



Technical Guidelines for Research on Sunscreen Cosmetics (Trial)

《防晒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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Attachment 5

Technical Guidelines for Research on Sunscreen Cosmetics (Trial)

National Institutes for Food and Drug Control

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I. Introduction

UV-filters added to sunscreen cosmetics function to absorb, reflect, or scatter UV rays, thereby safeguarding the skin and lips against damages caused by specific UV rays. Given that sunscreen cosmetics are applied directly on the skin, and may be exposed to sunlight for extended periods, the safety and stability of ingredients thereof are directly related to consumer health. It is therefore necessary to conduct research on sunscreen cosmetics, covering aspects such as their mechanism of action, quality controllability, safety, product efficacy, labelling, and labelling claims, so as to ensure the effectiveness and safety of such cosmetics.

In accordance with the *Cosmetic Supervision and Administration Regulation* (CSAR), sunscreen cosmetics are classified as special cosmetics, and subject to registration management. Since the formal implementation of CSAR on January 1, 2021, higher requirements have been put forward for the quality and safety of sunscreen cosmetics. For the purpose of regulating and guiding the research on sunscreen cosmetics, these guidelines are hereby formulated.

These guidelines are formulated based on existing laws, administrative regulations, departmental rules, mandatory national standards, and technical standards, as well as the current level of knowledge. They will be revised and improved in a timely manner with the continuous improvement of regulations, standards, and practices, the deepening of cognition, and the 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*), sunscreen cosmetics as referred to in these guidelines are defined as cosmetics intended to protect the skin and lips from damage caused by specific UV rays. These guidelines apply to the research of sunscreen cosmetics.

Registrants shall apply these guidelines under the premise of complying with existing laws, administrative regulations, departmental rules, mandatory national standards, and technical standards. If there are other applicable technical guidelines, the relevant technical requirements therein shall also be referred to.

III. General Principles

Registrants shall, in accordance with the interpretations and claim guidelines for sunscreen

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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 5

防晒化妆品研究技术指导原则（试行）

中国食品药品检定研究院

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一、前言

防晒化妆品中加入的防晒剂能吸收、反射或散射紫外线，保护皮肤、口唇免受特定紫外线所带来的损伤。由于防晒化妆品直接作用于皮肤，且有可能长时间暴露在阳光下，其成分的安全性和稳定性直接关系到消费者健康，因此，有必要对防晒化妆品作用机理、质量可控性、安全性、产品功效、标签以及标签宣称相关研究等内容开展研究，确保防晒化妆品的有效性和安全性。

根据《化妆品监督管理条例》（以下简称《条例》），防晒化妆品属于特殊化妆品，实行注册管理，2021年1月1日《条例》正式施行，对其质量安全提出更高要求。为规范和指导防晒化妆品研究，制定本指导原则。

本指导原则是在现行法律、行政法规、部门规章、强制性国家标准、技术规范以及当前认知水平的基础上制定，随着法规、标准、规范的不断完善，认知的深入以及科学技术的发展，本指导原则也将适时进行修订和完善。

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，本指导原则中的防晒化妆品是指用于保护皮肤、口唇免受特定紫外线所带来的损伤的化妆品。本指导原则适用于防晒化妆品研究。

注册人应在遵循现行法律、行政法规、部门规章、强制性国家标准和技术规范的前提下使用本指导原则，如同时符合其他技术指导原则的适用范围的，还应参考相关技术要求。

三、一般原则

注册人应根据《分类目录》中防晒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》（以下简称《资料管理规定》）《化妆品安全技术规范》（以下简称《技术规范》）《化妆品注册和备案检验工作规范》（以下简称《检验规范》）《化妆品功效宣称评价规范》（以下简称《功效评价规范》）《分类目录》《化妆品标签管理办法》（以下简称《标签管理办法》）等相关规定，对防晒化妆品开展充分研究，确保防晒化妆品的有效性和安全性。

四、主要内容

防晒化妆品研究内容主要包括作用机理、质量可控性、安全性、产品功效、标签以及标签宣称相关研究等。

（一）作用机理研究



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