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## **SAFETY ASSESSMENT**

### **Product Name: Bishofit**

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).

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.

### Ingredient Safety Review

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

Aqua  
Magnesium chloride

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

### **FINISHED PRODUCT SAFETY**

This formula range is based on known ingredients with history of safe use in cosmetic products. The main constituent other than water is magnesium chloride which is considered safe to skin when used as directed.

### **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 Bishofit is considered safe for sale in all EU countries.

**LABEL & PACKAGING REQUIREMENTS:**

It is a requirement of this Safety Assessment that the label carries easily legible statements in Capital Letters:

**KEEP OUT OF THE REACH OF CHILDREN  
DO NOT DRINK**

It is a requirement of this Safety Assessment that the product is packaged in a bottle with a Child Resistant Closure.

Dated: August 2<sup>nd</sup> 2006

*John Hopkins*

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

**Safety Assessor**

**MAGNESIUM CHLORIDE**

A review of the historical published safety data indicates that magnesium chloride has a low order of acute toxicity. The material may be an irritant on prolonged contact with skin and eyes, but is considered safe when used as directed.