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Safety Assessment for a Cosmetic Product

Reference WSC030410

This safety assessment for a cosmetic product has been carried out in accordance with the requirements of current EU and UK legislation, namely Council Directive 76/768/EEC, including any additional Commission Directives applicable at the date of signature below. In accordance with the requirements of the Cosmetic Directive, this assessment takes account of the following –

- a) the general toxicological profile of each ingredient used;
- b) the chemical structure of each ingredient;
- c) the level of exposure of each ingredient;
- d) the specific exposure characteristics of the areas on which the cosmetic product will be applied;
- e) the specific exposure characteristics of the class of individuals for whom the cosmetic product is intended.

Product description

A series of solid soaps (rinse off products), made using commercial “Melt and Pour” pre-manufactured bases, the final compositions of which are based on a prescribed combination of the ingredients listed below

Specifically, the final product formulation is as follows –

Product Series 1

Common Base Ingredients (Commercial pre-manufactured base products - Crystal ST & Pearl 510 Base Mix)

Ingredients: Aqua, Glycerine, Sodium Stearate, Propylene Glycol, Sorbitol, Sodium Laurate, Sodium Laureth Sulfate, Sodium Chloride, Stearic Acid, Lauric Acid, Pentasodium Pentetate, Tetrasodium Etidronate, Sodium Palmate, Sodium Palm Kernelate, Palm Kernel Acid, Potassium Palmate, Potassium Palm Kernelate, Parfum Titanium Dioxide.

Product Name	Additional Ingredients
Ylang Ylang & Rose	CI 42090, CI 16185
Dewberry	CI 16185
Sea Breeze	CI 394433, CI 42090
Coconut	CI 15985
Patchouli	CI 16185, CI 19140, CI 42090
Tuberose	CI 16185, CI 19140
Orange & Grapefruit	CI 16185, CI 15985
Jasmine	CI 394433
Watermelon	CI 3597, CI 16185, CI 19140
Honey	CI 19140, CI 42090, CI 77499
Honeysuckle	CI 16185
Cool Water	CI 42090, CI 9220, CI 77499, CI 19140
Tangerine	CI 16185, CI 19140, CI 15985
Vanilla	CI 19140, CI 77499
Sandalwood & Orange	CI 11557
Applejack	CI 77499, CI 9220
Frankincense	CI 42090
Pine & Tangerine	CI 3597, CI 42090, CI 19140, CI 77499
Spice & Orange	CI 3597, CI 16185, CI 19140, CI 260236
Old Xmas	CI 11557
Gingerbread	CI 9220, CI 15985, CI 16185, CI 42090
Olive & Herb	CI 11557, CI 3597
Lily of the Valley	CI 19025
Musk	CI 16185
Green Tea	Chlorophyll
Ice cream	CI 9220, CI 16185
Ginger	CI 9220, CI 16185, CI 19140
All at Sea	CI 42090
Green Apple	CI 42090, CI 19140
Lime	CI 11710
Banana	CI 19140, CI 15985, CI 16185, CI 42090
Champagne	CI 16185
Bluebell	CI 42090, CI 16185
Cherry	CI 19025, CI 77499, CI 42090, CI 19140
Orange & Cinnamon	CI 15985, CI 11557
Freesia	CI 42090
Lemon & Eucalyptus	CI 42090, CI 19140
Passion fruit	CI 16185, CI 19140

Product Name	Additional Ingredients
Guava & Passion fruit	CI 13597, CI 16185, CI 19140
Pineapple	CI 19140, CI 42090
Sandalwood	CI 260236, CI 11557
Spearmint	CI 42090
Strawberry	CI 16185, CI 19140
Rose	CI 16185, CI 19140
Tulip	CI 42090, CI 19025, CI 3597
Ylang & Jasmine	CI 19140
Daisy	CI 19140
Hay	CI 42090, CI 19140
Spa	CI 42090
Raspberry	CI 260236, CI 19140
Blackberry	CI 260236, CI 16185, CI 42090
Izzy	CI 16185, CI 19140
Mango	CI 15985
Cappuchino	CI 15985, CI 16185, CI 42090
Olive	CI 42090, CI 19140
Grapefruit	CI 16185, CI 19140
Violet	CI 42090, CI 16185
White Musk & Lavender	Lavandin Essential Oil, CI 42090, CI 16185
Lemon & Lime	Lemongrass Essential Oil CI 3597, CI 19140

Product Series 2

Common Base Ingredients (Commercial pre-manufactured base products - Crystal ST & Pearl 510 Base Mix)

Ingredients: Aqua, Glycerine, Sodium Stearate, Propylene Glycol, Sorbitol, Sodium Laurate, Sodium Laureth Sulfate, Sodium Chloride, Stearic Acid, Lauric Acid, Pentasodium Pentetate, Tetrasodium Etidronate, Sodium Palmate, Sodium Palm Kernelate, Palm Kernal Acid, Potassium Palmate, Potassium Palm Kernelate, Titanium Dioxide.

Product Name	Additional Ingredients
Lemongrass	Lemongrass Essential Oil, CI 19140
Peppermint & Tea Tree	Peppermint Essential Oil, Tea tree Essential Oil, CI 42090
Tea Tree	Tea tree Essential Oil, Chlorophyll
Peppermint	Peppermint Essential Oil
Peppermint & lavender	Peppermint Essential oil, Lavandin Essential Oil, CI 42090
Lavender	Lavandin Essential Oil, CI 16185 CI 42090

Product Series 3

Common Base Ingredients (Commercial pre-manufactured base products - Opal 510 Base Mix)

Ingredients: Sodium Palmate, Sodium Palmkernalate, Aqua, Sodium Chloride, Glycerin

Product Name	Additional Ingredients
Peppermint & Lavender	Peppermint & lavender Essential Oil, Mentha Piperita
HONEY & BRAN	Parfum, Bran, Miel
ROSE	Parfum, Rose Geranium Essential Oil, CI 16185
CARROT & CALENDULA	Parfum, Calendula officianalis
Tea Tree	Tea Tree Essential Oil
Lavender	Lavandin Essential Oil
Energise	Bergamot Essential Oil, Lemongrass Essential Oil
Ylang Ylang	Ylang Ylang Essential Oil
Lavender Blossom	Lavandin Essential Oil, Lavendula angustifolia
Mint & Rosemary	Peppermint Essential Oil, Rosemary Essential Oil, Mentha piperita, chlorophyll
Calendula & Honey	Parfum, Calendula Officionalis, miel
Kava Kava	Parfum, Myrrh
Seaweed & Orange	Parfum, Kelp
Chamomile Flowers	Parfum, Anthemis nobilis

Fragrance Oils – INCI Parfum

Conditions of use -

Fragrance oils may be added to maximum concentration of 2% (w/w) in the final product, either singly or in combination, providing the following criteria are met -

1. The fragrance oil must be obtained from a EU registered supplier.
2. The fragrance oil must be approved for cosmetic use.
3. The fragrance oil must have an accompanying Manufacturer's MSDS and allergen content statement.
4. The fragrance oil must not contain any ingredient that is prohibited under the Cosmetics Directive.
5. The chemical composition of the fragrance oil must comply with current IFRA guidelines.
6. The fragrance oil(s) must not be used in conjunction with essential oils.

Essential Oils – INCI = Botanical name

Conditions of use -

Essential oils may be added to maximum concentration of 2% (w/w) in the final product.

Fragrance Oil and Essential oil Allergen Labelling requirements

In a rinse off product such as bar soap, any of the 26 allergens detailed in the European Commission Directive 2003/15/EC, that are present in the final product at a concentration greater than or equal to 0.01% must be declared on the product labelling. A supplier allergen declaration must be provided with any fragrance oil intended for use in a cosmetic product.

Safety Assessment conditions.

1. The base products detailed are sourced from an EU registered supplier, and have been manufactured in accordance with current industry GMP guidelines.
2. All manufacture must be to standards of good hygiene and to standards of Good Manufacturing Practice, by qualified and / or experienced personnel.
3. No deviation shall be made from the specified final product concentration values for any of the ingredients listed on this assessment.
4. All raw material specifications and finished product specifications must comply with current Good Manufacturing Practices in regard to raw material quality and that no ingredients are used that are prohibited under the Cosmetics Products Directive.
5. The product will not be specifically marketed for use by children under the age of 3 years.
6. Labelling and other legal requirements specified in the EU Cosmetics Directive at the date of signature are adhered to by the manufacturer.
7. Care must be taken not to infringe upon the food imitation (safety) regulations-where appropriate, labelling should clearly indicate that the product is not edible.
8. All packaging must be food or cosmetic grade material.

Failure to comply with any of the Safety Assessment conditions detailed above, will nullify this document.

Additionally,

This Safety Assessment is applicable only to the named manufacturer and is not transferable to any other party.

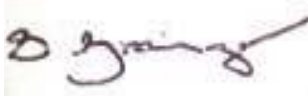
Cosmetic Safety Consultants Ltd. and its directors will accept no liability for the misuse of this document or for any cosmetic product formulated outside the remit of this document.

Final product safety statement –

Solid soap (rinse off product)

Manufactured by

This category of product has an extremely well established history of safe use. A review of the toxicology and history of safe use profiles of the ingredients specified in this safety assessment (alone and in combination indicates no significant risk under normal and foreseeable conditions of use, and is safe to market in the EU and UK.



Scott Grainger CSci CChem MRSC
Chartered Chemist, Chartered Scientist

03/03/10