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## **SAFETY ASSESSMENT**

**Product: Bath Potions Range (Ancient Wisdom)**

**Product variants:**

**Total Unwind Potion**

**Total Detox potion**

**PMT Rescue Potion**

**Passion Potion**

**Wake up Potion**

**Cold & Flu Potion**

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.

This Assessment relates to a range of variants which being similar in terms of base are considered together.

## DESCRIPTION OF THE PRODUCT

This is a rinse-off product range, for application to the body via bathing.

## DESCRIPTION OF INTENDED AND REASONABLY FORESEEABLE USE

The product may reasonably be typically used up to 1-2 times daily as required.

## QUALITATIVE COMPOSITION OF THE PRODUCT

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

**A summary of the toxicology profile of all ingredients is held on file by Innovant Research.**

### **BASE:**

Maris sal (sea salt)	98.8%
Essential oils	0.66%
Colours	0.39%
Aqua	0.15%

+/\_ may contain:

CI 19140  
 CI 47005  
 CI 15885  
 CI 14720

CI 16255  
CI 45430  
CI 18050  
CI 16035  
CI 42051  
CI 73015  
CI 42090  
CI 44090  
CI 28440  
CI 60730  
CI 16255

## **Variants**

### **Total Unwind Potion**

Base (above)  
Lavandula angustifolia  
Citrus aurantium dulcis  
Ocimum basilicum

### **Total Detox Potion**

Base (above)  
Litsea cubeba  
Melaleuca alternifolia  
Juniperus communis

### **PMT Rescue Potion**

Base (above)  
Pelargonium graveolens  
Lavandula angustifolia  
Citrus bergamia

### **Passion Potion**

Base (above)  
Cananga odorata  
Citrus limonum  
Citrus aurantium dulcis

### **Wake up Potion**

Base (above)  
Citrus aurantifolia  
Mentha piperita  
Litsea cubeba

## **Cold & Flu Potion**

Base (above)

Eucalyptus globulus

Zingiber officinale

Piper nigrum

It is a requirement that Lime oil (citrus aurantifolia) must be lime distilled (not Lime expressed)

It is a requirement that Bergamot is FCF(furocoumarin free) grade

It is a requirement that the grade of Basil used meets EU Cosmetics Directive requirements for minimal content of Methyl Eugenol such that the level of Methyl Eugenol does not exceed 0.001% in the final formula.

## **Labelling**

The label for Ingredients will read:

Maris sal, ..... followed by the latin/INCI names for each essential oil, each color, aqua and EU allergens where these exceed 0.01% in the final formula.

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.

The use of the essential oils is to IFRA Guidelines for dermal safety. The listing of essential oil ingredients for labelling is considered safe in this application.

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 cosmetic products. This Safety Assessment has taken account of:

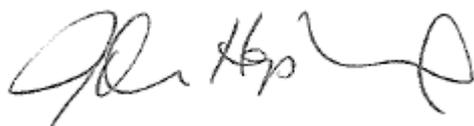
1. The Quantitative/Qualitative composition of the product, and including the predicted preservative efficacy to prevent microbial spoilage.
2. The intended and reasonably foreseeable use of the product.
3. Margins of Safety for all ingredients considered both individually and in combination.
4. Standards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

## SUMMARY

In reviewing the safety test data, the safety and toxicity profile of the ingredients used and their quantity, it is concluded that there is no likely safety hazard with this product.

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

Dated: June 23<sup>rd</sup> 2010



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

**Safety Assessor**