

ICS 13.300; 11.100  
CCS A 80



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

**GB/T 27826-2011**

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**Chemicals -- Test method of developmental neurotoxicity**

化学品 神经发育毒性试验方法

**(English Translation)**

**Issued on: December 30, 2011**

**Implemented on: August 1, 2012**

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**Issued by: Standardization Administration of China**

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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 testing guidelines No.426 (2007 Nian) "neurodevelopmental toxicity test" (English Chinese Version) consistent with the technical content.

This standard configuration and do the following editorial changes.

- Increasing the range a chapter;
- Change the unit of measure of legal units of measurement;
- The OECD426 original in the "Introduction" and "initial consideration" as part of the introduction of this standard.

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, Shanghai Entry-Exit Inspection and Quarantine of China Engineering Technology Development Center.

### Introduction

June 1995, reproductive and developmental toxicity OECD Working Group met in Copenhagen to discuss the existing OECD Reproduction and Development Fertility toxicity test guidelines are updated, but is not included on the original endpoint improvement [1]. The Working Group recommends that developmental neurotoxicity tests Guidelines should be based on EPA test guidelines [2]. June 1996, the Working Group held its second consultative meeting in Copenhagen, the General Assembly Submit a new

neurodevelopmental toxicity test guidelines outline, including animal species selection rules, exposure period, the test period, end point and knot If the evaluation criteria and other details of the test points. In 1998 the United States published a neurodevelopmental toxicity hazard evaluation guidelines [3], in 2000 in October, OECD expert consultation and ILSI Risk scientific working group have been met, and in 2005 the Association of experts convened in Tokyo Suppliers Conference [4-7]. The meeting discussed the current guidelines for testing scientific and technical issues involved.

The standard reference to the OECD Chemicals Test Guidelines No.426 (2007 Nian) "neurodevelopmental toxicity test" (in English). Test Guide Regarding the operation and interpretation of terms used in the test information with reference test guidance document No.43 "reproductive toxicity testing and evaluation." [8] and no.20 "neurotoxicity test" [9].

Many chemicals can cause humans and other animals neurodevelopmental toxicity [10-13]. Or a mixture of individual chemicals (known as test Was) the potential neurodevelopmental toxicity testing can be used to evaluate the test substance toxicity characteristics. Neurodevelopmental toxicity studies reflect the offspring in the womb Morphological and functional changes in the factors and early life due to exposure caused by the nervous system abnormalities, and to provide a dose - response relationship information.

Neurodevelopmental toxicity tests may be carried out separately, can also be combined reproductive toxicity and/or neurotoxicity study in adult animals, or prenatal development Toxicity studies [14-17]. Such as developmental neurotoxic merged into another test, we must ensure the integrity of the two trials. All tests should comply Animal experiments and research institutions, local governments use the guidelines [18].

Prior to testing, data analysis should consider all of the test substance, including the name of the test substance, chemical structure, physical and chemical properties and other in vivo or in vitro toxicity tests; Toxicology information structurally related compounds and the intended use of the test substance and the like. This information not only helps test Providing the necessary information for the protection of human health, but also help to select the appropriate test initial dose.

Toxicity Test Methods for Chemical neurodevelopmental

## 1 Scope

This standard specifies the chemical rodents neurodevelopmental toxicity test Abbreviations, principles of testing, test preparation, test procedures, test Data and reports.

This standard is applicable to the detection of neural chemicals developmental toxicity.

## 2 Acronyms

The following abbreviations apply to this document.

NOAEL. No deleterious effects were observed dose (no-observed-adverseEffect) GD. gestational day (gestationday) PND. delivery day (postnatalday) DMPT. Delayed matching state (delayed-matching-to-position) CNS. central nervous system (centralnervoussystem) PNS. peripheral nervous system (peripheralnervoussystem) GFAP. glial fibrillary acidic protein (glialfibrillaryacidicprotein)

## 3 Test principle

### 3.1

pairs of pregnancy and lactation animals were exposed not only to evaluate the effect of the test substance during pregnancy and breast-feeding mother, but also to compare Different toxicity of parent and progeny of animals appear. Neurological toxicity evaluation by the progeny of animals should be randomly selected. Neurotoxicity evaluation main to evaluate abnormalities including neural behavior overall and postnatal and adult brain weight and neuropathological evaluation, including evaluation of neurobehavioral abnormalities body Development, individual behavior, motor activity, motor and sensory function, and learning and memory.

### 3.2

If the neurodevelopmental toxicity tests carried out independently, in addition to the basic project, the amount of animals should meet specific neurobehavioral, and neuropathology Electrophysiological examination required inspection of these items is a basic standard inspection items important supplement [16,19-21]. When evaluating some experience dependent Concept Police, the expected, when the mechanism/mode of action indicate that a particular type of neurotoxicity, the inspection of these items is particularly useful. These checks Head of the information obtained may evaluate the toxicity of parent and progeny of animals are useful. Furthermore, as the body does not change the integrity of the experiment, but also for Off test or in vitro test pieces.

### 4.1 Selection of animal species

The preferred test in rats, can also choose other suitable animal. But the number of days of pregnancy and lactation in this standard is intended to mean the general rat; as Other animal species or specific strain of rats, should be selected corresponding to the number of days. If you select a different species of animal should be based on relevant Toxicology, pharmacokinetics and/or other materials be justified, including the use of animals born after the neurobehavioral development of species-specific and God Pathological evaluation of feasibility. If the conventional trials of concern, should concern the animal species and

strains considered. Because it does not Rat strains with different characteristics, shall ensure that there are sufficient animal strains breeding ability and sensitivity. Choose other animal species detect God After the reliability and sensitivity of developmental toxicity shall have the appropriate documentation basis.