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## **SAFETY ASSESSMENT**

**Product Name: Melt & Pour Soap Range  
(by Ancient Wisdom)**

**Formula:**

- 1. ExerS-01 Cellu Buster**
- 2. ExerS-02 Extreme Exfoliate**
- 3. ExerS-03 Rub Relax & Refresh**
- 4. ExerS-04 Firm & Tone Scrub**

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 (7<sup>th</sup> Amendment), 2003/83/EC (30<sup>th</sup> Amendment), and 2003/80/EC (31<sup>st</sup> Amendment) and subsequent Amendments.

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.

#### DESCRIPTION OF THE PRODUCT

This is a rinse off range for application to the skin on any part of the body during washing/bathing.

#### DESCRIPTION OF INTENDED AND REASONABLY FORESEEABLE USE

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

#### QUANTITATIVE/QUALITATIVE COMPOSITION OF THE PRODUCT

Ingredients are listed below. Detailed information on the safety and toxicology of ingredients is held as a Master File by Innovant Research.

This is a range of soaps based on variants in essential oils and additives. As the bases are very similar all variants are considered together in one Assessment.

## **1. ExerS-01 Cellu Buster**

Aqua  
Glycerin  
Sodium Stearate  
Propylene Glycol  
Sorbitol  
Sodium Laurate  
Sodium Laureth Sulfate  
Coconut oil (Cocos nucifera)  
Sodium Lauryl Sulfate  
Sodium Chloride  
Stearic Acid  
Lauric Acid  
Geranium oil (Pelargonium graveolens)  
Cypress oil (Cupressus sempervirens)  
Grapefruit oil (Citrus paradisi)  
Titanium dioxide  
Pentasodium Pentetate  
Tetrasodium Etidronate  
\*Citral, \*Citronellol, \*Geraniol, \*Limonene, \*Linalool  
(+/- CI 19140)

## **2. ExerS-02 Extreme Exfoliate**

Aqua  
Glycerin  
Sodium Stearate  
Propylene Glycol  
Sorbitol  
Sodium Laurate  
Sodium Laureth Sulfate  
Coconut oil (Cocos nucifera)  
Sodium Lauryl Sulfate  
Sodium Chloride  
Stearic Acid  
Lauric Acid  
Peppermint oil (Mentha piperita)  
Eucalyptus oil (Eucalyptus globulus)  
Lemon oil (Citrus limonum)  
Titanium dioxide  
Pentasodium Pentetate  
Tetrasodium Etidronate  
\*Citral, \*Geraniol, \*Limonene, \*Linalool  
(+/- CI 42090)

### **3. ExerS-03 Rub Relax & Refresh**

Aqua  
Glycerine  
Sodium Stearate  
Propylene Glycol  
Sorbitol  
Sodium Laurate  
Sodium Laureth Sulfate  
Coconut oil (Cocos nucifera)  
Sodium Lauryl Sulfate  
Sodium Chloride  
Stearic Acid  
Lauric Acid  
Orange oil (Citrus sinensis)  
Lavender oil (Lavandula angustifolia)  
Peppermint oil (Mentha piperita)  
Titanium dioxide  
Pentasodium Pentetate  
Tetrasodium Etidronate  
\*Citral, \*Coumarin, \* Geraniol, \*Limonene, \*Linalool  
(+/- CI 60730)

### **4. ExerS-04 Firm & Tone Scrub**

Aqua  
Glycerine  
Sodium Stearate  
Propylene Glycol  
Sorbitol  
Sodium Laurate  
Sodium Laureth Sulfate  
Coconut oil (Cocos nucifera)  
Sodium Lauryl Sulfate  
Sodium Chloride  
Stearic Acid  
Lauric Acid  
Grapefruit oil (Citrus paradisi)  
Frankincense oil (Boswellia thurifera)  
Ginger oil (Zingiber officinale)  
Titanium dioxide  
Pentasodium Pentetate  
Tetrasodium Etidronate  
\*Citral, \*Limonene, \*Linalool  
(+/- CI 19140, CI 18050)

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

In addition in some instances data is available for systemic and sub-chronic toxicity.

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

#### FINISHED PRODUCT SAFETY

The above formulation range is based on known ingredients with history of safe use in cosmetic products. The colours and other ingredients must comply to EU purity requirements. Care should be taken to avoid infringing the “Foods Imitation Regulations” in product design.

The Grapefruit oil should be “Distilled” not “Expressed”

This Safety Assessment has taken account of:


1. The Quantitative/Qualitative composition of the product,
2. The intended and reasonably foreseeable use of the product,
3. Margins of Safety for all ingredients considered both individually and in combination and
4. Standards of Good Manufacturing Practice (GMP) and product Microbial Quality.

## **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.

The product is considered safe for sale in all EU countries.

Dated: October 10<sup>th</sup> 2008

A handwritten signature in black ink, appearing to read 'Dr. Hopkins', written in a cursive style.

**Dr. JOHN HOPKINS BSc. PhD. MI Biol. C Biol.  
Safety Assessor**

Note: This Safety Assessment is a legal document provided in accordance with the Cosmetics Directive. Neither this Safety Assessment, nor the names of Innovant Research or Dr J Hopkins shall be used in any form of advertising or promotion. Failure to comply with these terms shall render this Safety Assessment invalid.

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