Guidelines for the Risk Assessment of Cosmetic Raw Materials

1. Scope

This standard specifies the terms, general rules, techniques and requirements used in the risk assessment of cosmetic raw materials.
This standard applies to the risk assessment of impurities, introduced from the production process or starting materials, in cosmetic raw materials and finished products.

2. Terms and definitions

The following terminologies and definitions apply to this standard.

2.1 Cosmetic raw material

A base substance and auxiliary materials used for production of cosmetic.

2.2 Hazard

Any adverse effect to an organism caused by a substance.

2.3 Risk

The probability and profile of the adverse effect in an organism, system or (sub) population are caused by any factor under the defined conditions of exposure.

2.4 Risk assessment

A systemic process intended to analyze the harmful effect to health following exposure to hazard factors or conditions scientifically, which includes four steps: hazard identification, dose-response assessment, exposure assessment and risk characterization.

2.5 Quantitative Structure-Activity Relationship, QSAR

Quantitative structure activity relationship is a type of mathematical and statistical

—SSA: skin surface area expected to be treated with the finished cosmetic product, reported as cm2, see Table 1 in Informative Annex I for estimated values of SSA

—F: frequency of application of the finished cosmetic product, reported as day-1, see Table 2 in Informative Annex II for estimated values.

—R: retention factor

— 60 kg: default human body weight

b) For calculating the SED as follows based on the amount of cosmetic raw material applied:

$$SED = \frac{A(g/day) \times 1000\,mg/g \times C(\%)/100 \times DA_P(\%)/100}{60kg}$$

Where:

—SED: systemic exposure dosage, reported as mg/kg·d

—A: amount of the finished cosmetic product applied daily, reported as g/day, see Table 2 in Informative Annex II for estimated values

—C: the concentration of raw material in the finished cosmetic product, expressed as %

—DAP: dermal absorption expressed as a percentage (%) of the test dose. The value of 100% may be used in cases where no or inadequate absorption data on animals are available.

—60 kg: default human body weight

4.4 Risk characterization

The probability that the cosmetic raw material will cause damage to human health and the level of risk are examined. The risk characterization for threshold compounds and non-threshold compounds should be described by using different methods.

4.4.1 Risk characterization of threshold compounds

a) For threshold compounds, the Margin of Safety (MOS) can be calculated according to the following formula to assess the risk:

$$MOS = \frac{NOAEL}{SED}$$

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