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Guidelines for Use of Cosmetic Ingredient Data (Draft for Comments) and Explanatory Notes

《化妆品原料数据使用指南（征求意见稿）》及修订说明

National Institutes for Drug Control

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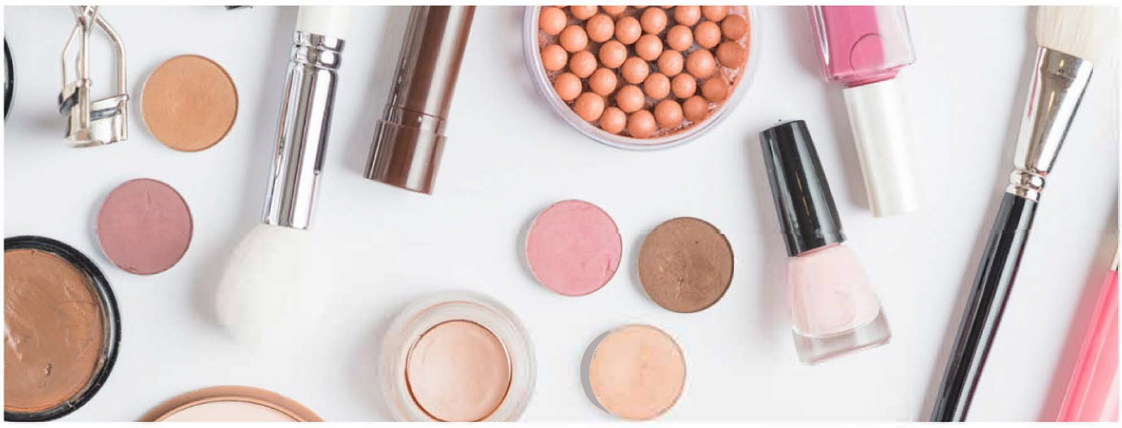
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Annex 1

Guidelines for Use of Cosmetic Ingredient Data

National Institutes for Drug Control

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To standardize and guide cosmetic safety assessments, the *Guidelines* is formulated in accordance with the requirements of relevant laws, regulations, and normative documents, including the *Cosmetic Supervision and Administration Regulation*, the *Administrative Measures on Cosmetics Registration and Notification*, the *Technical Guidelines for Cosmetic Safety Assessment 2021* (hereinafter referred to as the "*Technical Guidelines*"), and the *Announcement of the National Medical Products Administration on Several Measures to Optimize the Management of Cosmetic Safety Assessment* (No. 50 of 2024).

The *Guidelines* specifies the main types of ingredient data that cosmetic registrants and notifiers may use in conducting safety assessments, the requirements governing the use of such data, and the supporting documentation that must be provided. Cosmetic registrants and notifiers shall analyze the information collected for safety assessment purposes in the context of the product formulas, including information on adverse reactions and safety incidents associated with the products and their ingredients. They shall conduct safety assessments scientifically in accordance with the weight-of-evidence principle, fulfill their primary responsibility for product safety, and ensure that their products are safe.

I. Main Types of Ingredient Data

(I) Restricted ingredients, permitted preservatives, permitted UV-filters, permitted colorants, and permitted hair dyes listed in the *Safety and Technical Standards for Cosmetics* (hereinafter referred to as "STSC").

(II) Safety assessment conclusions published by international organizations specializing in cosmetic safety assessment.

(III) Safety limits or safety assessment conclusions published by authoritative organizations such as the World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO).

(IV) Information published by regulatory authorities on the use of ingredients in cosmetic products already on the market.

(V) A history of at least three years of safe use of an ingredient.

(VI) A history of safe consumption.

(VII) Polymers with stable molecular structures and properties (excluding ingredients with high biological activity).

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



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+ Cosmetics notification
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+ Cosmetic test service
+ Label & advertisement review



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+ Preparation of Product Information File (PIF)



+ Cosmetic formula and label compliance review
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+ California Safe Cosmetics Program (CSCP)
+ Toxicological Risk Assessment (TRA)
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附件 1

化妆品原料数据使用指南

中国药品检定研究院

目 录

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二、数据使用要求和证明材料 14

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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《国家药监局关于发布优化化妆品安全评估管理若干措施的公告》（2024 年第 50 号）等相关法律法规和规范性文件要求，制定本指南。

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）国际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）监管部门公布的已上市产品原料使用信息。

（五）原料 3 年安全使用历史。

（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）国际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）以及其他国际化妆品安全评估机构已公布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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