



Technical Guidelines for Filling in and Submitting Safety Information of Cosmetic Ingredients

化妆品原料安全信息填报技术指导原则

National Institutes for Food and Drug Control

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I. Introduction

The quality and safety of cosmetic products are closely related to 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. Annex 14 to the *Provisions for Management of Cosmetic Registration and Notification Dossiers* defines the main contents and reference template of cosmetic ingredient safety information. In order to further guide the research, filling and submission of cosmetic ingredient safety information, the *Guidelines* is hereby developed in accordance with the *Cosmetic Supervision and Administration Regulation (CSAR)* and supporting regulations.

The *Guidelines* is to provide scientific suggestions based on current understanding. The applicability thereof shall follow the principle of making specific analysis of specific issues. With the development of technology, deepening of understanding, and accumulation of experience, the *Guidelines* will be gradually revised and improved.

II. Applicable Scope

The term “cosmetic ingredient safety information” (hereinafter referred to as “ingredient safety information”) in the *Guidelines* refers to the ingredient safety information documents for the ingredients used in the formula as required by Article 29 of the *Provisions for Management of Cosmetic Registration and Notification Dossiers* for the registration or notification of the cosmetics concerned, i.e. the relevant contents specified in Annex 14. The *Guidelines* is applicable to situations where a cosmetic registrant or notifier (or Chinese domestic responsible person) fills in and submits ingredient safety information in the cosmetic registration or notification documents independently, and is not applicable to situations where an ingredient manufacturer fills in and submits ingredient safety information through the ingredient platform.

Cosmetic registrants and notifiers shall use the *Guidelines* in accordance with relevant regulations and technical standards. If the scope of other technical guidelines is applicable at the same time, the technical suggestions or requirements of the corresponding guidelines shall also be referred to.

III. General Principles

The quality and safety of cosmetics are based on the quality and safety of ingredients.

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- + Cosmetic formula and label compliance review
- + Product registration and notification
- + New cosmetic ingredient (NCI) registration and notification
- + Ingredient safety information submission
- + Cosmetic efficacy evaluation



- + Cosmetic formula and label compliance review
- + EDI Notification
- + Cosmetic QC test service
- + Functional cosmetic registration
- + Ingredients registration by ICID



- + Marketing license application
- + Cosmetics notification
- + Ingredients analysis and full ingredient list translation
- + Cosmetic test service
- + Label & advertisement review



- + Responsible Person (RP) service in the EU & UK
- + Cosmetic Product Notification Portal (CPNP)
- + Cosmetic Product Safety Report (CPSR)
- + Preparation of Product Information File (PIF)



- + Cosmetic formula and label compliance review
- + FDA Voluntary Cosmetic Registration Program (VCRP)
- + California Safe Cosmetics Program (CSCP)
- + Toxicological Risk Assessment (TRA)
- + INCI application

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化妆品原料安全信息填报

技术指导原则

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一、前言

化妆品的质量安全与所用原料密切相关，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。在《资料管理规定》附 14 中，明确了化妆品原料安全信息的主要内容和参考式样。为进一步指导原料安全信息的研究和填报，参照《化妆品监督管理条例》及配套法规，制定本指导原则。

本指导原则仅基于当前认知，提出科学性建议，其适用性应遵循具体问题具体分析的原则。随着技术的发展、认知的深入和经验的积累，本指导原则也将逐步进行修订和完善。

二、适用范围

本指导原则的化妆品原料安全信息（以下简称“原料安全信息”）是指《资料管理规定》第二十九条要求的化妆品注册备案时需提供的配方所用原料的原料安全信息文件，即附 14 相关内容。本指导原则适用于化妆品注册人、备案人（及其境内责任人）在化妆品注册备案资料中自行填报、提交原料安全信息的情形，不适用于原料生产商通过原料平台报送原料安全信息的情形。

化妆品注册人、备案人应在遵循相关法规和技术标准的前提下使用本指导原则。如同时符合其他技术指导原则适用范围的，还应同时参考相应指导原则的技术建议或技术要求。

三、一般原则

化妆品的质量安全以原料的质量安全为基础。按照《化妆品监督管理条例》有关规定，化妆品注册人、备案人对化妆品的质量安全和功效宣称负责。因此，化妆品注册人、备案人应当在原料供应商筛选、原料采购、原料验收、原料使用等各个环节，对原料质量安全相关信息进行询问、验证和管理，必要时开展相关研究工作，确保对所用原料的质量安全情况予以充分了解，并在此基础上填报原料安全信息。

一般地，化妆品原料安全信息主要有以下来源：（1）由原料生产商提供的质量规格文件或相关资料、数据、信息等，（2）文献资料，（3）自行质量控制或实验研究。其中，原料生产商是指对原料安全承担责任的企业，可以是原料的实际生产企业、与原料实际生产企业隶属同一集团公司的关联企业或者原料委托生产行为中的委托企业。与原料本身属性和生产加工过程密切相关的内容，如原料基本信息、原料生产工艺简述、质量控制要求、风险物质限量要求等，一般以原料生产商提供的质量规格文件或相关资料、数据、信息为基础。化妆品注册人、备案人需对原料生产商提供的资料和信息予以甄别，必要时，也可自行查阅文献资料、采取质量控制措施或开展相关研究，并在此基础上对原料安全信息内容进行补充或完善。化妆品注册人、备案人应基于相关资料和研究工作，据实填报原料安全信息，重点关注与化妆品质量安全密切相关的内容。



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