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SAFETY ASSESSMENT

Product: Alphabet Soaps (Ancient Wisdom)

The following Safety Assessment is carried out according to the Council Directive 76/768/EEC, on the Safety of Cosmetic Products and as amended by Commission Directives 2003/15/EC (7th Amendment), 2003/83/EC (30th Amendment), and 2003/80/EC (31st Amendment)

The product may also be considered under the General Product Safety Directive 2001/95/EC

The Assessment is conducted in accordance with the principles of Good Laboratory Practice referred to in Article 1 of Council Directive 2004/10/EC on the applications of the principles of good laboratory practice and the verification of their application for tests on chemical substances.

This assessment takes account of:

- 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.

REVIEW OF INGREDIENTS

All of the ingredients have a history of use in cosmetic and toiletry products. Ingredients that are:

- Prohibited under the Cosmetics Directive
- Restricted when used beyond the allowed authorised conditions
- With toxicological data incompatible with the intended concentration and use
- Which have insufficient toxicological data nor safety in use experience
- Which are not properly characterised with regard to purity and analytical composition

Are excluded.

ASSESSMENT

Assessment is based on ingredient safety review and information on the final formulation, including the intended and reasonably foreseeable use, the physico-chemical and microbiological specifications of the raw materials and the finished product, stability and a history and record of any reported undesirable effects linked to the use of the product. The Assessment relates to a range of fragrance/ colour variants.

DESCRIPTION OF THE PRODUCT

This is a rinse-off product for application to any part of the body as a cleanser.

DESCRIPTION OF INTENDED AND REASONABLY FORESEEABLE USE

The product may reasonably be typically used up to 1-5 times daily as required.

QUANTITATIVE COMPOSITION OF THE PRODUCT

Ingredients are listed below. Detailed information on the safety and toxicology of ingredients is provided held on file.

The product comprises a Soap Base as supplied by Stephenson's to which additions of fragrance/ colours are made

Formula Base	96-98%
Colours	0.4 -0.5%
Parfum	1.5-2.0%

BASE:

Aqua	25 - 50 %
Glycerin	10 - 25 %
Sodium Stearate	10 - 25 %
Propylene Glycol	10 - 25 %
Sorbitol	5 - 10 %
Sodium Laurate	5 - 10 %
Sodium Laureth Sulfate	5 - 10 %
Sodium Lauryl Sulfate	1 - 5 %
Sodium Chloride	0.5 - 1.0 %
Stearic Acid	0.5 - 1.0 %
Lauric Acid	0.5 - 1.0 %
Pentasodium Pentetate	< 0.1
Tetrasodium Etidronate	< 0.1

Colours:

CI 77891
CI 77499
CI 18050
CI 19140
CI 42090
CI 47005
CI 16255
CI 15985
CI 14720
CI 42090
CI 45430
CI 20285

Parfums

Are supplied by Fragrance Oils International and are to meet IFRA Guidelines for proposed use, and be supplied with list of % allergens

Listed as below:

Further parfums may be added providing these meet IFRA Guidelines for a Soap use.

Alloy
Aloe Vera
Apple & Blackcurrant
Apple & Elderflower
Apple Fresh
Baby Powder
Bakewell Tart
Banana
Blackberry
Black Pepper
Bluebell
Blueberry
Boulevard
Bouquet
Brandy Butter
Calendula
Cappucino
Cedarwood

Christmas Pudding
Coconut
Cool Musk
Cranberry
Cucumber
Dark Chocolate
Dewberry
Dragons Blood
Evening Primrose
Fig & Cassis
Frankincense
Ginger & Lime
Ginger Stem & Walnut
Golden Honey
Gooseberry & White Tea
Grapefruit & Mandarin
Green Tea
Guava Lava
Gurjam
Honey & Oatmeal
Honeysuckle
Jasmine
Kannabis
Kola Cube
Lemongrass
Lily of the Valley
Lotus Flower
Louisa
Lychee
Mango
Mango 2
Mima
Musk

Orange & Melon
Orange & Warm Ginger
Orchid
Ozone
Ozonic
Passion Fruit
Patchouli
Peach
Pharoah
Pineapple Crush
Pomegranate
Raspberry
Satin
Sensual Feelings
Sweet Bubblegum
Sweet Fennel & Jojoba
Sweet Pea
Tuberose
Turkish Delight
Vanilla
White Chocolate
White Freesia
White Musk
Wild Cherry
Woodland Walk
Ylang

Ingredients labelling

Aqua

Glycerin

Sodium Stearate

Propylene Glycol

Sorbitol

Sodium Laurate

Sodium Laureth Sulfate

Sodium Lauryl Sulfate

Sodium Chloride

Stearic Acid
Lauric Acid
Pentasodium Pentetate
Tetrasodium Etidronate

.....followed by Parfum, any colours and all EU allergens > 0.01%

The above ingredients have been reviewed for potential to be skin irritants, sensitisers or photo-sensitisers.

Where data is available for systemic and sub-chronic toxicity this has been taken into account.

A review of the literature and of the structural chemistry has been made for each ingredient to estimate the likely potential for genotoxicity, reproductive effects and carcinogenicity.

MARGINS OF SAFETY

Based on the available toxicological literature, Margins of Safety have been calculated for both topical and systemic effects. It was concluded that all ingredients, when considered both individually and in combination have an adequate Margin of Safety.

Taking the above into account and taking the safety data on file, it is considered that this formulation is safe for marketing.

GOOD MANUFACTURING PRACTICE

The product is to be manufactured to adequate standards of Good Manufacturing Practice and there are to be adequate controls in regards to Microbial quality.

FINISHED PRODUCT SAFETY

The above formulation is based on known ingredients with history of safe use in consumer products. This Safety Assessment has taken account of:

1. The Quantitative/Qualitative composition of the product, and including the predicted preservative efficacy to prevent microbial spoilage.
2. The intended and reasonably foreseeable use of the product.
3. Margins of Safety for all ingredients considered both individually and in combination.
4. Standards of good manufacturing practice.
5. Adequate advice and on pack warnings.

Care should be taken not to infringe the Foods Imitation Regulations in the design of the product

SUMMARY

In reviewing the safety and toxicity profile of the ingredients used and their history of safe use, it is concluded that there are no likely safety hazards from normal use of this product and when used as directed or from foreseeable conditions of misuse.

There should be label advice for correct use.

It is a requirement that all ingredients must meet EU specifications for purity. The product is considered safe for sale in all EU countries.

Dated: December 16th 2011

A handwritten signature in black ink, appearing to read 'Dr. Hopkins', with a stylized flourish at the end.

Dr. JOHN HOPKINS BSc. PhD. MSB. C Biol.

Safety Assessor

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