Workshop on the Guidelines for the Safety Assessment of a Cosmetic Product

The workshop on the Guidelines for the Safety Assessment of a Cosmetic Product was held in Siem Reap, Cambodia on 12 – 13 June, 2006.

The draft of the guidelines was presented to the meeting and finalized with minimal amendments. Key points of the guidelines are as follows:

1. Objective and general approach
• Product safety under normal and reasonably foreseeable conditions of use is of top priority
• The main purpose of the guidelines is:
(a) to help the industry assess the safety of their products
(b) to help the authorities audit the data in the product information files
(c) to highlight important considerations in the safety assessment process

2. Main concerns
• Skin irritation & sensitization for all products, and
• Photo-irritation & photo-sensitization for products used when sun exposure is possible
• Eye tolerance for products used on the face and scalp, and
• Systemic toxicity of product via percutaneous absorption and/or ingestion

3. Approach
• Major basis is the toxicity profile of the ingredients, together with local tolerance of the finished product
• Other important aspects include application of cosmetic GMP, adequate packaging, QC, appropriate labeling, adequate processes for handling & management of consumer complaints, management of product changes and corrective action for adulteration.
• Finished product toxicity tests on animals is not necessary, nor is it recommended

4. Ingredients
• Careful selection on ingredients is critical
• Important points to note include raw material impurities, interactions between ingredients, the potentiation of skin penetration and exposure conditions
• Ingredients need to comply with current legislative requirements and those with insufficient/incompatible data or not properly characterized should be avoided
• The main source of toxicity data for ingredients should be the supplier. There are times when additional testing by the supplier need to be conducted. Additional data can also be obtained via public literature
• For fragrances, a safety evaluation by the supplier together with certification declaring conformity to current IFRA guidelines should suffice
• Ingredients listed in Annex III to VI do not need supporting data if used within conditions specified in the Directive

5. Safety assessment of Products
• Safety assessment of products is related to the manner of use and is based on the properties the ingredients, interpreted with consideration of human exposure
• For new products which are simple variants of existing products or are using existing raw materials at the same level in the same type of products, probably no additional data is required
• However, new and/or additional data would be required for new ingredients or existing ingredients

used in new ways
• Local tolerance testing of the finished formulation is necessary when data on ingredients is not enough to define local tolerance
• Tolerance testing on humans is to be conducted under Good Clinical Practice

6. Safety claims
For example, dermatologist tested, ophthalmologist tested:
• These claims need to be supported by evidence from human testing of the finished product
• Testing needs to be conducted ethically and pre-test safety evaluation is necessary

7. Safety Assessor responsibilities
• The safety assessor is responsible for making sure that legislative requirements are met, all necessary endpoints have been considered and that data is relevant and sufficient. He/she will also need to consider if ingredient interactions or potentiation of penetration will occur and also if complementary data is required
• There should be close collaboration between assessor and formulator so that requirements are met while the formulating process occurs
• All information on the ingredients and the formulation should be made accessible by the suppliers and formulators to the assessor
• The safety assessor needs to be qualified in a relevant field and be suitably trained in cosmetic safety assessment
• He/she should not have involvement in commercial aspects of the product
• Recommendations of the safety assessor has to be followed, e.g. product cannot be marketed if assessor concludes that the product cannot be marketed safely
• This recommendation signed by the Safety Assessor is to form part of the safety statement in the product information file
• The meeting also clarified that
(a) The selection of a suitable safety assessor is the responsibility of the manufacturer and as such, a wrong assessment made by the assessor is the responsibility of the manufacturer
(b) However, safety concerns with a product will be the responsibility of the company placing the product in the local market
(c) The product information file is to contain a safety assessment/statement and a copy of the safety assessor's qualifications

8. Raw material supplier responsibilities
• To provide customers with adequate information regarding safety of the ingredient supplied
• Type of information required for chemicals, botanical extracts and ingredients of animal origin are also lined out, e.g. pesticide levels and identification of plant/part for botanical extracts, declaration on absence of TSE and identification of animal/part for materials of animal origin

9. Manufacturer, distributor and regulator responsibilities
The meeting also agreed to make the following recommendations to the ASEAN Cosmetic Committee
• To adopt the safety evaluation
• To disseminate the guidelines to regulators & industry via training seminars
• To create a curriculum, including examinations, for the training of industry and authority safety assessors and to involve the ASEAN Cosmetic Scientific Body in the preparation of the training modules and examination
• To look into involving institutions of higher learning for the longer term

The ASEAN Member States will go through the guidelines and recommendations before they are finalized at the next ACC meeting in December 2006.

RM supplier Responsibilities
Chemical
Physical/ chemical/ micro specifications, purity
Absence of Annex II ingredients
Tox data (acute tox, dermal absorption, skin & eye irritation, mucus membrane irritation (if applicable), skin sensitization, subchronic tox, mutagenicity, phototox, photomutagenicity (if applicable), human data (if available)

Botanical extracts
Physical/ chemical/ microb specifications, purity,
Pesticide levels, proper identification of plant & parts used
Tox data

Material of animal origin
Physical/ chemical/ microb specifications, purity,
Proper identification of plant & parts used
Absence of TSE & Annex II ingredients beyond unavoidable traces e.g. hormones

Tox data