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Replacing GB 20597-2006

Rules for classification and labelling of chemicals - Part 23: Carcinogenicity

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Foreword

Chapter 4 and Chapter 6 of this Part are mandatory. The rest are recommended.

The expected structure of "Rules for classification and labelling of chemicals" and the national standards to be replaced are as follows:

- Part 1: General rules (replacing GB 13690-2009);
- Part 2: Explosives (replacing GB 20576-2006);
- Part 3: Flammable gases (replacing GB 20577-2006);
- Part 4: Aerosols (replacing GB 20578-2006);
- Part 5: Oxidizing gases (replacing GB 20579-2006);
- Part 6: Gases under pressure (replacing GB 20580-2006);
- Part 7: Flammable liquids (replacing GB 20581-2006);
- Part 8: Flammable solids (replacing GB 20582-2006);
- Part 9: Self-reactive substances and mixtures (replacing GB 20583-2006);
- Part 10: Pyrophoric liquids (replacing GB 20585-2006);
- Part 11: Pyrophoric solids (replacing GB 20586-2006);
- Part 12: Self-heating substances and mixtures (replacing GB 20584-2006);
- Part 13: Substances and mixtures which, in contact with water, emit flammable gases (replacing GB 20587-2006);
- Part 14: Oxidizing liquids (replacing GB 20589-2006);
- Part 15: Oxidizing solids (replacing GB 20590-2006);
- Part 16: Organic peroxides (replacing GB 20591-2006);
- Part 17: Corrosive to metals (replacing GB 20588-2006);
- Part 18: Acute toxicity (replacing GB 20592-2006);
- Part 19: Skin corrosion/irritation (replacing GB 20593-2006);
- Part 20: Serious eye damage/eye irritation (replacing GB 20594 a 2006);

- Part 21: Respiratory or skin sensitization (replacing GB 20595-2006);
- Part 22: Germ cell mutagenicity (replacing GB 20596-2006);
- Part 23: Carcinogenicity (replacing GB 20597-2006);
- Part 24: Reproductive toxicity (replacing GB 20598-2006);
- Part 25: Specific target organ toxicity. Single exposure (replacing GB 20599-2006);
- Part 26: Specific target organ toxicity. Repeated exposure (replacing GB 20601-2006);
- Part 27: Aspiration hazard;
- Part 28: Hazardous to the aquatic environment (replacing GB 20602-2006);
- Part 29: Hazardous to the ozone layer;
- Part 30: Work safety warning signs.

This Part is Part 23 of GB 30000.

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

This Part shall replace GB 20597-2006 "Safety rules for classification, precautionary labelling and precautionary statements of chemicals - Carcinogenicity".

Compared with GB 20597-2006, the major technical content changes are as follows:

- MODIFY the standard name. The Chinese name is changed to "Rules for classification and labelling of chemicals. Part 23: Carcinogenicity". The English name is changed to "Rules for classification and labelling of chemicals. Part 23: Carcinogenicity";
- MODIFY the content of Chapter 1 "Scope". The "warning label" is changed to "label". DELETE "precautionary statements";
- MODIFY the introductory phrase in Chapter 2 "Normative references";
ADD GB 13690 and GB/T 16483 as reference documents;
- ADD the introductory phrase in Chapter 3 "Terms and definitions".
- MODIFY the format of Table 2 according to GHS (fourth revised edition);

Rules for classification and labelling of chemicals -

Part 23: Carcinogenicity

1 Scope

This Part of GB 30000 specifies the terms and definitions, classification criteria, decision logic and guidance, and labels of chemicals with carcinogenicity.

This Part is applicable to the classification and labelling of chemicals with carcinogenicity according to "Globally Harmonized System of Classification and Labelling of Chemicals" (hereafter referred to as GHS) of the United Nations.

2 Normative references

The following documents are essential for the application of this document. For dated references, only the dated editions apply to this document. For undated references, the latest editions (including all corrections) of the referenced documents apply to this document.

GB 13690 General rules for classification and hazard communication of chemicals

GB/T 16483 Safety data sheet for chemical products - Content and order of sections

United Nations "Recommendations on the transport of dangerous goods - Model regulation" (Seventeenth revised edition)

United Nations "Globally Harmonized System of Classification and Labelling of Chemicals" (Fourth revised edition)

3 Terms and definitions

Those defined in GB 13690 AND the following terms and definitions apply to this document.

3.1

Carcinogen

A substance or a mixture which induces cancer or increases its incidence. Substances and mixtures which have induced benign and malignant tumours

	additional considerations, such evidence may be from either limited evidence of carcinogenicity in human studies or from limited evidence of carcinogenicity in animal studies. Classification: Category 2 Carcinogen
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4.2.2 Carcinogen classification is made on the basis of evidence from reliable and acceptable methods, and is intended to be used for substances which have an intrinsic property to produce such toxic effects. The evaluations should be based on all existing data, peer-reviewed published studies and additional data accepted by regulatory agencies.

4.2.3 Carcinogen classification is a one-step, criterion-based process that involves two interrelated determinations: evaluations of strength of evidence and consideration of all other relevant information to place substances with human cancer potential into hazard categories.

4.2.4 Strength of evidence involves the enumeration of tumours in human and animal studies and determination of their level of statistical significance. Sufficient human evidence demonstrates causality between human exposure and the development of cancer, whereas sufficient evidence in animals shows a causal relationship between the agent and an increased incidence of tumours. Limited evidence in humans is demonstrated by a positive association between exposure and cancer, but a causal relationship cannot be stated. Limited evidence in animals is provided when data suggest a carcinogenic effect, but are less than sufficient. The terms “sufficient” and “limited” are used here as they have been defined by the International Agency for Research on Cancer (IARC) and are outlined in 5.1.

4.2.5 Additional considerations (weight of evidence).

4.2.5.1 The factors can be viewed as either increasing or decreasing the level of concern for human carcinogenicity. The relative emphasis accorded to each factor depends upon the amount and coherence of evidence bearing on each. Generally there is a requirement for more complete information to decrease than to increase the level of concern. Additional considerations should be used in evaluating the tumour findings and the other factors in a case-by-case manner.

4.2.5.2 Some important factors which may be taken into consideration, when assessing the overall level of concern are:

- Tumour type and background incidence;
- Multisite responses;
- Progression of lesions to malignancy;

- Reduced tumour latency.

Additional factors which may increase or decrease the level of concern include:

- Whether responses are in single or both sexes;
- Whether responses are in a single species or several species;
- Structural similarity or not to a substance(s) for which there is good evidence of carcinogenicity;
- Routes of exposure;
- Comparison of absorption, distribution, metabolism and excretion between test animals and humans;
- The possibility of a confounding effect of excessive toxicity at test doses;
- Mode of action and its relevance for humans, such as mutagenicity, cytotoxicity with growth stimulation, mitogenesis, immunosuppression.

4.2.5.3 Mutagenicity: It is recognized that genetic events are central in the overall process of cancer development. Therefore evidence of mutagenic activity in vivo may indicate that a substance has a potential for carcinogenic effects.

4.2.5.4 The following additional considerations apply to classification of substances into either Category 1 or Category 2. A substance that has not been tested for carcinogenicity may in certain instances be classified in Category 1 or Category 2 based on tumour data from a structural analogue together with substantial support from consideration of other important factors such as formation of common significant metabolites, e.g. for benzidine congener dyes.

4.2.5.5 The classification should also take into consideration whether or not the substance is absorbed by a given route(s); or whether there are only local tumours at the site of administration for the tested route(s), and adequate testing by other major route(s) show lack of carcinogenicity.

4.2.5.6 It is important that whatever is known of the physico-chemical, toxicokinetic and toxicodynamic properties of the substances, as well as any available relevant information on chemical analogues, i.e. structure activity relationship, is taken into consideration when undertaking classification.

4.2.6 It is realized that some regulatory authorities may need flexibility beyond that developed in the hazard classification scheme. For inclusion into Safety Data Sheets, positive results in any carcinogenicity study performed according

to good scientific principles with statistically significant results may be considered.

4.2.7 The relative hazard potential of a chemical is a function of its intrinsic potency. There is great variability in potency among chemicals, and it may be important to account for these potency differences. The work that remains to be done is to examine methods for potency estimation. Carcinogenic potency as used here does not preclude risk assessment. The proceedings of a WHO/IPCS workshop on the Harmonization of Risk Assessment for Carcinogenicity and Mutagenicity (Germ cells)-A Scoping Meeting (1995, Carshalton, UK), points to a number of scientific questions arising for classification of chemicals, e.g. mouse liver tumours, peroxisome proliferation, receptor-mediated reactions, chemicals which are carcinogenic only at toxic doses and which do not demonstrate mutagenicity. Accordingly, there is a need to articulate the principles necessary to resolve these scientific issues which have led to diverging classifications in the past. Once these issues are resolved, there would be a firm foundation for classification of a number of chemical carcinogens.

4.3 Classification criteria for mixtures

4.3.1 Classification of mixtures when complete data are available for the mixture

Classification of mixtures will be based on the available test data of the individual ingredients of the mixture using cut-off values/concentration limits for those ingredients. The classification may be modified on a case-by-case basis based on the available test data for the mixture as a whole. In such cases, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors such as duration, observations and analysis (e.g. statistical analysis, test sensitivity) of carcinogenicity test systems. Adequate documentation supporting the classification should be retained and made available for review upon request.

4.3.2 Classification of mixtures when complete data are not available for the mixture: bridging principles

4.3.2.1 Where the mixture itself has not been tested to determine its carcinogenic hazard, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following agreed bridging principles. This ensures that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture without the necessity for additional testing in animals.

4.3.2.2 Dilution:

Annex C.

6.1.3 Required information on the label includes hazard pictograms, signal words, hazard statements, precautionary statements, product identifiers, and supplier logo, etc.

Note: For those not-yet standardized label elements, such as the precautionary statements, they also need to be included on the label. Competent authorities may also request additional information. The supplier may also provide supplemental information.

6.2 Hazard pictograms

Hazard pictograms shall use a black symbol on a white background, with a red frame sufficiently wide to be clearly visible.

6.3 Signal words

Signal words refer to the phrases that are used to indicate the relative severity of the hazard and alert the reader to the potential dangers. For carcinogens of different hazard categories, use the signal word "Danger" and "Warning". For Category 1 carcinogens, use the signal word "Danger". For Category 2 carcinogens, use the signal word "Warning".

6.4 Hazard statements

Hazard statements refer to the phrases that are assigned to a hazard class and category. It is used to describe the dangerous nature of a dangerous product. In the appropriate circumstances, it also includes the degree of danger. Hazard statements of self-reactive substances and mixtures are shown in Annex D.

6.5 Precautionary Statements

Precautionary statements are phrases (and / or pictograms) used to describe the recommended measures, in order to reduce as much as possible or prevent the adverse effect because of contacting dangerous products, or inappropriately storing or handling dangerous products. There are total 5 types of precautionary statements: general, prevention, emergency response, storage and disposal. Precautionary statements of carcinogenicity are shown in Annex D.

6.6 Product Identifier

6.6.1 The label shall include product identifier. And it shall be consistent with the product identifier in the Material Safety Data Sheet. If a substance or mixture is included in the "Model Regulations", the United Nations shipping name shall also be used properly on the packaging.

6.6.2 The label shall include the chemical name of the substance. For mixture or alloy, when acute toxicity, skin or respiratory sensitive or specific target organ toxicity APPEAR on the label, the label shall include all ingredients that may cause these dangers, or chemical name of alloy elements. Competent authorities may require to list all ingredients that may cause mixture or alloy danger, or chemical name of alloy elements on the label.

6.7 Supplier Identification

The label shall include the manufacturer who provides the substance or mixture, or the supplier's name, address, and telephone number.

6.8 Label examples

Label examples of carcinogenicity is shown in Annex E.

Annex D

(Informative)

Hazard statements and precautionary statements of carcinogenicity

D.1 Introduction

D.1.1 This Annex provides how to use the hazard statements and precautionary statements guidance to comply with GHS for self-reactive substances and mixtures. List of hazard statements and precautionary statements of each hazard class and hazard category of self-reactive substances and mixtures is shown in GB 13690.

D.1.2 Codification of hazard statements

D.1.2.1 Codification of hazard statements is shown in Annex 3 of GHS.

D.1.2.2 Hazard statements are assigned a unique alphanumerical code which consists of one letter and three numbers, as follows:

- a) the letter “H” (for “hazard statement”);
- b) the first number designating the type of hazard to which the hazard statement is assigned according to the numbering of the different parts of the GHS, as follows:
 - “2” for physical hazards;
 - “3” for health hazards;
 - “4” for environmental hazards;
- c) the next two numbers corresponding to the sequential numbering of hazards arising from the intrinsic properties of the substance or mixture, such as explosivity (codes from 200 to 210), flammability (codes from 220 to 230), etc.

D.1.2.3 All assigned hazard statements should appear on the label unless there are other specifications. The competent authority may specify the order in which they appear. Also, where a combined hazard statement is indicated for two or more hazard statements, the competent authority may specify whether the combined hazard statement or the corresponding individual statements should appear on the label, or may leave the choice to the manufacturer/supplier.

D.1.3 Precautionary statements, together with the harmonized hazard communication elements (pictograms, signal words and hazard statements), shall appear on the label which complies with the requirements. Additional supplemental information, such as instructions for use, may also be provided at the discretion of the manufacturer/supplier and/or the competent authority.

D.1.3.1 Codification of precautionary statements is shown in Annex 3 of GHS.

D.1.3.2 Codification of precautionary statements

D.1.3.2.1 Precautionary statements are assigned a unique alphanumerical code which consists of one letter and three numbers as follows:

- a) the first letter “P” (for “precautionary statement”)
- b) one number designating the type of precautionary statement as follows:
 - “1” for general precautionary statements;
 - “2” for prevention precautionary statements;
 - “3” for response precautionary statements;
 - “4” for storage precautionary statements;
 - “5” for disposal precautionary statements;
- c) the next two numbers (corresponding to the sequential numbering of precautionary statements).

D.1.3.2.2 The precautionary statement codes are intended to be used for reference purposes. They are not part of the precautionary statement text and should not be used to replace it.

D.2 General precautionary statements

General precautionary measures shall be adopted for all substances and mixtures which are classified as hazardous to human health or the environment. The following general precautionary statements on the GHS label are appropriate under the given conditions (see Table D.1).

Table D.1 General precautionary statements

Object	Supplemental information	Code	General precautionary statements
General public	Label, supplemental label information	P101	If medical advice is needed: Have product container or label at hand.
		P102	Keep out of reach of children.

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