CHEMLINKED
by REACH24H Consulting Group

Guidelines for Research and Determination of Safe Use History of New Cosmetic Ingredients (Trial)

化妆品新原料安全使用历史研究和判定指南（试行）

National Institutes for Food and Drug Control

Release Date: Jun 24, 2025
Implementation Date: Jun 24, 2025

Translated by ChemLinked

Disclaimer

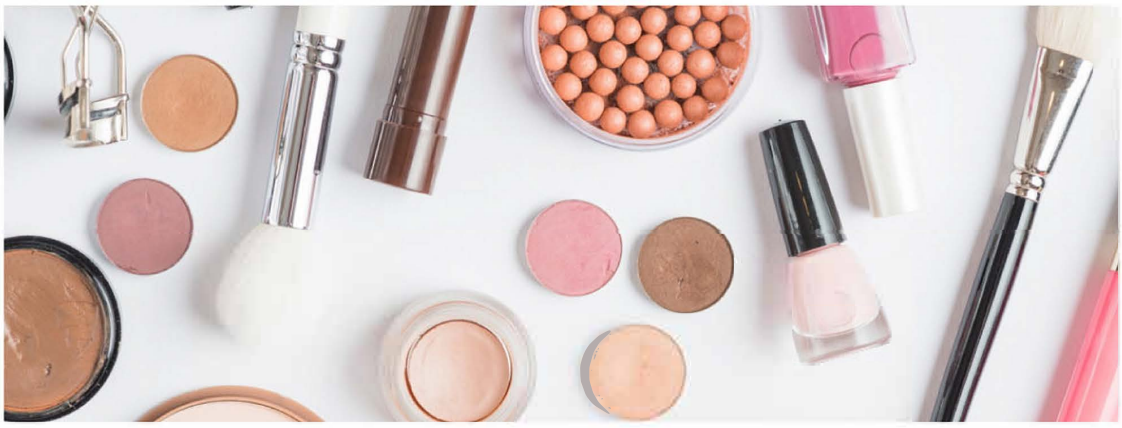
ChemLinked provides translation services to assist clients in understanding the content of regulatory documents. We strive for the accuracy and reliability of our translations, but we do not warrant the accuracy, completeness, or suitability of the translated content.

Clients are responsible for the risks inherent in utilizing our translation services and should consult with professional legal advisors as required. ChemLinked disclaims any liability for any losses or damages arising from the use of our translation services.

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 contact@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

— CSAR —

Attachment 1

Guidelines for Research and Determination of Safe Use History of New Cosmetic Ingredients (Trial)

National Institutes for Food and Drug Control

I. Overview

New ingredients are classified into different situations based on their characteristics, functions, use history, consumption history, *etc.*, in the *Provisions for Management of New Cosmetic Ingredient Registration and Notification Dossiers* (hereinafter referred to as the *Dossier Provisions*), and corresponding toxicological test item requirements are proposed based on risk management concepts. The new ingredients that have a sufficient history of safe use in marketed cosmetics overseas may be exempted from providing some toxicological test data as their actual use can reflect their safety to a certain extent.

For the purpose of standardizing the research and evaluation of new cosmetic ingredients, guiding the collection, determination and application in safety assessment of safe use history dossiers of ingredients, and leading registrants and notifiers to reasonably choose corresponding situations when applying for registration or handling notification of new ingredients, these guidelines are hereby formulated in accordance with the requirements of the *Cosmetic Supervision and Administration Regulations* (*CSAR*), *Administrative Measures on Cosmetic Registration and Notification*, *Dossier Provisions* and other relevant regulations.

These guidelines are formulated based on current regulations and standards, and level of scientific understanding, and the applicability thereof shall follow the principle of specific analysis of specific issues. In addition to the forms specified in these guidelines, registrants and notifiers of new ingredients may choose other scientific and effective data information depending on actual situations, but shall provide scientific and reasonable basis and fully describe that the new ingredients to be registered or notified have a sufficient safe use history. Adjustment will be made to these guidelines in a timely manner with the updating and improvement of regulations and standards, and development of science and technology.

II. Application Scope

These guidelines apply to the research and determination of safe use history of new cosmetic ingredients.

Registrants and notifiers of new cosmetic ingredients shall apply these guidelines on the premise of following relevant regulations and technical standards. If there are other applicable technical guidelines or guiding principles, relevant technical requirements shall also be referred to.

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 notificaion
+ 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

CONTACT US | ☎ +353 1 8899 951 / +86 (0)571 8609 4444 ✉ cosmetic@chemlinked.com

附件 1

化妆品新原料安全使用历史研究和判定指南（试行）

中国食品药品检定研究院

一、概述

在《化妆品新原料注册备案资料管理规定》（以下简称《资料规定》）中，根据原料特性、功能、使用历史、食用历史等情况，将新原料分为不同情形，并基于风险管理理念提出相应的毒理学试验项目要求。其中，对于在境外上市化妆品中已有充足的安全使用历史的新原料，其实际使用情况能够一定程度上反映其安全性，能够减免部分毒理学试验数据。

为规范化妆品新原料研究和评价，指导原料安全使用历史相关资料的收集、判定以及在安全评估中的应用，引导注册人、备案人（以下简称注备人）在新原料申请注册或进行备案时合理选择对应情形，根据《化妆品监督管理条例》《化妆品注册备案管理办法》《资料规定》及相关法规要求，制定本指南。

本指南是在现行法规和标准以及当前科学认知水平下制定，其适用性应遵循具体问题具体分析原则。除本指南明确的形式外，新原料注备人可根据实际情况选用其他科学有效的数据信息，但应具有科学合理的依据，并能够充分说明拟注册备案新原料具有充足的安全使用历史。随着法规和标准更新完善，以及科学技术发展，将适时进行调整。

二、适用范围

本指南适用于化妆品新原料安全使用历史的研究和判定。

化妆品新原料注备人应在遵循相关法规和技术标准的前提下，使用本指南。如同时符合其他技术指南或指导原则适用范围的，还应同时参考相关技术要求。

三、一般原则

注备人应对新原料使用历史开展全面、充分的研究，并结合拟注册备案新原料的实际情况进行合理分析和安全评估。注备人应充分掌握拟注册备案新原料在已上市化妆品中的实际使用情况，并根据其销售、使用的具体方式，自行整理形成证明资料。所提供证明资料应具有关联性、可追溯性，并体现必要的生产经营等关键信息。如已上市化妆品非新原料注备人生产，应说明信息来源并取得相应授权。

经研究，如能够获得充足、确切的安全使用历史，并能够充分说明拟注册备案新原料在化妆品实际使用中的安全性，可按照《资料规定》中的对应情形申请注册或进行备案，同时应按照《资料规定》要求，提交相应的安全使用历史、毒理学试验和安全评估等相关资料。相关资料的真实性、准确性、完整性和可追溯性由新原料注备人负责。

四、安全使用历史证明资料基本要求

安全使用历史相关证明资料应能够充分说明拟注册备案新原料在已上市化妆品中的使用情况以及上市时间、使用数量、安全性等有关信息。具体可从原料一致性、已上市化妆品类型和产品信息、产品上市时间和使用数量、安全使用情况分析等方面，开展资料信息收集工作并进行判定。

（一）原料一致性

新原料注备人应掌握已上市化妆品中所用原料的具体信息，确保其与拟注册备案新原料的一致性，具体可从原料来源、生产工艺、原料组成、质量规格等方面进行分析。

CHEMLINKED
by REACH24H Consulting Group

SUBSCRIBE TO CHEMLINKED NOW

REMOVE COSMETIC REGULATORY BARRIERS EXPEDITE GLOBAL 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

CHEMLINKED.COM

Paramount Court, Corrig Road, Sandyford, Dublin 18, Ireland
Tel: +353 1 8899 951 / +86 (0)571 8609 4444 / E-mail: cosmetic@chemlinked.com
Visit our website for more information about global cosmetic news & regulation updates