Counter (OTC) antacid drug products.

CI 15985 (Yellow 6) Sunset Yellow in petrolatum or in aqueous solutions was not irritant to human or rabbit skin and was minimally irritant to the rabbit eye. No reports of contact dermatitis induced by Sunset Yellow were identified. The acute toxicity in rodents was low by both oral and intraperitoneal routes. Studies in a variety of laboratory animals involving repeated oral or dermal exposure failed to generate any consistent indication of specific target organ toxicity. No foetal malformations were observed on oral administration to rats or rabbits but decreased pup survival and birth weights were reported in rats. There was no convincing evidence of carcinogenic activity in a number of long-term feeding studies in rats and mice or in a limited skin-painting study in mice. Western studies have found little evidence that Sunset Yellow possesses significant genotoxic potential either when given orally or by injection to rodents, in mammalian cells in culture, or in bacterial assays, including a large number of Ames tests.

Amyl Cinnamal The Food and Drug Administration (FDA) has approved the use of Amyl Cinnamal as a flavoring agent for direct addition to food. The safety of Amyl Cinnamal has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of Amyl Cinnamal in fragrances because of potential sensitization. The Cosmetic Ingredient Review (CIR) defers review of individual fragrance ingredients to the IFRA program unless the ingredient has significant uses other than as a fragrance. In this case, the ingredient may be assessed by both the CIR Expert Panel and REXPAN. Toxicity:)ral-rat LD50 3730 mg/kg. Food and Cosmetics Toxicology. Vol. 2, Pg. 327, 1964.

Benzyl Salicylate The Food and Drug Administration (FDA) has approved the use of Benzyl Salicylate as a flavoring agent for direct addition to food. The safety of Benzyl Salicylate has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The Cosmetic Ingredient Review (CIR) defers review of individual fragrance ingredients to the IFRA program unless the ingredient has significant uses other than as a fragrance. In this case, the ingredient may be assessed by both the CIR Expert Panel and REXPAN.

Hexyl Cinnamal Fragrance allergens. Hexyl Cinnamal is FDA approved and is approved by the Cosmetics Working Group for topical use. However, the DIMDI (German Institute of Medical Documentation and Information) rates it as a Class B allergen when used in high concentrations (Wikipedia). Skin care products and cosmetics use Hexyl Cinnamal in low concentrations, and it is therefore considered a safe ingredient. Ames mutagenicity test: negative. Adverse effects on the skin (allergic dermititis), blood, liver, kidneys and gastrointestinal system were observed in a repeat dose dermal study on rats. The LOAEL (Lowest-observable-adverse-effect-level) for a 90-day dermal study in rats was reported to be 0.125 g/kg bw/day. Oral (rat) LD50: 2,450 mg/kg. Dermal (Rabbit) LD50: 3,000 mg/kg. Oral (rat) LD50: 3,100 mg/kg

Butylphenyl Methylpropional The safety of Butylphenyl Methylpropional has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of Butylphenyl Methylpropional in fragrances because of potential sensitization. The Cosmetic Ingredient Review (CIR) defers review of individual fragrance ingredients to the IFRA program unless the ingredient has significant uses other than as a fragrance. In this case, the ingredient may be assessed by both the CIR Expert Panel and REXPAN. Oral Rat LD50:3,700 mg/kg; Oral Rat LD50: 2,880 mg/kg; Skin Dermal Rabbit LD50: > 2,000 mg/kg; Oral Rat LD50: 1,390 mg/kg.

Limonene Limonene, also known as d–limonene, l–limonene or dipentene, is widely used as a flavour and fragrance additive in cleaning and cosmetic products, food and pharmaceuticals. It is also present in most of the essential oils commonly used, particularly citrus oils. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) has assessed limonene and the report was published in May 2002. Following are the main findings of the assessment. Limonene is not very toxic. However in contact with light or air, limonene can break down to form small amounts of oxidation products. These can cause skin allergy. Contact with limonene or limonene products can cause eye and skin irritation. Risk to the general public of exposure to limonene is low because the majority of limonene consumer products contain low concentrations.ORL-RAT LD50 4400 mg kg-1. IPR-RAT LD50 3600 mg kg-1. IVN-RAT LD50 110 mg kg-1. ORL-MUS LD50 5600 mg kg-1. IPR-MUS LD50 600 mg kg-1. SKN-RBT LD50 > 5000 mg kg-1. SCU-MUS LD50 3170 mg kg-1.

Please note that the allergens are displayed as 0% because they are a part of the essential oil or perfume percentage. The actual figures are calculated out on the INCI tab of the PIP booklet.

ALWAYS CHECK THE MANDATORY WARNINGS ON THE EU LEGAL TAB [columns P and AA] : Number of warnings to add = 2

Suggested warnings

Young children should be supervised
Use only as directed
Not to be used around the eye
In the unlikely event of rash or irritation, discontinue use
In the event of contact with the eye. Wash with copious volumes of water
For external use only
Avoid contact with eyes

CPNP Rule

Rule 14 Bath salts/cubes containing inorganic sodium salts N/A

The total concentration of sodium salts must be specified. An updated notification is required when the total concentration of inorganic sodium salts changes by more than 20% of the value declared previously."

Rule 17 Products containing essential oils, camphor, menthol or eucalyptol

Except for perfume and some limited other product categories, when a manufacturer introduces in a formula essential oils, camphor, menthol or eucalyptol with a total level higher than 0.5%, the total level concentration must be indicated. If essential oils, camphor, menthol or eucalyptol are not present in the product or if the level of essential oils, camphor, menthol or eucalyptol does not exceed 0.5%, then 'not applicable' must be checked. For each individual essential oil, camphor, menthol or eucalyptol with a level higher than 0.5% (0.15 % in case of camphor), the manufacturer must state the name and quantity of this essential oil/essential oil derivative. If no individual essential oil, camphor, menthol or eucalyptol are present with a level higher than 0.5% (0.15 % in case of camphor), then 'not applicable' must be checked. An updated notification is required when the concentration changes by more than 20% of the value declared previously."

Rule 8 Products containing cationic surfactants with two or more chain lengths below C12.

The INCI name and the concentration of cationic surfactants with two or more chain lengths below C12 must be specified if the surfactant is used for non preservative purpose. An updated notification is required when the concentration changes by more than 20% of the value declared previously. Typical examples for cationic surfactants covered by this rule:

• behentrimonium chloride
• distearyldimonium chloride
• cetrimonium chloride
• dicetyldimonium chloride

If cationic surfactants with two or more chain lengths below C12 are not present in the product, then 'not applicable' must be checked."

Rule 18 Other Ingredients

In addition to the rules above, a number of substances have been identified by European Poison Control Centres as posing a particular concern with regard to an acute poisoning emergency.

The concentration, above the indicated threshold, of any of these ingredients in a formulation must be specified. If no threshold is indicated, the concentration must always be specified.

An updated notification is required when the concentration changes by more than 20% of the value declared previously:

Glycols and Glycol ethers

BUTETH-2 ACETATE (above 1%)
BUTOXYDIGLYCOL (above 1%)
BUTOXYETHANOL (above 1%)
BUTOXYETHYL ACETATE (above 1%)
DIETHOXYDIGLYCOL (above 1%)
DIPROPYLENE GLYCOL (above 10%)
DIPROPYLENE GLYCOL DIMETHYL ETHER (above 10%)
DIPROPYLENE GLYCOL ISOBORNYL ETHER (above 10%)
ETHOXYDIGLYCOL (above 1%)
ETHOXYDIGLYCOL ACETATE (above 1%)
GLYCOL (above 1%)
GLYCOL ETHERS (not polymers) (above 1%)
METHOXYISOPROPANOL (above 10%)
METHOXYISOPROPYL ACETATE (above 10%)
PPG-2 METHYL ETHER (above 10%)
PPG-2 METHYL ETHER ACETATE (above 10%)
PROPYLENE GLYCOL (above 10%)
PROPYLENE GLYCOL BUTYL ETHER (above 10%)
Hydrocarbons solvents
CYCLOHEXANE (above 5%)
HYDROGENATED DIDODECENE (above 5%)
ISOPENTANE (above 5%)
PENTANE (above 5%)
TOLUENE (above 5%)
TURPENTINE (above 5%)
Alcohols other than ethanol and isopropanol
BENZYL ALCOHOL (above 1%)
FURFURYL ALCOHOL (above 1%)
HEXYL ALCOHOL (above 5%)
N-BUTYL ALCOHOL (above 1%)
PROPYL ALCOHOL (above 1%)
T-BUTYL ALCOHOL (above 1%)
Others
ACETONE (above 5%)
BENZYL BENZOATE (above 1%)
BRUCINE SULFATE
BUTYL ACETATE (above 1%)
BUTYROLACTONE (above 0,1%)
BUTOXYETHYL ACETATE (above 1%)
CHLOROPLATINIC ACID (above 0,1%)
COPPER SULFATE (above 0,1%)
CYCLOHEXANONE (above 5%)
DIMETHYLTOLYLAMINE (above 0,1%)
ETHYL ACETATE (above 1%)
ETHYL ETHER (above 5%)
FORMALDEHYDE (above 0,2%)
HYDROXYLAMINE HCL; HYDROXYLAMINE SULFATE (above 1%)
M-CRESOL, O-CRESOL, P-CRESOL, MIXED CRESOLS (above 0,1%)
MEK (above 5%)
METHYL ACETATE (above 0,1%)
METHYL PYRROLIDONE (above 5%)
MIBK (above 5%)

POTASSIUM CHLORATE (above 0,1%)
SODIUM CHLORATE (above 0,1%)
TRIETHYL PHOSPHATE (above 0,1%)
The user should also notify in the dedicated field any other information on the product that would be of significance for poison centres or similar bodies, where such centres or bodies have been established by Member States (using English only). "

Rule 1 Ethanol and/or isopropanol

The percentage weights (w/w) of ethanol and/or isopropanol must be specified for all products. An updated notification is required when the content of either ingredient or the sum of both ingredients changes by more than: - 5 if the value declared previously is < 30%. Examples: A change from 20% of ethanol to 26% ethanol constitutes a change of 6 in the ethanol content in the formulation and therefore requires an updated notification. A change from 20% of ethanol and 20% isopropanol to 23 % of ethanol and 24 % of isopropanol constitutes a change of 7 of the sum of ethanol and isopropanol in the formulation and therefore requires an updated notification. - 10 if the value declared previously is ≥ 30%. If ethanol or isopropanol are not present in the cosmetic product, then 'not applicable' must be checked. Note: declarations of percentage weights may be rounded to the nearest whole number. Note: if the percentage weight is below 1%, it can be specified as 1%."

Rule 16 Products with a pH lower than 3 or higher than 10, and pH of hair coloring products. **N/A**

The pH of single-component products or individual component (except for hair dyes) must be specified in the pH field if it is lower than 3 or higher than 10. In the case of multiple component products (except for hair dyes) that are mixed prior to use, the pH of the mixed product must be specified in the respective pH field if it is lower than 3 or higher than 10. It is acknowledged that different mixing ratios of components (e.g. to achieve different strengths) can lead to pH variations. In case the exact pH cannot be determined for the mixed product then the pH can be expressed in range form of no more than one unit (e.g. 9.5 – 10.5). For the case of single-component or multi-component hair dyes, the pH must always be indicated, even if it is within the range of pH 3 to pH 10. However given pH variations between color shades of the same product, the indication of an exact pH may not be relevant. For these products, the pH of the components and the mixed products can be expressed in range form of no more than one unit (e.g. 8.5 – 9.5) In all cases above, an updated notification is required when the pH declared previously changes by more than 0.5. For any product or component with a pH higher than 10, the INCI name and concentration of each alkaline agent, and – if applicable – ammonium hydroxide liberator must be specified. An updated notification is required when either of these concentrations changes by more than 20% of the value declared previously Examples for alkaline agents typically used are:

• sodium / potassium hydroxide
• sodium / potassium carbonate
• sodium/potassium metasilicate
• calcium oxide
• ammonium hydroxide
• ethanolamine

A typical ammonium hydroxide liberator is

• ammonium chloride

Perfume NOAEL values are shown, but the calculation for perfume margin of safety and their allergens is performed using the IFRA guidelines where set limits have been set. Please see the IFRA QRA table included in this report. The PIP workbook also has proposed new allergens (see INCI tab).

MARGINS OF SAFETY

Raw Material	MOS	NOAEL	<100
Aqua (Water)	44,025	100,000	0
Sodium Laureth Sulfate	9,419	2,000	0
Sodium Chloride	30,913	3,000	0
Cocamidopropyl Betaine	58,424	4,000	0
Eucalyptus Globulus Leaf Oil	44,146	2,480	0
Menthol	35,602	1,000	0
Parfum (Fragrance)	0	0	1
Decyl Glucoside	129,462	2,000	0
Polysorbate 20	2,634,546	37,000	0
Sodium Sheabutteramphoacetate	237,346	2,000	0
Hydroxypropyl Guar Hydroxypropyltrimonium Chloride	356,020	2,000	0
Sodium Styrene/Acrylates Copolymer	374,758	2,000	0
Benzophenone-3	1,756,364	7,400	0
Disodium EDTA	1,463,637	4,070	0
Citric Acid	6,143,622	6,730	0
Triethylene Glycol	24,209,340	17,000	0
Propylene Glycol	47,469,293	20,000	0
Sodium Lauryl Sulfate	10,190,075	1,288	0
Alcohol Denat.	114,357,843	10,600	0
Caramel	254,299,786	15,000	0
Magnesium Nitrate	215,194,130	5,440	0
Methylchloroisothiazolinone	139,441,049	2,350	0
Magnesium Chloride	576,751,914	8,100	0
Methylisothiazolinone	320,417,730	1,800	0
Sodium Hydroxide	178,009,850	500	0
CI 15985 (Yellow 6)	1,780,098,499	10,000	0
Amyl Cinnamal	Allergen	3,000	0
Benzyl Salicylate	Allergen	3,100	0
Hexyl Cinnamal	Allergen	3,100	0
Butylphenyl Methylpropional	Allergen	4,000	0
Limonene	Allergen	4,400	0

Shampoo, Rinse-Off Conditioners, Bar Soap, Feminine Hygiene Pads & Liners, Other Aerosols (including air fresheners sprays but not including deodorant/antiperspirants, hair styling aids spray)			IFRA QRA		
Allergens from perfume	**0.01% Rinse-off**	**0.001% Leave-on**	**9**	**IFRA Status**	**%w/w**
Amylcinnamyl Alcohol	ok	ok	5.00	safe	0.0000
Amyl Cinnamal	declare	declare	5.00	safe	0.0113
Anise Alcohol	ok	ok	5.00	safe	0.0000
Benzyl Alcohol	ok	ok	5.00	safe	0.0001
Benzyl Benzoate	ok	declare	5.00	safe	0.0047
Benzyl Cinnamate	ok	ok	5.00	safe	0.0000
Benzyl Salicylate	declare	declare	5.00	safe	0.0100
Cinnamyl Alcohol	ok	ok	0.40	safe	0.0000
Cinnamal	ok	ok	0.05	safe	0.0000
Citral	ok	ok	5.00	safe	0.0000
Citronellol	ok	declare	5.00	safe	0.0018
Coumarin	ok	ok	5.00	safe	0.0000
Eugenol	ok	ok	0.50	safe	0.0000
Farnesol	ok	ok	5.00	safe	0.0000
Geraniol	ok	ok	5.00	safe	0.0000
Hexyl Cinnamal	declare	declare	5.00	safe	0.0113
Hydroxycitronellal	ok	ok	1.00	safe	0.0000
Isoeugenol	ok	ok	0.02	safe	0.0000
Butylphenyl Methylpropional	declare	declare	5.00	safe	0.0113
Limonene	declare	declare	2.00	safe	0.1680
Linalool	ok	ok	2.00	safe	0.0001
Hydroxyisohexyl 3-cyclohexene Carboxaldehyde	ok	ok	0.20	safe	0.0000
Methyl 2-Octynoate	ok	ok	0.01	safe	0.0000
Alpha-isomethyl Ionone	ok	declare	5.00	safe	0.0023
Evernia Prunastri (Oakmoss) Extract	ok	ok	0.10	safe	0.0000
Evernia Furfuracea (Treemoss) Extract	ok	ok	0.10	safe	0.0000
The status rinse off or leave on status has been decided, but both allergen options are shown					
Special IFRA essential oils					
Angelica Archangelica Root Oil	#N/A				
Camellia Sinensis Leaf Extract	#N/A				
Cananga Odorata Flower Oil	#N/A				
Citrus Aurantifolia (Lime) Oil Expressed	#N/A	#N/A			
Citrus Aurantium Amara (Bitter Orange) Peel Oil	#N/A	#N/A			
Citrus Aurantium Bergamia (Bergamot) Peel Oil Expressed	#N/A	#N/A			
Citrus Limon (Lemon) Peel Oil Expressed	#N/A	#N/A			
Citrus Paradisi (Grapefruit) Peel Oil	#N/A	#N/A			
Colophonium	#N/A				
Commiphora Erythrea Glabrescens Gum Oil	#N/A				
Commiphora Erythrea Gum Extract	#N/A				
Cuminum Cyminum Seed Oil	#N/A				
Jasminum Grandiflorum (Jasmine) Flower Extract	#N/A				
Jasminum Sambuc (Jasmine) Flower Extract	#N/A				
Liquidambar Styraciflua Oil	#N/A				
Melissa Officinalis Leaf Oil	#N/A				
Myroxylon Pereirae (Balsam Peru) Oil	#N/A				
Tagetes Minuta Flower Oil	#N/A				

DWECK DATA

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Consultant on Natural Products to the Cosmetic and Toiletry industry

Overall Product Rating
SAFE

Introduction
The raw materials used to formulate this product are all well-known ingredients with a long history of safe use. They are used at levels that have been seen and assessed in similar products held in our data base with no reports of irritation. The formulation is typical of its type and formulated by a company with a long history of safety and quality. The toxicology statements relate to the material when used at 100% and we have taken into account the lower amounts used in this product. Different countries have different requirements and this section relates solely to European sales.
Effects of the product as applied on the skin
The formulation may cause only minimal skin irritation even if exposure is prolonged and /or repeated. The product is unlikely to produce phototoxic reactions. There is unlikely to be any systemic reaction caused by absorption through the skin. We have calculated the margin of safety for all ingredients and found the safety factor to be acceptable. Our calculations had considered the total exposure of raw materials used in this product.
This is a rinse off or product that is used diluted, we have calculated the effect of that dilution and applied a suitable factor
This product is not a nail polish or remover, there are no special considerations with respect to the nails.
The margin of safety is above a value of 100 and there are no causes for concern. Fragrances are considered separately.
This product contains little or no alcohol and no stinging would be expected
Effect of ingestion
The formulation as supplied is unlikely to cause any problems if ingested.
This product does not contain oils or materials expected to exhibit a laxative effect.
Spilt product or residual product is unlikely to cause a physical hazard.
Internal use or ingestion of this product is not expected
There are no solvents or diluents that would give rise for concern.
Effect of the product on the eye
This product contains no particles or particles too small to be of concern should they enter the eye
This product contains surface active agents (e.g. soap or detergent) that may also cause transient irritation should they come into contact with the eye.
This product is an aqueous solution of active materials that is unlikely to cause irritation should it come into contact with the eye.
Rinsing the eye will quickly remedy any irritation or discomfort. Suitable warnings should be employed in these cases.
This product is not an emulsion and has been evaluated under a different category.
The risk of this product entering the eye is minimal, an eye warning is at the client's discretion. As assessors we would say that although it is not mandatory to have an eye warning in today's world of litigation an eye warning would be prudent.
This product contains little or no alcohol and no stinging would be expected
Effect of Inhalation
Inhalation is not considered an issue as there are no dust particles.
Inhalation is not considered an issue because there are no solvents to give concern.

Sunscreen Labeling
No SPF has been claimed
No special instructions are required with reference to SPF values
There are no special instructions in relation to sun protection
There are no special precautions to be advised with respect to sun protection.
There are no special warnings with relation to sun exposure required.
Suggested product warnings are covered in an earlier section.
The advice to get medical help or contact a Poison Control Center right away in the event of ingestion is good for any prodcut.
Alpha Hydroxy Acids (AHAs)
The level of AHAs or BHAs in this product is not a concern
This is not a professional peel product and the level of AHAs gives no concerns.
Legal compliance
The preservatives, colours and UV sunscreens have all been checked against the limits set in the various annexes as defined in the Regulation of the European Parliament and of the Council on cosmetic products (recast) 2008/0035 (COD) dated 10 November 2009. All necessary warning have been checked and are in place. The 26 potential allergens present in the Parfum and essential oils have been calculated and declared where required. The company has demonstrated that it produces to Good Manufacturing Practice. **Take notice of any warnings in the Toxicology Assessment and legal sections. Ensure that all perfume allergens found in the INCI section are accounted for in the ingredient listing.** (This is the final responsibility of the client). Mandatory warnings are shown in the Excel workbook and have been highlighted on the relevant country legal tab. The need and number of European warnings are highlighted above the suggested warnings of this report (the client must ensure these are in place)..
We have taken into account the toxicology of each and every raw material and on the basis of those calculations shown on this page have made an assessment with a rating as shown above.
Specific Warnings
See the PIP Booklet for mandatory warnings under specific country legislation.
Arbitrary Warnings
Children should be supervised. We suggest this because the product may cause damage to furnishings and fabrics etc.
Qualification of the Safety Assessor
Anthony C. Dweck
BSc CChem CSci FLS FRSC FRSPH
Chartered Chemist, Chartered Scientist, Fellow of the Linnean Society, Fellow Royal Society of Chemistry, Fellow Royal Society for Public Health. Worked in the personal care industry since 1971 as a chemist, production manager, technical director, technical editor and technical consultant. Also acts as expert witness to the Trading Standards Office.
Notification.
Now that the safety assessment has been carried out and before you place the product on the UK market, if the UK is the first market in the EU, please ensure your Responsible Person is registered with the European Commission Authentication Service (ECAS) by going to https://webgate.ec.europa.eu/aida/selfreg and following the instructions. Once you have registered with ECAS you must go to the Cosmetic Products Notification Portal (CPNP) at https://webgate.ec.europa.eu/aida/cpnp where you can create your organisation. At this stage you can follow the instructions given in the CPNP User manual to register your product. Dweck Data regret that this is a service that we are unable to offer.

Curriculum Vitae of Anthony C. Dweck BSc, CChem, CSci, FRSC, FLS, FRSPH.

Dweck has worked for Smith & Nephew, S.C. Johnson, Marks & Spencer, and Peter Black (now LF Beauty). In 1998 he formed Dweck Data in order to devote more time to the study of botanicals and their chemistry. He is author and compiler of the "Toxicology Assessments Software Programme", that will go on sale in 2015.

Past member of Council (1984-1986) Society of Cosmetic Scientists, Past President Society of Cosmetic Scientists (1996-1997), Past President Society of Cosmetic Scientists (2001 – 2002), Honorary Member of Society Cosmetic Scientists (awarded 2004), Technical Editor Personal Care Magazine (Asia Pacific 1999-2010) (Europe 2008-2010) now Technical Consultant (since 2010), Associate Editor International Journal of Cosmetic Science (2001-2003), Moderator and creator of the Formulators' Discussion Group (1998-2005), Honorary Organiser SCS Spring Conference 100% Natural in 2007, Member of the Scientific Advisory Committee of the CTPA (1992-1998). Member of the Advisory Board of Cosmetics & Toiletries Magazine (1997-1998), Member of the Advisory Board of International Society of Cosmetic Dermatology (2003-2013), Member of the Editorial Scientific Advisory Panel of SPC Magazine (1997-2001), Member of the Editorial Scientific Advisory Board of SOFW Journal (1988 - 1999), Member of the LCLN (Ingredient Nomenclature) of the C.T.P.A. (1994-1998), Member of the IFSCC Monograph Review Committee (1997 - 1999), External Examiner for Society of Cosmetic Scientists (since 1991), Referee (reviewer) for International Journal of Cosmetic Science (1992-2013), Chairman Sponsorship Committee of IFSCC Congress in 2002, Edinburgh (1998-2000), IFSCC listed conference speaker. Chairman of the SCS 50th Anniversary Book Committee, 1998. Joint Organiser of the Post Graduate Course in Cosmetic Science (1998, 2000, 2001, 2003, 2005, 2007), Council of Europe - Botanical Task Force (Committee of Experts) (appointed 1998). Consultant and expert witness (listed) to the Trading Standards Office. Member of the Scientific Advisory Board to Union Swiss (since 2008). Consultant Member IFRA (since 2014). 43 years in the industry.

Author of over a hundred articles and papers on various aspects of the Cosmetic and Toiletry industry and numerous book chapters, Anthony is also a frequent lecturer on his favourite topic of botanicals/medicinal plants and has presented over 80 papers at conferences all over the world. He was a regular organiser of the conference programme for PCIA (Personal Care Ingredients Asia) and the honorary organiser for the SCS Spring Symposium 13-15th May 2007 "the 100% Natural Conference" at Staverton Park, Northants. He is Co-Organiser of "Making Cosmetics" (2012, 2013). His data base on naturals and natural derivatives is one of the largest in the world. A full list of publications may be found at www.dweckdata.com

He has written four books.

- Handbook of Cosmetic Ingredients - their use, safety and toxicology. 4th ed. Is temporarily unavailable.
- Handbook of Natural Ingredients. 3rd ed. eBook is temporarily unavailable
- Formulating Natural Cosmetics. ISBN: 978-1-932633-75-7. Allured Business Media. 2nd ed in July 2014.
- Handbook of Natural Ingredients" Not for sale. Book only available to clients of CLR. Chemisches Laboratorium Dr. Kurt Richter GmbH