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by REACH24H Consulting Group

Safety Evaluation of Long-term Using Tests of Cosmetics on Human Body

人体长期试用试验方法

National Medical Products Administration

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Translated by ChemLinked

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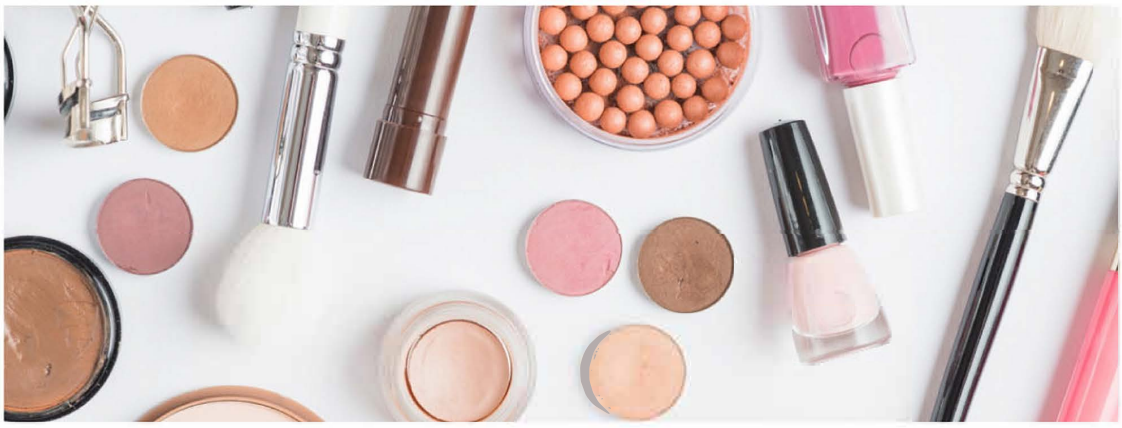

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Attachment 5

Safety Evaluation of Long-term Using Tests of Cosmetics on Human Body

1 Scope

This method specifies the objective, subject requirements, and test procedures for safety evaluation of long-term using tests of cosmetics on human body.

This method applies to the evaluation of adverse skin reactions to new cosmetic ingredients intended for freckle-removing and whitening purposes.

2 Test Objective

To evaluate the potential of adverse reactions on human skin induced by long-term use of new cosmetic ingredients intended for freckle-removing and whitening purposes.

3 Basic Principles

3.1 Select qualified volunteers as test subjects;
3.2 The ingredient must have undergone toxicological safety evaluation as required by relevant national cosmetic regulations, and be confirmed to be safe under the recommended conditions of use;
3.3 Before the test, potential adverse reactions shall be estimated based on the characteristics of the ingredient, and appropriate management measures shall be established.

4 Selection of Subjects

4.1 Select volunteers aged 18–60 years who meet the study requirements as test subjects.
4.2 Individuals falling under any of the following circumstances cannot be selected as subjects:
4.2.1 Those who have used antihistamines within the past week, or immunosuppressants, immunomodulatory biologics, or small molecule drugs within the past month;
4.2.2 Those who have applied any anti-inflammatory drugs (including topical application, occlusive dressing, and local injection) to the area to be tested within the past two months;

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附件 5

人体长期试用试验方法

Safety Evaluation of Long-term Using Tests of Cosmetics on Human Body

1 范围

本方法规定了人体长期试用试验的目的、受试者要求和方法。

本方法适用于评价化妆品祛斑美白新原料对人体皮肤的不良反应。

2 试验目的

评价长期使用化妆品祛斑美白新原料引起人体皮肤不良反应的可能性。

3 基本原则

3.1 选择合格的志愿者作为试验对象；

3.2 原料必须经过国家相关法规对化妆品要求的毒理学安全性评价，并确认在推荐的使用条件下是安全的；

3.3 试验前根据原料性质估计试验可能发生的不良反应，并提出相应的处理措施。

4 受试者的选择

4.1 选择 18～60 岁符合试验要求的志愿者作为受试对象。

4.2 不能选择有下列情况者作为受试者：

4.2.1 近一周使用抗组胺药或近一个月内使用免疫抑制剂或免疫调节相关生物制剂与小分子药物者；

4.2.2 近两个月内受试部位应用（包括外涂、封包及局部封闭）任何抗炎药物者；

4.2.3 患有炎症性皮肤病临床未愈者；

4.2.4 胰岛素依赖性糖尿病患者；

4.2.5 正在接受治疗的哮喘或其他慢性呼吸系统疾病患者；

4.2.6 患有癌症等严重系统性健康问题者；

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