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Technical Guidelines for Research on Sunscreen Cosmetics (Trial) (Draft for Comments)

防晒化妆品研究技术指导原则（试行）（征求意见稿）

National Institutes for Food and Drug Control

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Translated by ChemLinked

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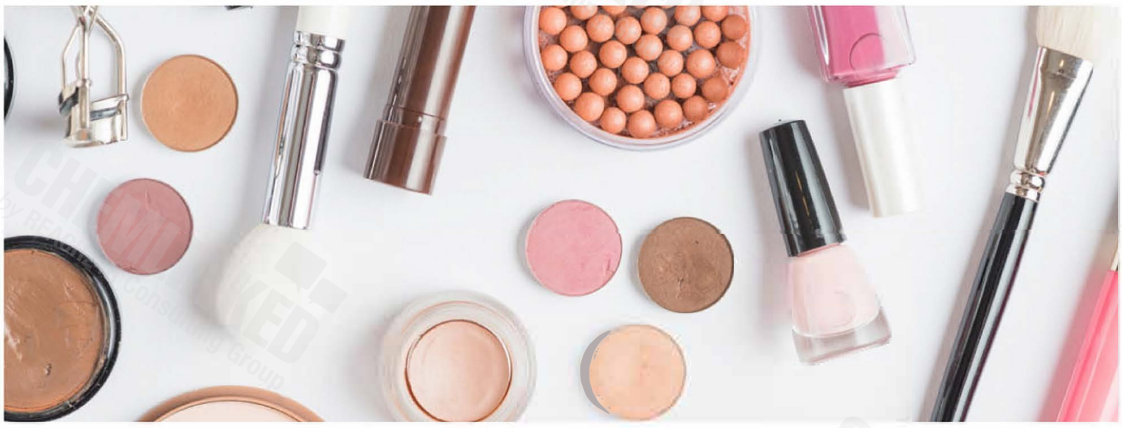

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Attachment 9

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I. Introduction

Sunscreens added to sunscreen cosmetics function to absorb, reflect, or scatter ultraviolet (UV) rays, thereby safeguarding the skin and lips against damage caused by specific UV rays. Given that sunscreen cosmetics are applied directly to the skin and may be exposed to sunlight for extended periods, the safety and stability of the ingredients thereof are directly related to consumer health. It is therefore necessary to conduct research on sunscreen cosmetics covering aspects such as their mechanisms of action, quality controllability, safety, product efficacy, labeling, and claims made on the labels. Such efforts aim to ensure that while these cosmetics effectively shield against UV rays, they avoid inducing skin irritation, sensitization, or other adverse reactions.

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

These guidelines are formulated based on existing laws, administrative regulations, departmental rules, mandatory national standards, technical standards, and 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 interpretive notes and claim guides outlined 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 and registration application 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, relevant technical requirements shall also be referred to.

III. General Principles

Registrants shall, in accordance with the interpretive notes and claim guides for sunscreen cosmetics set forth in the *Classification Catalog*, conduct thorough research on sunscreen cosmetics in compliance with relevant provisions including the *CSAR*, the *Administrative Provisions on Cosmetic Registration and Notification Dossiers* (hereinafter referred to as the *Dossier Administrative Provisions*), the *Safety and Technical Standards for Cosmetics* (*STSC*), the *Working Rules for Cosmetic Registration and Notification Testing* (hereinafter referred to as the *Testing Rules*), the *Standards for Cosmetic Efficacy Claim Evaluation* (hereinafter referred to as the *Efficacy Evaluation Standards*), the *Classification Catalog*, the *Administrative Measures on Cosmetic Labeling* (hereinafter referred to as the *Labeling Administrative Measures*), *etc.* Such research shall ensure that sunscreen cosmetics, while effectively protecting against UV rays, avoid causing skin irritation, sensitization, or other adverse reactions.

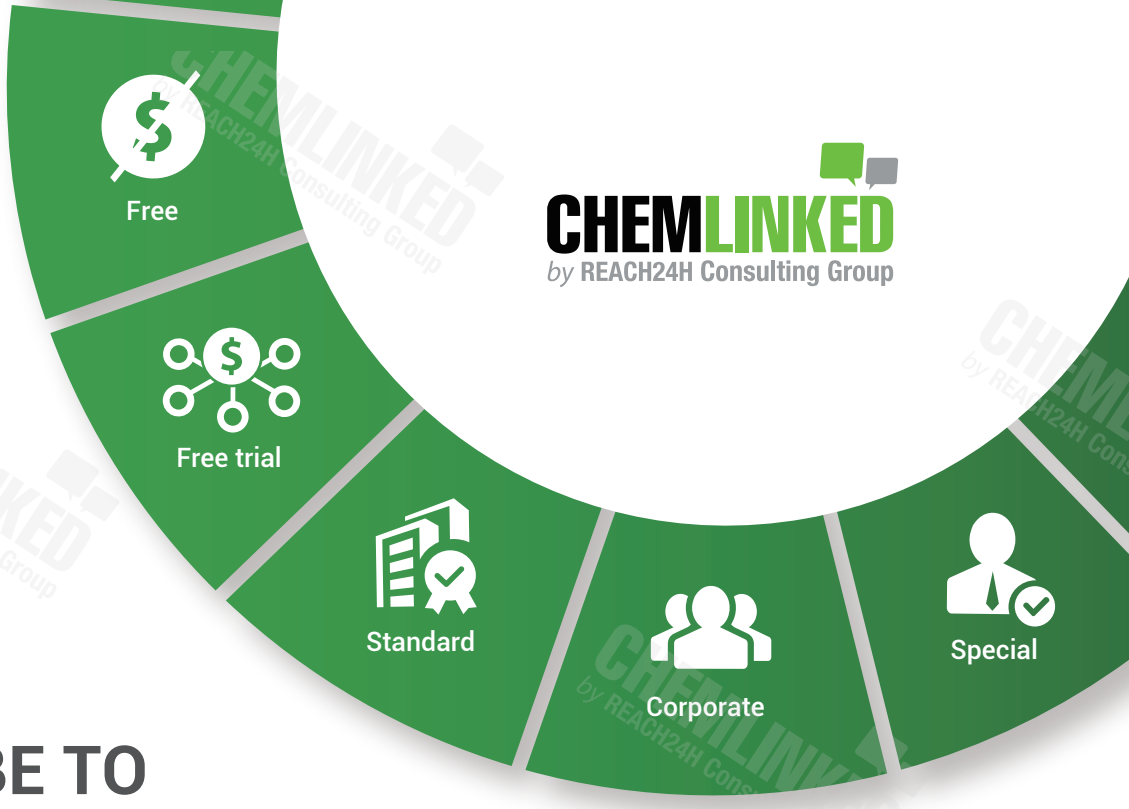
IV Main Content

The content of research on sunscreen cosmetics mainly encompasses studies related to their mechanisms of action, quality controllability, safety, product efficacy, labeling, and labeling claims, among others.

(I) Research on Mechanisms of Action

In conducting research on sunscreen cosmetics, it is necessary to determine their mechanisms of action. Overexposure to UV radiation may cause skin damage, and different UV wavelength bands can exert distinct biological effects. UVA, with a wavelength range of 320~400 nm, is also known as the “tanning band”. It possesses strong penetrability, capable of reaching the dermal layer, accelerating melanin formation, and darkening the skin tone. Prolonged exposure to UVA will damage skin elastic fibers and collagen fibers, leading to photoaging. UVB, ranging from 280~320 nm, is referred to as the “erythema band” and constitutes the primary wavelength band responsible for UV sunburn. It can cause skin erythema and swelling, and pain, and in severe cases, may result in blisters and peeling. UVC, with wavelengths between 200~280 nm, is mostly absorbed by the atmospheric ozone layer and generally does not pose a hazard to human skin.

The functional ingredients in sunscreen cosmetics, namely sunscreens, consist of physical sunscreens and chemical sunscreens. Physical sunscreens primarily function by reflecting



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Paramount Court, Corrig Road, Sandyford, Dublin 18, Ireland
Tel: +353 1 8899 951 / +86 (0)571 8609 4444 / E-mail: cosmetic@chemlinked.com
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