



EXAMPLE (*) OF TOXICOLOGICAL ASSESSMENT CERTIFICATE

PRODUCT: **Alcoholic Extract of Arnica**

MANUFACTURER: **ACME Botanicals GmbH**

Preamble: The Company ACME Botanicals GmbH manufactures and markets an Alcoholic extract of Arnica for use in cosmetic products.
It provides a toxicological assessment file for this product that is contained in the appendix and is composed of 5 chapters (product description, recommendations of use, bibliographical review, tests and toxicological results, precautions of use).

Study: The product, in liquid form, is based on a solvent system (water, ethyl alcohol) used for lixiviation extraction. The manufacturer mentions that this product is recommended for use in cosmetic applications, in concentrations varying from 0.5 to 10%. There is not a large amount of bibliographical study about the use of arnica-based preparations: but it indicates the presence of some alkaloids in the plant (leaves). Although toxicity of these alkaloids is orally shown only with very high concentrations, their presence in a cosmetic product for non-rinse use does not seem recommended. Analytical information on the Alcoholic Extract of Arnica of the ACME Botanicals GmbH, however, show the absence of alkaloids in the extract. Skin and ocular tolerance tests (according to OECD Guidelines n°.....) made on a representative batch of the Alcoholic extract of Arnica from ACME Botanicals GmbH, with a 10 % concentration in water, allergenic risk test (sensitisation according to Magnusson/Kligman method) and systemic toxicity tests (maximum oral dose and mutagenesis test according to AMES) do not indicate any contraindication to the cosmetic use of the product. The manufacturer does not mention any precaution of use.

Conclusion: On the basis of the **file** studied, it is possible to conclude that the use of ALCOHOLIC EXTRACT OF ARNICA of ACME Botanicals GmbH can be used in cosmetic products if it does not undergo modification and within in the limits of recommended conditions.

Expert's Name and Signature:

Date:

Qualification:



EXAMPLE (*) OF TOXICOLOGICAL ASSESSMENT CERTIFICATE

PRODUCT: Hydroglycolic Extract of Chamomile

MANUFACTURER: ACME Botanicals Ltd

Preamble: The Company ACME Botanicals Ltd manufactures and markets an Hydroglycolic extract of Chamomile for use in cosmetic products. It provides a toxicological assessment file for this product that is attached in the appendix and is composed of 5 chapters (product description, recommendations of use, bibliographical review, tests and toxicological results, precautions of use).

Study: The product, in liquid form, is based on a solvent system (water, propyleneglycol) used for maceration extraction. The manufacturer mentions that this product is recommended for use in cosmetic application, in concentrations varying from 0.5 to 10%. There is a large amount of bibliographical data about the use of chamomile-based preparations: they do not indicate any general or specific contraindications about the use of chamomile extracts. Skin and ocular tolerance tests (according to OECD Guidelines n°.....) made on a representative batch of the non diluted (100%) Hydroglycolic Extract of the ACME Botanicals Ltd, allergenic risk test (sensitisation according to RIPT method) and systemic toxicity tests (maximum oral dose and mutagenesis test according to AMES) do not indicate any contraindication to the cosmetic use of the product. The manufacturer does not mention any precaution of use.

Conclusion: On the basis of the **file** studied, it is possible to conclude that the use of HYDROGLYCOLIC EXTRACT OF CHAMOMILE of ACME Botanicals Ltd in recommended conditions of cosmetic use does not present any reasonably foreseeable risk in case of its incorporation into a cosmetic product without undergoing any chemical modification.

Expert's Name and Signature:

Date:

Qualification: