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

GB/T 27828-2011

**Chemicals -- Test method of in vitro skin corrosion --
Transcutaneous electrical resistance test (TER)**

化学品 体外皮肤腐蚀 经皮电阻试验方法

(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.430 (2004) "In vitro skin corrosion. transcutaneous resistance test Test method "(in English) is consistent technical content.

This standard configuration and do the following editorial changes.

- Increasing the range a chapter;
- The OECDNo.430.2004 "Introduction" section incorporated into the "Introduction" section;
- Removed OECDNo.430.2004 "Introduction" section "in this guide as defined in Appendix";
- The OECDNo.430.2004 "initial consideration" section incorporated in the "Introduction" section;
- The OECDNo.430.2004 "Appendix. Definitions" chapter incorporates the "Terms and Definitions" section;
- Change the units of measurement become 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, Ningbo Inspection and Quarantine Institute of Science and Technology, Chinese Academy of Inspection and Quarantine, China Chemical Industry Development Center.

Introduction

Skin corrosion effect refers to irreversible skin tissue damage after contact with the skin test was produced [see GHS classification and Labelling (Globally Harmonized System of Classification and Labeling of Chemicals, GHS) in a given Yi] [1]. This standard provides a living animal can be carried out without the use of test methods for the evaluation of skin corrosion.

Skin corrosion test typically requires the use of laboratory animals [2]. Chemicals in OECD Test Guidelines 404 and its 2002 revision of growth Up takes into account the animal test method might cause pain and injury. Therefore, considering the change of party in vitro skin corrosion test Law in order to avoid causing suffering to animals and injury.

The main difficulty completely replace animal skin corrosion test (OECD404) is no formal, independent, confirmed the body External corrosion test methods. The first step in the establishment of alternative test methods for skin corrosion should be carried out before the pre-validated test method validation [3], and to formal vitro skin corrosion test [4-5] method validation studies [6-8]. According to the outcome of the trial and other related Literature that human skin model test (OECD431) and percutaneous resistance test method (this standard) can be used to evaluate the in vivo skin Corrosion [9-11].

The results confirm the test and other relevant studies published show that percutaneous rats Test Method for Resistance (TER test Test) [12-13] can reliably identify known skin-corrosive and non-corrosive skin [5,9].

This test can be used to identify corrosive chemicals and mixtures thereof. Further, according to available information (such as pH, structure - activity Off Department of human and/or animal data) and by weighing the evidence analysis, this standard can also be used to identify chemicals and mixtures of non-corrosive of [1-2,11,14]. This standard does not usually provide information about skin irritation aspects of the test substance nor corrosive substance according to GHS rules into Step to classify [1].

Is a comprehensive evaluation of a single percutaneous exposure to the test substance after local effect on the skin, it is recommended to adopt a before and after sequential testing strategy (see OECD404 [2] and the GHS [1])). The testing strategy includes the first in vitro tests for skin corrosion and in vitro skin irritation test, and then test Consider the use of live animals for testing.

Chemicals vitro skin corrosion Test method of skin resistance

1 Scope

This standard specifies the terms and definitions of chemicals in vitro percutaneous skin corrosion resistance test method, the test principle, test methods, test number and, according to the report.

This standard applies to percutaneous resistance in vitro skin corrosion test.

2 Terms and definitions

The following terms and definitions apply to this document.

In vivo skin corrosion skin corrosion in vivo 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.

Percutaneous resistance transcutaneous electrical resistance, TER Skin resistance, electrical resistance (kohm) to represent. Using Wheatstone bridge to record the skin permeability to ions, it is a simple Method for evaluating skin barrier function of a single stable.

3 Test principle

The test substance is applied to the two-tier test system placed in the skin surface, keeping 24h. In this test system, the test between layers Skin can be used as a separate functional layer. Skin test from 28 days to 30 days the rats were euthanized in. According to skin and to reduce the degree of skin stratum corneum deficient skin barrier function (TER below the threshold) to identify the test case of whether the substance is corrosive [12].

TER results in rats showed a large number of chemicals, most of the TER value is much higher than 5kohm (often greater than 10kohm) or below 5kohm (often Less than 3kohm), it will be determined whether or not the rat skin TER corrosion threshold set to 5kohm [12].

Typically, live animals skin corrosive substances, whether or not irritating, TER value measured no less than 5kohm.

In addition, when using different skins or different test device, the TER threshold may change this case, the need for further verification.

This test procedure is added to the staining method to confirm positive results (including the TER value is close to 5kohm time). If the cuticle was Damage, will increase ion permeability, which can be used staining method was validated. Existing evidence, carried out using rat skin TER Test can predict corrosion test in rabbits (OECD404 [2]) results. It should be noted that the use of a skin test in rabbits rot Corrosion test results and skin irritation and skin patch test results with a high degree of consistency [15].

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4.1 Experimental Animals

It has been proved that rat skin more sensitive to chemicals, so the selection of rat skin test [10]. The rat and mouse strains are age