



Guidance for Safety Risk Assessment of Cosmetics (Draft)

化妆品安全风险评估指南（草案）

China Food and Drug Administration (CFDA)



Guidance of Safety Risk Assessment for Cosmetics

This guidance is enacted in order to guarantee the health safety of consumers, identify and control the safety risk of cosmetics.

1. Applicable Scope

It is applicable to the risk assessment of cosmetic raw materials and the safety evaluation of the products, including risk assessment of safety-risking substances which are inevitably brought in during the production of raw materials and products.

2. General principle and Requirement

2.1 Cosmetics generally could be considered as a combination of different kinds of raw materials, so the safety of raw materials is the pre-requisite of the safety of cosmetics. The safety assessment of cosmetics should be based on the risk assessment of all raw materials and risk substances. If determined that there are chemical or biological reactions between certain raw materials, the risk substance derived from it should be assessed.

2.2 The safety assessment of cosmetics should be based on proved existing scientific results and related information, adhering to the principles of being scientific, fair, transparent and individual case processing. The independence of the risk assessment work should be guaranteed during implementation.

2.3 The safety risk assessment of cosmetics should be conducted by qualified safety-risking evaluators according to the requirements of this guidance, and the risk assessment report should be provided.

2.4 The data of safety risk assessment of cosmetic products should be updated timely, and the results should be preserved until 10 years later after the guarantee period of the last batch of products putting in the market.

2.5 If the safety risk assessment of cosmetics could not exclude the risk of the products to human health, the safety of the products should be assessed by traditional toxicological testing methods.

3. The requirement of the cosmetics safety risk evaluators

Cosmetics safety risk evaluators should meet the following requirements:

3.1 Possess professional knowledge of cosmetics, and know the production processes of cosmetics and the control of quality and safety;

3.2 Qualified with the ability to consult and analyze toxicological information, and ability of analyzing, evaluating and interpreting the toxicological data;

3.3 Can fairly and objectively analyze the safety of cosmetics, and can conduct the risk assessment work after a comprehensive analysis of all the acquired data and the exposure conditions;

3.4 Should possess professional basis of medicine, pharmacy, chemistry, toxicology or similar majors, and have acquired undergraduate or higher diploma or other formal qualification certificates, and have more than 5 years' working experience in related industry;

3.5 Should participate in related professional training regularly. Keep learning knowledge about

risk assessment, understand and grasp the new risk assessment method, comprehend information about cosmetics safety risk assessment.

4. Risk Assessment Procedures

The risk assessment procedures of cosmetic raw materials and risk substances could be divided into the following four steps:

4.1 Hazard Identification

Based on the results of toxicological tests, clinical research, the adverse reaction monitoring, and human epidemiological study result, the potential hazards of raw materials or risk substances to human health should be identified according to their physical, chemical and toxicological characteristics.

4.1.1 Health Hazard Effects of Cosmetics

Mainly include:

- (1)acute toxicity: include oral, or dermal or inhalation toxicity.
- (2)irritation: including skin and eye irritation effects.
- (3)sensitization: mainly skin sensitization.
- (4)phototoxicity: include phototoxicity after exposure to ultraviolet radiation and photosensitive effect.
- (5)Mutagenicity: include genetic mutation and chromosome aberration effect, etc.
- (6)Chronic toxicity: include functional and/or organic changes of the tissues and target organs after long exposure.
- (7)The developmental and reproductive toxicity: include changes of the fetus developmental malformation.
- (8)Carcinogenicity: include the type, area and incidence of tumour developed.

4.1.2 Hazard Identification

(1)Hazard identification is mainly based on the toxicological results of raw materials and risk substances. By the principles of the current cosmetic technical standard in China or the commonly applied international toxicological testing results, the toxic characteristics of acute toxicity, skin irritation/corrosivity, acute eye irritation/corrosivity, sensitization, phototoxicity, mutagenicity, chronic toxicity, the developmental and reproductive toxicity, carcinogenicity of raw materials and risk substances could be identified, and their main toxic characteristics and degree of the materials or risk substances determined.

(2)Identify the potential hazard effects of raw materials and risk substances to human health according to the provided related data of the human epidemiology research, population monitoring

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