

Formula Ref	1628
Product	MUSTARD BATH SALTS
Project	B2002

**LEGISLATION**

This document addresses the requirements of the EU for an assessment of safety for human health of finished cosmetic products (Directive 93/35/EEC, Article 7a subsection d) by considering the general toxicological profile of the ingredients and an assessment of the final product.

**1. COMPANY POLICY**

This product and its ingredients have been assessed to ensure compliance with company policy requirements for product safety assessment.

**2. PRODUCT COMPOSITION**

**MATERIAL:** E.O Medicated mix

**INCI:** Eucalyptus Globulus (Eucalyptus Oil)  
 Gaultheria procumbens (Wintergreen oil)  
 Rosmarinus Officinalis (Rosemary Oil)  
 Styrax Benzoin (Gum Benzoin)  
 Thymus Vulgaris (Thyme Oil)

**SAFETY ASSESSMENT:** Wintergreen Oil - ( Gaultheria procumbens ) Tisserand reports that Wintergreen is classed as a very mild irritant and is not a sensitiser nor is it phototoxic.

Eucalyptus Oil - ( Eucalyptus globulus ) Tisserand reports that Eucalyptus is classed as a very mild irritant and is not a sensitiser nor is it phototoxic.

Rosemary Oil - ( Rosmarinus officianalis ) Tisserand reports that Rosemary is non irritant and is not a sensitiser nor is it phototoxic.

Thyme Oil - ( Thymus vulgaris ) Tisserand reports that Thyme is moderatley irritant and is not a sensitiser nor is it phototoxic.

Benzoin - Styrax benzoin is classed at a non sensitiser.

At the levels in the finished products, all the above ingredients are assessed as safe to use.

**MATERIAL:** Mustard Flour

**INCI:** Sinapis alba (Mustard flour)

**SAFETY ASSESSMENT:** This material from natural sources is widely used in foodstuffs. It has a long history of use and is considered unlikely to be "unsafe" when used in a cosmetic within the levels of use of this product.

**MATERIAL:** Sodium Carbonate

**INCI:** Sodium Carbonate

**SAFETY ASSESSMENT:** Sodium Sesquicarbonate, Sodium Carbonate and Sodium Bicarbonate are used in cosmetic products at concentrations ranging up to 50%. The LD50 in rats for Sodium Bicarbonate ranged from 7.6 g/kg to 8.9 g/kg. Sodium Sesquicarbonate, Sodium Carbonate and Sodium Bicarbonate caused

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conjunctivitis. Sodium Bicarbonate was not an ocular irritant to laboratory animals. Neither Sodium Bicarbonate nor Sodium Carbonate was a teratogen to laboratory animals. Sodium Sesquicarbonate and Sodium Bicarbonate were not mutagenic to two different cell cultures. Dermatitis, but not sensitisation, was observed in employees of a Trona (Sodium Sesquicarbonate) mining facility. Sodium Carbonate, but not Sodium Bicarbonate, is a skin and eye irritant due to the alkaline nature of its solutions. The cosmetic use of Sodium Carbonate at high concentrations is mainly limited to products designed to be diluted before use and in products where pH is buffered to near neutrality. It is concluded that Sodium Sesquicarbonate, Sodium Bicarbonate and Sodium Carbonate are safe as presently used in cosmetics.

### 3. INCIDENTAL MATERIALS

Other materials present in the product have been introduced as secondary or minor parts of the principal ingredients; these additives have been checked and all are deemed safe for use in the finished product at the concentrations advised. Where the materials are preservatives their total concentrations do not exceed the provision of current EU legislation.

### 4. ASSESSMENT OF SAFETY OF THE FINISHED PRODUCT

The product is based on conventional cosmetic ingredients for this type of product. Similar formulations have been marketed for many years without significant adverse effects. The product is not considered to represent any undue hazards with respect to human health in normal use and under reasonably foreseeable misuse.

This assessment is based on information supplied by material manufacturers and from published information in recognised authoritative sources and, whilst best endeavours have been used to check the accuracy of this information, the undersigned cannot be held responsible for any erroneous information supplied to it and used for preparing this assessment.

Signed