



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

GB 30000.21-2013

Replacing GB 20595-2006

**Rules for classification and labelling of chemicals - Part 21:
Respiratory or skin sensitization**

化学品分类和标签规范 第21部分：呼吸道或皮肤致敏

Issued on: October 10, 2013

Implemented on: November 1, 2014

**Issued by: General Administration of Quality Supervision, Inspection and
Quarantine of the People's Republic of China;
Standardization Administration of China**

Table of Contents

1	Scope
2	Normative references
3	Terms and definitions
4	General instructions
5	Classification criteria
5.2	Substance classification criteria
5.2.1	Respiratory sensitizers
5.2.2	Skin sensitizers
5.2.2.1	Hazard category
5.2.2.2	Human evidence
5.3	Classification criteria for mixtures
6	Decision logic
7	Labels
7.1	Overview
7.6	Product identifier

1 Scope

GB 30000.21-2013 is the Chinese national standard on rules for classification and labelling of chemicals - part 21: respiratory or skin sensitization. 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.

This Part of GB 30000 specifies the terms and definitions, general descriptions, classification standards, judgment logic, labels for chemicals with respiratory or skin sensitization. This Part applies to the classification and labeling of chemicals, which have respiratory or skin sensitization, in accordance with the United Nations' Globally Harmonized System of Classification and Labeling of Chemicals (hereinafter referred to as

GHS).

2 Normative references

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) is applicable to this standard.

GB 13690 General rule for classification and hazard communication of chemicals

GB 16483 General rules to drafting safety data sheet for dangerous chemicals United Nations "Recommendations on the Transport of Dangerous Goods - Model Regulations" (17th Revised Edition) United Nations "Globally Harmonized System of Classification and Labeling of Chemicals" (Fourth Revised Edition)

3 Terms and definitions

The terms and definitions as defined in GB 13690, as well as the following terms and definitions, apply to this document.

3.1 Respiratory sensitizer Substances that can cause respiratory allergies if inhaled.

3.2 Skin sensitizer Substances that can cause allergies after skin exposure.

4 General instructions

4.1 Sensitization includes two stages. The first stage is when an individual is exposed to a certain allergen and induces a specific immune memory; the second stage is triggering, that is, an allergic individual develops cell-mediated or antibody-mediated allergic reactions due to exposure to a certain allergen.

4.2 As far as respiratory sensitization is concerned, induction is followed by a triggering phase, which is the same characteristic as skin sensitization.

4.3 For skin sensitization and respiratory sensitization, the amount required for induction is generally lower than the amount required for triggering.

4.4 The hazard category "Respiratory or skin sensitization" is divided into.

5 Classification criteria

5.1 General principles General principles for classification and labeling of respiratory or skin sensitization are provided in GB 13690.

5.2.1 Respiratory sensitizers

5.2.1.2 Human evidence 5.2.1.2.1 Evidence that a substance may cause specific respiratory allergic reactions is generally based on human experience. In this context, allergic reactions usually manifest as asthma, but can also be combined with other allergic reactions such as rhinitis/conjunctivitis and alveolitis. Symptoms shall have clinical features of allergic reaction. However, immunological mechanisms do not necessarily have to be proven. 5.2.1.2.2 When making judgments based on human evidence, classification decisions need to incorporate, in addition to case evidence. 5.2.1.2.4 The clinical case shall include both medical and occupational history, to determine the relationship between exposure to specific substances and respiratory allergic reactions.

5.2.1.3 Animal studies Data obtained from appropriate animal studies 1) indicating that a substance has the potential to cause 2) sensitization in humans by respiration include.

5.2.2 Skin sensitizers

1 There is currently no recognized and effective animal model for testing respiratory allergic reactions. In some cases, data from animal studies can provide important information in the weight of evidence assessment.

5.3 Classification criteria for mixtures

5.3.1 Classification of mixtures when data on the entire mixture are available Where a mixture possesses reliable, high-quality evidence from human experience or appropriate experimental animal studies, as described in the material standard, the mixture may be classified based on an assessment of the weight of evidence of these data. Care shall be taken when evaluating mixture data, so that doses used do not produce ambiguous results.

5.3.2 Classification of mixtures without data on the mixture as a whole. bridging principle

6 Decision logic

The decision logic is for reference only. See Appendix A for the decision logic. It is particularly recommended that those responsible for classification study Chapter 5 before and during the use of decision logic.

7.1 Overview

7.1.1 Hazard category labels for respiratory or skin sensitization are listed in the specified order of pictograms, signal words, hazard statements. The types or categories of hazards covered by the "Model Regulations" shall be listed in the label with the designated corresponding graphic symbol for each category.

7.1.2 See Appendix C for classification and labeling elements related to respiratory tract or skin sensitization.

7.1.3 The information required on the label includes hazard pictograms, signal words, hazard statements, precautionary statements, product identifiers, supplier logos, etc.

7.2 Hazard pictograms Hazard pictograms specified by GHS shall use black symbols with a white background; the red frame shall be wide enough to be eye-catching.

7.3 Signal words Signal words are words on labels used to indicate the relative severity of a hazard and to alert readers to potential hazards. The signal words "Danger" and "Warning" are used to classify different hazard categories for respiratory or skin sensitization. Use the signal word "Danger" for Category 1, Category 1A, Category 1B respiratory sensitizers. Use the signal word "Warning" for Category 1, Category 1A, Category 1B skin sensitizers.

7.4 Hazard statements Hazard statement means a phrase assigned to a hazard type and category that describes the hazardous nature of a chemical and, where appropriate, its degree of hazard. See Appendix C and Appendix D for hazard statements and precautionary statements for respiratory or skin sensitizers.

7.5 Precautionary statements A precautionary statement is a word (and/or pictogram) used to describe recommended measures to minimize or prevent adverse effects resulting from exposure to a hazardous product or improper storage or handling of a hazardous product. To meet GHS requirements, there are five categories of precautionary statements. General, precautionary, emergency, storage, disposal.

7.6 Product identifier

7.7 Supplier identification The name, address, telephone number of the manufacturer or supplier of the substance or mixture shall be provided on the label.