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

SN/T 4154-2015

Chemicals--Skin sensitization local lymph node assay: DA

化学品 皮肤变态反应 局部淋巴结试验: DA

(English Translation)

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Foreword

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

This standard and the United Nations Economic Cooperation and Development Organization (OECD) Chemical Test Method No.442A (2010) "Skin Allergy Bureau Department of lymph node test. DA "(English version) of the technical content of the same.

This standard has the following structure and editorial changes.

- change the introduction to the introduction;
- the addition of the "scope" chapter;
- the addition of the "normative reference" chapter;
- replace Appendix 1 with terms, definitions and abbreviations;
- delete the OECD reference section.

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

The drafting unit of this standard. Tianjin Entry-Exit Inspection and Quarantine Bureau of the People's Republic of China, Zhejiang Entry-Exit Inspection and Quarantine Bureau, Ningbo Entry-Exit Inspection and Quarantine Bureau.

Introduction

OECD Guidelines for Chemical Testing Given the progress of science, the need for change and adjustment, and animal welfare, it is regularly reviewed.

The first edition of the guidelines for the detection of skin sensitization in mice - the local lymph node test (abbreviated as LLNA, guideline 429), was published in 2002 Revised. A summary of LLNA's verification details and related work has been published. In LLNA, radioisotope labeled thymidine or Iodine to detect lymphocyte proliferation, the method has

limitations in the acquisition, use and disposal of radioactive tracers. LLNA. DA (Developed by Daicel Chemical Industries, Inc.) is a non-radioactive improved LLNA test method that is detected by bioluminescence Adenosine triphosphate (ATP) content, as an indicator of lymphocyte proliferation. LLNA. DA test method has passed the international peer test Evidence, review and recommendation, that can be used to identify certain skin allergens. This standard is used to assess the skin sensitization of chemicals to animals Sex. GB/T 21608-2008 using guinea pigs as experimental animals, divided into guinea pig maximum test and Buehler test. LLNA (guideline

429) and two non radioactive improvement assays, LLNA. DA (guideline 442A) and LLNA. BrdU-ELISA (guideline 442B) Optimize the use of animals should be better than GB/T 21608-2008.

Similar to LLNA, LLNA. DA studied the skin sensitization during induction and obtained a quantitative number for dose-response assessment according to. In addition, this standard does not require the use of radiolabeled DNA to detect skin sensitizers, avoiding the possibility of radioactive occupational exposure and waste disposal issues. This method may increase the amount of mouse used to reduce the number of guinea pigs as skin sensitization tests.

Chemical skin allergies localized Lymph node test. DA

1 Scope

This standard specifies the terms, definitions and acronyms for local lymph node tests in the testing and evaluation of chemical contact sensitization tests.

Items and limitations, test principles, test preparation, test procedures, test procedures, observations, results calculations, data and reports.

This standard is applicable to the detection of skin sensitization of chemicals.

2 Normative reference documents

The following documents are indispensable for the application of this document. For dated references, only the dated edition applies to this article Pieces. For undated references, the latest edition (including all modifications) applies to this document.

Test method for skin sensitization of chemicals GB/T 21608-2008

3 Terms, definitions and abbreviations

The following terms, definitions and abbreviations are defined for this document.

Accuracy

According to the development of the test method to obtain the results and the approximate

reference value between the degree of close. It is a measure of the operation of the test method and whether it is A suitable aspect. The term "consistency" is often used to define the proportion of the correct results of the test method.

Standard material benchmark substance A sensitized or non-sensitized reference substance compared to the test substance. The standard substance shall have the following attributes. (1) Consistent and reliable Source. (2) Similar to the structure and function of the test substance. (3) known physical/chemical properties; (4) data of known influence; (5) There is a known effect in the reaction range.

False negative the test results of the test substance are mistakenly identified as negative or inactive, and in fact it is positive or active.

False positive the test results of the test substance are mistakenly identified as positive or active, and in fact it is negative or inactive.

Risk

Adverse health or the potential for the ecological environment. Adverse effects occur only when sufficient concentration is exposed.

Inter-laboratory reproducibility inter-laboratory reproducibility Measure the possibility of using different test laboratories with the same test procedures and the results of similar results on the quality and quantity produced. real Inter-laboratory reproducibility is determined during the initial validation and validation process, indicating the extent to which the test method is successfully implemented between different laboratories.