



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

GB 30000.22-2013

Replacing GB 20596-2006

**Rules for classification and labelling of chemicals - Part 22:
Germ cell mutagenicity**

化学品分类和标签规范 第22部分：生殖细胞致突变性

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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 30000.22-2013 is the Chinese national standard on rules for classification and labelling of chemicals - part 22: germ cell mutagenicity. 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, classification criteria have germ cell mutagenicity of chemicals, and decision logic Guide, label. This section applies to having a germ cell mutagenicity of chemicals according to the United Nations' Globally Harmonized System of Classification and Labelling "(hereinafter Acronym 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 30000.23 classification and labeling of chemicals - Part 23. carcinogenic

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 Germ cell mutagenicity germcelmutagenicity Chemicals cause human reproductive cells can be inherited mutations. When the substances and mixtures classified in this hazard category, further To be noted that in vitro mutagenicity/genotoxicity tests and mammalian somatic cells in vivo mutagenicity and genotoxicity tests. In this section, Repeatedly referred to the terms mutagenic, mutagen, mutations and genetic toxicity.

"Mutation" is defined as the occurrence of permanent cell amount or structure of the genetic material Durability changes. "Mutation" applies to the performance may be dominant genetic changes and potential DNA modification (for example, aware of the particular base Pair changes and chromosomal translocations). "Mutagenic" and "mutagen" two words apply to the incidence of causing mutations in cells and/or organisms within the Community Substance increasing. "Genetic Toxicity" and "genetic toxicity", applied to alter the DNA structure, information content, or the isolated substance or process, including that of These interfere with the normal replication process by causing DNA damage, or can be non-physiological manner (temporarily) alter the substance or the process of DNA replication. Genotoxicity test results are often used as indicators for mutagenic effects.

4 Classification Standard

4.1 General principles General principles of germ cell mutagenicity classification and labeling see GB 13690.

4.2 classification standard substance

4.2.1 The classification system provides for two different categories of germ cell mutagenicity hazard to accommodate heavy weight of evidence available, see Table 1.

Table

1 Classification of germ cell mutagens Category 1. Known to cause human reproductive cells heritable mutations or regarded as likely to cause genetic mutations in germ cells of humans substance Category 1A. Known human reproductive cells cause heritable mutations in substance. Positive evidence from human epidemiological studies. criteria Category 1B. it should be considered likely to cause genetic mutations in germ cells of humans substance Criteria.

--- Mammals heritable germ cell mutagenicity tests positive result; or

--- Mammal body cell mutagenicity tests positive results, combined with some evidence that the substance has caused mutations in germ cells may can. For example, such supporting evidence may be derived from in vivo germ cell mutagenicity/genotoxicity tests, or proof substance or its metabolite Ability and the genetic material of germ cell interactions; or

--- Mutagenic effects of positive results from tests showing germ cells of humans, without having to prove whether the mutation to their offspring, for example, contacting the object Aneuploidy frequency of sperm cells in a qualitative increase in the population. Category 2. As the germ cells of humans may cause genetic mutations caused concern substances Criteria. Mammal for a positive test evidence, and/or sometimes give positive evidence from a number of in vitro experiments, the evidence from.

--- Mammalian cell mutagenicity tests in vivo body; or Other in vivo somatic cell mutagenicity tests in vitro

--- get supported by positive results of genotoxicity tests. NOTE. Positive results should be obtained in vitro mammalian mutagenicity assays, and to known germ cell mutagens chemical structure activity relationship chemical Products classified as Category 2 mutagens.

4.2.2 In order to try to classify, to be combined with contact with animals of germ cells and/or mutagenic effects of somatic and/or genetic toxicity effect Test results. It can also be combined mutagenic and/or toxic effects in vitro genetic testing to determine.

4.2.3 The classification system is built on the basis of risk, cause mutations in germ cells based on the intrinsic ability of substance, the substance may be classified. Thus, the classification scheme is different from the risk assessment of chemicals (quantitative).

4.2.4 germ cells of humans Classification for heritable effects in well conducted, sufficiently validated test basis, in accordance with relevant national standards Quasi-experiment. Expert judgment should be used to evaluate the test results, and classification should combine all available evidence.

4.2.5 Individual Classification requires expert material to all available weight of evidence as a basis for making judgment. In a single, well-conducted Information on the test substance should be classified, it should provide clear and unambiguously positive results. If new, well validated test Experience, the totality of the evidence can also be used in conjunction with the right to their weight. Note Comparative Experiment study of chemical exposure pathways and likely crowd Route of exposure, to see whether there is a relationship.

4.3 mixture classification criteria

5 Decision logic and guidance

Decision logic and guidance purposes only. Decision logic See Appendix A. Front and special recommendations person responsible for classification using decision logic Research on the use of Chapter 4. Decision logic for reference only.

6.1 Overview

6.1.1 for germ cell mutagenicity labels, hazard categories are specified in the order pictograms, signal words and hazard statements are listed. United Nations "on the Recommendations on the Transport of Dangerous Goods Model Regulations" (hereinafter referred to as "Model Regulations") hazard class or category should be covered in the standard Tab lists each category assigned a corresponding graphic signs. Germ cell mutagenicity assigned label elements are shown in Appendix B.

6.1.2 classification criteria and labeling elements relating to germ cell mutagenicity in Appendix C.

6.1.3 Requirements on the label information including hazard pictograms, signal words,