



## Technical Guidelines for Research on Hair Dye Cosmetics (Trial)

《染发化妆品研究技术指导原则（试行）》

National Institutes for Food and Drug Control

Release Date: Apr 15, 2026  
Implementation Date: Apr 15, 2026

*Translated by ChemLinked*

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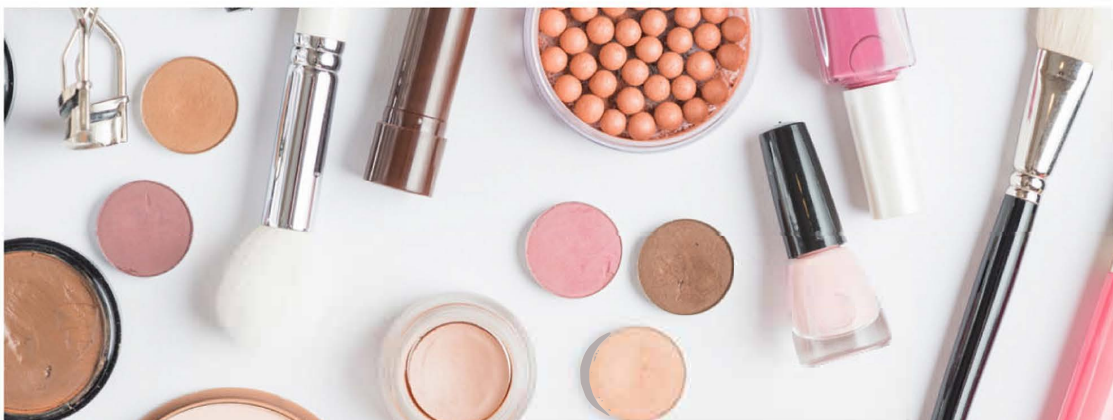
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**Attachment 1**

**Technical Guidelines for Research on Hair Dye Cosmetics (Trial)**

**National Institutes for Food and Drug Control**

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## I. Introduction

In accordance with the *Cosmetic Supervision and Administration Regulation* (CSAR), cosmetics intended for hair dyeing are classified as special cosmetics, and subject to registration management. Since the formal implementation of CSAR in 2021, higher requirements have been put forward for the quality and safety of hair dye cosmetics. For the purpose of regulating and guiding the research on hair dye cosmetics, these guidelines are hereby formulated.

These guidelines are formulated based on existing regulations and standards, as well as the current level of scientific cognition. Relevant contents will be adjusted in a timely manner with the update of regulations and standards, and the continuous development of science and technology.

## II. Application Scope

In accordance with the interpretations and claim guidelines set forth in the *Cosmetic Classification Rules and Catalog* (hereinafter referred to as the *Classification Catalog*), hair dye cosmetics as referred to in these guidelines are defined as cosmetics intended to alter hair colors, after application of which the original hair colors cannot be restored through immediate washing. These guidelines apply to the research on hair dye cosmetics.

Registrants shall use these guidelines under the premise of complying with relevant laws, administrative regulations, mandatory national standards, and technical standards. If there are other applicable technical guidelines for the relevant contents, the technical requirements in the corresponding guidelines shall also be referred to.

## III. General Principles

Registrants shall, in accordance with the interpretations and claim guidelines for hair dye cosmetics in the *Classification Catalog*, conduct thorough research on hair dye cosmetics surrounding the product quality, safety, efficacy, labelling claims, and other related technical contents in compliance with the relevant provisions including CSAR, the *Provisions for Management of Cosmetic Registration and Notification Dossiers*, the *Working Rules for Cosmetic Registration and Notification Testing* (hereinafter referred to as the *Testing Rules*), the *Safety and Technical Standards for Cosmetics* (STSC), the *Administrative Measures on Cosmetics Labeling* (hereinafter referred to as the *Labeling Administrative Measures*), etc.

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- + Cosmetic formula and label compliance review
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- + Preparation of Product Information File (PIF)



- + Cosmetic formula and label compliance review
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- + California Safe Cosmetics Program (CSCP)
- + Toxicological Risk Assessment (TRA)
- + INCI application

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附件 1

## 染发化妆品研究技术指导原则 (试行)

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## 一、前言

根据《化妆品监督管理条例》（以下简称《条例》），用于染发的化妆品属于特殊化妆品，实行注册管理。2021 年，《条例》正式施行，对其质量安全提出更高要求。为规范和指导染发化妆品研究，制定本指导原则。

本指导原则是在现行法规、标准以及当前科学认知水平下制定的，随着法规、标准的调整以及科学技术的不断发展，相关内容将适时进行调整。

## 二、适用范围

依据《化妆品分类规则和分类目录》（以下简称《分类目录》）中的释义说明和宣称指引，本指导原则中的染发化妆品是指以改变头发颜色为目的，使用后即时清洗不能恢复头发原有颜色的化妆品。本指导原则适用于染发化妆品的研究。

注册人应在遵循相关法律、行政法规、强制性国家标准和技术规范的前提下使用本指导原则。如相关内容同时符合其他技术指导原则适用范围的，还应同时参考相应指导原则的技术要求。

## 三、一般原则

注册人应根据《分类目录》中染发化妆品的释义说明和宣称指引，按照《条例》《化妆品注册备案资料管理规定》《化妆品注册和备案检验工作规范》（以下简称《检验规范》）《化妆品安全技术规范》（以下简称《技术规范》）《化妆品标签管理办法》（以下简称《标签管理办法》）等有关规定，围绕产品的质量、安全、功效、标签宣称等技术内容，对染发化妆品开展充分研究。

## 四、主要内容

染发化妆品研究内容主要包括作用机理、质量可控性、安全性、功效和标签宣称等。

### （一）作用机理研究

开展染发化妆品研究时，需要确定其作用机理。染发化妆品按作用机理一般可分为氧化型和非氧化型。氧化型染发化妆品一般由染剂和氧化剂（显色剂）两剂组成，两剂按一定比例混合后使用，使用过程中存在氧化还原反应。漂浅头发的染发化妆品一般仅含有氧化剂，不含染发剂，属于氧化型染发化妆品。非氧化型染发化妆品的着色过程不发生氧化还原反应。对于新型染发化妆品（如单剂氧化型染发化妆品等），需结合配方深入研究并阐明其染发机理。



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