



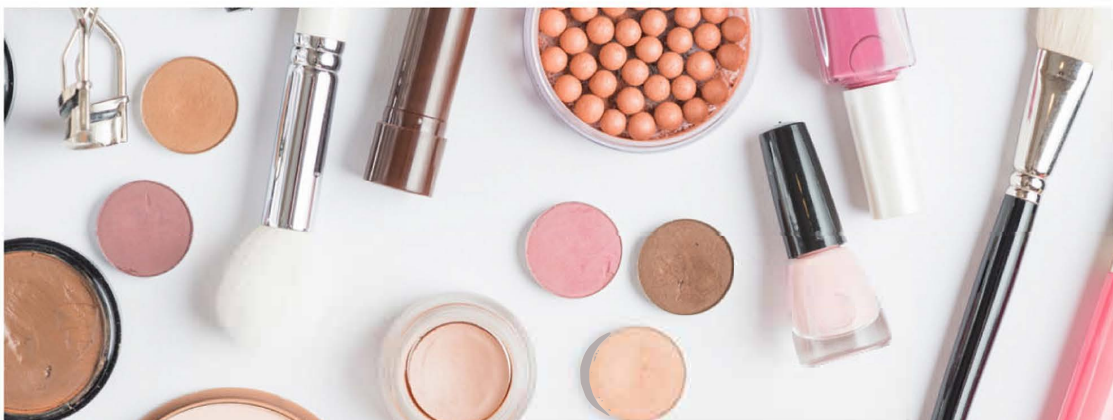
Technical Guidelines for Filling in and Submitting Cosmetic Formula

化妆品配方填报技术指导原则

National Institutes for Food and Drug Control

Release Date: Sept. 04, 2023
Implementation Date: Sept. 04, 2023

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Technical Guidelines for Filling in and...
Attachment

Technical Guidelines for Filling in and Submitting Cosmetic Formula

National Institutes for Food and Drug Control

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I. Introduction

To further guide the filling and submission of cosmetic formulas, the *Guidelines* is hereby developed in accordance with the *Cosmetic Supervision and Administration Regulations*, *Administrative Measures on Cosmetic Registration and Notification*, *Provisions for Management of Cosmetic Registration and Notification Dossiers*, *NMPA's Announcement on Further Optimizing Measures for Cosmetic Ingredient Safety Information Management* (No. 34 of 2023), and other regulations.

The *Guidelines* has sorted out the specific issues involved in the filling and submission process based on different situations of ingredients used in cosmetic product formulas, providing suggestions and guidance for the filling and submission of product formulas. Cosmetic registrants, notifiers or domestic responsible persons shall comply with the actual situation of cosmetic research and development and the basic requirements of the *Guidelines* when filling in and submitting product formulas.

The *Guidelines* is developed based on current regulations and standards, as well as the current level of scientific understanding. With the updating and improvement of regulations and standards, as well as the development of science and technology, adjustments will be made to the *Guidelines* in a timely manner.

II. Application Scope

The *Guidelines* is applicable to guide the filling of cosmetic product formulas, including the requirements for formula components, formula filling and submission methods, filling of ingredient name, ingredient concentration, main use purpose and remarks column in formula table, as well as ingredient safety information. Cosmetic registrants, notifiers or domestic responsible persons shall use the *Guidelines* in accordance with relevant regulations and technical standards. If the scope of other technical guidelines is met at the same time, the technical suggestions or requirements of the corresponding guidelines shall also be referred to.

III. General Principles

Cosmetic formula components refer to the components that are purposefully added to the

ChemLinked Team, REACH24H Consulting Group | <http://cosmetic.chemlinked.com>

14F, #3 Bldg., Haichuang Technology Center, No. 1288 Wenyi West Road, Hangzhou, China. PC: 311121

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- + Label & advertisement review



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- + 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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Technical Guidelines for Filling in and...

附件

化妆品配方填报技术指导原则

中国食品药品检定研究院

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一、前言

为进一步指导化妆品配方的填报，依据《化妆品监督管理条例》《化妆品注册备案管理办法》《化妆品注册备案资料管理规定》《国家药监局关于进一步优化化妆品原料安全信息管理措施有关事宜的公告》（2023 年第 34 号）等法规，制定本指导原则。

本指导原则结合化妆品产品配方所使用原料的不同情形，对填报中涉及的具体问题进行了梳理，为产品配方的填报提供建议和指导。化妆品注册人、备案人或境内责任人在填报产品配方时应符合化妆品研发的实际情况以及本指导原则的基本要求。

本指导原则是在现行法规和标准以及当前科学认知水平下制定的，随着法规和标准的更新完善，以及科学技术的发展，将适时进行调整。

二、适用范围

本指导原则适用于指导化妆品产品配方的填报，包括配方成分的要求，配方填报形式，原料名称、原料含量、主要使用目的和配方表备注栏填写以及原料安全信息填报等内容。化妆品注册人、备案人或境内责任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

化妆品配方成分是指生产过程中有目的地添加到产品配方中，并在最终产品中起到一定作用的成分，包括防腐剂、防晒剂、染发剂、着色剂、保湿剂、pH 调节剂、粘度调节剂等；不包括为了保证化妆品原料质量而在原料中添加的且在配方中极其微量的成分（如抗氧化剂等），原料本身所带有或残留的技术工艺上不可避免的微量杂质，以及在产品生产工艺中添加但不与其他成分发生化学反应、对最终产品不起作用的在后续生产步骤中去除的加工助剂。

化妆品注册人、备案人或境内责任人应结合所使用化妆品原料的实际情况，通过原料生产商出具的相关资料、查阅文献资料、开展研究试验等方式，判断原料/原料成分是否符合上述化妆品配方成分的要求，不作为配方成分的，在产品配方中可以选择不予填写，但《化妆品安全技术规范》准用防腐剂列表中的成分、为保护产品本身加入的准用防晒剂列表中的成分除外。

化妆品注册人、备案人或境内责任人应对所选用原料的质量负责，不作为配方成分的原料/原料成分，可不在产品配方中进行填报，但仍应当对其进行充分分析和安全评估。

四、配方填报形式

按照配方表式样（附件 1），填写原料序号、原料名称、百分含量、主要使用目的等内容。



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