



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

**GB 30000.24-2013**

Replacing GB 20598-2006

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**Rules for classification and labelling of chemicals - Part 24:  
Reproductive toxicity**

化学品分类和标签规范 第24部分：生殖毒性

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## Table of Contents

- 1 Scope
- 2 Normative references
- 3 Terms and Definitions
- 4 Classification Standard
  - 4.2.2 The basis of classification
  - 4.2.3 The weight of evidence
  - 4.2.4 Maternal toxicity
  - 4.2.5 Animal and experimental data

### Foreword

Part 4 of this chapter 6 are mandatory, the rest are recommended. GB 30000 "chemical classification and labeling norms," the expected structure and national standards will be replaced as follows:

- Part 1. General (instead of GB 13690-2009);
- Part 2. Explosives (instead of GB 20576-2006);
- Part 3. flammable gases (instead of GB 20577-2006);
- Part 4. Aerosol (instead of GB 20578-2006);
- Part 5. oxidizing gas (instead of GB 20579-2006);
- Part 6. pressurized gas (instead of GB 20580-2006);
- Part 7. flammable liquids (instead of GB 20581-2006);
- Part 8. Flammable solids (instead of GB 20582-2006);
- Part 9. Self-reactive substances and mixtures (instead of GB 20583-2006);
- Part 10. Pyrophoric liquids (instead of GB 20585-2006);
- Part 11. Spontaneous solid (instead of GB 20586-2006);
- Part 12. Self-heating substances and mixtures (instead of GB 20584-2006);
- Part 13. water, emit flammable gases and mixtures (instead of GB 20587-2006);

### 1 Scope

GB 30000.24-2013 is the Chinese national standard on rules for classification and labelling of chemicals - part 24: reproductive toxicity. It carries no /T suffix, which in the Chinese system means compliance is mandatory: a product or a practice within its scope has to meet it to be lawfully made, sold or carried out in China. It was issued on 10 October 2013 by the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China; Standardization Administration of China, and has been in force since 1 November 2014. Classification: ICS , CCS A80. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

GB This section 30000 specifies the terms and definitions reproductive toxicity of chemicals, classification criteria, decision logic and labels. This section applies to reproductive toxicity of chemicals by the United Nations' Globally Harmonized System of Classification and Labelling "(hereinafter referred to as GHS) of classification and labeling.

## 2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member. For undated references, the latest edition (including any amendments) applies to this document.

GB 30000.22-2013 chemical classification and labeling specifications - Part 22. germ cell mutagenicity

GB 13690 chemical classification and hazard communication General The United Nations' Globally Harmonized System of Classification and Labelling "(fourth revised edition) United Nations "on the Recommendations on the Transport of Dangerous Goods Model Regulations" (Seventeenth revised Edition)

## 3 Terms and Definitions

GB 13690 and defined by the following terms and definitions apply to this document.

3.1 Reproductive toxicity reproductivetoxicity Harmful effects on adult male and female sexual function and fertility, and offspring developmental toxicity. Conducting hazard classification When, on the known genetic offspring to induce heritable effects will make regulations in Article

3.5 of the UN GHS in germ cell mutagenicity Be, because in the current classification system, the effect is more appropriate in accordance with this unique germ cell mutagenicity hazard classification. In sub Class system, reproductive toxicity is subdivided into two main areas. the adverse effects on sexual function and fertility, and on development of offspring harmful Movies ring. Some reproductive toxicity is unable to clear harmful

effects of sexual function and fertility or harmful effects on development of offspring. but, For chemicals with such reproductive toxicity, should be given a general description of the harm.

Note. For details of germ cell mutagenicity visible GB 30000.22-2013.

**3.2 Adverse effects on sexual function and fertility** Any effect of chemicals interfere with sexual function and fertility, including (but not limited to) the female and male reproductive system changes to green Beginning of the spring, germ cell production and transport, reproductive cycle normality, sexual behavior, fertility, childbirth, the harmful effects of pregnancy outcomes, Premature or change other features related to the integrity of the reproductive system and reproductive capacity. Harmful effects on the harmful effects of lactation by lactation produced or belong to the scope of reproductive toxicity, but for classification purposes, such Effect In this section are listed separately (see 4.2). This is because the adverse effects of chemicals hoping lactation for classification as a special order The hazards of this effect is provided to the nursing mother.

**3.3 Harmful effects on the development of offspring** adverse effects on development of the offspring In the broadest sense, developmental toxicity includes prenatal or postnatal interfere with any affect normal fetal development, this effect It was the result of contact with a parent before conception or developing offspring before or after birth before the sexual maturity The contact period. However, developmental toxicity classification, its main purpose is for pregnant women and women of childbearing potential and men provide risk warnings Advertisement. Thus, for practical purposes in terms of classification, developmental toxicity mainly refers to the harmful effects during pregnancy or due to contact parents caused Harmful effects. These effects can be revealed at any stage of the life cycle of the organism. The main manifestations of developmental toxicity include development The death of the organism, structural abnormality, altered growth and functional defects.

## 4 Classification Standard

**4.1 General principles** General principles of classification and labeling of reproductive toxicity See GB 13690.

**4.2 classification standard substance**

**4.2.1 Hazard category** For classification purposes, reproductive toxicity, chemical substances are divided into two hazard categories. On sexual function and fertility and hair Effect of Fertility was evaluated separately. Moreover, the impact on lactation individually into a dangerous category, hazard classification criteria in Table 1 and Table 2. Table 1 reproductive toxicant classification criteria and categories Category 1. Known or presumed human reproductive toxicant This category includes known to human sexual function and

fertility or developmental effects harmful substances, or animal research evidence (there may be other information as Supplement) showed it to interfere with reproduction in humans is very likely substances. According to classified evidence, mainly from human data (Category 1A) or from animal Data (Category 1B), the substance may be further divided.

Category 1A. Known human reproductive toxicant The material in this category is largely based on human evidence. Category 1B. presumably human reproductive toxicant The substance in this category is largely based on animal data. Data from animal studies should provide clear evidence that in the absence of other toxic effects Under the circumstances, the sexual function and fertility or have harmful effects on development, or if occurring together with other toxic effects, harmful effects on reproduction It is not considered a non-specific consequence of other toxic effects. However, when there is mechanistic information for suspecting that influence and relevance of the human will Its classification to Category 2 may be more appropriate.

Category 2. Suspected human reproductive toxicant The substance in this category are some of the human or animal studies evidence (there may be other information supplemented) show that in the absence of other toxic effects, On sexual function and fertility or development have harmful effects; or if concurrently with other toxic effects, but it can determine the harmful effects on reproduction is not Other non-specific consequence of toxic effects, and there is no sufficient evidence to support divided into categories 1. For example, the presence of a lack of experimental study design, the guide Convincing evidence caused poor. At this point it should be classified in Category 2 may be more appropriate. Table

2 Effect of nursing or classification criteria and categories affected by breast-feeding Effect of breastfeeding or via lactation It will affect breastfeeding or via lactation is divided into separate categories. Although many substances there is no information that they may have through breast-feeding Have harmful effects on the progeny, but there may be some substances interfere with breast-feeding women action after being absorbed, or the substances (including metabolites) may appear in the milk, In an amount sufficient to affect the breast-fed baby's health, these substances should be classified into this category, in order to show the impact of breast-fed infants caused. This classification can Determined according to the following.

- a) the absorbing material, metabolism, distribution and excretion studies have shown that the concentration in breast milk may reach the level of potentially toxic effects; and/or
- b) the results of one or two generations animal studies provide clear evidence that, since the substances can enter breast milk, or harmful effect on the quality of breast milk DESCENDANTS a detrimental effect; and/or
- c) evidence in humans that substances harmful to nursing infants.

#### **4.2.2 The basis of classification**

4.2.2.1 classification should be based on the standards and the overall weight of evidence