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90-day Dermal Toxicity Test

90天经皮毒性试验方法

National Medical Products Administration

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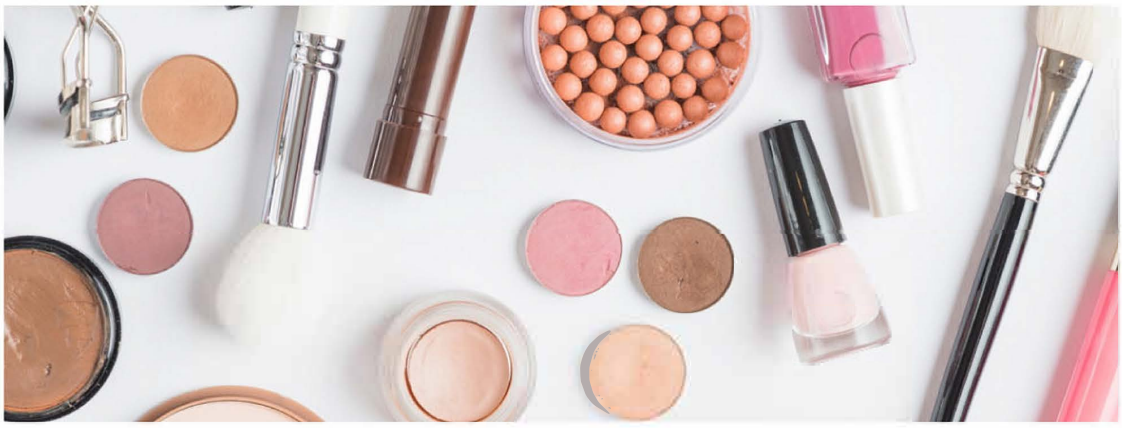
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Attachment 9

90-Day Dermal Toxicity Test

1 Scope

This method specifies the basic principles, requirements, and methods for conducting a 90-day dermal toxicity test in animals.

This method applies to the evaluation of the 90-day dermal toxicity of cosmetic ingredients.

2 Test Objectives

This test is designed to obtain information on the potential health hazards resulting from repeated dermal exposure to a test substance over a defined period, helping to identify the target organ, dose-response relationship, reversibility and potential for accumulation of toxic effects, and estimate the no observed adverse effect level (NOAEL) and/or lowest observed adverse effect level (LOAEL), thereby providing a basis for selecting doses, observation indicators, and toxicity endpoints for chronic toxicity tests, as well as for establishing safe thresholds for human exposure.

3 Definitions

3.1 No Observed Adverse Effect Level (NOAEL)

The highest dose at which no toxic effects related to the test substance are observed using available technical means or testing indicators under specified test conditions.

3.2 Lowest Observed Adverse Effect Level (LOAEL)

The lowest dose at which the test substance induces adverse effects on the histomorphology, function, growth and development of experimental animals under specified test conditions.

3.3 Target Organ

The organ of experimental animals exhibiting significant toxic effects caused by the test substance.

3.4 Cumulative Toxicity

The capacity of the test substance to cause functional or organic damage in organisms following repeated exposure at doses below the acute toxicity threshold, due either to progressive accumulation (absorption exceeding elimination) or to cumulative toxic effects.

4 Basic Test Principles

The test substance is administered dermally to each group of experimental animals at different doses on a daily basis for a continuous period of at least 90 days. At least three dose groups and one control group shall be set up, with each provided with a single dose level. Through comprehensive clinical observations, clinical examinations, gross necropsy, and histopathological examinations, *etc.*, the target organ and dose-response relationship are systematically identified, and ultimately the NOAEL and/or LOAEL are determined, which provide(s) key safety basis for chronic toxicity studies and human risk assessments.

5 Test Methods

5.1 Preparation of the Test Substance

For a solid test substance, it shall be pulverized and thoroughly moistened with water or a vehicle and/or excipient that is non-irritant to the skin and will not affect the dermal absorption of the test substance, so as to ensure optimal contact between the test substance and the skin surface. A liquid/semi-solid test substance is generally used as-is, and if necessary, it may be diluted with an appropriate vehicle or excipient based on the dose design before the test. If a vehicle or excipient is used, the impact thereof on the skin permeability of the test substance shall be considered. Commonly used vehicles or excipients include olive oil, lanolin, vaseline, *etc.*

5.2 Experimental Animals and Housing Environment

5.2.1 Selection of Animal Strain

Adult rats, rabbits, or guinea pigs may be used for the test; other species of animals can

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附件 9

90 天经皮毒性试验方法
90-day Dermal Toxicity Test

1 范围

本方法规定了动物 90 天经皮毒性试验的基本原则、要求和方法。

本方法适用于评价化妆品原料的 90 天经皮毒性。

2 试验目的

通过本试验可获得在一定时期内经皮肤重复暴露受试物可能产生的健康危害的信息，了解其作用靶器官、剂量-反应关系、可逆性以及蓄积的可能性，并估计未观察到有害作用水平（NOAEL）和/或观察到有害作用最低水平（LOAEL），为慢性毒性试验剂量、观察指标、毒性终点的选择及建立人体暴露的安全阈值提供依据。

3 定义

3.1 未观察到有害作用水平 no observed adverse effect level（NOAEL）

在规定的试验条件下，用现有的技术手段或检测指标未观察到任何与受试物有关的毒性作用的最大剂量。

3.2 观察到有害作用最低水平 lowest observed adverse effect level（LOAEL）

在规定的试验条件下，受试物引起实验动物组织形态、功能、生长发育等有害效应的最低剂量。

3.3 靶器官 target organ

实验动物出现由受试物引起的明显毒性作用的器官。

3.4 蓄积毒性 cumulative toxicity

机体以低于急性中毒阈值的剂量反复接触受试物，吸收量大于排出量逐渐累积或毒作用累加，引起功能性或器质性损害的能力。

4 试验的基本原则

受试物以不同剂量每日经皮给予各组实验动物，至少设立3个剂量组和1个对照组，每组1个剂量水平，连续给予至少90 d。通过全面的临床观察、临床检查、大体解剖和

组织病理学检查等，系统性地确定靶器官、剂量-反应关系，并最终确定NOAEL和/或LOAEL，为慢性毒性研究和人类风险评估提供关键安全性依据。

5 试验方法

5.1 受试物制备

若受试物为固体，应将其粉碎并用水或无皮肤刺激性、不影响受试物经皮吸收的溶媒和/或赋形剂充分湿润，以保证受试物与皮肤有良好的接触。液体、半固体受试物一般采用原样，根据剂量设计选用适宜的溶媒或赋形剂稀释后（若需）进行试验。采用溶媒或赋形剂时应考虑其对受试物皮肤通透性的影响。常用的溶媒或赋形剂有橄榄油、羊毛脂、凡士林等。

5.2 实验动物和饲养环境

5.2.1 动物种系的选择

可采用成年大鼠、兔或豚鼠进行试验，也可使用其他种属的动物，但需说明理由。建议试验开始时实验动物的体重范围为：大鼠200 ~ 300 g（不超过9周龄）；兔2.0 ~ 3.0 kg；豚鼠350 ~ 450 g。试验开始时同性别体重差异应在平均体重的±20%之内。当该试验作为慢性试验的预备试验时，则在两项试验中所使用的动物品系应当相同。

5.2.2 动物的性别和数量

主试验组每一剂量组实验动物数，啮齿类一般不少于 10 只/性别，非啮齿类一般不少于 5 只/性别，皮肤健康完整。雌性应为未妊娠和未经产的动物。应至少在对照组和最高剂量组增设恢复期卫星组，啮齿类一般不少于 5 只/性别，非啮齿类一般不少于 2 只/性别。若试验设计包含中期剖检，则应相应增加动物数量。

5.2.3 动物饲养

实验动物及动物试验环境、饲料、饮水均应符合国家相应规定。试验期间，动物自由饮水和摄食。给予受试物期间，建议动物单笼饲养。

5.3 剂量设计

试验剂量的设计可参考急性经皮毒性试验LD_{50}剂量、预试验剂量或相关结构化合物经皮毒性剂量进行。试验时至少要设3个剂量组和1个对照组。如果需要，还应设置溶媒和/或赋形剂对照组。本方法采用等面积给予受试物的方式，即动物在相同体表面积的皮肤区域（如背部脱毛区）给予受试物，应记录受试物浓度（mg/mL或%）和单位面积涂敷量（mg/cm²）。在暴露部位面积不变的情况下，应通过改变受试物浓度



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