



General Technical Guidelines for Notification and Registration Dossier of New Cosmetic Ingredients (Draft for Comments)

化妆品新原料注册备案资料技术通则 (征求意见稿)

National Institutes for Food and Drug Control

Release Date: Sep. 24, 2025
Implementation Date: /

Translated by ChemLinked

Disclaimer

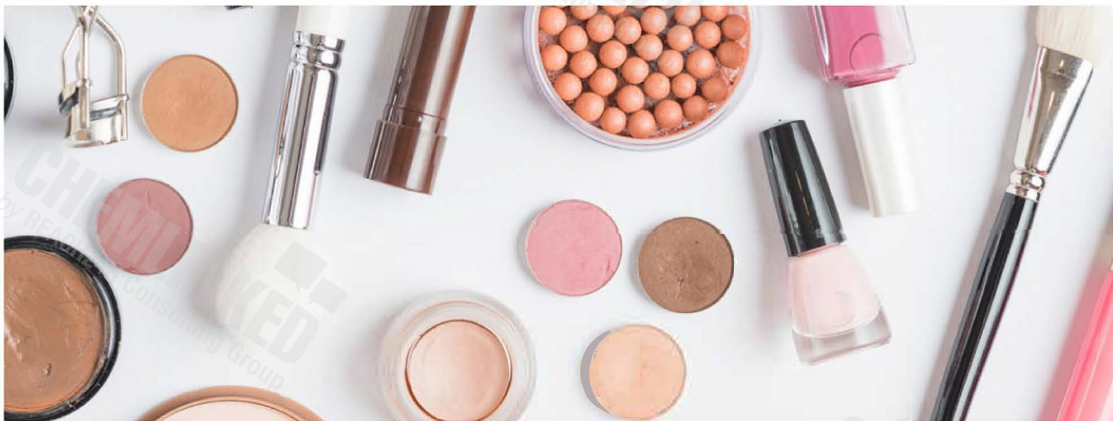
ChemLinked provides translation services to assist clients in understanding the content of regulatory documents. We strive for the accuracy and reliability of our translations, but we do not warrant the accuracy, completeness, or suitability of the translated content.

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

**General Technical Guidelines on Registration and Notification
Dossiers of New Cosmetic Ingredients
(Draft for Comments)**

National Institutes for Food and Drug Control

ChemLinked Team, REACH24H Consulting Group

Website: <http://www.chemlinked.com> | Email: contact@chemlinked.com

Tel: +353 1 8899 951 / +86 (0)571 8609 4444

Contents

I. Overview	- 1 -
II. Application Scope	- 1 -
III. General Principles	- 1 -
(I) Basic Requirements	- 1 -
(II) Requirements for Dossier Format	- 2 -
(III) Requirements for Keeping on File for Future Reference	- 3 -
IV. Situation Classification	- 3 -
(I) Classification by Source and Technique	- 3 -
(II) Classification by Risk Degree	- 5 -
V. Requirements for Dossier Items	- 5 -
VI. Basic Requirements for Various Dossiers	- 16 -
(I) Basic Information	- 16 -
1. Registration/Notification Information Form for New Ingredients	- 16 -
2. Ingredient Names and Naming Basis	- 16 -
(II) Development Reports	- 16 -
1. R&D Background and Related Dossiers	- 16 -
2. Chemical Composition and Structural Identification	- 17 -
3 Physical and Chemical Properties of Ingredients	- 19 -
4 Function Basis	- 21 -
(III) Preparation Techniques and Quality Control Standards	- 22 -
1. Brief Description of Preparation Techniques	- 22 -
2 Analysis of Impurities and Risk Substances	- 22 -
3 Quality Standards and Related Dossiers	- 23 -
4. Stability Research	- 25 -

(IV) Safety assessment Related Dossiers.....	- 26 -
1. Existing Data and Information	- 27 -
2 Toxicological and Human Body Safety Tests	- 29 -
3 Safety Assessment Reports	- 32 -
(V) Other Research or Explanatory Dossiers	- 32 -
(VI) Technical Requirements for New Ingredients.....	- 33 -
Attachment 1	- 34 -
Attachment 2	- 37 -
Attachment 3	- 39 -

I. Overview

In order to clarify the technical requirements for registration and notification dossiers of new cosmetic ingredients, guide and standardize the registration and notification work of new ingredients, these general guidelines are hereby formulated in accordance with the *Cosmetic Supervision and Administration Regulations (CSAR)*, *Administrative Measures on Cosmetic Registration and Notification*, and *Provisions for Management of New Cosmetic Ingredient Registration and Notification Dossiers* (hereinafter referred to as the *Dossier Provisions*).

These general guidelines are formulated based on existing regulations and standards, and the current level of scientific understanding, and the applicability thereof shall follow the principle of specific analysis of specific issues. Adjustments will be made to these general guidelines in a timely manner with the updating and improvement of regulations and standards, and the development of science and technology.

II. Application Scope

The dossiers submitted by registration applicants/notification applicants of new cosmetic ingredients when applying for registration/notification shall comply with the requirements of these general technical guidelines. If there are other applicable technical guidelines or guiding principles to be complied with, relevant technical requirements shall also be referred to.

III. General Principles

(I) Basic Requirements

Registration applicants/notification applicants of new cosmetic ingredients shall submit registration/notification dossiers as required, and be responsible for the compliance, authenticity, accuracy, completeness, and traceability of the submitted dossiers. Before applying for registration/notification of new ingredients, the registration applicants/notification applicants shall conduct a comprehensive investigation and survey on the new ingredients to be registered/notified, conduct necessary test research, and fully study and confirm the techniques, quality, efficacy, safety, etc. of the new ingredients.

Unless otherwise specified by relevant regulations or these general guidelines, registration applicants and notification applicants of new ingredients may conduct relevant research on their own or entrust third parties to undertake the research work. If there are qualification,

ChemLinked Team, REACH24H Consulting Group

Website: <http://www.chemlinked.com> | Email: contact@chemlinked.com

Tel: +353 1 8899 951/+86 (0)571 8609 4444

capability, or other requirements for the entrusted third parties, relevant requirements shall be complied with, and relevant qualification certification materials shall be provided together with the test reports. Registration applicants and notification applicants of new ingredients shall provide authentic and effective testing samples to the entrusted institutions, and take necessary supervision measures to confirm the compliance, scientificity, and standardization of the research carried out by the institutions. They shall conduct scientific and reasonable statistical analysis on the research data obtained. The testing reports shall be issued in accordance with the testing report format attached to the *Working Rules for Cosmetic Registration and Notification Testing* to ensure clear and complete content.

Those who cite scientific literature or other materials shall standardize the citation in the relevant content of the registration/notification dossiers to ensure effective traceability. It is necessary to fully analyze the consistency or correlation between the research object in the cited literature and the new ingredient to be registered/notified, and if necessary, provide proof materials or relevant explanations. Key literature materials related to the functionality and safety of the new ingredient shall be provided in their original and translated versions.

On the basis of various research, all data and information shall be comprehensively integrated, and a summary analysis shall be conducted in combination with the characteristics of the new ingredient to be registered/notified. All information of the new ingredient shall be described objectively and accurately, and the safety and risk controllability thereof when used in cosmetics under conditions such as its purpose, scope, and amount of use shall be fully demonstrated, so as to form standardized and complete registration/notification dossiers.

(II) Requirements for Dossier Format

In the registration and notification dossiers for new cosmetic ingredients, standardized Chinese characters published by the state shall be used. Except for other necessary characters such as registered trademarks, website addresses, patent names, names and addresses of overseas enterprises, as well as English abbreviations used in Chinese regulation documents, all dossiers using other characters shall be fully and normatively translated into Chinese, with the original text attached to the corresponding translations; the main body of the text shall be black in color, and the content shall be complete, clear, and easily recognizable; the punctuation marks, charts, terms, etc. shall be used normatively, and appropriate line spacing and page margins shall be set; Chinese legal units of measurement shall be adopted, and if other units of measurement are employed, such units shall be converted into Chinese legal units of measurement. The signature and



Free



Free trial



Standard



Corporate



Special

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



Solutions

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



Databases

Regulatory Database, English Translations
Inventories/Lists



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

