

ICS 13.300; 11.100
CCS A 80



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

GB/T 27817-2011

Chemicals -- Test method of immunotoxicity

化学品 免疫毒性试验方法

(English Translation)

Issued on: December 30, 2011

Implemented on: August 1, 2012

Issued by: Standardization Administration of China

Table of Contents

Foreword
Introduction
1 Scope
2 Normative references
3 Terms and Definitions
4 Test principle
5 Test methods
5.1 Experimental Animals

Foreword

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

This standard and the US Environmental Protection Agency (USEPA) prevention, pesticides and toxic substances released Prevention Office the biochemicals Test Guide OPPTS880.3550 (1996) immunotoxicity (EPABiochemicalsTestGuidelinesOPPTS880.3550.1996, Immu-notoxicity) agreement (in English) of technical content.

The standard structure and made the following editorial changes.

--- The original text of this standard the following as "Introduction" content. "Introduction"; under (a) Title (1) "suitability" and (2) "back King "; (1) (b) under the heading" Product Registration for immunotoxicity testing requirements, "(2)" purpose "and (5)" test substance "; (f) Title Content. "To immunotoxicity testing stage";

--- Increasing the range chapter (see Chapter 1) and normative references a chapter (Chapter 2);

--- 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 Control of Occupational Health and Poison Control, Chinese Chemical Technology Development Center, China State Inspection and Quarantine Science Research Institute.

Introduction

This standard reference USEPA OPPTS 880.3550.1996 immunotoxicity test (in English), the technical content of the test guidelines OPPTS 880.3550 (1996) immunotoxicity consistent.

The test guide is the United States Environmental Protection Agency (USEPA) prevention, pesticides and toxic substances Prevention Office (The Office of Prevention - One series of tests Directory tion, Pesticides and Toxic Substances, OPPTS) published with a subject as pesticides and toxic Substance; toxicological data obtained after the submission for review in accordance with EPA regulations.

The test OPPTS guide published by merger and weigh multiple test guidelines (including the Office of Pollution Prevention and Toxic Substances (the Chapter I Chapter Office of Pollution Prevention and Toxics, OPPT) published guidelines, 40 under the title American specification Daquan R sub-chapter in the guide (Title 40, Chapter I, Subchapter R of the Code of Federal Regulations, CFR), pesticides Planning Office (the Office of Pesticide Programs, OPP), the Organization for Economic Cooperation and Development (the Organization for Economic Cooperation and Development, guide a coordinated OECD) after the final formation.

Integration of multiple purpose test guidelines to form a single set of guidelines OPPTS test is to test the number of US Environmental Protection Agency reached According to requirements, so that differences in test methods is reduced to a minimum.

Applicability. To meet the US Federal on pesticides, fungicides and rodenticides regulations requirements.

Background. The original document was drafted with reference OPP guide 152-18.

Product registration for immunotoxicity testing requirements. product registration immune toxicity data requirements based on availability. When asked to carry out sub Chronic (90d) oral toxicity test (OPPTS 870.3100), sub-chronic (90d) dermal toxicity test (OPPTS 870.3250) or sub-slow Sexual (90d) inhalation toxicity testing (OPPTS 870.3465), immunization is required toxicity tests; immunotoxicity test from infected animals Ways should be consistent with toxic exposure pathways sub-chronic toxicity tests.

Objective. to understand subchronic exposure to the test substance by immune toxicity test (usually oral exposure) on the body for health damage use. These immune toxicity tests may be qualitative or quantitative evaluation of the test substance to the antibody-mediated and humoral specific and nonspecific cells Immune of.

Test substance. technical grade test substance should be measured in each of the active ingredient.

Immunotoxicity testing stage. If any of the first phase of the immune toxicity test proved immune toxicity test substance should be open Immune toxicity tests show the second

stage (OPPTS880.3800). If the results of the first phase of the immune toxicity test can not be clearly explained Data shows that the test substance or its structural analogues having immunotoxicity, may also be the second phase of the immune toxicity tests. If the first A phase of the trial clearly demonstrated that the test was not immune toxicity, or no relevant data to prove the test substance or its structural analogs immune when toxicity, does not require a phase II trial.

Immune toxicity testing of chemicals

1 Scope

This standard specifies the terms and definitions chemicals immunotoxicity test method, the test principle, test methods and test reports.

This standard applies to detect chemicals immunotoxicity.

2 Normative references

The following documents for the application of this standard is essential. For dated references, only the dated version applies to this standard quasi. For undated references, the latest edition (including any amendments) applies to this standard.

US Environmental Protection Agency (USEPA) Biochemical Test Guideline
OPPTS880.3800 (1996) immunoreactivity
(EPABiochem-icalsTestGuidelinesOPPTS880.3800.1996, ImmuneResponse)

3 Terms and Definitions

The following terms and definitions apply to this document.

Immunotoxicity Test substance inducing the immune system disorder or inappropriate inhibition or irritation reactions.

4 Test principle

This standard immune toxicity tests, the test substance can be evaluated whether to change or damage the functional state of the immune system. Evaluation indicators include.

Immunohistochemistry, cell structure and weight of immune organs; clinical and biochemical blood analysis; blood tests; humoral immune function; cellular immunity.

Different groups of animals exposed to different doses of the test substance at least 30d, every day the animals were any clinical toxicity table that appears to observe and record Now. After exposure, the animals were sacrificed on the above evaluation index detection or analysis; some of them need to test the animals with the antigen Sensitization.

5.1.1 Species and Strains

Preferred mice or rats, using the commonly used animal strains. If other species of animal should be justified. All animals should be no parasites and pathogens. Female animals should not yield, not pregnant.

5.1.2 Age

Use healthy animals. In the beginning of the experiment, the weight of individual animals should not exceed $\pm 20\%$ of average weight. At 6 weeks of age -Exposure start 8 weeks of age.

5.1.3 Gender

The use of single-sex animals. If the test substance is known to one of the more sensitive animal sex, you should use this gender animals.