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

SN/T 2245-2009

Chemicals. 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

(English Translation)

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Foreword

This standard is identical with the Organisation for Economic Co-operation and Development (OECD) Chemicals Test Method No. 431 (April 2004) "in vitro skin Corrode human skin model test "(in English).

This standard is the standard text format according to GB/T 1.1-2000 made the following editorial changes.

--- Increasing the scope section;

--- The OECD Chemicals Test Method No. 431 relating to the method of introduction, purpose, scope, etc. instead of the standard introduction;

Appendix A of this standard is an informative annex.

This standard is proposed and managed by the National Certification and Accreditation Administration Committee.

Introduction

Skin corrosion refers to the skin after exposure to chemicals produced irreversible skin tissue damage (as defined in the GHS). This standard Without providing a live animal test and corrosion test methods for chemical analyzes will be conducted.

The corrosivity evaluation usually requires laboratory animals. GB/T 21604-2008 taking into account the experimental animal suffering and pain Pain, allows the use of in vitro methods for skin corrosion was measured in its appendix, in order to avoid animal suffering and pain.

Completely replace GB/T 21604-2008 main difficulty is formal, independent, in vitro test methods for scientific missing. Former research validation it can be used as an in vivo study

to develop an alternative to the first step of the test, with the progress of this research has been carried out in vitro skin corrosion test Experimental study on verification methods. These studies led to the creation of the test and percutaneous resistance tests.

Studies have shown that the use of human skin model test can be well aware of the difference between the non-corrosive for skin corrosion and skin, but also Provide some relevant differences between serious and minor corrosion corrosive information.

This standard can be identified on the corrosive compounds and mixtures thereof. If combined with other existing information (eg pH, structure-activity Off Department of Human and (or) animal data) by weight of evidence analysis, this standard can also be the identification of non-corrosive compounds and mixtures thereof.

This standard test substance often do not provide information on skin irritation, nor corrosive substances according to GHS classification rules further.

In order to fully assess the local skin reaction after a percutaneous exposure, it is recommended according to GB/T 21604-2008 in the sequential test policy Related methods provided little or GHS tested.

Chemicals vitro skin corrosion Human skin model test

1 Scope

This standard specifies the chemical corrosion human skin in vitro skin model test principle, test methods and procedures.

This standard applies to chemical corrosion human skin in vitro skin model test.

2 Normative references

The following documents contain provisions which, through reference in this standard and become the standard terms. For dated references, subsequent Amendments (not including errata content) or revisions do not apply to this standard, however, encourage the parties to the agreement are based on research Whether the latest versions of these documents. For undated reference documents, the latest versions apply to this standard.

GB/T 21604-2008 chemicals acute dermal irritation/corrosion test methods

3 Terms and definitions

The following terms and definitions apply to this standard.

Skin exposure to chemicals produced in vitro after 4h irreversible skin damage, namely the epidermis and dermis visibility gangrene. Corrosive effect Characteristic ulcers, bleeding and scarring, skin discoloration due to hot and 14d, the partial alopecia areata and scarring. Applications histopathology Review Price suspicious injuries.

Total activity of the cell (such as cell mitochondrial dehydrogenase MTT reducing ability) measured parameters, depending on the endpoint measured and test Test design and the number and activity of cells.

Principle 4

Test was applied to a three-dimensional human skin model, skin model used comprises at least one having a functional transformation of epithelial cuticle.

According to a specific action at the time, cell viability (e.g. by the MTT reduction assay) is reduced to the predetermined threshold, to identify corrosive chemicals substance.

Principles of human skin model test is based on the assumption corrosive chemicals can penetrate the horny by diffusion or corrosive effect Layer to the underlying layer of cells to produce cytotoxic effects based on.

5.1 Human skin model

5.1.1

Human skin models can be created or obtained (eg EpiDerm™ and EPISKINTM model) commercially or yourself Laboratory prepared. Using human skin model must meet national and international ethical requirements.

5.1.2

Any new skin model must be legally certified (as described at least 5.3). Human skin models used for this test required the full 5.2 and 5.3 foot conditions.

5.2 General skin conditions Model

5.2.1

human keratinocytes should be used to build the model of the skin epithelium. The following functional stratum corneum covered multilayer epithelium, skin mold