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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 21608-2025

Replacing GB/T 21608-2008

Chemicals - Test method of skin sensitization

化学品 皮肤致敏试验方法

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Table of Contents

Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting.

This document replaces GB/T 21794-2008 "Test method for chromosome aberration of mammalian cells in vitro by chemicals" and is in line with GB/T 21794- Compared with 2008, in addition to structural adjustments and editorial changes, the main technical changes are as follows.

a) Added the terms and definitions of "chromatid clefting", "genotoxicity", "relative cell growth number" and "relative population doubling number" (see 3.1, 3.5, 3.9, 3.10); deleted the term and definition of "cleft" (see 2.4 of the 2008 edition); changed the term "chromatid abnormality" Definitions of "chromosomal aberration", "endoreplication", "mitotic index", "numerical aberration", "polyploidy" and "structural aberration" (see 3.2, 3.3, 3.4, 3.6, 3.7, 3.8 and 3.11, 2.1, 2.2, 2.3, 2.5, 2.6, 2.7 and 2.8 of the 2008 edition);

b) Added the "Abbreviations" section (see Chapter 4);

c) The "Preparation" section has been modified to refine the cell selection conditions and add cell preservation conditions and gas or volatile test conditions.

The preparation conditions of the organisms were revised, and the concentration of S9 in the culture medium was revised (see 6.1, 4.1 of the 2008 edition);

d) The solvent selection conditions have been changed to specify the concentration of organic solvents in the final contact concentration (see 6.2.1, 4.2.1 of the 2008 edition);

e) The names and CAS numbers of cyclophosphamide and cyclophosphamide (monohydrate) have been changed (see Table 1, 4.2.3.2 of the 2008 edition);

f) The content of the "Test Procedures" was changed to specify the concentration of colchicine and the time of culture treatment, and to add the required Count the number of metaphase cells (see 6.3, 4.3 of the 2008 edition);

g) Modified the "Data Processing" section (see 7.1, 5.1 of the 2008 edition);

h) Added content on cytotoxicity assessment and provided calculation methods for various toxicity assessment indicators (see Appendix A).

Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents.

This document is proposed and coordinated by the National Technical Committee for Standardization of Hazardous Chemicals Management (SAC/TC251).

This document was drafted by: Institute of Occupational Health and Poison Control, Chinese Center for Disease Control and Prevention, Qingdao University, and the Solid Waste Management Bureau of the Ministry of Ecology and Environment.

and Chemicals Management Technology Center, Ningde Standardization Association.

The main drafters of this document are: Yu Dianke, Xu Lin, Chen Xiao, Yang Kun, Liu Xiaojian, Li Bin, Jin Yuan, Zhao Kunming, and Miao Xianyu.

The previous versions of this document and the documents it replaces are as follows.

- First published in 2008 as GB/T 21794-2008;

- This is the first revision. GB/T 21794-2025

Introduction

The in vitro cell chromosome aberration test is suitable for identifying or characterizing chemicals that can cause chromosome structural aberrations in mammalian cells cultured in vitro.

Chemical mutagens. Chromosome structural aberrations generally take two forms. chromosome aberrations and chromatid aberrations. Most chemical mutagens The increase in polyploidy indicates that the test substance has the potential to cause chromosome number aberration.

This method is not used to detect chromosome numerical aberrations.

Chromosomal mutations and related events are the cause of many human genetic

diseases, and there is ample evidence that somatic oncogenes Chromosome aberrations and tumor suppressor gene changes and related events are related to the induction of tumors in humans and experimental animals.

The aberration test has the advantages of high sensitivity, intuitiveness and complementarity. This test can directly detect whether the test substance induces changes in chromosome structure or number.

Abnormalities in the amount of phospholipids (such as breaks, deletions, translocations, aneuploidy, etc.) can be used to predict their potential carcinogenicity or mutagenicity, and to be applied to drug development and chemical safety. Comprehensive evaluation.

In vitro chromosome aberration tests use established cell lines, cell strains or primary cells for culture.

It is often necessary to add an exogenous metabolic activation system, but it is impossible for an exogenous metabolic activation system to completely simulate the metabolic conditions in mammals.

Therefore, this test is careful to avoid false positive results that do not truly reflect the mutagenic effect, which may be due to changes in pH, osmotic pressure or This is due to the high cytotoxicity of the test substance and requires in vivo testing to exclude false positives. GB/T 21794-2025 Chemicals induce chromosomal aberrations in mammalian cells in vitro Test methods

1 Scope

This document establishes the basic principles of in vitro mammalian cell chromosome aberration testing for chemicals, describes the test methods, and specifies the test Data and report content.

This document applies to in vitro mammalian cell chromosome aberration tests for chemicals.

2 Normative references

This document has no normative references.

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 chromatid gap

A chromatin-free region that appears on a single chromatid and is smaller than the width of the chromatid's cross section.

3.2 chromatid-type aberration

It refers to the phenomenon of chromatid breakage or chromosome structural damage caused by breakage and reconnection between chromatids.

3.3 chromosome-type aberration

It refers to the phenomenon of chromosome structural damage in which two chromatids break or rejoin at the same site.

3.4 Endoreduplication

After the S phase of DNA replication, the cell nucleus begins another S phase without undergoing mitosis.

Note. The result is that the chromosomes have 4, 8, or 16 fold chromatin.

3.5 genotoxic

The ability to damage the genome.

Note. This includes mutagenicity and other various effects caused by toxic effects on the genome.

3.6 Mitotic index

The ratio of the number of cells in mitosis to the total number of cells.

Note. This is an indicator used to measure the number of proliferating cells.

3.7 Numerical distortion

An alteration in the number of chromosomes that is different from the normal number of chromosomes in the cells being used. GB/T 21794-2025