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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 27830-2011

**Chemicals -- Test method of in vitro skin corrosion -- Human
skin model test**

化学品 体外皮肤腐蚀 人体皮肤模型试验方法

(English Translation)

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Foreword

This standard was drafted in accordance with GB/T 1.1-2009 given rules.

The Standards and Organisation for Economic Co-operation and Development OECD Chemicals Test Guidelines No.431 (2004 Nian) "in vitro skin corrosion. human skin Model Test "(in English) is consistent technical content.

The standard structure and made the following editorial changes.

- Increasing the range a chapter;
- The OECD431 original in the "Introduction" and "initial consideration" content as the introduction of this standard;
- The original OECD431 Appendix "definition" of the present standard "2 Terms and Definitions";
- The original OECD431 in Table 2 of this standard as "Appendix A (informative)";
- Change the unit of measure of legal units of measurement.

This standard is managed by the National Standardization Technical Committee chemicals dangerous (SAC/TC251) and focal points.

This standard was drafted. Chinese Center for Disease Prevention and Control of Occupational Health and Poison Control, Guangdong Exit Inspection and Quarantine, China seized Inspection and Quarantine Science Research Institute, China Chemical Technology Development Center.

Introduction

Skin corrosion refers to irreversible tissue damage skin after exposure to the test substance caused (according to GHS definitions [1] This standard provides a Species of live animals

or animal tissue without skin corrosion evaluation methods.

Skin corrosion evaluation usually requires the use of laboratory animals [2]. Taking into account the experimental animal suffering and injury, in 2002, OECD Test Guideline "acute chemical skin irritant and corrosive" (TG404) revision and in the annex are allowed for in vitro Generation skin corrosion test methods, to avoid animal suffering and injury. Of GB/T 21604-2008 is equivalent to using the method.

404 (or GB/T 21604-2008) the main difficulties in vivo skin corrosion test is the lack of formal guidelines completely replaced, independent in vitro test methods and authenticated. An alternative method of regulation in accordance with the purpose of alternative tests for skin corrosion, the first step needed Formal validation study validation studies [3] ago, followed by in vitro evaluation of skin corrosion test methods [4-5] conducted [6-8]. According to these studies the results and other published literature [9], we recommend the following tests to assess in vivo skin corrosion. human skin model test (see this standard) and percutaneous resistance test (see TG430) [10-13].

Validation studies show that the use of human skin model test can distinguish well known skin corrosives and non-corrosive to skin [3-5,9]. also Provide information to distinguish between serious and less serious skin resistance.

Test methods described in this standard can identify corrosive chemical substances and mixtures. In combination with other existing information (eg pH, structure-activity Relations, human and/or animal data) [1-2,13-14], by weight of evidence analysis, this standard may be further identified non-corrosive substances and mixing Thereof. This standard does not provide enough information usually test substance skin irritation, nor according to the GHS system into the corrosive substances Step classification [1-2,13-14].

For a comprehensive evaluation of local skin reactions after a single dermal exposure, it is recommended according to GB/T 21604-2008 [2] and in order to provide GHS Column test policy program [1] experiment. Test sequences are included in the policy before considering the test live animals, the first in vitro skin corrosion (eg this standard) and skin irritation test.

Chemicals vitro skin corrosion Human skin model test method

1 Scope

This standard specifies the terms and definitions chemical corrosion human skin in vitro skin model test method, the test principle, test methods and several According to the reports.

This standard applies to chemical skin corrosion screening and detection, can be used as animal skin corrosion test alternative chemicals.

But also as part of toxicity testing, in combination with other chemicals toxicity test for the overall rating.

2 Terms and definitions

The following terms and definitions apply to this document.

In vivo skin corrosion skincorrosioninvivo Skin contact with the test substance after 4h produce irreversible damage, necrosis appears visibility from the epidermis into the dermis. Corrosive effects special Levy. ulcers, bleeding, bloody scabs, 14d later manifested as skin atrophy discoloration, local alopecia areata and crusting and other changes. For suspicious skin damage Injury to histopathological examination.

Cell activity celviability Index measuring overall cell population viability [e.g. mitochondrial dehydrogenase reducing activity tetrazolium dye (3- (4,5-dimethyl-thiazol-2) -2,5-diphenyl tetrazolium bromide, MTT) (CASNo.298-93-1) capacity], depending on the endpoint measured and the indicators used provided Meter program, and associated with the total number of cells and/or activity of a cell number.

3 Test principle

Test substance locally on a three-dimensional human skin model, the model used is at least one skin reconstruction containing a functional stratum corneum.

According to a specific action at the time, the cell activity test substance (e.g. MTT reduction assay) [15] is reduced to the threshold level is set to identify rot Corrosion substances. Skin model test is based on the principle of human body after exposure to corrosive chemicals through the skin by diffusion or corrosive effect Through the stratum corneum, the assumption that produce cytotoxicity to the underlying cell layers.

Test Method 4

4.1 Human skin model

Human skin models can build your own or are commercially available [16-19] or by the developer preparation laboratory [20-21]. Make human skin should meet with national and international ethical requirements. Any new skin model should be validated (at least meet the requirements of 4.3). The test Mortem human skin model used should meet the conditions set out in 4.2 and 4.3.

General Conditions 4.2 Skin Model 4.2.1 human keratinocytes should be used to build the model of epithelial skin, the stratum corneum should contain the following functional multilayer active epithelial cells