



Guidelines for the Determination of New Cosmetic Ingredients (Trial) (Draft for Comments) and Explanatory Notes

《化妆品新原料界定指导原则(试行)(征求意见稿)》
及起草说明

National Institutes for Drug Control

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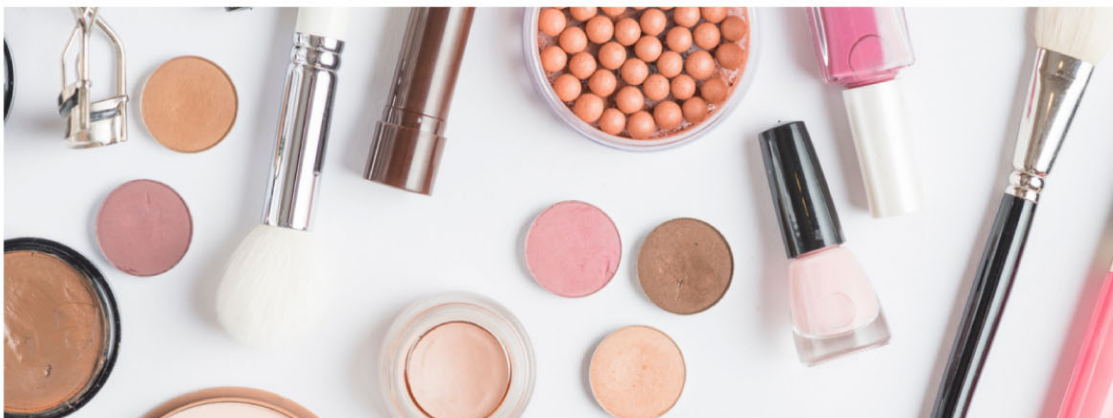
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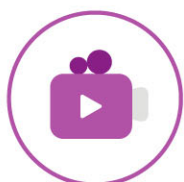


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Annex 1

Guidelines for the Determination of New Cosmetic Ingredients (Trial)
(Draft for Comments)

National Institutes for Drug Control

I. Overview

The *Guidelines* are formulated to clarify the basic principles for the determination of new cosmetic ingredients (NCIs) and to guide and standardize the determination of NCIs and related research work in accordance with the requirements of the *Cosmetic Supervision and Administration Regulation* (hereinafter referred to as “CSAR”), the *Administrative Measures on Cosmetics Registration and Notification*, the *Administrative Provisions on Registration, Notification and Dossier Management of New Cosmetic Ingredients*, and other relevant laws, regulations, and technical documents.

The *Guidelines* are formulated based on the laws, regulations, and standards currently in force and the current state of scientific knowledge, and the principle of conducting a case-by-case analysis shall be followed. The *Guidelines* will be adjusted as appropriate in response to updates to laws, regulations, and standards and developments in science and technology.

II. Scope of Application

The *Guidelines* apply to the determination of NCIs and related research work. NCI registrants and notifiers shall use the *Guidelines* while complying with relevant laws, regulations, and technical standards. Where the scope of other technical guidelines or guiding principles also applies, the relevant technical requirements therein shall also be taken into account.

III. General Principles

According to CSAR, China implements classified management of cosmetic ingredients based on the level of risk. Article 11 of CSAR stipulates that natural or synthetic ingredients used in cosmetics for the first time within the territory of China are NCIs. Among them, NCIs with preservative, sunscreen, coloring, hair-dyeing, or freckle-removing and whitening functions can be used only after registration; other NCIs shall be notified before use. The *Inventory of Existing Cosmetic Ingredients in China* (hereinafter referred to as the “IECIC”) is a compilation of ingredients that have been used in cosmetics within the territory of China. IECIC I is an objective compilation of ingredients used in cosmetics manufactured or sold within the territory of China, and Inventory II is a compilation of NCIs that have been registered or notified within the territory of China, have completed the safety monitoring period, and meet the conditions for inclusion in IECIC. In the determination of NCIs and related research work, a thorough analysis shall be conducted in light of the information included in IECIC and the actual conditions of use.

China’s regulations impose restrictions on the intended use and safe application amount

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- + 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



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- + Cosmetic formula and label compliance review
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