



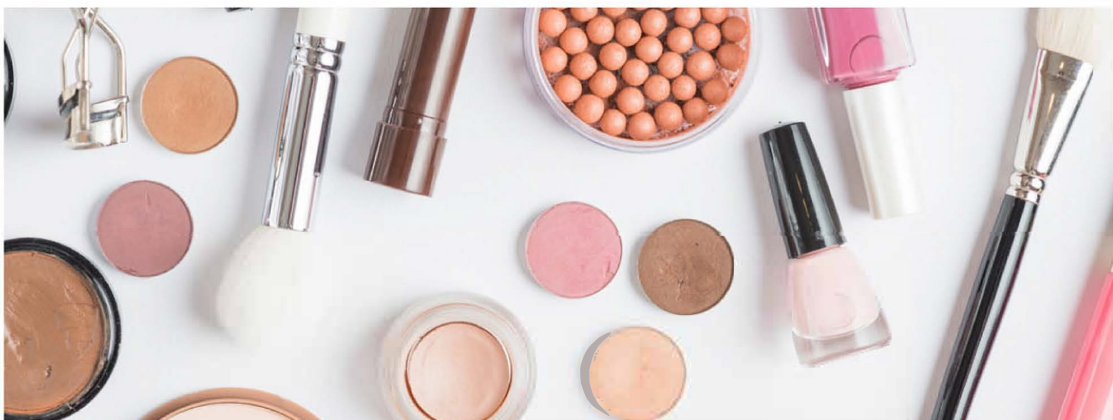
Guidelines for Use of Cosmetic Ingredient Data (Draft for Comments)

化妆品原料数据使用指南 (征求意见稿)

National Institutes for Food and Drug Control

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Translated by ChemLinked



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Attachment 1

Guidelines for Use of Cosmetic Ingredient Data
(Draft for Comments)

National Institutes for Food and Drug Control

April 2024

In order to standardize and guide the safety assessments of cosmetics, this *Guidelines* is hereby formulated in accordance with the *Cosmetic Supervision and Administration Regulations (CSAR)*, *Administrative Measures on Cosmetic Registration and Notification*, *Technical Guidelines for Cosmetic Safety Assessment (2021)*, requirements of the National Medical Products Administration (NMPA) for optimizing the management of cosmetic safety assessments, and other relevant laws, regulations, and normative documents. It clarifies the main types of ingredient data that cosmetic registrants and notifiers can use when conducting safety assessments, the requirements for use, and the supporting documents that need to be provided.

Cosmetic registrants and notifiers shall analyze the collected safety assessment dossiers based on product formula systems, including adverse reactions and safety events related to the products and ingredients. They shall follow the principle of weight of evidence to scientifically conduct safety assessments, fulfill their primary responsibility, and ensure the safety of products.

I. Main Types of Ingredient Data

- (I) The restricted ingredients, permitted preservatives, permitted sunscreens, permitted colorants, and permitted hair dyes specified in the *Safety and Technical Standards for Cosmetics (STSC)*.
- (II) Assessment conclusions published by authoritative cosmetic safety assessment institutions.
- (III) Safety limits or conclusions published by authoritative institutions such as the World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO).
- (IV) Information on use of ingredients published by cosmetic administration departments.
- (V) 3-Year use history of ingredients.
- (VI) Safe consumption history.

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- + 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
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- + 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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化妆品原料数据使用指南 (征求意见稿)

中国食品药品检定研究院

2024 年 4 月

为规范指导化妆品安全评估, 根据《化妆品监督管理条例》《化妆品注册备案管理办法》《化妆品安全评估技术导则(2021年版)》(以下简称《导则》)以及国家药监局优化化妆品安全评估管理工作相关要求等相关法律法规和规范性文件要求, 制定本指南, 明确了化妆品注册人、备案人在开展安全评估时可采用的主要原料数据类型、使用要求和需要提供的证明材料。

化妆品注册人、备案人应基于产品配方体系, 对收集的安全评估相关资料进行分析, 包括产品和原料的不良反应、安全事件等, 遵循证据权重的原则科学开展安全评估, 履行企业主体责任, 保证产品的安全性。

一、主要的原料数据类型

(一)《化妆品安全技术规范》(以下称《技术规范》)中的限用组分、准用防腐剂、准用防晒剂、准用着色剂和准用染发剂。

(二)权威化妆品安全评估机构公布的评估结论。

(三)世界卫生组织(WHO)、联合国粮农组织(FAO)等权威机构已公布的安全限量或结论。

(四)化妆品监管部门公布的原料使用信息。

(五)原料3年使用历史。

(六)安全食用历史。

(七)结构和性质稳定的高分子聚合物(具有较高生物活性的原料除外)。

二、数据使用要求和证明材料

(一)《技术规范》中的限用组分、准用防腐剂、准用防晒剂、准用着色剂和准用染发剂

使用《技术规范》中的限用组分、准用防腐剂、准用防晒剂、准用着色剂和准用染发剂列表中的原料, 应满足《技术规范》要求。

(二)权威化妆品安全评估机构公布的评估结论

欧盟消费者委员会(SCCS)、美国化妆品原料评价委员会(CIR)、德国联邦风险评估研究所(BfR)等评估机构已公布化妆品安全评估结论的原料, 需对相关评估资料进行分析, 在符合我国化妆品相关法规及使用条件下, 可采用相关评估结论, 对有限制使用条件的原料, 应在满足限制条件的情况下采用其评估结论。不同的权威机构评估结果不一致时, 根据数据的可靠性和相关性, 科学合理地采用相关评估结论。



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