

SAFETY ASSESSMENT REPORT
SAFETY ASSESSMENT SUMMARY
INTRODUCTION

This document offers guidance to the safety assessors evaluating the safety of the product formula in view of the ASEAN Cosmetic Directive requirements expressed in its article 3 “product should not cause damage to human health when applied under normal or reasonably foreseeable conditions of use”.

In order to help some companies comply with the requirements set forth in the ASEAN Safety Assessment Guidelines, this document provides guidance on how to write the safety assessment report and the safety assessment summary. It is not a mandatory format requirement nor a mandatory set of requirements, but a guidance document to help safety assessors in doing a proper evaluation.

Name and address of safety assessor or company

SAFETY ASSESSMENT

Product name:

Formula number:

1. Background:

This assessment is conducted based on the formulation of the product, the review of the safety data on the ingredients used, the intended use as well as the reasonably foreseeable conditions of use taking into account product presentation and instructions for use.

The assessment takes account of:

1. The general toxicological profile of each ingredient used;
2. The chemical structure of each ingredient;
3. The level of exposure of each ingredient;
4. The specific exposure characteristics of the areas where the product will be applied;
5. The population intended to use the product;

2. Review of ingredients:

The formula does not contain any of the following:

- Prohibited ingredient;
- Restricted ingredients used beyond the allowed authorized conditions;
- Ingredients with toxicological data incompatible with the intended concentration and use;

- Ingredients which have insufficient toxicological data or safety in use experience;
- Ingredients which are not properly characterized with regard to purity and analytical composition;

3. Quantitative composition of the product

Ingredients are listed below:

<i>Ingredient</i>	<i>Concentration in %</i>	<i>Function</i>

4. Safety Assessment of cosmetic ingredients:

Review of the safety assessment of each ingredient;

5. Product presentation and application

Physico chemical information on the product e.g. product type, colour, pH, viscosity, etc. intended use as well as directions for use;

Any testing done in relation to packaging stability, preservative efficacy, or safety (including consumer use tests) should be reported here;

6. Safety Assessment of Finished product

In reviewing the toxicity profile of the ingredients used, their chemical structure and/or their history of safe use, it is concluded that there are no likely safety hazards from normal use of this product when used as directed or from foreseeable conditions of use.

Based on the assessment of the safety for human health of the finished product, its ingredient, chemical structure and its level of exposure it is concluded that the product formula is considered as safe for use;

Dated:

Signature and qualification of safety assessor

Name and address of safety assessor or company

SAFETY ASSESSMENT Summary

Product name:

Formula number:

Product presentation and application

Intended use of the product, including the directions for use;

Finished product Safety Assessment

In reviewing the toxicity profile of the ingredients used, their chemical structure and/or their history of safe use, it is concluded that there are no likely safety hazards from normal use of this product when used as directed or from foreseeable conditions of use.

Based on the assessment of the safety for human health of the finished product, its ingredient, chemical structure and its level of exposure it is concluded that the product formula is considered as safe for use;

Dated:

Signature and qualification of safety assessor