



# Technical Guidelines for Cosmetic Safety Assessment

## 化妆品安全评估技术导则

National Medical Products Administration

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*Translated by ChemLinked*



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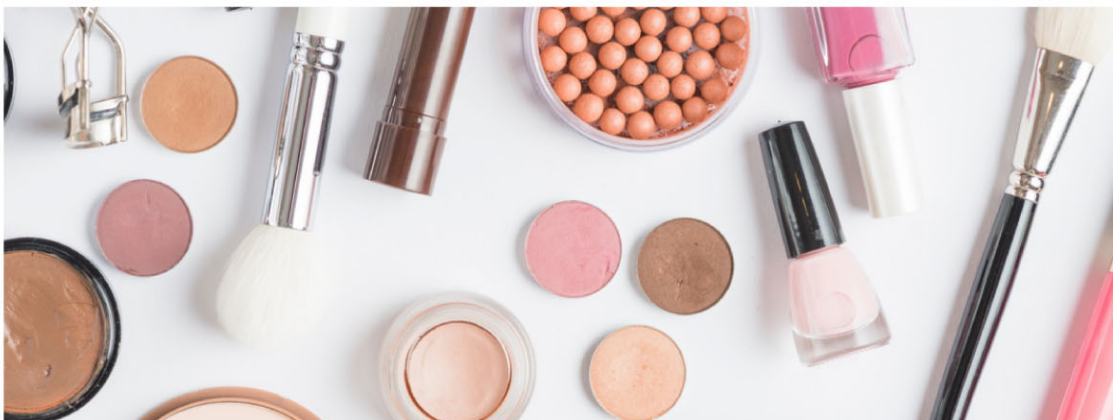
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**Technical Guidelines for Cosmetic Safety Assessment  
(2021)**

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## **Technical Guidelines for Cosmetic Safety Assessment**

The Guidelines are hereby formulated to ensure the use safety of cosmetics, regulate the safety assessment of cosmetics, and guide the implementation of related work.

### **1. Application Scope**

The Guidelines are applicable to the safety assessment of cosmetic ingredients and products.

### **2. Basic Principles and Requirements**

2.1 Safety of ingredients is the precondition of safety of cosmetic products. Risk assessment of cosmetic ingredients includes assessment of ingredients themselves and of the risk substances that may be brought in; cosmetic products are generally recognized as a combination of various ingredients and shall be assessed based on all the ingredients and risk substances. If certain ingredients are confirmed to have chemical and/or biological and other interactions, the risk substances generated and/or the potential safety risk arising from the interactions shall be assessed.

2.2 Safety assessment of cosmetics shall follow the principle of weights of evidence and be based on the existing scientific data and related information, abide by the principles of science, fairness, transparency and case-by-case analysis. During the assessment implementation, the independence of the safety assessment work shall be ensured.

2.3 References cited in the safety assessment of cosmetics shall be technical reports, notices, professional books or academic papers publicly published in the full text form, and the data or risk assessment documents issued by international authorities, etc.; when unpublished research results are used, the consent of the owner of the data shall be obtained, and the scientificity, accuracy, authenticity and reliability of the results shall be analyzed.

2.4 Safety assessment work of cosmetics shall be carried out by qualified safety assessors in accordance with the requirements in the Guidelines, with an assessment report issued.

2.5 Cosmetic registrants and notifiers shall carry out safety assessment by themselves or by entrusting a professional institution to form an assessment report, and be responsible for the authenticity and scientificity of the report.

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2.6 Safety assessment documents of cosmetics shall be updated timely as needed, and shall be kept for not less than 10 years after the shelf life of the last batch of marketed products expires.

2.7 Cosmetic safety assessors, when carrying out safety assessment, shall take the Guidelines as the reference basis, and perform analysis according to the specific conditions of ingredients and products.

2.8 Resumes of assessors shall be attached to the assessment report, which shall include the assessors' educational experiences, cosmetics related working experiences, professional training experiences, *etc.*

### **3. Requirements for Cosmetic Safety Assessors**

Cosmetic safety assessors shall meet the following requirements:

3.1 They shall have professional knowledge related to cosmetic quality and safety, e.g. medicine, pharmacy, biology, chemistry or toxicology, *etc.*, know production process and quality and safety control requirements of cosmetic finished products or ingredients, and have more than 5 years of relevant professional working experiences.

3.2 They shall be able to consult and analyze literature information related to chemistry and toxicology, *etc.* and analyze, assess and explain relevant data.

3.3 They shall be able to analyze cosmetic safety fairly and objectively, and carry out safety assessment work on the basis of comprehensively analyzing all the available data and exposure conditions, and shall be responsible for the scientificity, accuracy, authenticity and reliability of the assessment report.

3.4 They shall be able to, by receiving corresponding professional training regularly and other ways, learn safety assessment related knowledge, understand and master new safety assessment theories, technologies and methods, and apply them in practice.

### **4. Risk Assessment Procedure**

The risk assessment procedure of cosmetic ingredients and risk substances consists of the following four steps:

#### **4.1 Hazard Identification**

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附件

## 化妆品安全评估技术导则

(2021 年版)

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## 化妆品安全评估技术导则

为保障化妆品使用安全，规范化妆品安全评估，指导开展相关工作，制定本导则。

### 1. 适用范围

本导则适用于化妆品原料和产品的安全评估。

### 2. 基本原则与要求

2.1 原料的安全性是化妆品产品安全的前提条件。化妆品原料的风险评估包括原料本身及可能带入的风险物质；化妆品产品一般可认为是各种原料的组合，应基于所有原料和风险物质进行评估，如果确认某些原料之间存在化学和/或生物学等相互作用的，应评估其产生的风险物质和/或相互作用产生的潜在安全风险。

2.2 化妆品安全评估应遵循证据权重原则，以现有科学数据和相关信息为基础，遵循科学、公正、透明和个案分析的原则，在实施过程中应保证安全评估工作的独立性。

2.3 化妆品安全评估引用的参考资料应为全文形式公开发表的技术报告、通告、专业书籍或学术论文，以及国际权威机构发布的数据或风险评估资料等；应用未公开发表的研究结果时，需经数据所有权方同意，并分析结果的科学性、准确性、真实性和可靠性等。

2.4 化妆品的安全评估工作应由具有相应能力的安全评估人员按照本导则的要求进行评估，并出具评估报告。

2.5 化妆品注册人、备案人应自行或委托专业机构开展安全评估，形成安全评估报告，并对其真实性、科学性负责。

2.6 化妆品的安全评估资料应当根据需要及时更新，保存期限不少于最后一批上市产品保质期结束以后 10 年。

2.7 化妆品安全评估人员开展安全评估时，以本导则作为参考依据，还应根据原料和产品的具体情况进行分析。

2.8 评估人员的简历应附在评估报告之后，简历内容应包括评估人员的教育经历、

化妆品相关从业经历、专业培训经历等。

### 3. 化妆品安全评估人员的要求

化妆品安全评估人员应符合以下要求：

3.1 具有医学、药学、生物学、化学或毒理学等化妆品质量安全相关专业知识，了解化妆品成品或原料生产过程和质量安全控制要求，并具有 5 年以上相关专业从业经历。

3.2 能查阅和分析化学、毒理学等相关文献信息，分析、评估和解释相关数据。

3.3 能公平、客观地分析化妆品的安全性，在全面分析所有可获得的数据和暴露条件的基础上，开展安全评估工作，并对评估报告的科学性、准确性、真实性和可靠性负责。

3.4 能通过定期接受相应的专业培训等方式，学习安全评估的相关知识，了解和掌握新的安全评估理论、技术和方法，并用于实践。

### 4. 风险评估程序

化妆品原料和风险物质的风险评估程序分为以下四个步骤：

#### 4.1 危害识别

基于毒理学试验、临床研究、不良反应监测和人群流行病学研究等的结果，从原料和/或风险物质的物理、化学和毒作用特征来确定其是否对人体健康存在潜在危害。

##### 4.1.1 健康危害效应

根据产品的使用方法、暴露途径等，确认原料和/或风险物质可能存在的健康危害效应，主要包括：

- (1) 急性毒性：包括经口和/或经皮接触后产生的急性毒性效应。
- (2) 刺激性/腐蚀性：包括皮肤和/或眼刺激性/腐蚀性效应。
- (3) 致敏性：主要为皮肤致敏性。
- (4) 光毒性：紫外线照射后产生的光刺激性。
- (5) 光变态反应：重复接触并在紫外线照射下引起的反应。
- (6) 遗传毒性：包括基因突变和染色体畸变效应等。



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