



# Technical Guidelines for Determination and Research of New Cosmetic Ingredients (Draft for Comments)

化妆品新原料界定及研究技术指导原则 (征求意见稿)

National Institutes for Food and Drug Control

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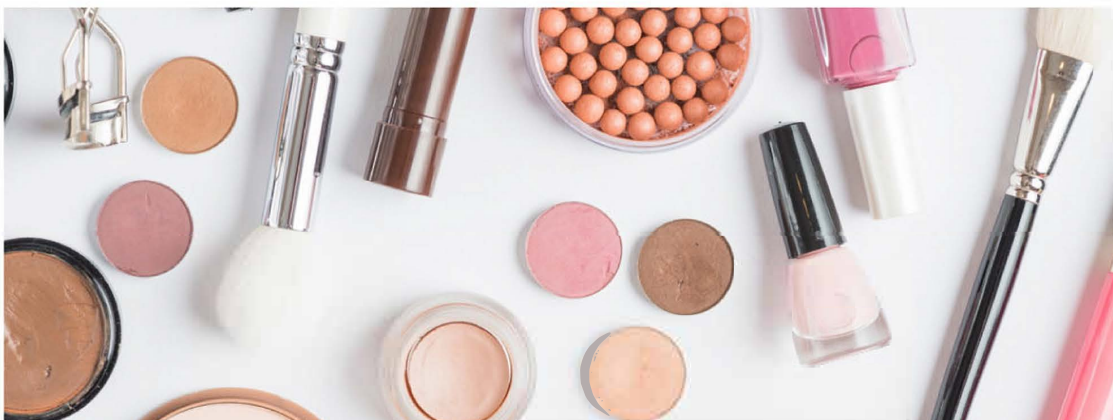
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Ingredients  
(Draft for Comments)**

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**December 2023**

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## I. Overview

Cosmetic ingredients refer to the components used in cosmetic formulas. As the foundation of cosmetic products, cosmetic ingredients play a decisive role in the properties, skin feeling, texture, efficacy, *etc.* of cosmetics. New cosmetic ingredients are the foundation of cosmetic innovation.

Registrants and notifiers of new cosmetic ingredients shall conduct sufficient investigation & survey and scientific research on the intended use purposes, mechanisms of action, safety, quality control, *etc.* of new ingredients in cosmetics during research & development of the new ingredients, in order to ensure that these ingredients fall within the situation category of new cosmetic ingredients and that their use purposes and actual efficacy comply with the definition of cosmetics.

In order to conduct scientific and standardized research on new cosmetic ingredients, this *Guidelines* is hereby formulated in accordance with the relevant regulations such as the *Cosmetic Supervision and Administration Regulations (CSAR)*, *Administrative Measures on Cosmetic Registration and Notification*, and *NMPA Announcement on Encouraging Innovation and Standardizing Management of New Cosmetic Ingredients (No. 143 of 2023)*. It is formulated based on current regulations & standards and levels of scientific cognition. With the updating and improvement of regulations and standards, as well as the development of science and technology, adjustments thereof will be made in a timely manner.

This *Guidelines* applies to registrants and notifiers of new cosmetic ingredients to determine and conduct related research on new cosmetic ingredients.

## II. Classification

Any natural or artificial ingredients used in cosmetics for the first time in China belong to new cosmetic ingredients. According to the performance and intended purpose, new cosmetic ingredients can be divided into new ingredients functioning on cosmetic products, new ingredients functioning on the surface of the human body, and new ingredients functioning on products and having an impact on the surface of the human body in terms of

*Technical Guidelines for Determination...*

management attributes. According to the degree of research & development and innovation, new cosmetic ingredients can be divided into new ingredients used for the first time domestically and overseas, new ingredients used for the first time domestically, and new ingredients derived from substantial improvement and innovation of existing cosmetic ingredients in terms of management requirements.

## **(I) Management Attributes**

### **1. Ingredients Functioning on Cosmetic Products**

The ingredients functioning on cosmetic products refer to those that have an effect on the dosage, stability, color, odor, *etc.* of products, in order to protect or improve products' performance, and do not have any impact on the human body within a certain scope of function. They mainly include matrix ingredients and auxiliary ingredients.

Matrix ingredients are the basic ingredients for forming cosmetic dosages, such as oily ingredients, powdered ingredients, gum ingredients, and solvent-based ingredients. Registrants and notifiers of new ingredients shall analyze the performance of new matrix ingredients during research, with a focus on their safety and quality controllability. They shall also analyze the safety risk substances that may be introduced by new matrix ingredients such as methanol, dioxane, diethylene glycol, acrylamide, pesticide residues, microorganisms, heavy metals, *etc.* based on their chemical composition characteristics, source attributes, *etc.* of the ingredients, clarify their safe use amounts, and establish targeted quality control indexes.

Auxiliary ingredients are those that stabilize and modify cosmetic dosages, such as stabilizers, colorants, preservatives, antioxidants, chelating agents, fragrances, pH regulators, *etc.* Registrants and notifiers of new auxiliary ingredients shall focus on their safety during research and fully study their use amounts in cosmetics for the functions, especially for preservatives and antioxidants, it is necessary to research and determine their safe use amounts to enable them to play a role in preservative, prevention and delay of oil and fat rancidity in cosmetics in combination with the composition of cosmetic formulas, dosages, use methods, intended users, *etc.*, in order to avoid their safety risks to



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- + California Safe Cosmetics Program (CSCP)
- + Toxicological Risk Assessment (TRA)
- + INCI application

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# 化妆品新原料界定及研究 技术指导原则 (征求意见稿)

中国食品药品检定研究院

2023 年 12 月

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## 一、概述

化妆品原料是指化妆品配方中使用的成分。化妆品原料是化妆品的基础，对化妆品的性质、肤感、质地和功效等起决定作用。化妆品新原料是化妆品创新的基础。

化妆品新原料注册人、备案人在开展新原料研发时，应对其预期使用于化妆品中的使用目的、作用机理、安全性、质量控制等开展充分的调研和科学研究，以确保其属于化妆品新原料的情形分类，确保其使用目的及实际功效符合化妆品定义范畴。

为科学、规范开展化妆品新原料研究工作，根据《化妆品监督管理条例》《化妆品注册备案管理办法》《国家药监局关于化妆品新原料鼓励创新和规范管理有关事宜的公告（2023 年第 143 号）》等相关法规，制定本指导原则。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。

本指导原则适用于化妆品新原料注册人、备案人开展化妆品新原料界定及相关研究。

## 二、分类

凡在我国境内首次使用于化妆品的天然或者人工原料为化妆品新原料。根据原料性能和预期用途，从管理属性上化妆品新原料可以分为作用于化妆品产品的新原料、作用于人体表面的新原料、作用于产品且对人体表面有影响的新原料。根据新原料的研发创新程度，从管理要求上化妆品新原料可以分为国内外首次使用的新原料、国内首次使用的新原料，以及对已使用化妆品原料进行实质性改进创新的新原料等。

### （一）管理属性

#### 1. 作用于化妆品产品的原料

作用于化妆品产品的原料是指对产品的剂型、稳定、颜色、气味等产生作用，以保护或提升产品性能，且在一定作用范围内对人体不产生影响的原料，主要包括基质原料和辅助原料。

基质原料是形成化妆品剂型的基本原料，如油质原料、粉质原料、胶质原料及溶剂类原料。新原料注册人、备案人在对新的基质原料研究时，应对原料的性能进行分析，重点关注其安全性和质量可控性。从其化学组成特征、来源属性等分析可能带入的安全风险物质，如甲醇、二噁烷、二甘醇、丙烯酰胺、农药残留、微生物、重金属等，明确其安全使用量，建立有针对性的质量控制指标。

辅助原料是对化妆品剂型起到稳定、修饰作用的原料，如稳定剂、着色剂、防腐剂、抗氧化剂、螯合剂、芳香剂、pH 调节剂等。新原料注册人、备案人在对新辅助原料研究时，重点关注其安全性，充分研究其在化妆品中发挥作用的使用量，尤其是防腐剂和

抗氧化剂，需结合化妆品配方组成、剂型、使用方法及适用人群等，研究确定满足其在化妆品中发挥防腐、防止或延缓油脂酸败作用的安全使用量，避免在正常使用条件下对人体健康带来安全风险。

## 2. 作用于人体表面的原料

作用于人体表面的原料是指对皮肤、毛发、指甲、口唇等人体表面产生实际功效作用的原料，如保湿剂、润肤剂、抗皱剂、美白剂、防晒剂、染发剂、防脱发剂等，使化妆品达到清洁、保护、美化、修饰的目的。

新原料注册人、备案人在研发新的作用于人体表面的原料时，需阐明其使用目的与其在化妆品中发挥实际作用的相关性，重点关注其安全性、有效性和质量可控性。注册人、备案人应研究清楚其来源属性或者化学组成和结构，明确其使用目的和作用机理，开展功效评价试验研究，逐一研究确定其各个使用目的的起效量（着色剂除外），明确其在该使用目的和适用范围下对人体所用剂量的安全性和有效性。新原料的功效评价方法和结果应能充分证明其在预期使用量下对人体具有与其预期使用目的相一致的实际功效。

## 3. 作用于产品且对人体表面有影响的原料

有些原料在作用于化妆品产品的同时，也会对人体表面产生影响。

部分基质原料除了对化妆品起赋型作用外，也会对人体产生重要作用，如滋润软化皮肤、抑制水分蒸发、保持皮肤柔嫩、防止外界不良刺激等。比如蜡类原料，在唇膏配方中，它是必须使用的在室温下形成锭状的主体原料，同时在使用时它也可以对唇部形成保护膜，起到润肤剂的功效。

新原料注册人、备案人应根据原料特性和预期在化妆品中发挥的作用，科学、准确地确定其使用目的，若其在化妆品中的实际功效是作用于人体，在关注其安全性和质量可控性基础上，还应关注其有效性，并开展能够证明原料具有与其使用目的相一致的相关研究。

### (二) 管理类别

在符合上述化妆品原料作用和属性前提下，根据新原料的研发创新程度，从管理要求上化妆品新原料可以分为国内外首次使用的新原料、国内首次使用的新原料，以及对已使用化妆品原料进行改进创新的新原料等。

#### 1. 国内外首次使用的新原料

首次发现并确认适用于化妆品的原料，或者是已知原料但在国内外尚未用于化妆品的原料。



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