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# SAFETY ASSESSMENT

**Product Name: Bath Bombs Range** 

(by Ancient Wisdom Marketing, Sheffield)

Formula: AWM 003

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 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.

Any additional essential oil and additive variants are considered as one product for the purpose of this Safety Assessment.

Ingredient Safety Review

Ingredients are listed below.

Toxicological data for the ingredients is held on file by Innovant Research Ltd.

### Base:

Sodium Bicarbonate	79.628%
Citric Acid	19.907%
Parfum	0.2654%
Aqua	0.1327%
Colour	0.0664%

## **ADDITIVES:**

Additives consist of

- 1. Colours
- 2. Manufactured fragrances
- 3. Other additions as listed.

#### 1. Colours

- CI 19140
- CI 47005
- CI 15985
- CI 14720
- CI 16255
- CI 45430
- CI 18050
- CI 16035
- CI 42051
- CI 73015
- CI 42090
- CI 44090
- CI 28440

# 2. Manufactured Fragrances

(supplied by Fragrance oils Intl Ltd)

Coconut Dream Fragrance 163653

**BLUEBERRY FRAGRANCE 333739** 

Sea Breeze Fragrance 331459

Honey & Oatmeal Fragrance 331460

Diproylene Glycol

MANGO FRAGRANCE 167593

PASSION FRUIT FRAGRANCE 161106

CHERRY FRAGRANCE 145521

GRAPEFRUIT & MANDARIN FRAGRANCE 330693

SWEET FENNEL & JOJOBA 184621

BANANA FRAGRANCE 194387

**DEWBERRY FRAGRANCE 333735** 

**CHERITA 158918** 

OZONE 330694

**OZONIC 330695** 

WHITE CHOCOLATE FRAGRANCE 332581

FESTIVE SPICE FRAGRANCE 332585

APPLE FRAGRANCE 332586

TEA TREE FRAGRANCE 177391

CHAMOMILE FRAGRANCE 114228

**MAY CHANG 141879** 

ALOE VERA 195042

**ROSE FRAGRANCE 333116** 

PEPPERMINT FRAGRANCE 333117

**MYRRH FRAGRANCE 333119** 

SANDALWOOD FRAGRANCE 333120

LAVENDER FRAGRANCE 333121

**DEWBERRY FRAGRANCE 333735** 

**VIOLET FRAGRANCE 333738** 

HARMONI FRAGRANCE 333977

**ALLOY FRAGRANCE 195146** 

GARDEN OF EDEN FRAGRANCE 333983

MIMA FRAGRANCE 333984

**IGLOO FRAGRANCE 333985** 

**PHAROAH 202546** 

BABY POWDER FRAGRANCE 176306

STRAWBERRY FRAGRANCE 334618

#### 3. Other Additions

% per kilo

Lavandula angustifolia (Lavender) flowers	10%
Rosa damascena (Rose) flowers and buds	10%
Calendula officinalis (Calendula) flowers	10%
Avena sativa (Oatmeal)	20%
Theobroma cacao (Cocoa) butter	50%
Mangifera indica (Mango) butter	50%
Butyrospermum parkii (Shea butter )	50%
Maris sal (Dead sea salt)	20%

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 subchronic toxicity.

The compounded fragrances are formulated in accordance with IFRA Guidelines for dermal safety.

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

Taking the above into account and based on the quantitative and qualitative usage of all of the ingredients, it is considered that Bath Bombs formulations based on the use of one or more of the essential oils and additives are safe for marketing.

#### FINISHED PRODUCT SAFETY

It is considered that the specific ingredients used and their quantities ensure that the finished formulation will be well tolerated in use.

#### **SUMMARY**

In reviewing 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 and that this product is safe for sale. This Safety Assessment is made on the understanding that all raw material specifications and finished product specifications comply to current Good Manufacturing Practices in relation to microbial purity and raw material quality.

Dated: February 14<sup>th</sup> 2006. Revised: October 12<sup>th</sup> 2007.

John Hopkins

JOHN HOPKINS BSc. PhD. M I Biol. C Biol.

**Safety Assessor** 

(Ancient Wisdom Marketing Bath Bombs range)

Note: This Safety Assessment is a legal document provided in accordance with the Cosmetics Directive. Neither this Safety Assessment, nor the name of 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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