



Technical Guidelines for Filling in and Submitting Safety Information of Cosmetic Ingredients (Draft for Comments)

化妆品原料安全信息填报技术指导原则
(征求意见稿)

National Institutes for Food and Drug Control

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Attachment 2

Drafting Instruction for *Technical Guidelines for Filling in and Submitting Safety Information of Cosmetic Ingredients (Draft for Comments)*

To standardize and guide the filling and submission of cosmetic ingredient safety information, the Cosmetics Supervision Department of the National Medical Products Administration (NMPA) organized the National Institutes for Food and Drug Control (NIFDC) to draft the *Technical Guidelines for Filling in and Submitting Safety Information of Cosmetic Ingredients (Draft for Comments)* (hereinafter referred to as the *Guidelines (Draft for Comments)*) in accordance with the requirements of the *Cosmetic Supervision and Administration Regulation (CSAR)*, *Administrative Measures on Cosmetic Registration and Notification*, and other relevant regulations and technical standards. The drafting information is explained as follows:

I. Necessity

The safety and effectiveness of cosmetic products are closely related to the quality and safety of the ingredients used. According to the *Technical Guidelines for Cosmetic Safety Assessment 2021*, when conducting cosmetic safety assessments, risk assessment procedures shall be followed for each ingredient and/or risk substance in cosmetics. According to the requirements of the *Provisions for Management of Cosmetic Registration and Notification Dossiers*, when registering and notifying cosmetics, safety information documents for the ingredients used in the formula shall be provided. In Annex 14 to the *Provisions for Management of Cosmetic Registration and Notification Dossiers*, the main contents and reference style of cosmetic ingredient safety information are provided. In order to further standardize the filling and submission of ingredient safety information, it is necessary to systematically sort out relevant technical issues and offer corresponding guidance.

II. Principles of Formulation

(I) The principle of compliance with the laws and regulations. The *Guidelines (Draft for Comments)* follow the principle of compliance with the laws and regulations, keep up the spirit of the CSAR, implement the requirements of relevant laws and regulation, and summarize relevant technical issues and principles in accordance with the work

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- + Toxicological Risk Assessment (TRA)
- + INCI application

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附件 2

《化妆品原料安全信息填报技术指导原则（征求意见稿）》起草说明

为规范和指导化妆品原料安全信息的填报，根据《化妆品监督管理条例》（以下简称《条例》）《化妆品注册备案管理办法》等相关法规和技术标准要求，国家药监局化妆品监管司组织中国食品药品检定研究院（以下简称中检院）起草了《化妆品原料安全信息填报技术指导原则（征求意见稿）》（以下简称《指导原则（征求意见稿）》）。现将起草的有关情况说明如下：

一、必要性

化妆品产品的安全性、有效性与所用原料的质量安全密切相关，根据《化妆品安全评估技术导则（2021 年版）》，在开展化妆品安全评估时，应按照风险评估程序对化妆品中的各原料和/或风险物质进行风险评估。根据《化妆品注册备案资料管理规定》（以下简称《资料管理规定》）要求，在化妆品注册备案时，应提供配方所用原料的原料安全信息文件，并在附 14 中，提供了化妆品原料安全信息的主要内容和参考式样。为进一步规范原料安全信息的填报，有必要对相关技术问题进行系统性梳理，给予相应指导。

二、制定原则

（一）依法依规原则。《指导原则（征求意见稿）》遵循依法依规原则，贯彻《条例》精神，落实相关法律法规要求，按照化妆品技术指导原则制定和发布的工作程序，对相关技术问题和技术原则予以总结。

（二）科学导向原则。《指导原则（征求意见稿）》充分考虑了相关领域的科学研究进展以及在化妆品行业的实际应用情况，对化妆品原料安全信息的填报进行基本的技术指导，同时保留了企业自研进步空间，以科学为导向，积极引导企业开展化妆品研究与创新。

（三）公开透明原则。《指导原则（征求意见稿）》起草过程中，坚持“公开透明、广泛参与”原则，充分参考国内外相关法规和技术标准，积极征求监管部门、专家、行业协会意见，同时根据意见反馈情况及时修改完善。

三、主要内容

《指导原则（征求意见稿）》正文共包括十一个部分。



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