



Technical Guidelines for Filling in and Submitting Cosmetic Formula (Draft for Comments)

化妆品配方填报技术指导原则 (征求意见稿)

National Institutes for Food and Drug Control

Release Date: May 4, 2023
Implementation Date: /

Translated by ChemLinked

Disclaimer

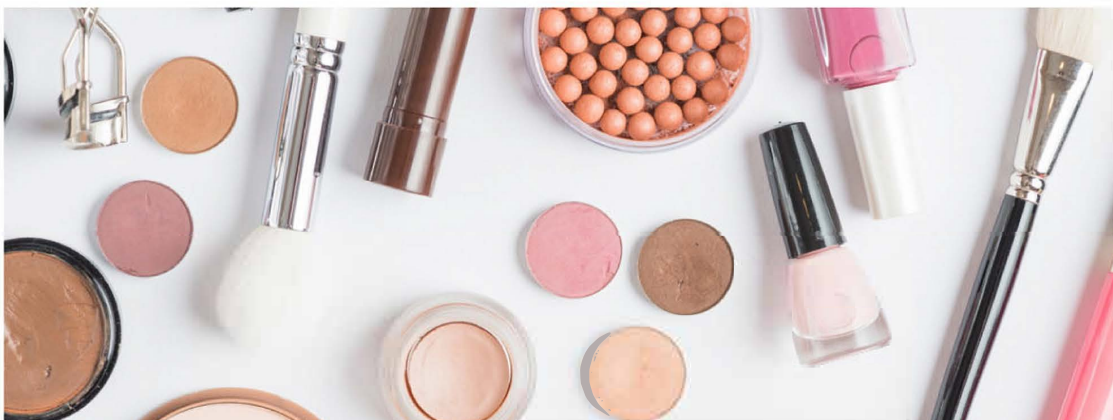
This is an unofficial document provided by **ChemLinked** (chemlinked.com), a platform of REACH24H Consulting Group, as an informational service to assist non-Chinese companies to better understand Asia Pacific especially China Chemical, Cosmetic, Food, Agrochemical and Drug regulatory issues.

This document should only be used as a reference and in case of any discrepancy between the English and original versions the original version shall prevail.

Nondisclosure:

You may not disclose this document to anyone else without the written permission of ChemLinked.

For further clarification and questions, you can read our [Privacy Policies](#) or contact us at cosmetic@chemlinked.com



You can now catch up with the latest updates of China CSAR on ChemLinked:



Stay tuned for more translations:

We will provide English translations of CSAR and supporting rules.



Watch our webinars:

Interpretation of China's Cosmetic Supervision and Administration Regulation



Check out the breaking news:

China Finalises the Long-Awaited Cosmetic Supervision and Administration Regulation



Visit the featured page for more information:

Featured — China Cosmetic Regulatory Reform Tracking

Technical Guidelines for Filling in and Submitting Cosmetic Formula

(Draft for Comments)

National Institutes for Food and Drug Control

Contents

I.Introduction	6
II.Scope	6
III.General Principles	6
IV.Formula Filling and Submitting Methods.....	7
(I)Single Component Ingredients.....	7
(II)Non-single Component Ingredients	7
(III)Group Ingredients.....	8
V.Ingredient Name in Formula.....	8
VI.Percentage Content of Ingredients in Formula	8
VII.Use Purpose of Ingredients in Formula	9
VIII.Remarks Column in Formula	9
(I)Remarks Column in Formula Table	9
(II)Remarks Column Below Formula Table	10
IX.Ingredient Safety Information	10
X. Safety Assessment of Ingredients/Ingredient Components Not Listed as Formula Components.....	10
Annex 1 Formula Table Template	12
Annex 2 Sample of Formula Table	13

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 and notifiers 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. 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, use purpose and remarks column in formula table, as well as ingredient safety information. Cosmetic registrants and notifiers 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 product formula during the production course and play a certain role in the final product,

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

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

Tel: +86 571 8609 4444 | Fax: +86 571 8700 7566 | Email: cosmetic@chemlinked.com

Make Sure Your Products Entering Global Market with Compliance

What we can do for you?



- + Responsible person (RP) service in China
- + 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

What makes us unique?

- ✓ Connect with officials and associations
- ✓ Flexible consulting service packages
- ✓ Team of qualified toxicology and regulatory experts

化妆品配方填报技术指导原则

(征求意见稿)

中国食品药品检定研究院

目 录

<u>一、 前言</u>	18
<u>二、 适用范围</u>	18
<u>三、 一般原则</u>	18
<u>四、 配方填报形式</u>	18
<u>(一) 单一组分原料</u>	18
<u>(二) 非单一组分原料</u>	19
<u>(三) 类别原料</u>	19
<u>五、 配方原料名称</u>	19
<u>六、 配方原料百分含量</u>	19
<u>七、 配方原料使用目的</u>	19
<u>八、 配方备注栏</u>	20
<u>(一) 配方表备注栏</u>	20
<u>(二) 配方表下方备注栏</u>	20
<u>九、 原料安全信息</u>	20
<u>十、 不作为配方成分的原料/原料成分的安全评估</u>	20
<u>附件 1 配方表式样</u>	21
<u>附件 2 配方表样例</u>	22

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、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 调节剂等。不包括为了保证化妆品原料质量而在原料中添加的、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，以及在生产工艺中添加、但不与其他成分发生化学反应、在最终产品中不存在的加工助剂。

化妆品注册人、备案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。

四、配方填报形式

（一）单一组分原料

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

将原料进行混合后再行投料的情况，混合所用原料应以单一组分原料的形式填写配方，混合过程填写在产品生产工艺部分。



Free



Free trial



Standard



Corporate



Special

SUBSCRIBE TO CHEMLINKED NOW

REMOVE COSMETIC REGULATORY BARRIERS EXPEDITE ASIA MARKET ACCESS

- In-time regulatory information and market access requirements
- Supported by local and experienced technically adept technical team
- Strategic partnerships with competent authorities and industrial associations worldwide
- Customized consulting service for complete compliance solutions.

OUR SERVICES



Information & Knowledge

News, Reports, Expert Analysis
Pedia-articles



Databases

Regulatory Database, English Translations
Inventories/Lists



Solutions

Regulatory Compliance Service, On-demand
Translation, Advertisement Service, Tailor-made
Service, E-commerce Solution



Training

Webinars, Online Course
Offline Events