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No. 2015- 011

**SUBJECT :** **GUIDANCE MANUAL FOR DAO 2015-09 "RULES AND PROCEDURES FOR THE IMPLEMENTATION OF THE GLOBALLY HARMONIZED SYSTEM (GHS) OF CLASSIFICATION AND LABELLING OF CHEMICALS IN PREPARATION OF SAFETY DATA SHEET(SDS) AND LABELLING REQUIREMENTS OF TOXIC CHEMICAL SUBSTANCES"**

Pursuant to Department Administrative Order (DAO) 2015-09, the following Manuals are issued for use by EMB and industry practitioners.

A. Guidance Manual for Classification of Chemicals
B. Initial List of Single Substances and Compounds Covered Under the Chemical Control Order (CCO) and Priority Chemical List (PCL)
C. GHS Pictograms
D. Guidance Manual on the Preparation of Labels
E. Guidance Manual on the Preparation of safety Data Sheet (SDS)

As such, DAO 2015-09 shall be implemented in accordance with the general rules, requirements and procedures described in these manuals.

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DENR Assistant Secretary and
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Department of Environment and
Natural Resources
ENVIRONMENTAL MANAGEMENT BUREAU
Office of the Director
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# GUIDANCE MANUAL FOR DEPARTMENT ADMINISTRATIVE ORDER 2015-09, "RULES AND PROCEDURES FOR THE IMPLEMENTATION OF THE GLOBALLY HARMONIZED SYSTEM (GHS) OF CLASSIFICATION AND LABELLING OF CHEMICALS IN PREPARATION OF SAFETY DATA SHEET (SDS) AND LABELING REQUIREMENTS OF TOXIC CHEMICAL SUBSTANCES"

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## A. GUIDANCE MANUAL FOR CLASSIFICATION OF CHEMICALS

## D. GUIDANCE MANUAL ON THE PREPARATION OF GHS LABELS

## E. GUIDANCE MANUAL ON PREPARATION OF SAFETY DATA SHEET (SDS)

# A. Guidance Manual for Classification of Chemicals

This "GHS Guidance Manual" for the Classification and Labeling of Substances has been prepared to assist companies, primarily the Small and Medium Enterprises (SMEs) and other business entities who are engaged in the manufacture, selling, trading, retailing and repacking of chemicals, in the classification and labeling of substances including preparation of Safety Data Sheet (SDS) for the initial sixty-four (64) pure chemicals on the basis of their health and environmental effects such as persistency to the environment, carcinogenicity, mutagenicity and reproductive toxicity as prescribed by this Order. The purpose is to provide practical methods for data collection and evaluation criteria for data reliability necessary in arriving at the appropriate classification.

This GHS Guidance is a manual based on the UN Purple Book Globally Harmonized System of Classification and Labeling of Chemicals fourth (4th) revised edition to consistently present global harmonization and allow GHS classification to be carried out correctly and effectively by the companies. Any results of classification obtained from the use of this guidance manual, including the responsibility of the results, shall be that of the company.

## 1.0 General rules

1.1 Classify all chemicals covered under the Priority Chemical List (PCL) and Chemical Control Order (CCO) according to the GHS classification criteria.

1.2 Classification shall be conducted by a competent person to ensure accuracy of information.

1.3 Testing of animals is discouraged during the classification of substances. Utilize the available information from recognized websites and information sources.

1.4 If classification is already provided by the original or principal manufacturer of the substance, an importer or trader will use such classification.

## 2.0 Classification guidance

This section presents the guidelines for the proper classification of chemicals including determination of appropriate category for each hazard class.

## 2.1 PHYSICAL HAZARDS

This section defines and explains the 16 hazard classes based on GHS physical hazards. However, during classification, they can be reduced depending on the state of the substance (gas, liquid and solid). Furthermore, they can also be narrowed down depending on their chemical structures. Figures below explain the narrowing down of classification.

## 2.2 PHYSICAL HAZARDS GUIDANCE

**Figure 2.2.1 Narrowing Down the Applicable Hazard Classes**

Narrowing down based on states of the chemicals

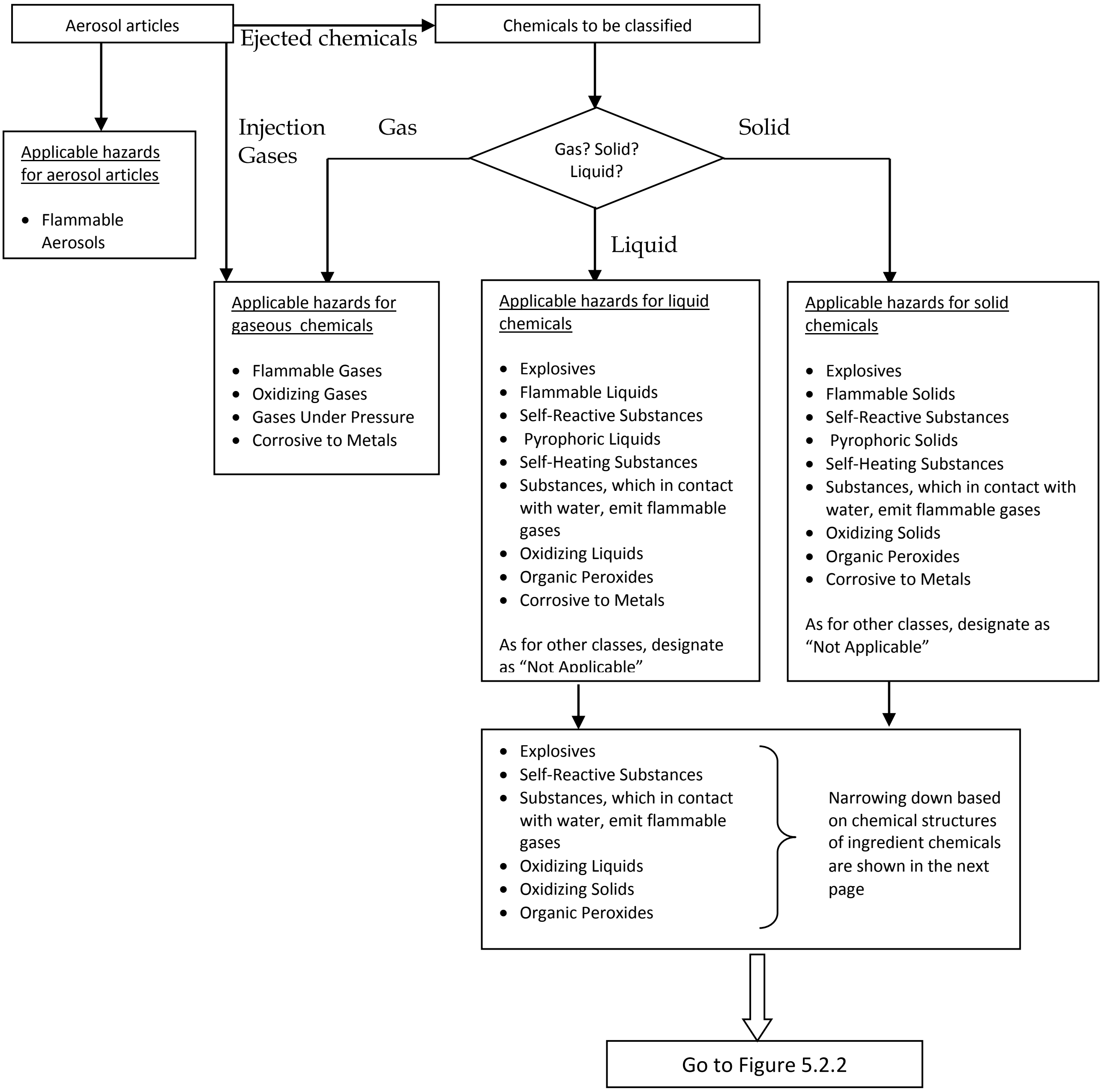


**Figure 2.2.2 Narrowing Down the Applicable Hazard Classes**

Narrowing down based on molecular structures of ingredient chemicals

If chemicals (mixture ingredients) do not contain in their molecules chemical groups shown in Table 2.5.2

As for Explosives, designate as “Not Applicable”

If chemicals (mixture ingredients) do not contain in their molecules chemical groups shown in Table 2.5.2 or Table 2.5.3

As for Self-Reactive Substances, designate as “Not Applicable”

If chemicals (mixture ingredients) do not contain in their molecules metals or mettaloids

As for Substances which, in contact with water, emit flammable gases, designate as “Not Applicable”

1. Organic substances which do not contain oxygen, chlorine, or fluorine, or which contain any of these elements that are bound to carbon or hydrogen only.
2. Inorganic substances not containing oxygen or any halogen element.

As for Oxidizing Liquids and Oxidizing Solids, designate as “Not Applicable”

1. Inorganic substances
2. Organic compounds which in their molecules do not contain any of O-O- linkage

As for Organic Peroxides, designate as “Not Applicable”

**Narrowing down based on contents of ingredient chemicals and the like**

1. Containing chemical groups in Table 2.5.2 including oxygen but the calculated result of oxygen balance is less than -200
   (Calculation) As for carbon, hydrogen, and oxygen in molecular formula (CxHyOz).
   Oxygen balance = $-1600 \times (2x + y/2 - z)$ / molecular weight

As for Explosives, designate as “Not Classified”

## 2.3 DEFINITION OF PHYSICO-CHEMICAL IN GHS

In GHS context, a substance means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurities deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

### 2.3.1 GASES

Gas is defined as a substance which (i) at 50°C has a vapour pressure greater than 300 kPa (absolute); or (ii) is completely gaseous at 20°C at a standard pressure of 101.3 kPa.

### 2.3.2 LIQUIDS

Liquid is defined as a substance which at 50°C has a vapour pressure of not more than 300 kPa (3 bar), which is not completely gaseous at 20°C and at a standard pressure of 101.3 kPa, and which has a melting point or initial melting point of 20°C or less at a standard pressure of 101.3 kPa. A viscous substance for which a specific melting point cannot be determined shall be subjected to the ASTM 2 4359-90 test; or to the test for determining fluidity (pemetrometer test) prescribed in section 2.3.4 of Annex A of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR).

### 2.3.3 SOLIDS

Solid is defined as a substance which does not meet the definitions of liquid or gas. Solids may be in the form of powder, granules, paste, mass, fiber, tablet, etc. It must be noted that the hazards of powdered substances vary depending on their particle size. That is why, hazards that a substance has in its current form should be assessed instead of hazards inherent to the substance.

# SECTION 2.4

# PHYSICAL HAZARDS

## SECTION 2.4.1

## EXPLOSIVES

### 2.4.1.1Definitions

2.4.1.1.1 An explosive substance (or mixture) is a solid or liquid substance (or mixture of substances) which is in itself capable by chemical reaction of producing gas at such a temperature and pressure and at such a speed as to cause damage to the surroundings. Pyrotechnic substances are included even when they do not evolve gases.

2.4.1.1.2 A pyrotechnic substance (or mixture) is a substance or mixture of substances designed to produce an effect by heat, light, sound, gas or smoke or a combination of these as the result of non-detonative self-sustaining exothermic chemical reactions.

2.4.1.1.3 An explosive article is an article containing one or more explosive substances or mixtures.

2.4.1.1.4 A pyrotechnic article is an article containing one or more pyrotechnic substances or mixtures.

The class of explosives comprises:

(a) Explosive substances and mixtures;

(b) Explosive articles, except devices containing explosive substances or mixtures in such quantity or of such a character that their inadvertent or accidental ignition or initiation shall not cause any effect external to the device either by projection, fire, smoke, heat or loud noise; and

(c) Substances, mixtures and articles not mentioned under (a) and (b) above which are manufactured with the view to producing a practical, explosive or pyrotechnic effect.

### 2.4.1.2Classification criteria in GHS

2.4.1.2.1 Substances, mixtures and articles of this class, which are not classified as an unstable explosive, are assigned to one of the following six divisions depending on the type of hazard they present:

(a) Division 1.1 Substances, mixtures and articles which have a mass explosion hazard (a mass explosion is one which affects almost the entire quantity present virtually instantaneously);

(b) Division 1.2 Substances, mixtures and articles which have a projection hazard but not a mass explosion hazard;

(c) Division 1.3 Substances, mixtures and articles which have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but not a mass explosion hazard:

  (i) combustion of which gives rise to considerable radiant heat; or

  (ii) which burn one after another, producing minor blast or projection effects or both;

(d) Division 1.4 Substances, mixtures and articles which present no significant hazard: substances, mixtures and articles which present only a small hazard in the event of ignition or initiation. The effects are largely confined to the package and no projection of fragments of appreciable size or range is to be expected. An external fire shall not cause virtually instantaneous explosion of almost the entire contents of the package;

(e) Division 1.5 Very insensitive substances or mixtures which have a mass explosion hazard: substances and mixtures which have a mass explosion hazard but are so insensitive that there is very little probability of initiation or of transition from burning to detonation under normal conditions;

(f) Division 1.6 Extremely insensitive articles which do not have a mass explosion hazard: articles which contain only extremely insensitive detonating substances or mixtures and which demonstrate a negligible probability of accidental initiation or propagation.

2.4.1.2.2 Explosives, which are not classified as an unstable explosive, are classified in one of the six divisions above based on Test Series 2 to 8 in Part I of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria according to the following table:

**Table 2.4.1.1: Criteria for explosives**

| Category | Criteria |
|---|---|
| Unstable [a] explosives or explosives of Division 1.1 to 1.6 | For explosives of Divisions 1.1 to 1.6, the following are the core set of tests that need to be performed:<br>Explosibility: according to UN Test Series 2 (Section 12 of the *UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria*). Intentional explosives [b] are not subject to UN Test series 2.<br>Sensitiveness: according to UN Test Series 3 (Section 13 of the *UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria*).<br>Thermal stability: according to UN Test 3(c) (Sub-section 13.6.1 of the *UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria*).<br>Further tests are necessary to allocate the correct Division. |

a *Unstable explosives are those which are thermally unstable and/or too sensitive for normal handling, transport and use. Special precautions are necessary.*

b *This comprises substances, mixtures and articles which are manufactured with a view to producing a practical, explosive or pyrotechnic effect.*

***NOTE 1:*** *Explosive substances or mixtures in packaged form and articles may be classified under divisions 1.1 to 1.6 and, for some regulatory purposes, are further subdivided into compatibility groups A to S to distinguish technical requirements (see UN Recommendations on the Transport of Dangerous Goods, Model Regulations, Chapter 2.1).*

***NOTE 2:*** *Some explosive substances and mixtures are wetted with water or alcohols or diluted with other substances to suppress their explosives properties. They may be treated differently from explosive substances and mixtures (as desensitized explosives) for some regulatory purposes (e.g. transport).*

***NOTE 3:*** *For classification tests on solid substances or mixtures, the tests should be performed on the substance or mixture as presented. If for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, the substance or mixture must also be tested in the new form.*

### 2.4.1.3 Guidance for classification

2.4.1.3.1Explosive properties are associated with the presence of certain chemical groups in a molecule which can react to produce very rapid increases in temperature or pressure. The screening procedure is aimed at identifying the presence of such reactive groups and the potential for rapid energy release. If the screening procedure identifies the substance to be a potential explosive, the acceptance procedure (see section 10.3 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria) has to be performed.

2.4.1.3.2 A substance shall not be classified as explosive if:

a. There are no chemical groups associated with explosive properties present in the molecule. Examples of groups which may indicate explosive properties are given in Table A6.1 in Appendix 6 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria; or

b. The substance contains chemical groups associated with explosive properties which include oxygen and the calculated oxygen balance is less than -200.

   The oxygen balance is calculated for the chemical reaction:

   $CxHyOz + [x + (y/4)]\, O_2 \rightarrow x.\, CO_2 + (y/2)\, H_2O$

   Using the formula :

   Oxygen balance = -1600 [2x + (y/2) – z]/ molecular weight;

c. When the organic substance or a homogeneous mixture of organic substances contain chemical groups associated with explosive properties but the exothermic decomposition energy is less than 500 J/g and the onset of exothermic decomposition is below 500°C. (The temperature limit is to prevent the procedure being applied to a large number of organic materials which are not explosive but which will decompose slowly above 500°C to release more than 500 J/g). The exothermic decomposition energy may be determined using a suitable calorimetric technique

2.4.1.3.3 Judgment of: “Not Applicable” (Narrowing down the applicable classes by the state and molecular structure of the substance)

2.4.1.2.3.1 If a substance falls under Gases, its “Classification result” shall be “Not Applicable”, and indicate “a gas according to GHS definition” for “Classification Grounds”

2.4.1.2.3.2 If a substance does not contain chemical groups related to explosivity, it shall be “Not Applicable”, and indicate “It does not contain chemical groups related to explosivity” for “Classification Grounds”.

2.4.1.3.4 Judgment of "Not Classified" (Narrowing down the applicable classes by the contents of ingredients or preliminary measurement results)

2.4.1.3.4.1 For substances having explosive chemical groups including oxygen and falling under the provisions of the following UN GHS the fourth edition 2.1.4.2.2 (b)-(d) (based on calculation result of oxygen balance, exothermic decomposition energy, and content of inorganic compounds), "Classification result" shall be "Not Classified", and "based on calculation result calculated value : XX)" shall be indicated for "Classification Grounds".

2.4.1.3.5 Judgment of "Classified"

When the existing classification results shown in Table 5.4.1.1are available, after examination of the classification result and the evidence data, the Category shall be determined.

2.4.1.3.6 Classification based on existing classifications such as UNRTDG

2.4.1.3.6.1 If the category is not determined after following the procedure described below, perform the pre-determined tests (or tests providing the equivalent judgment), and determine the Category.

2.4.1.3.6.1.1 Substances cited in (8.4.1.6) shall be classified according to the UNRTDG Classification

2.4.1.3.6.1.2 Based on results of test series for UNRTDG classification, "Desensitized Explosives" do not fall under Classes 1.1 – 1.6, and accordingly, not in "explosives" in GHS either. For substances falling under "Desensitized Explosives", regarding "Explosives", "Classification result" shall be "Classification Not Possible", and "Test method not determined" shall be indicated for "Classification Grounds".

### 2.4.1.4 Testing Methods

2.4.1.4.1 Classify unstable explosives and explosives of Category 1.1 through Category 1.6 with the following tests:

2.4.1.4.1.1 Explosive properties : UNRTDG Manual of Tests and Criteria Item 12, Test series 2

2.4.1.4.1.2 Sensitivity : UNRTDG Manual of Tests and Criteira Item 13, test series 3

2.4.1.4.1.3 Thermal Stability : UNRTDG Manual of Tests and Criteria Item 13.6.1, Test series (C)

2.4.1.4.1.4 Articles designated as packaged articles may be categorized into Categories 1.1. to 1.6, and UNRTDG furthermore sub-categories to clearly show the technical requirements.

2.4.1.4.1.5 If explosives are desensitized by wetting with water or alcohols or dilutin with other substances, they may be classified other than explosives as desensitized explosives.

2.4.1.4.1.6 Unstable explosives are explosives being thermally unstable and too sensitive for usual handling.

### 2.4.1.5 Data availability

It must be noted that the performance of explosives depends on their composition, and data regarding explosive performance of each substant are limited.

### 2.4.1.6 Comparison with conventional classification systems

Divisions 1.1 – 1.6 described above follow the definition of Divisions of UNRTDG 2.1.1.4

### 2.4.1.7 Sources of information for classification results under conventional systems

The UNRTDG list of dangerous goods (for example, the Annex 1: Dangerous Goods Regulations) includes the following substance:

| Division | Explanation | Examples of UN Number and Substance |
|---|---|---|
| Division 1.1 | Equivalent to UNRTDG 1.1 | 0004 AMMONIUM PICRATE dry or wetted with less than 10% water, by mass<br>0028 BLACK POWDER (GUNPOWDER), COMPRESSED or BLACK POWDER (GUNPOWDER), IN PELLETS<br>0072 CYCLOTIMETHYLENETRINITAMINE (CYCLONITE; HEXOGEN; RDX), WETTED with not less than 15% water, by mass<br>0074 DIAZODINITROPHENOL, WETTED with not less than 40% water, or mixture of alcohol and water, by mass<br>0075 DIETHYLENEGLYCOL DINITRATE, DESENSITIZED |

| | | |
|---|---|---|
| | | with not less than 25% non-volatile, water-insoluble phlegmatizer, by mass<br>0076 DINITORPHENOL, dry or wetted with less than 15% water, by mass |
| Division 1.2 | Equivalent to UNRTDG 1.2 | At present, only articles have UN numbers, but substances may be included in accordance with the definition. |
| Division 1.3 | Equivalent to UNRTDG 1.3 | 0161 POWDER, SMOKELESS<br>0234 SODIUM DINITRO-o-CRESOLATE, dry or wetted with less than 15% water, by mass<br>0235 SODIUM PICRAMATE, dry or wetted with less than 20% water, by mass<br>0236 ZIRCONIUM PICRAMATE, dry or wetted with less than 20% water, by mass<br>0342 NITROCELLULOSE, WETTED with not less than 25% alcohol by mass |
| Division 1.4 | Equivalent to UNRTDG 1.4 | 0407 TETRAZOL-1-ACETIC ACID<br>0448 5-MERCAPTOTETRAZOL-1-ACETIC ACID |
| Division 1.5 | Equivalent to UNRTDG 1.5 | 0331 EXPLOSIVE, BLASTING, TYPE B (AGENT, BLASTING, TYPE B) |
| Division 1.6 | Equvalent to UNRTDG 1.6 | There is no article with a specific name that fall under this division |

| Division | Explanation | Examples of UN Number and Substance |
|---|---|---|
| Unstable explosives | Explosive substances and articles whose transport is prohibited, and explosives listed in 1979 Notice 549 from the Ministry of Transport" Public Notice to provide Standards, etc., for Carriage of Dangerous Goods by ship" Article 5 (1). | (a) AMMONIUM BROMATE<br>(b) AMMONIUM BROMATE SOLUTION<br>(c) AMMONIUM CHLORATE<br>(d) AMMONIUM CHLORATE SOLUTION<br>(e) AMMONIUM CHLORITE<br>(f) AMMONIUM NITRATE (excluding those listed in Annex 1) |
| Desensitized explosives (GHS 2.1.2.2 Note 2) | Some explosives which are wetted with water or alcohols, etc. to suppress their explosive properties does not meet the criteria for GHS Explosives. They are included in Class 3 and a part of Class 4.1 in | UNRTDG 3*EmS:F-E<br>1204 NITROGLYCERIN SOLUTION IN ALCOHOL with not more than 1% nitroglycerin<br>2059 NITROCELLULOSE SOLUTION, FLAMMABLE with not more than 12.6% nitrogen, by dry mass, and not |

| | | |
|---|---|---|
| | UNRTDG, and they fall under the substance specified in Schedule 113 (Flammable Solids-Toxic substances (wetted/ desensitized explosives) in ERG. They are F-E (Flammable Liquids not reacting with water) and S-J (wetted explosives and self-exothermic substances) in EmS | more than 55% nitrocellulose<br>UNRTDG 4.1*ERG113<br>1310 AMMONIUM PICRATE, WETTED with not less than 10% water, by mass<br>UNRTDG 4.1*EmS:S-J<br>1320 DINITROPHENOL, WETTED with not less than 15% water by mass<br>1336 NITROGUANDINE (PICRITE), WETTED with not less than 20% water, by mass<br>1337 NITROSTARCH, WETTED with not less than 20% water, by mass<br>1354 TRINITOBENZENE, WETTED with not less than 30% water, by mass<br>1355 TRINITROBENZOIC ACID, WETTED with not less than 30% water, by mass |

### 2.4.1.8 Hazard Communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labelling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.4.1.2: Label elements for explosives**

| | ***Unstable Explosive*** | ***Division 1.1*** | **Division 1.2** | **Division 1.3** | **Division 1.4** | **Division 1.5** | **Division 1.6** |
|---|---|---|---|---|---|---|---|
| **Symbol** | Exploding bomb | Exploding bomb | Exploding bomb | Exploding bomb | Exploding bomb;<br>***or***<br>1.4 on orange background[a] | 1.5 on orange background[a] | 1.6 on orange background[a] |
| **Signal word** | Danger | Danger | Danger | Danger | Warning | Danger | *No signal word* |
| **Hazard statement** | Unstable Explosive | Explosive; mass explosion hazard | Explosive; severe projection hazard | Explosive; fire, blast or projection hazard. | Fire or projection hazard | May mass explode in fire | *No hazard statement* |

[a] *Applies to substances, mixtures and articles subject to some regulatory purposes (e.g. transport).*

# SECTION 2.4.2

## FLAMMABLE GASES (INCLUDING CHEMICALLY UNSTABLE GASES)

### 2.4.2.1 Definitions

2.4.2.1.1 A flammable gas is a gas having a flammable range with air at 20 °C and a standard pressure of 101.3 kPa.

2.4.2.1.2 A chemically unstable gas is a flammable gas that is able to react explosively even in the absence of air or oxygen.

### 2.4.2.2 Classification Criteria in GHS

2.4.2.2.1 A flammable gas shall be classified in one of the two categories for this class according to the following table:

**Table 2.4.2.1 Criteria for Flammable Gases**

| Category | Criteria |
|---|---|
| 1 | Gases, which at 20°C and a standard pressure of 101.3 kPa:<br>(a) Are ignitable when in a mixture of 13% or less by volume in air; or<br>(b) Have a flammable range with air of at least 12 percentage points regardless of the lower flammable limit. |
| 2 | Gases, other than those of Category 1, which, at 20°C and a standard pressure of 101.3 kPa, have a flammable range while mixed in air. |

Note 1: Ammonia and methyl bromide may be regarded as special cases for some regulatory purposes.

Note 2: Aerosols should not be classified as flammable gases.

2.4.2.2.2 A flammable gas that is also chemically unstable is additionally classified in one of the two categories for chemically unstable gases using the methods described in Part III of the Manual of Tests and Criteria according to the following table:

**Table 2.4.2.2 Criteria for chemically unstable gases**

| Category | Criteria |
|---|---|
| A | Flammable gases which are chemically unstable at 20°C and a standard pressure of 101.3 kPa |
| B | Flammable gases which are chemically unstable at a temperature greater than 20°C and/or a pressure greater than 101.3 kPa |

### 2.4.2.3 Hazard Communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labelling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.4.2.3 Label Elements for Flammable Gases (including chemical unstable gases)**

| | Flammable gas | | Chemically unstable gas | |
|---|---|---|---|---|
| | **Category 1** | **Category 2** | **Category A** | **Category B** |
| **Symbol** | Flame | No symbol | No additional symbol | No additional symbol |
| **Signal word** | Danger | Warning | No additional signal word | No additional signal word |
| **Hazard statement** | Extremely flammable gas | Flammable gas | May react explosively even in the absence of air | May react explosively even in the absence of air at elevated pressure and/or temperature |

### 2.4.2.4 Guidance for classification

2.4.2.4.1 Flammability shall be determined by tests or by calculation in accordance with methods adopted by ISO (see ISO 10156:2010 “Gases and gas mixtures – Determination of fire potential and oxidizing ability for the selection of cylinder valve outlets”). Where insufficient data are available to use these methods, tests by a comparable method recognized by the competent authority may be used.

2.4.2.4.2 Chemical instability shall be determined in accordance with the method described in Part III of the Manual of Tests and Criteria. If the calculations in accordance with ISO 10156:2010 show that a gas mixture is not flammable it is not necessary to carry out the tests for determining chemical instability for classification purposes.

2.4.2.4.3 Judgmentof “Not Applicable” (Narrowing down the applicable classes by the state and molecular structure of the substance)

A product which does not meet the GHS definition for gases shall be judged as “Not Applicable”.

2.4.2.4.4 Judgment of “Not Classified”

Non-combustible and oxidative gases shall be judged as “Not classified”.

2.4.2.4.5 Judgment of “Classified”

When the existing classification results shown in Table 2.4.2.1 or Table 2.4.2.2 are available, after examination of the classification result and the evidence data, the Category shall be determined.

2.4.2.6 Classification based on existing classifications and the like (such as UNRTDG)

Substances designated as Class 2.1 (or Subsidiary Class 2.1) in the UNRTDG classification Table shall be categorized in GHS Category 1.

2.4.2.6.1 Classification based on data from prescribed literatures

Classification shall be performed based on data of combustible range or explosion limit in prescribed review documents according to the UN GHS 4th revised edition 2.2.2

**2.4.2.7 Data availability**

Physical properties of gaseous substances with single ingredient are relatively easy to obtain from such as literatures. All of combustible / flammable gases at ambient temperature and pressure shall be flammable gases. When data of combustible range (what is called explosive limit) are available, it is easy to pass a judgment for classification of a single gas

**2.4.2.8 Sources of information for classification results under conventional systems**

2.4.2.8.1 UN Dangerous Goods Transportation

The definition of Division 2.1 described in UNRTDG 2.2.2.1 is in accordance with that of GHS Category 1

Category 1 = UNRTDG 2.1 and 2.3.2 (2.1)

Category 2 = Flammable gas which is not included in Category 1

2.4.2.8.2 In GHS, “flammable gases” may include gases with ambient pressure because of the omission of the condition of gases under pressure.

| Category | Explanation | Examples of UN Number and Substance |
|---|---|---|
| 1 | Equivalent to UNRTDG 2.1 | 1012 BUTYLENE<br>1036 ETHYLAMINE<br>1049 HYDROGEN, COMPRESSED<br>1978 PROPANE<br>2203 SILANE<br>2454 METHYL FLOURIDE (REFRIGERANT GAS R-41)<br>3153 PERFLUORO (METHYL VINYL ETHER) |
|  | Equivalent 2.3 (2.1) | 1053 HYDROGEN SULPHIDE<br>1082 RIFLUOROCHLOROETHYLENE, STABILIZED<br>2188 ARSINE<br>2204 CARBONYL SULPHIDE |
| 2 |  | 1062 METHYL BROMIDE |

2.4.2.8.3 Other classification

It corresponds to Schedule F-D in EmS. S-U also includes toxic gases. In ERG, the provisions for flammable gases are divided into Schedules 115, 116, 117, 118 and 119.

In EU DSD classification, gaseous substances with R-phrase 12 meet these criteria (Categories 1 and 2), but no categorization is shown

# SECTION 2.4.3

# AEROSOLS

## 2.4.3.1 Definitions

2.4.3.1.1 Aerosols, this means aerosol dispensers, are any non-refillable receptacles made of metal, glass or plastics and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state or in a gaseous state.

## 2.4.3.2 Classification Criteria

2.4.3.2.1 Aerosols shall be considered for classification as flammable if they contain any component which is classified as flammable according to the GHS criteria, i.e.:

Flammable liquids (see 2.4.6)

Flammable gases (see 5.4.2)

Flammable solids (see 5.4.7)

Note 1: Flammable components do not cover pyrophoric, self-heating or water-reactive substances because such components are never used as aerosol contents.

Note 2: Aerosols do not fall additionally within the scope of section 2.4.2 (Flammable gases), section 2.4.5 (Gases under pressure), section 2.4.6 (Flammable liquids) and section 2.4.7 (Flammable solids). Depending on their contents, aerosols may however fall within the scope of other hazard classes, inclusding their labelling elements.

2.4.3.2.2An aerosol is classified in one of the three categories for this Class on the basis of its components, of its chemical heat of combustion and, if applicable, of the results of the foam test (for foam aerosols) and of the ignition distance test and enclosed space test (for spray aerosols). Aerosols which do not meet the criteria for inclusion in Category 1 or Category 2 (extremely flammable or flammable aerosols) should be classified in Category 3 (non-flammable aerosols).

2.4.3.2.3 The GHS classification criteria are summarized as follows:

Category 1 : Aerosols whose content of flammable components is 85% or more and whose heat of combustion is 30kJ/ g or larger, or

Spray aerosols for which ignition occurs at a distance of 75 cm or more in the ignition distance test, or

Foam aerosols which have, in the foam test, 20 cm or more of the flame height and 2 seconds or longer of the flame duration of have 4 cm or more of the flame height and 7 seconds or longer of the flame duration

Category 2 : Spray aerosols for which the heat of combustion is 20kJ/g or larger and either for which ignition occurs at a distance of 15 cm or more in the ignition distance test or for which the time equivalent is 300 second/ $m^3$ or less, or the deflagration density is 300 g/$m^3$ or less, in the enclosed space ignition test

Foam aerosols which have, in the foam test, 4 cm or more of the flame height and 2 seconds or longer of the flame duration

Not Classified : (1) aerosols whose content of flammable components is 1% or less and the heat of combustion is smaller than 20 kJ/g

(2) aerosols which was not judged as " Category 1 or 2" in the enclosed space ignition test for spray aerosols

(3) aerosols which was not judged as "Category 1 or 2" in the foam test for foam aerosols

### 2.4.3.3 Guidance for classification

2.4.3.3.1 Judgment of "Not Applicable"

In classification of a chemical substance, regarding "flammable aerosols", "classification result" shall be "Not Applicable", and "not an aerosol product" shall be indicated for "Classification Grounds and Problems"

2.4.3.3.2 Judgment of "Not Classified"

A product which has no flammable components or whose flammable components is 1% or less and whose heat of combustion smaller than 20kJ/g shall be "Not Classified".

2.4.3.3.3 Judgment of "Classified"

When the existing classification results shown in 2.4.3.2.3 are available, after examination of the classification result and the evidence data, the Category shall be determined.

### 2.4.3.4 Data availability

The composition of an aerosol product shall be determined by its product manufacturer. The categories of spray solutions and propellant gases should be determined according to the 2.3.4.1 of theGHS Purple book with necessary test, if any.

### 2.4.3.5 Comparison with conventional classification systems

A judging method in the Special provision 63 of the UN Number 1950 (Aerosols) in UNRTDG 3.2.1 Dangerous Goods List has been adopted to the GHS decision logic.

### 2.4.3.6 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labelling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.4.3.1 Label elements for flammable and non-flammable aerosols**

| | **Category 1** | **Category 2** | **Category 3** |
|---|---|---|---|
| **Symbol** | Flame | Flame | No symbol |
| **Signal word** | Danger | Warning | Warning |
| **Hazard statement** | Extremely flammable aerosol<br>Pressurized container; May burst if heated | Flammable aerosol<br>Pressurized container: May burst if heated | Pressurized container: May burst if heated |

# SECTION 2.4.4

# OXIDIZING GASES

## 2.4.4.1 Definitions

2.4.4.1.1 An oxidizing gas is any gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than the air does.

2.4.4.1.2 Note : “Gases which cause or contribute to the combustion of other material more than air does” means pure gases or gas mixtures with an oxidizing power greater than 23.5% as determined by a method specified in ISO 10156:2010.

## 2.4.4.2 Classification criteria

2.4.4.2.1 An oxidizing gas shall be classified in a single category for this class according to the following table:

**Table 2.4.4.1 Criteria for oxidizing gases**

| Category | Criteria |
|---|---|
| 1 | Any gas which may, generally by providing oxygen, cause or contribute to the combustion of other materials more than air does |

## 2.4.4.3 Guidance for classification

2.4.4.3.1 Judgment of “Not Applicable”

A product which does not meet the GHS definition of gases shall be judged as “Not Applicable”

2.4.4.3.2 Classification based on existing classifications such as UNRTDG

The substance to be evaluated that is listed as a dangerous good (a gas product whose division number of for its subsidiary hazard is 5.1) in the Dangerous Goods List based on UNRTDG classification shall belong to “Category 1”.

The following gases described in ISO 10156-2 shall also belong to “Category 1”.

| Name of gas | Oxygen equivalency coefficient (Ci) |
|---|---|
| Bis-trifluoromethylperoxide | C i = 40 |
| Bromine pentafluoride | C i = 40 |
| Bromine trifluoride | C i = 40 |

| | |
|---|---|
| Chlorine | C i = 0.7 |
| Chlorine pentafluoride | C i = 40 |
| Chlorine trifluoride | C i = 40 |
| Fluorine | C i = 40 |
| Iodine pentafluoride | C i = 40 |
| Nitric oxide | C i = 0.3 |
| Nitrogen dioxide | C i = 1 |
| Nitrogen trifluoride | C i = 1.6 |
| Nitrogen trioxide | C i = 40 |
| Oxygen difluoride | C i = 40 |
| Ozone | C i = 40 |
| Tetrafluorohydrazine | C i = 40 |

For reference: ISO 10156-2, describing an international test method on “oxidizing gases” was established in August 2005. Because this test requires an immense amount of time and effort and involves risk of explosion, the measurement results for coefficient of oxygen equivalency have been obtained only for a few substances before the establishment of the ISO.

2.4.4.3.3 Judgment of “Not Classified”

Other (non-oxidizing) gases than described above shall be judged as “Not Classified”.

2.4.4.3.4 Judgment of “Classified”

When the existing classification results shown in Table 8.4.4.1are available, after examination of the classification result and the evidence data, the Category shall be determined.

### 2.4.4.4 Data availability

Calculation shall be performed in accordance with ISO 10156: 2010 based on the composition as prescribed in GHS 2.4.4.2 4th edition of the UN Purple Book.

### 2.4.4.5 Comparison with conventional classification systems

The UNRTDG definition (UNRTDG 2.5.2) for oxidizing substances (Division 5.1) is limited to liquids and solids. In UNRTDG, no classification criteria are available for oxidizing gases, while some gases assigned with the division number 5.1 for their subsidiary hazard, but the assignment is not comprehensive. Oxidizing gases fall under Schedule 122 in ERG and S-W in EmS on the basis of which oxidizing gases can be selected.

### 2.4.4.6 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labelling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.4.4.2 Label elements for oxidizing gases**

| | **Category 1** |
|---|---|
| **Symbol** | Flame over circle |
| **Signal word** | Danger |
| **Hazard statement** | May cause or intensify fire; oxidizer |

# SECTION 2.4.5

# GASES UNDER PRESSURE

### 2.4.5.1 Definitions

2.4.5.1.1 Gases under pressure are gases which are contained in a receptacle at a pressure of 200 kPa (gauge) or more at 20°C, or which are liquefied or liquefied and refrigerated.

2.4.5.1.2 Gases under pressure comprise compressed gases, liquefied gases, dissolved gases and refrigerated liquefied gases.

### 2.4.5.2 Classification criteria

2.4.5.2.1 Gases under pressure shall be classified, according to their physical state when packaged, in one of four groups in the following table:

**Table 2.4.5.1 Criteria for gases under pressure**

| Group | Criteria |
|---|---|
| **Compressed gas** | A gas which when packaged under pressure is entirely gaseous at -50°C; including all gases with a critical temperature $\leq$ -50°C |
| **Liquefied gas** | A gas which when packaged under pressure, is partially liquid at temperatures above -50°C. A distinction is made between:<br>(a) High pressure liquefied gas: a gas with a critical temperature between -50°C and +65°C; and<br>(b) Low pressure liquefied gas: a gas with a critical temperature above +65°C |
| **Refrigerated liquefied gas** | A gas which when packaged is made partially liquid because of its low temperature |
| **Dissolved gas** | A gas which when packaged under pressure is dissolved in a liquid phase solvent |

The critical temperature is the temperature above which a pure gas cannot be liquefied, regardless of the degree compression.

### 2.4.5.3 Guidance for classification

2.4.5.3.1 Judgment of "Not Applicable"

Substances that are liquid or solid according to the GHS definition shall be judged ad "Not Applicable".

2.4.5.3.2 Classification based on data from prescribed literatures

In GHS classes of gas, “gases under pressure” are conditions made in the pressure vessels by manufacturers depending on their purposes such as transport and use. And other properties (flammable gases, oxidizing gases, acute inhalation toxicity) are based on hazards when these gases exist in air at a standard pressure.

2.4.5.3.3 Judgment of “Classified”

When the existing classification results shown in Table 5.4.5.1are available, after examination of the classification result and the evidence data, the Category shall be determined.

### 2.4.5.4 Data availability

The data required are vapor pressure at 50°C physical properties at 20°C and atmospheric pressure, and critical temperature (GHS 2.5.4.2). All of them can be obtained easily. Physical conditions, pressure and the like, when compresses in cylinders, depend on the design of manufacturers.

In order to classify a gas, the above data are needed. Data can be found in literature, calculated or determined by testing. Most pure gases are already classified in the UN Recommendations on the Transport of Dangerous Goods, Model Regulations.

### 2.4.5.5 Comparison with conventional classification systems

The definition of Class 2 (gas) set in UNRTDG 2.2.1.2 is in accordance with that of gas in GHS: “a substance that at 50°C has a vapor pressure greater than 300 kPa (absolute pressue); or is completely gaseous at 20°C at a standard pressure of 101.3 kPa”.

On the other hand, UNRTDG does not provide the definition of “gases under pressure”, which are newly defined by GHS as “gases with vapor pressure of 200 kPa or more”.

### 2.4.5.6 Sources of information for classification results under conventional systems

These depend on the design selected by the manufactuers. Inaddition to temperature range and intrinsic pressure of the gas substance set by the manufactuers, literature data such as temperature, vapor pressure curve and critical temperature should be used for classification.

### 2.4.5.7 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labelling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.4.5.2 Label elements for gases under pressure**

| | **Compressed gas** | **Liquefied gas** | **Refrigerated liquefied gas** | **Dissolved gas** |
|---|---|---|---|---|
| **Symbol** | Gas cylinder | Gas cylinder | Gas cylinder | Gas cylinder |
| **Signal word** | Warning | Warning | Warning | Warning |
| **Hazard statement** | Contains gas under pressure; may explode if heated | Contains gas under pressure; may explode if heated | Contains refrigerated gas; may cause cryogenic burns or injury | Contains gas under pressure; may explode if heated |

# SECTION 2.4.6

# FLAMMABLE LIQUIDS

## 2.4.6.1 Definitions

2.4.6.1.1 A flammable liquid means a liquid having a flash point of not more than 93°C.

## 2.4.6.2 Classification criteria

2.4.6.2.1 A flammable liquid shall be classified in one of the four categories for this class according to the following table:

**Table 2.4.6.1 Criteria for flammable liquids**

| Category | Criteria |
|---|---|
| **1** | Flash point <23°C and initial boiling point ≤35°C |
| **2** | Flash point <23°C and initial boiling point >35°C |
| **3** | Flash point ≥ 23°C and ≤ 60°C |

**Note 1:** Gas oils, diesel and light heating oils in the flash point range of 55°C to 75°C may be regarded as a special group for some regulatory purposes.

**Note 2:** Liquids with a flash point of more than 35°C and not more than 60°C may be regarded as non-flammable liquids for some regulatory purposes (e.g. transport) if negative results have been obtained in the sustained combustibility test L.2 of Part III, section 32 of the UN Recommendations on the Transport of Dangerous, Manual of Tests and Criteria.

**Note 3:** Viscous flammable liquids such as paints, enamels, lacquers, varnishes, adhesives and polishes may be regarded as a special group for some regulatory purposes (e.g. transport)> The classification or the decision to consider these liquids as non-flammable may be determined by the pertinent regulation or competent authority.

**Note 4:** Aerosols should not be classified as flammable liquids. See Section 2.4.3

### 2.4.6.3 Guidance for classification

2.4.6.3.1 Judgment of “Not Applicable”

Substances that are gases and solids shall be judged as “Not Applicable”.

2.4.6.3.2 Judgment of “Not Classified”

Non-combustible liquids shall be judged as “Not Classified”. (Dangerous goods among Class 4, Type 4 petroleum and animal oils, and liquids of specified combustible substances shall also be deemed as “Not Classified” with regard to these classes, but the boundary between combustibility and flame resistance is not clearly defined. Accordingly, if judgment is impossible, measure the flash point, and determine the classification.

2.4.6.3.3 Classification based on data from existing literatures

With regards to GHS classification of flammable liquids, categories based on flash points obtained from various information sources and in-house data shall take precedence, and classification based on UNRTDG shall be adopted only when flash points data are not available.

Since Category 4 of flammable liquids in GHS classification does not fall under Dangerous Goods in UNRTDG classification, as for Category 4, UNRTDG classification results cannot be used for GHS classification.

2.4.6.3.4 Judgment of “Classified”

When the existing classification results shown in Table 2.4.6.1are available, after examination of the classification result and the evidence data, the Category shall be determined.

### 2.4.6.4 Comparison with conventional classification systems

In general, Categories 1-3 is in accordance with Class 3 of UNRTDG.

Category 1 = UNRTDG 3I (No upper limits are provided for flash points, but no combustible substance with an initial boiling point of 35°C and lower and a flash point of 23°C or higher has been reported)

Category 2 = UNRTDG 3II

Category 3 = UNRTDG 3III

Category 4 = They are non-dangerous articles in UNRTDG

### 2.4.6.5 Test Methods

2.4.6.5.1 The following test methods for determining the flash point of flammable liquids shall be used:

International standards:

ISO 1516
ISO 1523
ISO 2719
ISO 13736
ISO 3679
ISO 3680

National standards:

American Society for Testing Materials International, 100Barr Harbor Drive, PO Box C 700, West Conshohocken, Pennsylvannia, USA 19428-2959:

ASTM D3828-07a, "Standard Test Methods for Flash Point by Small Scale Closed Cup tester"
ASTM D56-05, "Standard Test Method for Flash Point by Tag Closed Cup Tester"
ASTM D3278-96 (2004)el, "Standard Test Methods for Flash Point of Liquids by Small Scale Closed Cup Apparatus"
ASTM D93-08, "Standard Test Methods for Flash Point by Pensky- Martens Closed Cup Tester"

Association francaise de normalization, AFNOR, 11, rue de Pressense. 93571 La Plaine Saint-Denis Cedex"

French Standard NF M 07-109
French Standards NF M 07-011/ NF T 30-050/ NF T 66-009
French Standard NF M 07-036

Deutsches Institut fur Normung, Burggrafenstr. 6, D-10787 Berlin:

Standard DIN 51755 (flash points below 65°C)

State Committee of the Council of Ministers for Standardization, 113813, GSP, Moscow, M-49 Leninsky Prospect, 9

GOST 12.1.044-84

2.4.6.5.2 The following methods for determining the initial boiling point of flammable liquids shall be used:

International standards:

ISO 3924
ISO 4626
ISO 3405

National standards

American Society for Testing Materials International, 100Barr Harbor Drive, PO Box C 700, West Conshohocken, Pennsylvannia, USA 19428-2959:

ASTM D86-07a, "Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure"
ASTM D1078-05, "Standard Test Method for Distillation Range of Volatile Organic Liquids"

Further acceptable methods:

Method A.2 as described in Part A of the Annex to Commission Regulation (EC) No.440/2008

### 2.4.6.5 Sources of information for classification results under conventional systems

2.4.6.5.1 UN Recommendations on the Transport of Dangerous Goods

Category 1 = UNRTDG 3I

Category 2 = UNRTDG 3II

Category 3 = UNRTDG 3III

Category 4

### 2.4.6.6 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labelling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

### Table 2.4.6.2 Label elements for flammable liquids

| | Category 1 | Category 2 | Category 3 |
|---|---|---|---|
| **Symbol** | Flame | Flame | Flame |
| **Signal word** | Danger | Danger | Warning |
| **Hazard statement** | Extremely flammable liquid and vapour | Highly flammable liquid and vapour | Flammable liquid and vapour |

# SECTION 2.4.7

# FLAMMABLE SOLIDS

## 2.4.7.1 Definitions

2.4.7.1.1 A flammable solid is a solid which is readily combustible, or may cause or contribute to fire through friction.

2.4.7.1.2 Readily combustible solids are powdered, granular, or pasty substances which are dangerous if they can be easily ignited by brief contact with an ignition source, such as a burning match, and if the flame spreads rapidly.

## 2.4.7.2 Classification criteria

2.4.7.2.1 Powdered, granular or pasty substances shall be classified as readily combustible solids when the time of burning of one or more of the test runs, performed in accordance with the test method described in the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Part III, sub-section 33.2.1, is less than 45 s or the rate of burning is more than 2.2 mm/s.

2.4.7.2.2 Powders of metals or metal alloys shall be classified as flammable solids when they can be ignited and the reaction spreads over the whole length of the sample in 10 min or less.

2.4.7.2.3 Solids which may cause fire through friction shall be classified in this class by analogy with existing entries (e.g. matches) until definitive criteria are established.

2.4.7.2.4 A flammable solid shall be classified in one of the two categories for this class using Method N.1 as described in Part III, sub-section 33.2.1 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, according to the following table:

**Table 2.4.7.1 Criteria for flammable solids**

| Category | Criteria |
|---|---|
| **1** | Burning rate test:<br><br>Substances other than metal powders:<br>(a) Wetted zone does not stop fire; and<br>(b) Burning time <45 s or burning rate > 2.2 mm/s<br><br>Metal powders: burning time $\leq$ 5 min |
| **2** | Burning rate test: |

| | |
|---|---|
| | Substances other than metal powders:<br>(a) Wetted zone stops the fire for at least 4 min; and<br>(b) Burning time <45 s or burning rate> 2.2 mm/s<br>Metal powders: burning time > 5 min and ≤ 10 min |

**Note 1:** For classification test on solid substances, the tests should be performed on the substance as presented. If for example, forthe purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, the substance must also be tested in the new form.

**Note 2:** Aerosols shall not be classified as flammable solids. See Section 2.4.8

### 2.4.7.3 Guidance for classification

#### 2.4.7.3.1 Judgment of "Not Applicable"

Substances that are gases and liquids shall be judged as "Not Applicable"

#### 2.4.7.3.2 Judgment of "Not Classified"

Solids known to be non-combustible or flame-resistant by literatures and in-house data, or knowledge regarding oxidation/ reduction reactions, shall be "Not Classified".

#### 2.4.7.3.3 Classification based on existing classifications and the like such as UNRTDG

If the name of the substance is included in UNRTDG classification, the substance may be classified according to UNRTDG; however, it shall be categorized after good examination since hazards of solid articles depend on their shapes and particle sizes.

If in doubt, perform the pre-determined test on the article, and categorize.

#### 2.4.7.3.4 Judgment of "Classified"

When the existing classification results shown in Table 2.4.7.1are available, after examination of the classification result and the evidence data, the Category shall be determined.

### 2.4.7.4 Data availability

Few result values of the rate of burning tests have been published.

### 2.4.7.5 Comparison with conventional classification systems

2.4.7.5.1 Flammable solid is in accordance with Class 4.1 of UNRTDG.

2.4.7.5.2 Category 4.1 also included 2.4.9 “Self-Reactive Substances” and 2.4.1 Explosives. Therefore, ERG shall also be considered.

Related ERG Schedules are as follows:
133 Flammable Solid
133 Flammable Solid – toxic/ corrosive
170 Metal (powder, dust, shavings, drilling chips, lathe chips, swarf, etc.)

2.4.7.5.3 In EmS, “Flammable Solid” is included in Schedule S-G along with “Sel-reactive Substances”.

2.4.7.5.4 These classification are also applied to the solids of R11 in EU DSD classification

### 2.4.7.6 Sources on information for classification results under conventional systems

2.4.7.6.1 UN Recommendations on the Transport of Dangerous Goods

Category 1 = UNRTDG 4.1 II ERG 133, 134, 170

Category 2 = UNRTDG 4.1 III ERG 133, 134, 170

### 2.4.7.7 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labelling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.4.7.2 Label elements for flammable solids**

| | Category 1 | Category 2 |
|---|---|---|
| **Symbol** | Flame | Flame |
| **Signal word** | Danger | Warning |
| **Hazard statement** | Flammable solid | Flammable solid |

# SECTION 2.4.8

# SELF-REACTIVE SUBSTANCES

## 2.4.8.1 Definitions

2.4.8.1.1 Self-reactive substances are thermally unstable liquid or solid substances or mixtures liable to undergo a strongly exothermic decomposition even without participation of oxygen (air). This definition excludes substances classified under the GHS as explosives, organic peroxides or as oxidizing.

2.4.8.1.2 A self-reactive substance is regarded as possessing explosive properties when in laboratory testing the formulation is liable to detonate, to deflagrate rapidly or to show a violent effect when heated under confinement.

## 2.4.8.2 Classification criteria

2.4.8.2.1 Any self-reactive substance shall be considered for classification in this class unless:

(a) They are explosives, according to the GHS criteria of Chapter 2.1;

(b) They are oxidizing liquids or solids, according to the criteria of Chapters 2.13 or 2.14, except that mixtures of oxidizing substances which contain 5% or more of combustible organic substances shall be classified as self-reactive substances according to the procedure defined in the note below;

(c) They are organic peroxides, according to the GHS criteria of Chapter 2.15;

(d) Their heat of combustion is less than 300 J/g; or

(e) Their self-accelerating decomposition temperature (SADT) is greater than 75°C for 50 kg package.

**Note:** Mixtures of oxidizing substances, meeting the criteria for classification as oxidizing substances, which contain 5.0% or more of combustible organic substances and which do not meet the criteria mentioned in (a), (c), (d) or (e) above, shall be subjected to the self-reactive substances classification procedure;

Such a mixture showing the properties of a self-reactive substance type B to F shall be classified as a self-reactive substance.

2.4.8.2.2 Self-reactive substances are classified in one of the seven categories of "types A to G" for this class, according to the following principles:

(a) Any self-reactive substance which can detonate or deflagrate rapidly, as packaged, will be defined **as self-reactive substance TYPE A**.

(b) Any self-reactive substance possessing explosive properties and which, as packaged, neither detonates nor deflagrates rapidly, but is liable to undergo a thermal explosion in that package will be defined as **self-reactive substance TYPE B**.

(c) Any self-reactive substance possessing explosive properties when the substance as packaged cannot detonate or deflagrate rapidly or undergo a thermal explosion will be defined as **self-reactive substance TYPE C**.

(d) Any self-reactive substance which in laboratory testing:

  a. Detonates partially, does not deflagrate rapidly and shows no violent effect when heated under confinement; or

  b. Does not detonate at all, deflagrates slowly and shows no violent effect when heated under confinement; or

  c. Does not detonate or deflagrate at all and shows a medium effect when heated under confinement;

shall be defined as **self-reactive substance TYPE D**.

(e) Any self-reactive substance which, in laboratory testing, neither detonates nor deflagrates at all and shows low or no effect when heated under confinement will e defined as **self-reactive TYPE E**.

(f) Any self-reactive substance which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows only a low or no effect when heated under confinement as well as low or no explosive power will be defined as **self-reactive substance TYPE F**.

(g) Any self-reactive substance which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows no effect when heated under confinement nor any explosive power, provided that it is thermally stable (self-accelerating decomposition temperature is 60°C to 75°C for a 5o kg package), and, for liquid mixtures, a diluents having a boiling point greater than or equal to 150°C is used for desensitization will be defined as **self-reactive substance TYPE G**. If the mixture is not thermally stable or a diluent having a boiling point less than 150°C is used for desensitization, the mixture shall be defined as self-reactive substance TYPE F.

**Note 1:** Type G has no hazard communication elements assigned but should be considered for properties belonging to other hazard classes.

**Note 2:** Types A to G may not be necessary for all systems.

### 2.4.8.3 Criteria for temperature control

Self-reactive substances need to be subjected to temperature control if their self-accelerating decomposition temperature (SADT) is less than or equal to 55C. Test methods for determining the SADT as well as the derivation of control and emergency temperatures are given in the UN Recommendations for the Transport of Dangerous Goods, Manual of Tests and Criteria, Part II, section 28. The test selected shall be conducted in a manner which is representative, both in size and material, of the package.

### 2.4.8.4 Guidance for classification

2.4.8.4.1 Judgment of "Not Applicable"

Gas, explosives, organic peroxides, and liquids and solid classified as oxidizing substances shall be "Not Applicable".

Substances not containing chemical groups concerned with explosive properties or self-reactivity shall not be "Not Applicable".

2.4.8.4.2 Judgment of "Not Classified"

Regarding the substances containing chemical groups related to explosive properties or self-reactivity, if data on SADT or exothermic decomposition are obtained from various information sources and in-house data and the guidance in the UN GHS 4th revised edition is applicable to the substances, fill in "Classification result" with "Not Classified", and fill in "Classification Grounds and Problems" with "SADT" ** °C (** is filled with a specific value).

2.4.8.4.3 Judgment of "Classified"

When the existing classification results shown in 2.4.8.2.1 and 2.4.8.2.2 are available, after examination of the classification result and the evidence data, the Category shall be determined.

2.4.8.4.4 Classification based on existing classifications (such as UNRTDG)

If the name of a substance is included in UNRTDG classification, the substance shall be classified according to it.

### 2.4.8.5 Data availability

Few measurement data related to the flow chart of UN GHS 4threvised edition 2.8.4 have been published. Mostly, self-reactive substances are traded and used as prepared chemicals in which diluents and/ or stabilizing agents are added to them, rather than as pure substance. Classification into TYPE A to G should be made based on a test for individual prepared chemicals.

### 2.4.8.6 Comparison with conventional classification systems

2.4.8.6.1 The flow chart of UN GHS 4threvised edition 2.8.4 is exactly the same as that of UNRDTG.

2.4.8.6.2 In EmS, self-reactive substances not requiring temperature control are classified into Schedule S-G along with Flammable Solid, and those requiring are classified into Schedule S-K.

### 2.4.8.7 Sources of information for classification results under conventional systems

2.4.8.7.1 UN Recommendations on the Transport of Dangerous Goods

Chemicals belonging to UNRTDG 4.1 ERG 149, 150 in UNRTDG and North- American Emergency Response Guidebook (NAERG) fall under this class.

| | The temperature necessity (150) | | Temperature management is unnecessary (149) | |
|---|---|---|---|---|
| | Liquid | Solid | Liquid | Solid |
| Type A | Transportation prohibition substance | | | |
| Type B | UN 3221 | 3222 | 3231 | 3232 |
| Type C | UN 3223 | 3224 | 3233 | 3234 |
| Type D | UN 3225 | 3226 | 3235 | 3236 |
| Type E | UN 3227 | 3228 | 3237 | 3238 |
| Type F | UN 3229 | 3230 | 3239 | 3240 |
| Type G | Non-dangerous articles | | | |

### 2.4.8.8 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labelling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.4.8.1 Label elements for self-reactive substances**

| | **Type A** | **Type B** | **Type C and D** | **Type E and F** | **Type G**[a] |
|---|---|---|---|---|---|
| **Symbol** | Exploding bomb | Exploding bomb and flame | Flame | Flame | There are no label elements allocated to this hazard category |
| **Signal word** | Danger | Danger | Danger | Warning | |
| **Hazard statement** | Heating may cause an explosion | Heating may cause an a fire and explosion | Heating may cause a fire | Heating may cause a fire | |

[a] Type G has no hazard communication elements assigned but should be considered for properties belonging to other hazard classes.

# SECTION 2.4.9

# PYROPHORIC LIQUIDS

### 2.4.9.1 Definitions

2.4.9.1.1 A pyrophoric liquid is a liquid which, even in small quantities, is liable to ignite within five minutes after coming into contact with air.

### 2.4.9.2 Classification criteria

2.4.9.2.1 A pyrophoric liquid shall classified in a single category for this class using test N.3 in Part III, sub-section 33.3.1.5 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, according to the following table:

**Table 2.4.9.1 Criteria for pyrophoric liquids**

| Category | Criteria |
|---|---|
| **1** | The liquid ignites within 5 min when added to an inert carrier and exposed to air, or it ignites or chars a filter paper on contact with air within 5 min. |

### 2.4.9.3 Guidance for classification

2.4.9.3.1 Judgment of “Not Applicable”

Substances that are gases and solids shall be judged as “Not Applicable”.

2.4.9.3.2 Judgment of “Not Classified”

If it is confirmed based on various information sources and handling experiences that a substance to be assessed does not self-ignite on contact with air of ambient temperature, fill in “Classification result” with “Not classified”, and fill in “Classification Grounds” with “Do not self-ignite in contact with air of ambient temperature”.

2.4.9.3.3 Judgment of “Classified”

When the existing classification results shown in Table 2.4.9.1are available, after examination of the classification result and the evidence data, the Category shall be determined.

2.4.9.3.4 Classification based on existing classification such as UNRTDG

When the name of a substance is included in UNRTDG classification, even if the article is considered not to self-ignite, the pre-determined tests shall be performed for the article and confirmed. When the UNRTDG classification is not conducted, judge based on handling experience. If it is confirmed that the substance does not self-ignite on contact with air of ambient temperature, the substance shall be classified as “Not Classified”.

### 2.4.9.4 Data availability

Data are described in reliable literatures and Safety Data Sheet (SDS).

### 2.4.9.5 Comparison with conventional classification systems

2.4.9.5.1 The definition of Pyrophoric Liquids in UN GHS fourth revised edition is identical with that of UNRTDG 2.4.3.2.2. In addition, as stated in 2.4.3.3.1, the Packing Group for it is defined as “I”.

2.4.9.5.2 In EmS, Pyrophoric Liquids, along with Solid described in 2-4-10, are classified into Schedule S-M (Pyrophoric Hazards) or S-L (Pyrophoric substances and water-reactive substances).

2.4.9.5.3 In ERG, they are included in Schedule 135 and 136 (Pyrophoric substances), but are not distinguished from Self-heating Substances and Mixtures described in 2-4-11.

### 2.4.9.6 Sources of information for classification results under conventional systems

2.4.9.6.1 UN Recommendations on the Transport of Dangerous Goods

It is judged that Class 1 is identical with UNRTDG 4.2.1 (Liquids). These substances may also have the property of “Substances and Mixtures which, in contact with water, emit flammable gses Z” mentioned in 2.4.12.

### 2.4.9.7 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labelling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

### Table 2.5.9.2 Label elements for pyrophoric liquids

| | **Category 1** |
|---|---|
| **Symbol** | Flame |
| **Signal word** | Danger |
| **Hazard statement** | Catches fire spontaneously if exposed to air |

# SECTION 2.4.10

# PYROPHORIC SOLIDS

### 2.4.10.1 Definitions

2.4.10.1.1 A pyrophoric solid is a solid which, even in small quantities, is liable to ignite within five minutes after comning into contact with air.

### 2.4.10.2 Classification criteria

2.4.10.2.1 A pyrophoric solid shall be classified in a single category for this class using test N.2 in Part III, sub-section 33.3.1.4 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria according to the following table:

**Table 2.4.10.1 Criteria for pyrophoric solids**

| Category | Criteria |
|---|---|
| **1** | The solid ignites within 5 min of coming into contact with air. |

**Note:** For classification tests on solid substances, the tests should be performed on the substance as presented. If for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, the substance must also be tested in the new form.

### 2.4.10.3 Guidance for classification

2.4.10.3.1 Judgment of “Not Applicable”

Substances that are gases and liquids shall be judged as “Not Applicable”.

2.4.10.3.2 Judgment of “Not Classified”

If it is confirmed based on various information sources and handling experiences that a substance to be assessed does not self-ignite on contact with air of ambient temperature, fill in “Classification result” with “Not classified”, and fill in “Classification Grounds” with “Do not self-ignite in contact with air of ambient temperature”.

2.4.10.3.3 Judgment of “Classified”

When the existing classification results shown in Table 2.4.10.1are available, after examination of the classification result and the evidence data, the Category shall be determined.

2.4.10.3.4 Classification based on existing classification such as UNRTDG

When the name of a substance is included in UNRTDG classification, even if the article is considered not to self-ignite, the pre-determined tests shall be performed for the article and confirmed. When the UNRTDG classification is not conducted, judge based on handling experience. If it is confirmed that the substance does not self-ignite on contact with air of ambient temperature, the substance shall be classified as “Not Classified”.

### 2.4.10.4 Data availability

Data are described in reliable literatures and Material Safety Data Sheet (MSDS).

### 2.4.10.5 Comparison with conventional classification systems

2.4.10.5.1 The definition of Pyrophoric Solids in UN GHS fourth revised edition is identical with that of UNRTDG 2.4.3.2.1. In addition, as stated in 2.4.3.3.1, the Packing Group for it is defined as “I”.

2.4.9.5.2 In EmS, Pyrophoric Solids, along with Liquids described in 2-4-9, are classified into Schedule S-M (Pyrophoric Hazards) or S-L (Pyrophoric substances and water-reactive substances).

2.4.9.5.3 In ERG, they are included in Schedule 135 and 136 (Pyrophoric substances), but are not distinguished from Self-heating Substances and Mixtures described in 2-4-11.

### 2.4.10.6 Sources of information for classification results under conventional systems

2.4.10.6.1 UN Recommendations on the Transport of Dangerous Goods

It is judged that Class 1 identical with UNRTDG 4.2.1 (Solid). These substances may also have the property of “Substances and mixtures which, in contact with water, emit flammable gases” mentioned in 2.4.12.

### 2.4.10.7 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labelling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.4.10.2 Label elements for pyrophoric solids**

| | **Category 1** |
|---|---|
| **Symbol** | Flame |
| **Signal word** | Danger |
| **Hazard statement** | Catches fire spontaneously if exposed to air |

# SECTION 2.4.11

# SELF-HEATING SUBSTANCES

## 2.4.11.1 Definition

2.4.11.1.1 A self-heating substance is a solid o liquid substance, other than a pyrophoric liquid or solid, which, by reaction with air and without energy supply, is liable to self-heat; this substance differs from a pyrophoric liquid or solid in that it will ignite only when in large amounts (kilograms) and after long periods of time (hours or days).

**Note:** Self-heating of a substance is a process where the gradual reaction of that substance with oxygen (in air) generated heat. If the rate of heat production exceeds the rate of heat loss, then the temperature of the substance will rise which, after an induction time, may lead to self-ignition and combustion.

## 2.4.11.2 Classification criteria

2.4.11.2.1 A substance shall be classified as a self-heating substance of this class, if in tests performed in accordance with the test method given in the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Part III, sub-section 33.3.1.6.

(a) A positive result is obtained using a 25 mm cube sample at 140 °C;

(b) A positive result is obtained in a test using a 100 mm sample cube a 140°C and a negative result is obtained in a test using a 100 mm cube sample at 120°C and the substance is to be packed in packages with a volume of more than 3 m$^3$;

(c) A positive result is obtained in a test using a 100 mm sample cube at 140°C and a negative result is obtained in a test using a 100 mm cube sample at 100°C and the substance is to be packed in packages with a volume of more than 450 liters;

(d) A positive result is obtained in a test using a 100 mm cube sample at 100°C

2.4.11.2.2A self-heating substance shall be classified in one of the two categories for this class if, in test performed in accordance with the test method N.4 in Part III, sub-section 33.3.1.6 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, the result meets the criteria shown in Table 2.11.1 of the GHS Purple Book.

**Table 2.4.11.1 Criteria for self-heating substances**

| Category | Criteria |
|---|---|
| **1** | A positive result is obtained in a test using a 25 mm sample cube at 140C |
| **2** | (a) A positive result is obtained in a test using a 100 mm sample cube a 140°C and a negative result is obtained in a test using a 100 mm cube sample at 120°C and the substance is to be packed in packages with a volume of more than 3 $m^3$;<br>(b) A positive result is obtained in a test using a 100 mm sample cube at 140°C and a negative result is obtained in a test using a 100 mm cube sample at 100°C and the substance is to be packed in packages with a volume of more than 450 liters;<br>(c) A positive result is obtained in a test using a 100 mm cube sample at 100°C |

**Note 1:** For classification tests on solid substances, the tests should be performed on the substance as presented. If for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, the substance must also be tested in the new form.

**Note 2:** The criteria are based on the self-ignition temperature of charcoal, which is 50°C for a sample cube of 27 $m^3$. Substances with a temperature of spontaneous combustion higher than 50°C for a volume of 27 $m^3$ should not be assigned to this hazard class. Substances with a self-ignition temperature higher than 50°C for a volume of 450 liters should not be assigned to hazard Category 1 of this hazard class.

### 2.4.11.3 Guidance for classification

2.4.11.3.1 Judgment of "Not Applicable"

1.) Substances that are gases shall be judged "Not Applicable".

2.) Pyrophoric liquids and solids shall be judged as "Not Applicable".

2.4.11.3.2 Judgment of "Not Classified"

Non-flammable liquids and solids shall be judged as "Not Classified".

2.4.11.3.3 Classification based on existing classifications such as UNRTDG

When the name of the substance is included in the UNRTDG classification, it is preferable to test the article. When the UNRTDG classification is not conducted, judge whether or not to perform the tests with referencing the judging results of combustibility and the like.

2.4.11.3.4 Classification based on information on various literatures

If the data of screening test described in the UN GHS 4threvised edition 2.11.4.2 are obtained for a substance from prescribed review documents, and the data show that it is not a self-heating substance, it shall be classified as "Not Classified", and "Classification Grounds and Problems" shall be filled in with the result of the test.

2.4.11.3.4.1 Screening Test

2.4.11.3.4.1.1 The Grewer Oven Test (VDI Guideline 2263, part I, 1990, Test Methods for the Determination of the Safety Characteristics of Dusts) with an onset temperature 80K above the reference temperature for a volume of 1L;

2.4.11.3.4.1.2 The Bulk Powder Screening Test (Gibson, N. Harper, D.J. Rogers, R. Evaluation of the fire and explosion risks in drying powders, Plant Operations Progress, 4 (3), 181-189, 1985) with an onset temperature 60K above the reference temperature for a volume o 1L

2.4.11.3.5 Judgment of "Classified"

When the existing classification results shown in Table 2.4.11.1are available, after examination of the classification result and the evidence data, the Category shall be determined.

**2.4.11.4 Data availability**

Few data for each substance have been published.

**2.4.11.5 Comparison with conventional systems**

5.4.11.5.1 In classification 4.2 described in UNRTDG 2.4.3.2.3, the definition of Self-heating substances is in accordance with the criteria of GHS 2.11.2.

Packing Group II corresponds to GHS Classification 1, and Packing Group III corresponds to Classification2. Classification 4.2 also includes Pyrophoric Solids (2.4.3.2.1) and Pyrophoric Liquids (2.4.3.2.2).

2.4.11.5.2 In ERG, self-heating substances are included in Schedule 135 and 136 (Self-heating Substances).

2.4.11.5.3 In EmS, they are included in Schedule S-J (wetted explosives and self-heating substances).

### 2.4.11.6 Sources of information for classification results under conventional systems

2.4.11.6.1 UN Recommendations on the Transport of Dangerous Goods

Substances classified into UNRTDG 4.2 EmS : S-J fall under this class.

### 2.4.11.7 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labelling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.4.11.2 Label elements for self-heating substances**

| | **Category 1** | **Category 2** |
|---|---|---|
| **Symbol** | Flame | Flame |
| **Signal word** | Danger | Warning |
| **Hazard statement** | Self-heating; may catch fire | Self-heating in large quantities; may catch fire |

# SECTION 2.4.12

## SUBSTANCES AND MIXTURES WHICH, IN CONTACT WITH WATER, EMIT FLAMMABLE GASES

### 2.4.12.1 Definitions

2.4.12.1.1 Substances or mixtures which, in contact with water, emit flammable gases are solid or liquids substances which, by interaction with water, are liable to become spontaneously flammable or to give off flammable gases in dangerous quantities.

### 2.4.12.2 Classification criteria

2.4.12.2.1 A substance or mixture which, in contact with water, emit flammable gases shall be classified in one of the three categories for this class, using test N.5 in Part III, sub-section 33.4.1.4 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, according to the following table:

**Table 2.4.12.1 Criteria for substances which, in contact with water, emit flammable gases**

| Category | Criteria |
|---|---|
| **1** | Any substance or mixture which reacts vigorously with water at ambient temperatures and demonstrates generally a tendency for the gas produced to ignite spontaneously, or which reacts readily with water at ambient temperatures such that the rate of evolution of flammable gas is equal to or greater than 10 liters per kilogram of substance over any one minute. |
| **2** | Any substance or mixture which reacts readily with water at ambient temperatures such that the maximum rate of evolution of flammable gas is equal to or greater than 20 liters per kilogram of substance per hour, and which does not meet the criteria for Category 1. |
| **3** | Any substance or mixture which reacts slowly with water at ambient temperatures such that the maximum rate of evolution of flammable gas is equal to or greater than 1 liter per kilogram of substance per hour, and which does not meet the criteria for Categories 1 and 2. |

**Note 1:** A substance or mixture is classified as a substance which, in contact with water, emits flammable gases if spontaneous ignition takes place in any step of the test procedure.

**Note 2:** For classification tests on solid substances or mixtures, the test should be performed on the substance as presented. If for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, the substance must also be tested in the new form.

### 2.4.12.3 Guidance for classification

2.4.12.3.1 Judgment of "Not Applicable"

2.4.12.3.1.1 Substances that are gases shall be judged as "Not Applicable".

2.4.12.3.1.2 Substances not containing metals or metalloids in their chemical structure shall be judged as "Not Applicable".

2.4.12.3.2 Judgment of "Not Classified"

If it is judged based on various information sources and in-house data that a substance containing metals or metalloids is stable even if it is in contact with water, fill in "Classification result" with "Not Classified", and fill in "Classification Grounds" with "Stable to water" with reference to UN GHS fourth revised edition 2.12.4.2 (b)(c).

2.4.12.3.3 Judgment of "Classified"

When the existing classification results shown in Table 2.4.12.1are available, after examination of the classification result and the evidence data, the Category shall be determined.

2.4.12.3.4 Classification based on existing classifications and the like such as UNRTDG

If the name of the substance is included in UNRTDG classification, the substance shall be classified according to it. As for substances whose capability was discussed in the following discussion on GHS Water Reactive Flammable Substances and Metalloids, perform test N.5 and categorize depending on the result.

### 2.4.12.4 Data availability

Few numerical data on the rate of evolution of gas have been published.

### 2.4.12.5 Comparison with conventional systems

2.4.12.5.1 Judgment criteria of GHS 2.12.2 completely in accordance with the definition of UNRTDG Classification 4.3.

Category 1 = UNRDTG 4.3 I
Category 2 = UNRTDG 4.3 II
Category 3 = UNRTDG 4.3 III

2.4.12.5.2 Substances classified into EU DSD Classification R15 meet GHS judgment criteria, but they do not correspond to Category 1, 2 and 3.

Judgment criteria of EU classification are in accordance with those of GHS, but further categorization is not given for the former.

2.4.12.5.3 In ERG, Schedules related to "Substances which, in contact with water, emit flammable gases" of GHS are as follows:

135 : Pyrophoric substances

138 : Water-reactive substances – emitting flammable gas

138 : Water-reactive substances – emitting flammable / toxic gas

### 2.4.12.6 Sources of information for classification results under conventional systems

2.4.12.6.1 UN Recommendations on the Transport of Dangerous Goods

Category 1 = UNRTDG 4.3 I

Category 2 = UNRTDG 4.3 II

Category 3 = UNRTDG 4.3 III

Substances classified into UNRTDG 4.2 (4.3) correspond to GHS Category 1.

### 2.4.12.7 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labeling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

### Table 2.4.12.2 Label elements for substances, which in contact with water, emit flammable gases

| | **Category 1** | **Category 2** | **Category 3** |
|---|---|---|---|
| **Symbol** | Flame | Flame | Flame |
| **Signal word** | Danger | Danger | Warning |
| **Hazard statement** | In contact with water releases flammable gases which may ignite spontaneously | In contact with water releases flammable gases | In contact with water releases flammable gases |

# SECTION 2.4.13

# OXIDIZING LIQUIDS

## 2.4.13.1 Definition

2.4.13.1.1 An oxidizing liquid is a liquid which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material.

## 2.4.13.2 Classification criteria

2.4.13.2.1 An oxidizing liquid shall be classified in one of the three categories for this class using test O.2 in Part III, sub-section 34.4.2 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, according to the following table:

**Table 2.4.13.1 Criteria for oxidizing liquids**

| Category | Criteria |
|---|---|
| 1 | Any substance or mixture which, in the 1:1 mixture, by mass, of substance and cellulose tested, spontaneously ignites; or the mean pressure rise time of a 1:1 mixture, by mass, of substance and cellulose is less than that of a 1:1 mixture, by mass, of 50% perchloric acid and cellulose; |
| 2 | Any substance or mixture which, in the 1:1 mixture, by mass, of substance and cellulose tested, exhibits a mean pressure rise time less than or equal to the mean pressure rise time of a 1:1 mixture, by mass, of 40% aqueous sodium chlorate solution and cellulose; and the criteria for Category 1 are not met; |
| 3 | Any substance or mixture which, in the 1:1 mixture, by mass, of substance and cellulose tested, exhibits a mean pressure rise time less than or equal to the mean pressure rise time of a 1:1 mixtures, by mass, of 65% aqueous nitric acid and cellulose; and the criteria for Categories 1 and 2 are met. |

## 2.4.13.3 Guidance for classification

2.4.13.3.1 Judgment of “Not Applicable”

2.4.13.3.1.1 Substances of gases and solids shall be judged as “Not Applicable”.

2.4.13.3.1.2 Organic substances which do not contain oxygen, fluorine, or chlorine or which containany of these elements that are bound to carbon or hydrogen only shall be judged “Not Applicable”.

2.4.13.3.1.3 Inorganic substances not containing oxygen or a halogen element shall be judged “Not Applicable”.

2.4.13.3.2 Judgment of “Not Classified

If it is confirmed that a substance based on review documents that a substance to be assessed is a “reductive material”, fill in the “Classification result” with “Not Classified”, and fill in “Classification Grounds” with “Reductive material”.

2.4.13.3.3 Classification based on existing classifications such as UNRTDG

If the name of the substance is included in the UNRTDG classification, the substance shall be classified according to it. As for a substances doubted as an oxidizing, if evident information for judging are not available, perform the pre-determined tests, and categorize

2.4.13.3.4 Judgment of “Classified”

When the existing classification results shown in Table 2.4.13.1are available, after examination of the classification result and the evidence data, the Category shall be determined.

### 2.4.13.4 Data availability

Few experimental data on oxidative materials have been published.

### 2.4.13.5 Comparison with conventional classification system

2.4.13.5.1 The definition in GHS 2.13.2 is equivalent to that of UNRTDG Classification 5.1 “Liquids” (UNRTDG 2.5.2.3.2).

2.4.13.5.2 In ERG, oxidative materials (including solids) are classified into Schedules 140, 141, 142, 143 and 144, but it does not serve as a reference for this GHS classification.

2.4.13.5.3 In EmS, oxidative materials (including solid) are classified into Schedule S-Q.

### 2.4.13.6 Sources of information for classification results under conventional systems

2.4.13.6.1 UN Recommendations on the Transport of Dangerous Goods

Category 1 = UNRTDG 5.1 I (Liquids)

Category 2 = UNRTDG 5.1 II (Liquids)

Category 3 = UNRTDG 5.1 III (Liquids)

### 2.4.13.7 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labeling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.4.13.2 Label elements for oxidizing liquids**

| | **Category 1** | **Category 2** | **Category 3** |
|---|---|---|---|
| **Symbol** | Flame over circle | Flame over circle | Flame over circle |
| **Signal word** | Danger | Danger | Warning |
| **Hazard statement** | May cause fire or explosion; strong oxidizer | May intensify fire; oxidizer | May intensify fire; oxidizer |

# SECTION 2.4.14

# OXIDIZING SOLIDS

## 2.4.14.1 Definitions

2.4.14.1.1 An oxidizing solid is a solid which, while in itself is not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material.

## 2.4.14.2 Classification criteria

2.4.14.2.1 An oxidizing solid shall be classified in one of the three categories for this class using test O.1 in Part III, sub-section 34.4.1 of the UN Recommendations on the Recommendations on the transport of Dangerous Goods, Manual of Tests and Criteria, according to the following table:

**Table 2.4.14.1 Criteria for oxidizing solids**

| Category | Criteria |
|---|---|
| 1 | Any substance or mixture which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning time less than the mean burning time of a 3:2 mixture, by mass, of potassium bromate and cellulose. |
| 2 | Any substance or mixture which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning time equal to or less than the mean burning time of a 2:3 mixtures (by mass) of potassium bromated and cellulose and the criteria for Category 1 are not met. |
| 3 | Any substance or mixture which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning time equal to or less than the mean burning time of a 3:7 mixture (by mass) of potassium bromated and cellulose and the criteria for Categories 1 and 2 are not met. |

**Note 1:** Some oxidizing solids may also present explosion hazards under certain conditions (e.g. when stored in large quantities). For example, some types of ammonium nitrate may give rise to an explosion hazard under extreme conditions and the "Resistance to detonate test" (BC Code[1], Annex 3, Test 5) may be used to assess this hazard. Appropriate comments should be made in the Safety Data Sheet.

[1] Code of Safe Practice for Solid Bulk Cargoes, IMO, 2005

**Note 2:** For classification tests on solid substances, the tests should be performed on the substance as presented. If for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, the substance must also be tested in the new form.

### 2.4.14.3 Guidance for classification

2.4.14.3.1 Judgment of "Not Applicable"

2.4.14.3.1.1 Gases and liquid substances shall be judged as "Not Applicable".

2.4.14.3.1.2 Organic substances which do not contain oxygen, fluorine, or chlorine or which contain any of these elements that are bound to carbon or hydrogen only shall be judged "Not Applicable".

2.4.14.3.1.3 Inorganic substances not containing oxygen or any halogen element shall be judged "Not Applicable".

2.4.14.3.2 Classification based on existing classifications such as UNRTDG

If the name of a substance is included in UNRTDG classification, the substance shall be classified according to it. As for substances being doubted to be oxidizing, if evident information for judging is not available, perform the predetermined tests, and categorize.

2.4.14.3.3 Judgment of "Classified"

When the existing classification results shown in Table 2.4.14.1are available, after examination of the classification result and the evidence data, the Category shall be determined.

### 2.4.14.4 Data availability

Few experimental data on oxidative materials have been published.

### 2.4.14.5 Comparison with conventional classification systems

2.4.14.5.1 The classification criteria of GHS 2.14.2 are equivalent to the definition of UNRTDG Classification 5.1 "Solid" (UNRTDG 2.5.2.2.2).

2.4.14.5.2 In ERG, oxidative materials (including liquids) are classified into Schedules 140, 141, 142, 143 and 144, but it does not serve as a reference for this GHS classification.

2.4.14.5.3 In EmS, oxidative materials (including Liquids) are classified into Schedule S-Q.

### 2.4.14.6 Sources of information for classification results under conventional systems

2.4.14.6.1 UN Recommendations on the Transport of Dangerous Goods

Category 1 = UNRTDG 5.1 I (Solid)

Category 2 = UNRTDG 5.1 II (Solid)

Category 3 = UNRTDG 5.1 III (Solid)

### 2.4.14.7 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labeling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.5.14.2 Label elements for oxidizing solids**

| | **Category 1** | **Category 2** | **Category 3** |
|---|---|---|---|
| **Symbol** | Flame over circle | Flame over circle | Flame over circle |
| **Signal word** | Danger | Danger | Warning |
| **Hazard statement** | May cause fire or explosion; strong oxidizer | May intensify fire; oxidizer | May intensify fire; oxidizer |

# SECTION 2.4.15

# ORGANIC PEROXIDES

## 2.4.15.1 Definition

2.4.15.1.1 Organic peroxides are liquid or solid organic substances which contain the bivalent –O-O- structure and may be considered derivatives of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals. The term also includes organic peroxide formulations (mixtures).

2.4.15.1.2 Organic peroxides are thermally unstable substances, which may undergo exothermic self-accelerating decomposition. In addition, they may be one or more of the following properties:

(a) be liable to explosive decomposition;

(b) burn rapidly;

(c) be sensitive to impact or friction;

(d) react dangerously with other substances.

2.4.15.1.3 An organic peroxide is regarded as possessing explosive properties when in laboratory testing the formulation is liable to detonate, to deflagrate rapidly or to show a violent effect when heated under confinement.

## 2.4.15.2 Classification criteria

2.4.15.2.1 Any organic peroxide shall be considered for classification in this class, unless it contains:

(a) not more than 1.0% available oxygen from the organic peroxides when containing not more than 1.0% hydrogen peroxide; or

(b) not more than 0.5% available oxygen from the organic peroxides when containing more than 1.0% but not more than 7.0% hydrogen peroxide.

**Note:** The available oxygen content (%) of an organic peroxide mixture is given by the formula:

$$16 \times \sum_{i}^{n} \left( \frac{n_i \times c_i}{m_i} \right)$$

where:

$n_i$ = number of peroxygen groups per molecule of organic peroxide i;

$c_i$ = concentration (mass %) of organic peroxide i;

$m_i$ = molecular mass of organic peroxide i.

5.4.15.2.2 Organic peroxides are classified in one of the seven categories of "Types A to G" for this class, according to the following principles:

1) Any organic peroxide which, as packaged, can detonate or deflagrate rapidly will be defined as **organic peroxide TYPE A**;

2) Any organic peroxide possessing explosive properties and which, as packaged, neither detonates nor deflagrates rapidly, but is liable to undergo a thermal explosion in that package will be defined as **organic peroxide TYPE B**;

3) Any organic peroxide possessing explosive properties when the substance as packaged cannot detonate or deflagrate rapidly or undergo a thermal explosion will be defined as **organic peroxide TYPE C**;

4) Any organic peroxide which in laboratory testing:

    a) detonates partially, does not deflagrate rapidly and shows no violent effect when heated under confinement; or

    b) does not detonate at all, deflagrates slowly and shows no violent effect when heated under confinement; or

    c) does not detonate or deflagrate at all and shows a medium effect when heated under confinement

    will be defined as **organic peroxide TYPE D**;

5) Any organic peroxide which, in laboratory testing, neither detonates nor deflagrates at all and shows low or no effect when heated under confinement will be defined as **organic peroxide TYPE E**;
6) Any organic peroxide which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows only a low or no effect when

heated under confinement as well as low or no explosive power will be defined as **organic peroxide TYPE F**;

7) Any organic peroxide which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows no effect when heated under confinement nor any explosive power, provided that it is thermally stable (self-accelerating decomposition temperature is 60◦C or higher for a 50 kg package), and, for liquid mixtures, a diluents having a boiling point of not less than 150◦C is used for desensitization, will be defined as **organic peroxide TYPE G**. If the organic peroxide is not thermally stable or a diluent having a boiling point less than 150◦C is used for desensitization, it shall be defined as **organic peroxide TYPE F**.

**Note 1:** Type G has no hazard communication elements assigned but should be considered for properties belonging to other hazard classes.

**Note 2:** Type A to G may not be necessary for all systems.

### 2.4.15.3 Criteria for temperature control

The following organic peroxides need to be subjected to temperature control:

(a) Organic peroxide types B and C with an SADT ≤50◦C;

(b) Organic peroxide type D showing a medium effect when heated under confinement with an SADT ≤ 50◦C or showing a low or no effect when heated under confinement with an SADT ≤ 45◦C; and

(c) Organic peroxide types E and F with an SADT ≤ 45◦C.

Tests methods for determining the SADT as well as the derivation of control and emergency temperatures are given in the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Part II, section 28. The test selected shall be conducted in a manner which is representative, both in size and material, of the package.

### 2.4.15.4 Guidance for classification

2.4.15.4.1 Judgment of “Not Applicable”

Inorganic substances and organic substances except Organic Peroxides shall be judged “Not Applicable”.

#### 2.4.15.4.2 Judgment of “Not Classified”

If the hydrogen peroxide content and the amount of available oxygen in an Organic Peroxide fall below the values stipulated in UN GHS fourth revised edition 2.15.2.1, fill in “Classification Result” with “Not Classified”, and in “Classification Ground” with “Active oxygen amount fails to satisfy the definition”.

#### 2.4.15.4.3 Classification based on existing classification such as UNRTDG

If the name of a substance is included in UNRTDG classification (for example, it is listed in the table of TMDGC 2.5.3.2.4), the substance shall be classified according to the UN number.

#### 2.4.15.4.4 Judgment of “Classified”

When the existing classification results shown in 2.4.15.2.1 and 2.4.15.2.2 are available, after examination of the classification result and the evidence data, the Category shall be determined.

### 2.4.15.5 Data availability

Few data of measurement experiments related to the flowchart of GHS 2.15.4 have been published.

### 2.4.15.6 Sources of information for classification results under conventional systems

#### 2.4.15.6.1 UN Recommendations on the Transport of Dangerous Goods

Chemicals which belong to UNRTDG 5.2 ERG 147, 148 in UNRTDG and North- American Emergency Response Guidebook (NAERG) fall under this class.

| | The temperature necessity (147) | | Temperature management is unnecessary (148) | |
|---|---|---|---|---|
| | Liquid | Solid | Liquid | Solid |
| Type A | Transportation prohibition substance | | | |
| Type B | UN 3101 | 3102 | 3111 | 3112 |
| Type C | UN 3103 | 3104 | 3113 | 3114 |
| Type D | UN 3105 | 3106 | 3115 | 3116 |
| Type E | UN 3107 | 3108 | 3117 | 3118 |
| Type F | UN 3109 | 3110 | 3119 | 3120 |
| Type G | Non-dangerous articles | | | |

### 2.4.15.7 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labeling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.4.15.2 Label elements for organic peroxides**

| | **Type A** | **Type B** | **Type C and D** | **Type E and F** | **Type G**[a] |
|---|---|---|---|---|---|
| **Symbol** | Exploding bomb | Exploding bomb and flame | Flame | Flame | There are no label elements allocated to this hazard category |
| **Signal word** | Danger | Danger | Danger | Warning | |
| **Hazard statement** | Heating may cause an explosion | Heating may cause a fire and explosion | Heating may cause a fire | Heating may cause a fire | |

[a] Type G has no hazard communication elements assigned but should be considered for properties belonging to other hazard classes.

# SECTION 2.4.16

# CORROSIVE METALS

## 2.4.16.1 Definition

2.4.16.1.1 A substance or a mixture which is corrosive to metals is a substance which by chemical reaction will materially damage, or even destroy metals.

## 2.4.16.2 Classification criteria

2.4.16.2.1 A substance or a mixture which is corrosive to metals shall be classified in a single category for this class, using the test in Part III, sub-section 37.4 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, according to the following table:

**Table 2.4.16.1 Criteria for substances corrosive to metal**

| Category | Criteria |
|---|---|
| **1** | Corrosion rate on either steel or aluminum surfaces exceeding 6.25 mm per year at a test temperature of 55◦C when tested on both materials. |

**Note:** Where an initial test on either steel or aluminum indicates the substance being tested is corrosive the follow-up test on the other metal is not required.

## 2.4.16.3 Guidance for classification

2.4.16.3.1 Judgment of “Not Classified”

Regarding “Corrosive to Metals”, if it is confirmed based on various information sources and in-house data that both steel and aluminum can be used as a container for the substance, fill in “Classification result” with “Not Classified”, and fill in “Classification Grounds” with “Steel and aluminum can be used as a container”.

2.4.16.3.2 Judgment for substances that cannot be classified

2.4.16.3.2.1 In case the test method is not established

The test method for “Corrosive to Metals” defined in UNRTDG classification and adopted in GHS classification cannot be applied to gases. It cannot be applied to liquids with a boiling point of 55◦C or lower, either. In case of solid, it cannot be applied to those with a melting point of 55◦C or lower.

Hence, indicate as follows:

In case of gases, fill in “Classification result” with “Classification not possible” regarding “corrosive to metals”, and fill in “classification grounds” with “No established test method suitable for Gas substances”.

In the case of liquids with a boiling point of 55◦C or lower, fill in “classification result” with “Classification not possible” regarding “Corrosive to Metals”, and fill in “Classification Grounds” with “No established test method suitable for low-temperature boiling Liquids”.

In the case of solid with a melting point of higher than 55C, fill in “Classification result” with “Classification not Possible” regarding “Corrosive to Metals”, and fill in “Classification Grounds” with “No established test method suitable for Solid substances”.

2.4.16.3.4 Judgment of “Classification not Possible”

For hazard items that cannot be classified by the above procedure, fill in “Classification result” with “Classification not Possible”, and fill in “Classification grounds” with “No data”.

2.4.16.3.5 Judgment of “Classified”

When the existing classification results shown in Table 2.4.16.1are available, after examination of the classification result and the evidence data, the Category shall be determined.

### 2.4.16.4 Data availability

Few numerical data on metal corrosion rate have been published.

### 2.4.16.5 Comparison with conventional classification systems

The definition completely in accordance with that of the Class 8 III “Metal corrosive properties” described in UNRTDG 2.8.2.5 (c) (ii).

### 2.4.16.6 Sources of information for classification results under conventional systems

2.4.16.6.1 UN Recommendations on the Transport of Dangerous Goods

Since metal corrosive properties is classified into UNRTDG Class 8 along with the skin corrosive properties, whether a substance has metal corrosive properties or cannot be judged from the fact that the substance is classified in Class 8. Metal corrosive properties thus cannot be attributed to a substance based on "Dangerous Goods Regulations Annex 1" alone. Therefore, a substance that clearly has metal corrosive properties shall be classified into this class.

### 2.4.16.7 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labeling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.4.16.1.2 Label elements for substances corrosive to metals**

| Category | Criteria |
|---|---|
| **Symbol** | Corrosion |
| **Signal word** | Warning |
| **Hazard statement** | May be corrosive to metals |

# SECTION 2.5
# HEALTH HAZARDS

## 2.5 HEALTH HAZARDS

This section defines and explains the 10 hazard classes based on GHS health hazards.

### 2.5.1 Information useful for classification

2.5.1.1 Substance shall be classified according to the GHS Classification Criteria, obtaining the required data from the information sources specified in the first part of this Guidance Manual.

2.5.1.2 When an in-house data or existing data from literature on the health hazards for the chemical substance are available, use the data to classify.

2.5.1.3 When there are several and conflicting existing data available, the company should verify the reliability of the data based on the following:

2.5.1.3.1Data verified by credible agencies, such as those derived from the materials specified in "Priority 1".

2.5.1.3.2 Data that are deemed reliable, such as those obtained by Good Laboratory Practice (GLP)-conforming laboratories or those whose scientific basis is available and verified.

2.5.1.3.3 Data obtained from other information sources, such as those derived from the materials specified in "Priority 2" and "Priority 3".

2.5.1.3.4 Latest data (where conflicting data of the same priority are available) or data derived from reliable publications.

2.5.1.3.5 Finally, conservative data shall be adopted, excluding measurement values that are considered abnormal when compared with other relevant data. When classification results based on conflicting data belong to several hazard categories, that supported by the largest amount of data shall be adopted.

2.5.1.4 In some cases, where there are no data available, classification may be carried out by utilizing the existing classifications derived from Safety Data Sheets (SDSs) as reference.

5.5.1.4.1 Preferably, check the evidence data for such as EU Classification (EU CLP classification).

# SECTION 2.5.2.1

# ACUTE TOXICITY

### 2.5.2.1.1 Definition

Acute toxicity refers to those adverse effects occurring following oral or dermal administration of a single dose of a substance, or multiple doses given within 24 hours, or an inhalation exposure of 4 hours.

### 2.5.2.1.2 Classification criteria

2.5.2.1.2.1 Substances shall be allocated to one of the five toxicity categories based on acute toxicity by the oral, dermal or inhalation route according to the numeric cut-off criteria as shown in the table below. Acute toxicity values shall be expressed as (approximate) $LD_{50}$ (oral, dermal) or $LC_{50}$ (inhalation) values. Explanatory notes are shown following the Table 5.5.2.1.1.

**Table 2.5.2.1.1 Acute toxicity hazard categories values defining the respective categories**

| | Category 1 | Category 2 | Category 3 | Category 4 |
|---|---|---|---|---|
| Oral (mg/kg bodyweight) See notes (a) and (b) | 5 | 50 | 300 | 2000 |
| Dermal (mg/kg bodyweight) See notes (a) and (b) | 50 | 200 | 1000 | 2000 |
| Gases (ppmV) See notes (a), (b) and (c) | 100 | 500 | 2500 | 5000 |
| Vapors (mg/L) See notes (a), (b), (c), (d) and (e) | 0.5 | 2.0 | 10 | 20 |
| Dusts and Mists (mg/L) See notes (a), (b), (c) and (f) | 0.05 | 0.5 | 1.0 | 5 |

Note : Gases concentration are expressed in parts per million per volume (ppmV).

**Notes to Table 5.5.2.1.1**

(a) The acute toxicity estimate (ATE) for the classification of a substances is derived using the $LD_{50}/LC_{50}$ where available;

(b) The acute toxicity estimate (ATE) for a substance in a mixture is derived using:

a. the $LD_{50}$/$LC_{50}$ where available; otherwise,

b. the appropriate conversion value from Table 5.5.2.1.2 that relates to the results of a range test; or

c. the appropriate conversion value from Table 5.5.2.1.2 that relates to a classification category;

(c) Inhalation cut-off values in the table are based on 4 hour testing exposures. Conversion of existing inhalation toxicity data which has been generated according to 1 hour exposures should be by dividing by a factor of 2 for gases and vapors and 4 for dusts and mists;

(d) It is recognized that saturated vapor concentration may be used as an additional element by some regulatory systems to provide for specific health and safety protection (e.g. UN Recommendations on the Transport of Dangerous Goods);

(e) For some substances the test atmosphere will not just be a vapor but will consist of a mixture of liquid and vapor phases. For other substances the test atmosphere may consist of a vapor which is near the gaseous phase. In these latter cases, classification should be based on ppmV as follows: Category 1 (100 ppmV), Category 2 (500 ppmV), Category 3 (2500 ppmV), Category 4 (20000 ppmV).

The terms "dust", "mist" and "vapor" are defined as follows:

(i) Dust: solid particles of a substance suspended in a gas (usually air);

(ii) Mist: liquid droplets of a substance suspended in a gas (usually air);

(iii) Vapor: the gaseous form of a substance released from its liquid or solid state

Dust is generally formed by mechanical processes. Mist is generally formed by condensation of supersaturated vapors or by physical shearing of liquids. Dusts and mists generally have sizes ranging from less than 1 to about 100 μm;

(f) The values for dusts and mists should be reviewed to adapt to any future changes to OECD Test Guidelines with respect to technical limitation in generating maintaining and measuring dust and mist concentrations in respirable form;

#### 2.5.2.1.3 Data availability

2.5.2.1.3.1 Classification shall be performed based on the toxicity values reported in information available for classification.

2.5.2.1.3.2 If the same Acute Toxicity value is found, check the original document to avoid overlapping of the same data. This is especially true, since the information from literature sources are often cited the same during reviews.

2.5.2.1.3.3 The following Test Methods are included in the OECD Test Guidelines relating to Acute Toxicity.

| | |
|---|---|
| OECD TG 420 | Acute oral toxicity – Fixed dose procedure |
| OECD TG 423 | Acute oral toxicity – Acute toxic class method |
| OECD TG 425 | Acute oral toxicity – Up and down procedure |
| OECD TG 402 | Acute dermal toxicity |
| OECD TG 403 | Acute inhalation toxicity |

2.5.2.1.3.4 EU CLP classification criteria are in accordance with the UN GHS.

2.5.2.1.3.5 R-Phrase 20, R-Phrase 21, R-Phrase 22, R-Phrase 23, R-Phrase 24, R-Phrase 25, R-Phrase 26 R-Phrase 28 (hereinafter abbreviated as R20 and so on) regarding Acute toxicity of EU DSD (Dangerous Substances Directive) classification may be used as reference.

**2.5.2.1.4 Comparison with conventional classification systems**

2.5.2.1.4.1 EU DSD classification shall be referred to as a rough guide but is not in accordance with UN GHS completely.

2.5.2.1.4.2 In EU CLP Regulations Annex VII, conversion to the acute toxicity of UN GHS classification is made using the R-phrases and symbol mark of EU DSD classification as shown in the following table:

<table>
<tr><th colspan="2">Category</th><th colspan="2">1</th><th colspan="2">2</th><th colspan="2">3</th><th colspan="2">4</th></tr>
<tr><td rowspan="3">Oral<br>(mg/kg)</td><td>GHS</td><td colspan="2">5</td><td colspan="2">50</td><td colspan="2">300</td><td colspan="2">2000</td></tr>
<tr><td>EU CLP Classification</td><td colspan="2">H300</td><td colspan="2">H300<br>T+ ; R28</td><td colspan="2">H301<br>T ; R25</td><td colspan="2">H302<br>Xn ; R22</td></tr>
<tr><td>EU DSD classification</td><td colspan="3">R28 25</td><td colspan="2">R25 200</td><td colspan="3">R22 2000</td></tr>
<tr><td rowspan="3">Dermal<br>(mg/kg)</td><td>GHS</td><td colspan="2">50</td><td colspan="2">200</td><td colspan="2">1000</td><td colspan="2">2000</td></tr>
<tr><td>EU CLP Classification</td><td colspan="2">H310<br>T+ ; R27</td><td colspan="2">H310</td><td colspan="2">H311<br>T ; R24</td><td colspan="2">H312<br>Xn ; R22</td></tr>
<tr><td>EU DSD classification</td><td colspan="2">R27 50</td><td colspan="3">R24 400</td><td colspan="3">R21 2000</td></tr>
<tr><td rowspan="3">Gases<br>(ppmV)</td><td>GHS</td><td colspan="2">100</td><td colspan="2">500</td><td colspan="2">2500</td><td colspan="2">20000</td></tr>
<tr><td>EU CLP Classification</td><td colspan="2">H330</td><td colspan="2">H330<br>T+ ; R26</td><td colspan="2">H331<br>T ; R23</td><td colspan="2">H332<br>Xn ; R20</td></tr>
<tr><td>EU DSD classification</td><td colspan="8">Not defined</td></tr>
<tr><td>Vapors</td><td>GHS</td><td colspan="2">0.5</td><td colspan="2">2</td><td colspan="2">10</td><td colspan="2">20</td></tr>
</table>

| | | | | | |
|---|---|---|---|---|---|
| (mg/l) | EU CLP Classification | H330<br>T+ ; R26 | H330<br>T ; R23 | H331 | H332<br>Xn ; R20 |
| | EU DSD classification | R26 0.5 | R23 2 | R20 20 | |
| Dust / mist (mg/l) | GHS | 0.05 | 0.5 | 1 | 5 |
| | EU CLP Classification | H330 | H330<br>T+ ; R26 | H331<br>T ; R23 | H332<br>Xn; R20 |
| | EU DSD classification | R26 0.25 | R23 1 | | R20 5 |

Note : Oral and Dermal are LD$_{50}$ values while Vapors and Dusts and Mists are LC$_{50}$ values. Gases are not defined in the present EU DSD classification.

2.5.2.1.4.3 UNRTDG Class 6.1 is not sub-categorized by exposure route.

**2.5.2.1.5 Guidance concerning data**

2.5.2.1.5.1 Units vary depending on the shape of the inhaled substance for inhalation toxicity.

2.5.2.1.5.2 Classification shall be performed on the basis of the values for gases (ppmV) if the test atmosphere consists of a gaseous phase including vapor that is substantially a gaseous phase, values for vapors (mg/L) if the test atmosphere consists of a liquid with a relatively low boiling point, and values for mists (mg/L) for other cases.

Conversion of ppmV and mg/L units (at 25°C and atmospheric pressure)

(ppmV) = {(mg/L) x 24.45 x 10$^3$} / molecular weight

(mg/L) = {(ppmV) x molecular weight x 10$^3$} / 24.45

**2.5.2.1.6 Guidance for classification and judgment**

2.5.2.1.6.1 When multiple data exists for Acute Toxicity given the high reliability of data, and when they fall under multiple categories, basis for the selection and judgment of data for the determination of category will be determined according to Section 5.5.1.3.

However, when the substance falls under multiple categories under the order of precedence, the category under which the greatest number of data fall is adopted.

Furthermore, if the numbers of data for the categories thus singled out are the same, the category with the higher degree of hazard is adopted.

2.5.2.1.6.2 Consideration in assessing the Acute Toxicity LC$_{50}$ in inhalation route

2.5.2.1.6.2.1 Values for inhalation toxicity should be based on a 4-hour animal test.

2.5.2.1.6.2.2When multiple data exists for Acute Inhalation Toxicity given the high reliability of data, and when they fall under multiple categories, basis for the selection and judgment of data for the determination of category will be determined according to Section 5.5.1.3.

2.5.2.1.6.2.3 However, if those data have the same reliability, data are adopted based on the following criteria, converted to the 4-hour values, and calculated.

(c) Use 4-hour data, and evaluate

(d) If the data satisfying the conditions in (a) are not available, use 1-hour data, converted to 4-hour values and evaluate.

(e) If the data satisfying the conditions in (a) and (b) are not available, use data from 30 minutes to 24 hours, converted to 4-hour values and evaluate

(f) If the data classifying the conditions in (a), (b) and (c) are not available, the substance is classified as "Classification not possible". However, a substance which shows lethal effect by exposure of 4 hours or less (including less than 30 minutes) with the concentration of the criterion value or below for Category 1 is classified as Category 1 (inhalation).

Method for converting LC50 value B for A hours into $LC_{50}$ estimate value D for C hours:

Gas / vapor : $D = B \sqrt{A/C}$

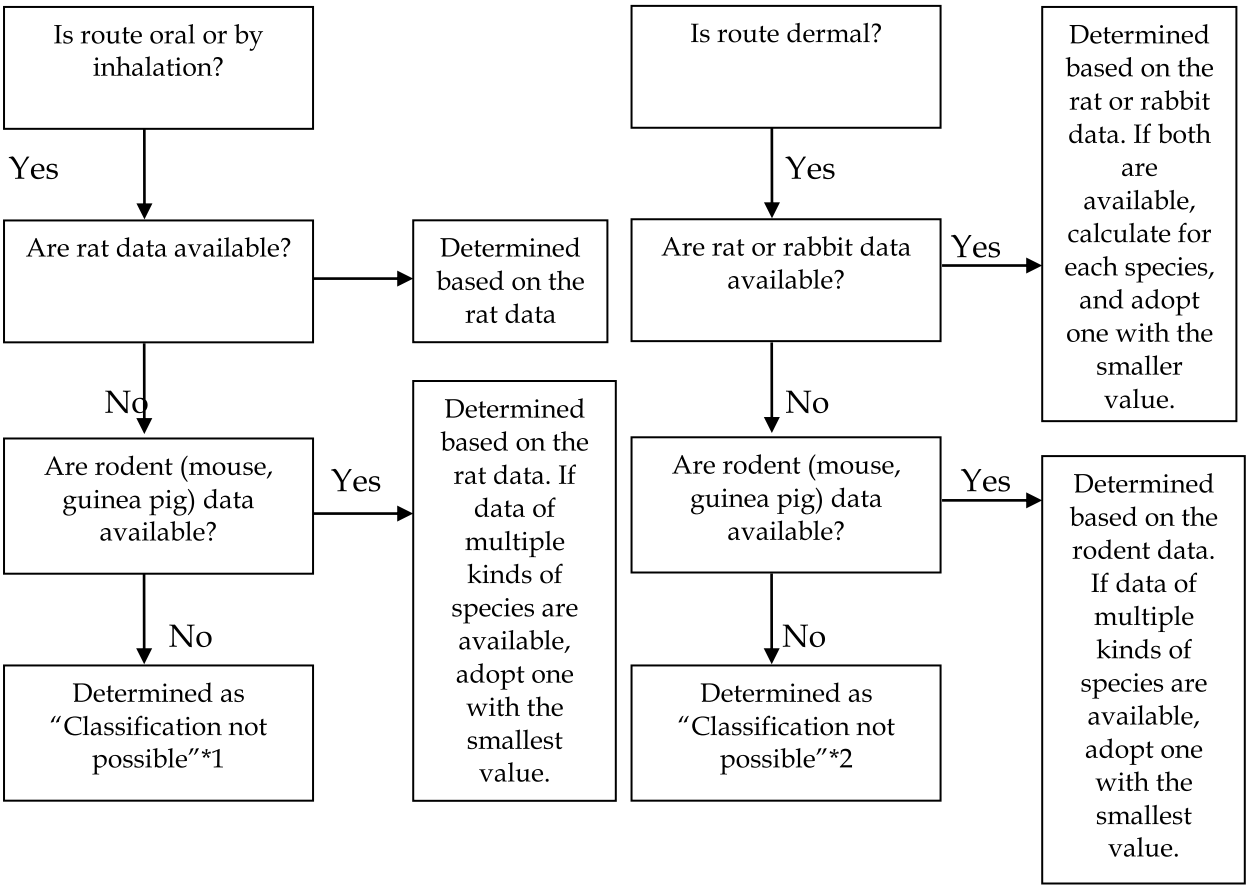
Dust / mist : $D = BA/C$

When performing GHS classification, enter 4 (hours) for C

2.5.2.1.6.2.4 In some cases, it is not clear whether the adopted data is from the vapor inhalation test or mist inhalation test. In these cases, the substance shall be determined as "Classification not possible" unless the obvious conclusion can be given based on physical properties such as vapor pressure.

### 2.5.2.1.7 Notes for handling of animal species difference

**Figure 2.5.2.1.7 Handling of animal species difference**



*1 Data for animals other than rodents are not adopted for classification

*2 Data for animals other than rodents and rabbits are not adopted for classification

### 2.5.2.1.8 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labeling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.5.2.1 Label elements for acute toxicity**

| | Category 1 | Category 2 | Category 3 | Category 4 |
|---|---|---|---|---|
| **Symbol** | Skull and crossbones | Skull and crossbones | Skull and crossbones | Exclamation mark |
| **Signal word** | Danger | Danger | Danger | Warning |
| **Hazard** | Fatal if | Fatal if | Toxic if | Harmful if |

| | | | | |
|---|---|---|---|---|
| **statement: Oral** | swallowed | swallowed | swallowed | swallowed |
| **Hazard statement: Dermal** | Fatal in contact with skin | Fatal in contact with skin | Toxic in contact with skin | Harmful in contact with skin |
| **Hazard statement: Inhalation** See Note | Fatal if inhaled | Fatal if inhaled | Toxic if inhaled | Harmful if inhaled |

**Note:** If a substance is also determined to be corrosive (based on data such as skin or eye data), corrosivity hazard may also be communicated by some authorities as symbol and/ or hazard statement. That is, in addition to an appropriate acute toxicity symbol, a corrosivity symbol (used for skin and eye corrosivity) may be added along with the corrosivity hazard statement such as “corrosive” or “corrosive to the respiratory tract”.

# SECTION 2.5.2.2

# SKIN CORROSION/ IRRITATION

## 2.5.2.2.1 Definition

2.5.2.2.1.1 Skin corrosion is the production of irreversible damage to the skin; namely, visible necrosis through, the epidermis and into the dermis, following the application of a test substance for up to 4 hours. Corrosive reactions are typified by ulcers, bleeding, bloody scabs, and, by the end of observation at 14 days, by discoloration due to blanching of the skin, complete areas of alopecia, and scars. Hispathology shall be considered to evaluate questionable lesions.

2.5.2.2.1.2 Skin irritation is the production of reversible damage to the skin following the application of a test substance for up to 4 hours.

## 2.5.2.2.2 Classification criteria

### 2.5.2.2.2.1 Corrosion

A single harmonized corrosion category is provided in Table 2.5.2.2.2.1, using the results of animal testing. A corrosive is a test material that produces destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least 1 of 3 tested animals after exposure up to a 4 hour duration. Corrosive reactions are typified by ulcers, bleeding, bloody scabs, and, by the end of observation at 14 days, by discoloration due to blanching of the skin, complete areas of alopecia, and scars. Hispathology shall be considered to evaluate questionable lesions.

**Table 2.5.2.2.2.1 Skin corrosion category and sub-categories**

| **Category 1: Corrosive** | Corrosive sub-categories | Corrosive in ≥ 1 of 3 animals | |
|---|---|---|---|
| (applies to auhtorities not using sub-categories | (only applies to some authorities) | Exposure | Observation |
| Corrosive | 1A | ≤ 3 min | ≤ 1 h |
| | 1B | >3 min ≤ 1 h | ≤ 14 days |
| | 1C | > 1 h≤ 4 h | ≤ 14 days |

### 2.5.2.2.2.2 Irritation

A single irritant category is provided in Table 2.5.2.2.2.2 that:

(a) is centrist in sensitivity among existing classifications;

(b) recognizes that some test materials may lead to effects which persist throughout the length of the test; and

(c) acknowledges that animal responses in a test may be quite variable. An additional mild irritant category is available for those authorities that want to have more than one skin irritant category.

**Table 2.5.2.2.2.2 Skin irritation categories**

| Categories | Criteria |
|---|---|
| **Irritant (Category 2)** | (1) mean value of ≥ 2.3 ≤ 4.0 for erythema / eschar or for oedema in at least 2 of 3 tested animals from gradings at 24, 48 and 72 hours after patch removal or, if reactions are delayed, from grades on 3 consecutive days after the onset of skin reactions; or<br>(2) inflammation that persists to the end of the observation period normally 14 days in at least 2 animals, particularly taking into account alopecia (limited area), hyperkeratosis, hyperplasia, and scaling; or<br>(3) in some cases where there is pronounced variability of response among animals, with very definite positive effects related to chemical exposure in a single animal but less than the criteria above. |

### 2.5.2.2.3 Data availability

2.5.2.2.3.1 Few data books that contain Draize scores to which GHS criteria can be applied.

2.5.2.2.3.2 OECD has proposed test method guideline (OECD TG) 435 (In vitro membrane barrier test method) for the classification into skin corrosion sub-categories (1A, 1B and 1C) since classification into sub-categories under Category 1 may not be possible without detailed data on exposure and observation time.

2.5.2.2.3.3 Finding of “Severe”, “Moderate”, “Mild (Slightly)” and others for skin corrosion/ irritation in test reports may be used as reference if irritation score (avergaed score values) based on appropriate irritation data cannot be easily obtained.

2.5.2.2.3.4 R-Phrases (R34, R35, R38, R36/37, R36/38, R37/38, R36/37/38) in EU DSD classification relating to skin corrosion/ irritation be used as reference.

2.5.2.2.3.5 The following Test Methods are OECD Test Guidelines relating to skin corrosion/ irritation:

| | |
|---|---|
| OECD TG 404 | Acute dermal irritation/ corrosion |
| OECD RG 430 | In vitro skin corrosion: Transcutaneous electrical resistance test |
| OECD TG 431 | In vitro skin corrosion: Human skin model test |
| OECD TG 435 | In vitro membrane barrier test method for skin corrosion |

2.5.2.2.3.6 When multiple data exists for skin corrosion/ irritation given the high reliability of data, and when they fall under multiple categories, basis for the selection and judgment of data for the determination of category will be determined according to Section 5.5.1.3.

### 2.5.2.2.4 Comparison with conventional classification systems

2.5.2.2.4.1 Substances shall be classified as Corrosive (C) with R34, R35 in EU DSD classification fall under Category 1.

2.5.2.2.4.2 Substances shall be classified as Irritant (Xi) with R38 and combination of R-Phrases (R36/38, R37/38, R36/37/38) in EU DSD classification fall under Category 2 (in GHS classification). But confirmation with detailed data is required.

2.5.2.2.4.3 EU CLP classification H314 is in accordance with Category 1, H315 is in accordance with Category 2.

2.5.2.2.4.4 Comparison between EU classification and GHS classification is as follows:

Skin corrosion

| | | | |
|---|---|---|---|
| EU DSD classification | C R35 | C R34 | |
| EU CLP classification | H314 (Note) | | |
| GHS classification | Category 1A | Category 1B | Category 1C |

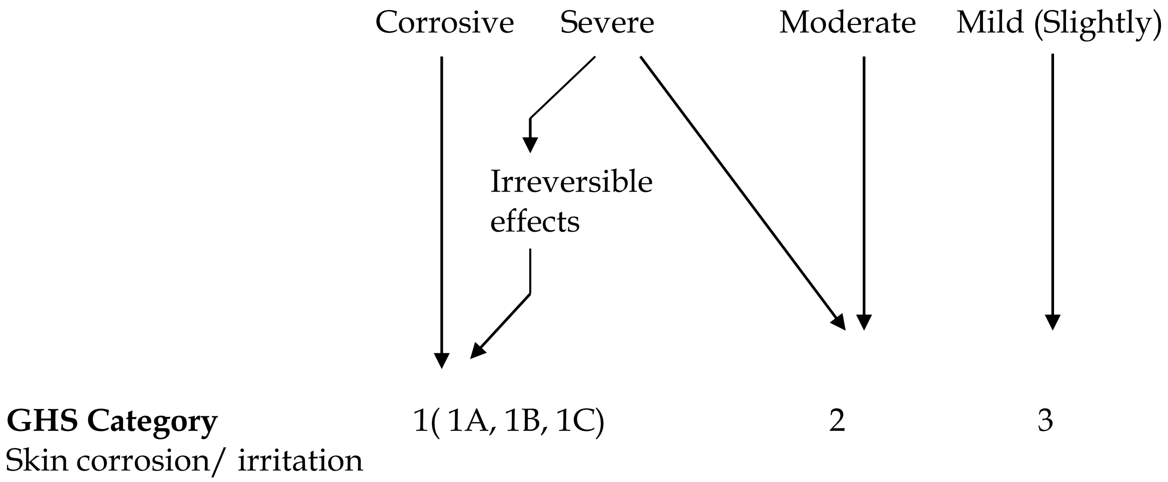
Skin irritation

| | | |
|---|---|---|
| EU DSD classification | Xi R38 | |
| EU CLP classification | H315 | |
| GHS classification | Category 2 | Category 3 |

Note: According to the criteria, H314 includes Category 1 B and 1C. However, in EU CLP regulations Annex VII, H314 is stated as 1B.

2.5.2.2.4.5 Findings of test reports

The following correlation may also be used as reference guide:



2.5.2.2.4.6 Decision based on physicochemical properties

2.5.2.2.4.6.1 Substances considered as strong acids (pH $\geq$ 2) or strong alkalis (pH$\leq$11.5) based on their physicochemical properties shall be classified as Category 1.

**2.5.2.2.5 Guidance for classification**

2.5.2.2.5.1 Judgment by reliable existing revelation course such as accidental cases

When a substance has cases to be judged as corrosion (any sub-categories 1A, 1B and 1C, or Category 1) or irritation (Category 2) in human or animal results, the substance shall be classified as such.

2.5.2.2.5.2 Judgment by existing test data

1.) Decision by in vivo test result

**Corrosion** (any sub-categories 1A, 1B and 1C or Category 1) in at least 1 of 3 animals after exposure for up to 4 hours:

(a) necrosis into the dermis

(b) ulcer, bleeding or bloody scabs in the applied area

(c) blanching of the skin, complete areas of alopecia and remaining scars are found at the end of the observation period of 14 days

(d) in the case of erythema/ eschar or oedema score of 4 more, the substance is determined as Corrosion (Category 1). When, however, no irreversible lesion is found, the substance is determined as irritation (Category2).

**Irritation** (Category 2) at 24, 48 and 72 hours after application:

(a) mean value of Draize Score (for each animal) is $\geq$ 2.3 to $\leq$ 4.0 for erythema/ eschar or oedema in at least 2 of 3 tested animal,

(b) inflammation and alopecia of limited area, hyperkeratosis, hyperplasia and scaling persist to the end of 14 days after application in at least 2 of 3 tested animal, or

(c) definite positive effects are recognized in an animal, but its extent does not satisfy criteria (a) and (b) above.

2.) Decision by comparison with existing classification

(a) the substance shall be classified as Severe or Corrosive is determined as Corrosive (Category 1) and the substance classified as Severe with no irreversible lesion observed is determined as Irritant (Category 2).

(b) the substance shall be classified as Moderate is determined as Irritation (Category 2).

3.) Decision by symptom when no other information is available

When described as necrosis, the substance is determined as corrosive (Category 1).

4.) Decision by in vivo test

If the data of a test based on OECD TG 431 (human skin model, Epiderm), OECD TG 430 (skin electric conductivity test) or OECD TG 435 is available, the substance is classified in accordance with the decision criteria with which each of the test is internationally accepted.

### 2.5.2.2.6 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labeling (Chapter 1.4) of the UN Purple

Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.5.2.2 Label elements for skin corrosion/ irritation**

| | **Category 1** | | | **Category 2** |
|---|---|---|---|---|
| | **1A** | **1B** | **1C** | |
| **Symbol** | Corrosion | Corrosion | Corrosion | Exclamation mark |
| **Signal word** | Danger | Danger | Danger | Warning |
| **Hazard statement** | Causes severe skin burns and eye damage | Causes severe skin burns and eye damage | Causes severe skin burns and eye damage | Causes skin irritation |

# SECTION 2.5.2.3

# SERIOUS EYE DAMAGE/ EYE IRRITATION

### 2.5.2.3.1 Definition

2.5.2.3.1.1 Serious eye damage is the production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application.

2.5.2.3.1.2 Eye irritation is the production of changes in the eye following the application of test substance to the anterior surface of the eye, which are fully reversible within 21 days of application.

### 2.5.2.3.2 Classification criteria

2.5.2.3.2.1 Irreversible effects on the eye/ serious damage to the eyes (Category 1)

A single harmonized hazard category shall be adopted for substances that have the potential to serious damage the eyes. This hazard category – Category 1 includes the criteria listed below:

**Table 2.5.2.3.2.1 Irreversible eye effects categories**

**An eye irritant Category 1 (irreversible effects on the eye)** is a test material that produces:

(a) At least in one animal effects on the cornea, iris or conjunctiva that are not expected to reverse or have not fully reversed within an observation period of normally 21 days; and/or

(b) At least in 2 of 3 tested animals, a positive response of:

(i) corneal opacity $\geq$ 3; and/or

(ii) iritis > 1.5;

calculated as the mean scores following grading at 24, 48 and 72 hours after installation of the test material.

2.5.2.3.2.2 Reversible effects on the eye (Category 2)

A single harmonized category shall be adopted for substances that have the potential to induce reversible eye irritation. This single hazard category provides the option to identify within the category a sub-category for substances inducing eye irritant effects reversing within an observation time of 7 days.

**Table 2.5.2.3.2.2 Reversible eye effects categories**

**An eye irritant Category 2 (irritating to eyes)** is a test material that produces:

(a) At least in 2 of 3 tested animals, a positive response of:

(i) corneal opacity ≥1; and/or

(ii) iritis > 1; and/or

(iii) conjunctival redness ≥; and/or

(iv) conjunctival oedema (chemosis) ≥ 2

calculated as the mean scores following grading at 24, 48 and 72 hours after installation of the test material, and which fully reverses within an observation period of normally 21 days.

### 2.5.2.3.3 Data availability

2.5.2.3.3.1 Few data books contain detailed Draize scores to which GHS classification criteria shall be applied.

2.5.2.3.3.2 Tests by application to animal eyes of corrosive materials are not typically conducted. Thus, in cases where eye irritation test are not available, a skin corrosive material shall be classified as a substance causing serious eye damage (Category 1).

2.5.2.3.3.3 Since data based on irritation score (mean score value) of appropriate irritation data cannot be easily obtained, “Severe”, “Moderate”, “Mild (Slightly)” and others for eye damage/ eye irritation test report findings shall be used as reference.

2.5.2.3.3.5 R-Phrases (R36, R41, R36/37, R36/38, R37/38, R36/37/38) in EU DSD classification relating to serious eye damage/ eye irritation shall be used as reference.

2.5.2.3.3.6 The following Test Methods are OECD Test Guidelines relating to Serious Eye Damage/ Eye Irritation:

OECD TG 405 Acute eye irritation/ corrosion

2.5.2.3.3.7 When multiple data exists for skin corrosion/ irritation given the high reliability of data, and when they fall under multiple categories, basis for the selection and judgment of data for the determination of category shall be determined according to Section 2.5.1.3.

**2.5.2.3.4 Comparison with conventional classification systems**

2.5.2.3.4.1 Substances classified as R41 in EU DSD classification fall under Category 1

2.5.2.3.4.2 Substances classified in R36 and combination of R-Phrases (R36/37, R36/38, R36/37/38) in EU DSD classification fall under Category 2.

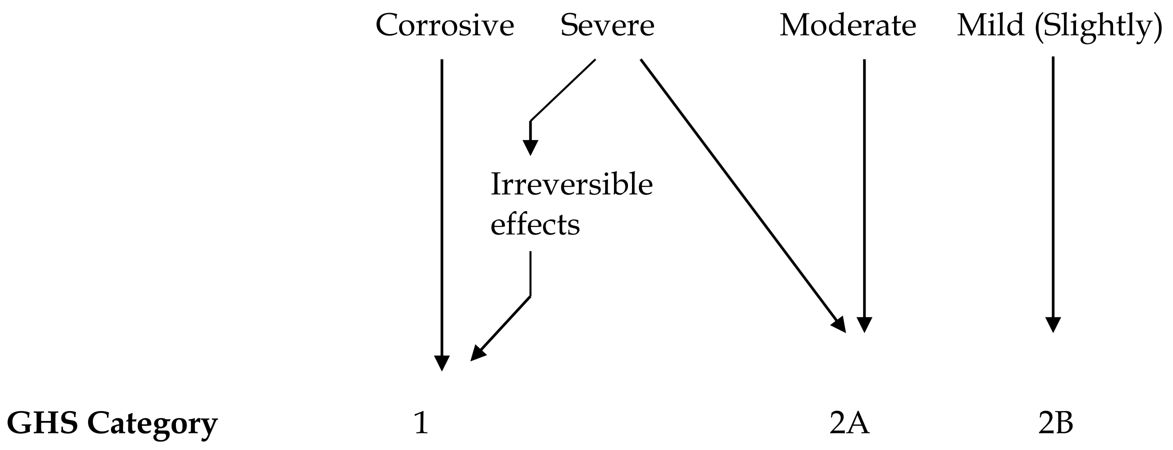
2.5.2.3.4.3 EU CLP classification H318 is in accordance with Category 1, and H319 is in accordance with Category 2.

2.5.2.3.4.4 Comparison between EU classification and GHS classification:

| **EU DSD classification** | Xi R41 | Xi R36 | |
|---|---|---|---|
| **EU CLP classification** | H318 | H319 | |
| **GHS classification** | Category 1 | Category 2A | Category 2B |

2.5.2.3.4.5 Findings of test reports

The following correlation may also be used as reference guide:



Serious Eye Damage/Eye Irritation

### 2.5.2.3.5 Guidance for classification

2.5.2.3.5.1 Judgment by reliable existing revelation course such as accidental cases

If there is a case that attributes to a substance irreversible effects on eye (Category 1) or reversible effects on eye (Category 2) in human or animal results, the substance shall be classified as such.

2.5.2.4.5.2 Judgment by liable existing test data

(1) Decision by in vivo test (Draize test) result:

a. Decision criteria for serious eye damage (irreversible effects) (Category 1):

- At least in one animal effects on the cornea, iris or conjunctiva that are not expected to reverse or have not fully reversed within an observation period of normally 21 days

- At least in 2 of 3 tested animals, the calculated mean scored following grading at 24, 48 and 72 hours after installation of the test material are corneal opacity $\geq 3$ and/or iritis > 1.5.

b. Decision criteria for irritation (reversible effects) (Categories 2A, 2B or Category 2):

- In the Draize test conducted using 3 animals, the calcluated mean values of the scores following grading at 24, 48 and 72 hours after installation of the test material are corneal opacity $\geq 1$ and/or iritis $\geq 1$ and/or conjunctival redness $\geq 2$ and/or conjunctival oedema $\geq 2$.

- The effects are fully reversed within an observation period of 21 days.

- The substance is classified as mildly irritant to eyes (Category 2B) when the above description applies to the substance and the effects reverse within an observation period of 7 days.

(2) Decision by existing classifications:

  (a) A substance which is classified as Severe or Corrosive is classified in Category 1

  (b) A substance which is classified as Moderate is classified as Category 2A.

  (c) A substance which is classified as Mild (Slightly) is classified as Category 2B.

(3) Decision by physicochemical properties

In the case of pH $\leq$ 2 or pH $\geq$ 11.5, the substance is classified in Category 1.

(4) Decision by In vitro test methods

Accepted validated in vitro test methods for eye irritation are OECD TG 437 and OECD TG 438.

### 2.5.2.3.6 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labeling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.5.2.3 Label elements for serious eye damage/ eye irritation**

| | **Category 1** | **Category 2** |
|---|---|---|
| **Symbol** | Corrosion | Exclamation mark |
| **Signal word** | Danger | Warning |
| **Hazard statement** | Causes serious eye damage | Causes serious eye irritation |

# SECTION 2.5.2.4

# RESPIRATORY OR SKIN SENSITIZATION

## 2.5.2.4.1 Definition

2.5.2.4.1.1 A respiratory sensitizer is a substance that will lead to hypersensitivity of the airways following inhalation of the substance.

2.5.2.4.1.2 A skin sensitizer is a substance that will lead to an allergic response following skin contact.

## 2.5.2.4.2 Classification criteria

2.5.2.4.2.1 Respiratory sensitizers

Respiratory sensitizers shall be classified in Category 1:

**Table 2.5.2.4.2.1 Hazard category for respiratory sensitizers**

| Category | Respiratory sensitizer |
|---|---|
| **1** | A substance shall be classified as a respiratory sensitizer:<br>(a) If there is evidence in humans that the substance can lead to specific respiratory hypersensitivity and/or<br>(b) If there are positive results from an appropriate animal test |

2.5.2.4.2.2 Skin sensitizers

Skin sensitizers shall be classified in Category 1:

**Table 5.5.2.4.2.2 Hazard category for skin sensitizers**

| Category | Skin sensitizer |
|---|---|
| **1** | A substance shall be classified as a skin sensitizer:<br>(a) If there is evidence in humans that the substance can lead to sensitization by skin contact in a substantial number of persons, or<br>(b) If there are positive results from an appropriate animal test |

### 2.5.2.4.3 Data availability

2.5.2.4.3.1 Decision on classification is performed based on the weight of evidence for respiratory or skin sensitization. Size of the populatin exposed and the extent of exposure shall be considered when looking into human evidenced.

2.5.2.4.3.2 A single category is adopted for classification of respiratory and skin sensitization. Judgment of expert shall be taken into consideration.

2.5.2.4.3.3 If there are appropriate animal test data showing positive results, classification for skin sensitization shall be based on these data.

2.5.2.4.3.4 The signal word used for skin sensitization Category 1 is "Warning", while the signal word for respiratory sensitization Category 1 is "Danger" since the latter is considered to produce more serious effects on human health.

2.5.2.4.3.5 Some helpful information:

- Frosch et al. Contact Dermatitis 4th Ed. Springer (413 substances)

- "Allergen List" Japanese Society for Contact Dermatitis (25 substances)

2.5.2.4.3.6 EU DSD classification: R42, R43, R42/43

2.5.2.4.3.7 Recommendation of Acceptable Concentration by the Japan Society for Occupational Health: Respiratory tract sensitization and skin sensitization

2.5.2.4.3.8 TLV Table of ACGIH: SEN or Sensitization substances

2.5.2.4.3.9 MAK (Germany): Labeling of Sensitization Substance (Sa, Sh, Sah)

2.5.2.4.3.10 OECD TG for respiratory or skin sensitization

OECD TG 406 Skin sensitization

OECD TG 429 Skin sensitization: Local Lymph Node Assay (LLNA)

2.5.2.4.3.11 When multiple data exists for skin / respiratory sensitization given the high reliability of data, and when they fall under multiple categories, basis for the selection and judgment of data for the determination of category will be determined according to Section 8.5.1.3.

**2.5.2.4.4 Comparison with conventional classification systems**

2.5.2.4.4.1 EU DSD classification categories related to sensitization are R42, R43 and R42/43.

2.5.2.4.4.2 The Recommendation of Acceptable Concentration of the Japan Society for Occupational Health includes the list of substances recognized as sensitizers.

2.5.2.4.4.3 In the TLV table of ACGIH, SEN Mark is assigned to sensitizers.

2.5.2.4.4.4 In the MAK table of MAK 9Germany), Sa, Sh, Sah marks are assigned.

2.5.2.4.4.5 EU DSD classification R42 and R42/43, as well as respiratory tract sensitization in the Recommendation of Acceptable Concentration by the Japan Society for Occupational Health, correspond to respiratory sensitization Category 1.

2.5.2.4.4.6 EU DSD classification R43 and R42/43, as well as skin sensitization in the Japan Society for Occupational Health, correspond to skin sensitization Category 1

2.5.2.4.4.7 EU CLP classification H334 is in accordance with respiratory sensitization Category 1, and H317 is in accordance with skin sensitization Category 1.

2.5.2.4.4.8 Whether SEN substances in ACGIH are respiratory sensitizers or skin sensitizers must be confirmed by reviewing the ACGIH documentations.

**2.5.2.4.5 Hazard communication**

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labeling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.5.2.4.1 Label elements for respiratory or skin sensitization**

| | **Respiratory sensitization Category 1** | **Skin sensitization Category 1** |
|---|---|---|
| **Symbol** | Health hazard | Exclamation mark |
| **Signal word** | Danger | Warning |
| **Hazard statement** | May cause allergy or asthma symptoms or breathing difficulties if inhaled | May cause an allergic skin reaction |

# SECTION 2.5.2.5

# GERM CELL MUTAGENICITY

### 2.5.2.5.1 Definition

2.5.2.5.1.1 This hazard class is primarily concerned with chemicals that may cause mutations in the germ cells of humans that can be transmitted to the progeny. However, mutagenicity/ genotoxicity tests in vitro and in mammalian somatic cells in vivo are also considered in classifying substances within this hazard class.

2.5.2.5.1.2 In the present context, commonly found definitions of the terms mutagenic, mutagen, mutations and genotoxic are sued. A mutation is defined as a permanent change in the amount or structure of the generic material in a cell.

2.5.2.5.1.3 The term mutation applies both to heritable genetic changes that may be manifested at the phenotypic level and to the underlying DNA modifications when known (including, for example, specific base pair changes and chromosomal translocations). The term mutagenic and mutagen will be used for agents giving rise to an increased occurrence of mutations in populations of cells and/or organisms.

2.5.2.5.1.4 Genotoxic and genotoxicity apply to agents or processes which alter the structure, information content, or segregation of DNA, including those which cause DNA damage by interfering with normal replication processes, or which in a non-physiological manner (temporarily) alter its replication. Genotoxicity test results are usually taken as indicators for mutagenic effects.

### 2.5.2.5.2 Classification criteria

2.5.2.5.2.1Classification for heritable effects in human germ cells shall be made on the basis of well conducted, sufficiently validated tests, preferably as described in OECD Test Guidelines. Evaluation of the test results should be done using expert judgment and all available evidence shall be weighed for classification.

2.5.2.5.2.1.1 Examples of *in vivo* heritable germ cell mutagenicity tests are:

Rodent dominant lethal mutation test (OECD 478)
Mouse heritable translocation assay (OECD 485)
Mouse specific locus test

2.5.2.5.2.1.2 Examples of *in vivo* somatic cell mutagenicity tests are:

Mammalian bone marrow chromosome aberration test (OECD 475)
Mouse spot test (OECD 484)
Mammalian erythrocyte micronucleus test (OECD 474)

**Table 2.5.2.5.1 Hazard categories for germ cell mutagens**

| | |
|---|---|
| **Category 1** | **Substances known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cells of humans** |
| **Category 1A** | **Substances known to induce heritable mutations in germ cells of human**<br>Positive evidence from human epidemiological studies. |
| **Category 1B** | **Substances which should be regarded as if they induce heritable mutations in the germ cells of humans**<br>(a) Positive result (s) from in vivo heritable germ cell mutagenicity tests in mammals; or<br>(b) Positive result (s) from in vivo somatic cell mutagenicity tests in mammals, in combination with some evidence that the substance has potential to cause mutations to germ cells. This supporting evidence may, for example, be derived from mutagenicity/ genotoxic tests in germ cells in vivo, or by demonstrating the ability of the substance or its metabolite (s) to interact with the genetic material of germ cells; or<br>(c) Positive results from tests showing mutagenic effects in the germ cells of humans, without demonstration of transmission to progeny; for example, an increase in the frequency of aneuploidy in sperm cells of exposed people. |
| **Category 2** | **Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans**<br>Positive evidence obtained from experiments in mammals and/or in some cases from in vitro experiments, obtained from:<br>(a) Somatic cell mutagenicity tests in vivo, in mammals; or<br>(b) Other in vivo somatic cell genotoxicity tests which are supported by positive results from in vivo mutagenicity assays.<br>**Note:** Substances which are positive in in vitro mammalian mutagenicity assays, and which also show structure activity relationship to known germ cell mutagens, should be considered for classification as Category 2 mutagens. |

### 2.5.2.5.3 Data availability

2.5.2.5.3.1 Results from many mutagenicity tests (or genotoxicity tests) are reported including in vitro tests, but results from in vivo tests using mammalian germ cells are rare. Expert's judgment is required.

2.5.2.5.3.2 Chemicals having dataset from *in vivo* and *in vitro* tests are less in number than chemicals having *in vitro* test data only. Generally, it is difficult to determine the existence of heritable mutagenicity based on results of *in vitro* tests only.

2.5.2.5.3.3 Results from rodent sperm shape abnormality test are better not to be used in this classification in principle since they may be affected by effects to other than genetic materials.

2.5.2.5.3.4 Data from various kinds of tests using drosophila (sex-linked or recessive lethal test, wing spot test, etc) are, generally, better not to be used in this classification since biological dynamics and reproduction development process are not the same between insects and mammals. However, when other suitable mammalian *in vivo* mutagenicity / genotoxicity test data are not available, and especially when positive results from drosophila sex-linked or recessive lethal test are available, judgment by experts in these fields shall be sought for using the data and GHS classification category.

2.5.2.5.3.5 There exist many kinds of *in vitro* genotoxicity tests (Comet testing mammalian culture cells, UDS test in mammalian culture cells, DNA (Re-assay) in Bacillus subtilis, umu test in Salmonella typhimurium, SOS test in Escherichia coli, chromatid aberration with aneuploid test in yeast) and Host-mediated assay, but results of these tests are, in principle, not used in this classification.

2.5.2.5.3.6 In *in vivo* mutagenicity/ genotoxicity tests, various administration routes are used. Although the common human exposure routes take precedence, test data with any administration route may be utilized unless the inappropriateness of the route is rationally explained.

2.5.2.5.3.7 Substances that have been concluded by epidemiological studies to induce heritable mutation in human population shall be classified in Category 1A.

2.5.2.5.3.8 Substances which have the potential to induce genetic mutations or chromosomal abnormality in human germ cells based on other information shall be classified in Category 2. Category 2 includes substances having positive evidence from *in vivo* somatic cell mutagenicity tests in mammals (mammaliam bone marrow chromosomal abnormality test, mammalian erythrocyte micronucleus test, mouse spot test), or positive results in *in vivo* somatic cell genotoxocity tests (*in vivo* liver unscheduled DNA synthesis (UDS) test, mammalian bone marrow sister chromatid exchange (SCE) test) and positive results from *in vitro* mutagenicity tests (*in vitro* mammalian chromosomal abnormality test, *in vitro* mammalian cell genetic mutation test, bacterial reverse mutation test). Substances which have positive results from *in vitro* mammalian mutagenicity tests only but show (strong) structural similarity with known germ cell mutagens (category 1) shall be classified in Category 2.

2.5.2.5.3.9 OECD Test Guidelines include the following test methods relating to mutagenicity/ genotoxicity.

TG 471 Bacterial Reverse Mutation Test (Ames Test)
TG 473 In Vitro Mammalian Chromosome Aberration Test
TG 474 Mammalian Erythrocyte Micronucleus Test
TG 475 Mammalian Bone Marrow Chromosome Aberration Test)
TG 476 In Vitro Mammalian Cell Gene Mutation Test
TG 477 Genetic Toxicology: Sex-linked Recessive Lethal Test in Drosophila Melanogaster
TG 478 Genetic Toxicology: Rodent Dominant Lethal Test
TG 479 Genetic Toxicology: In Vitro Sister Chromatid Exchange Assay in Mammalian Cells
TG 480 Genetic Toxicolgy: Saccharomyces Cerevisiae Gene Mutation Assay
TG 481 Genetic Toxicolgy: Saccharomyces Cerevisiae Mitotic Recombination Assay
TG 482 Genetic Toxicolgy: DNA Damage and Repair, Unscheduled DNA Synthesis in Mammalian Cells In Vitro
TG 483 Mammalian Spermatogonial Chromosome Aberration Test
TG 484 Genetic Toxicology: Mouse Spot Test
TG 485 Genetic Toxicology: Mouse Heritable Translocation Assay
TG 486 Unscheduled DNA Synthesis (UDS) Test with Mouse Liver Cells In Vitro
TG 487 In Vitro Mammalian Cell Micronucleus Test, Draft

### 2.5.2.5.4 Comparison with conventional classification systems

2.5.2.5.4.1 The concept of GHS classification for Germ Cell Mutagenicity is in accordance with that for Mutagen Categories 1,2, and 3 in EU DSD classification.

2.5.2.5.4.2 Mutagens classified as Category 1 (R46) in EU DSD classification corresponds to substances in Category 1A.

2.5.2.5.4.3 Mutagens classified as Category 2 (R46) in EU DSD classification corresponds to substances in Category 1B.

2.5.2.5.4.4 Mutagens classified as Category 3 (R68) in EU DSD classification corresponds to substances in Category 2.

2.5.2.5.4.5 EU CLP classification H340 is in accordance with Category 1B and H341 with Category 2.

### 2.5.2.5.5 Guidance for classification

2.5.2.5.5.1 Data concerning mutagenicity tests are relatively abundant, and the data concerning mutagenicity in human germ cells (in vivo tests rather than in vitro, tests using human cells rather than mammalian cells, tests using germ cells rather than somatic cells) shall be given a high priority.

2.5.2.5.5.2 As can be seen from the classification criteria described in the GHS document, generally, positive results from in vitro mutagenicity tests alone do not serve as a basis for classification to Category 2. Similar attention should be paid to results from in vivo mutagenicity tests in drosophila. Some test reports may contain several negative or positive results, and classification based on only some of the positive results needs to be verified.

### 2.5.2.5.6 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labeling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.5.2.5.1 Label elements for gem cell mutagenicity**

| | **Category 1 (Category 1A, 1B)** | **Category 2** |
|---|---|---|
| **Symbol** | Health hazard | Health hazard |
| **Signal word** | Danger | Warning |
| **Hazard statement** | May cause genetic defects (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard) | Suspected of causing genetic defects (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard) |

# SECTION 2.5.2.6

# CARCINOGENICITY

## 2.5.2.6.1 Definition

2.5.2.6.1.1 Carcinogen denotes a substance which induces cancer or increases its incidence. Substances which have induced benign and malignant tumors in well performed experimental studies on animals are considered also to be presumed or suspected human carcinogens unless there is strong evidence that the mechanism of tumor formation is not relevant for humans.

2.5.2.6.1.2 Classification of a substance as posing a carcinogenic hazard is based on its inherent properties and does not provide information on the level of the human cancer risk which the use of the substance may represent.

## 2.5.2.6.2 Classification criteria

**Table 2.5.2.6.1 Hazard categories for carcinogens**

| Category | Criteria |
|---|---|
| **1** | **Known or presumed human carcinogens**<br>The placing of a substance in Category 1 is done on the basis of epidemiological and/or animal data. An individual substance may be further distinguished: |
| **1A** | **Known to have carcinogenic potential for humans; the placing of a substance is largely based on human evidence.** |
| **1B** | **Presumed to have carcinogenic potential for humans; the placing of a substance is largely based on animal evidence.**<br>Based on strength of evidence together with additional considerations, such evidence may be derived from human studies that establish a causal relationship between human exposure to a substance and the development of cancer (known human carcinogen). Alternatively, evidence may be derived from animal experiments for which there is sufficient evidence to demonstrate animal carcinogenicity (presumed human carcinogen). In addition, on a case by case basis, scientific judgment may warrant a decision of presumed human carcinogenicity derived from studies showing limited evidence of carcinogenicity in humans together with limited evidence of carcinogenicity in experimental animals |

| | |
|---|---|
| | **Classification:** Category 1 (A and B) Carcinogen |
| **2** | **Suspected human carcinogen**<br>The placing of a substance in Category 2 is done on the basis of evidence obtained from human and/or animal studies, but which is not sufficiently convincing to place the substance in Category 1. Based on strength of evidence together with additional considerations, such evidence may be from either limited evidence of carcinogenicity in human studies of from limited evidence of carcinogenicity in animal studies.<br>**Classification:** Category 2 Carcinogen |

2.5.2.6.2.1Carcinogen classification is a one-step, criterion-based process that involves two interrelated determinations; evaluation of strength of evidence and consideration of all other relevant information to place substances with human cancer potential into hazard categories.

2.5.2.6.2.2 *Strength of evidence* involves the enumeration of tumors 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 tumors. 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 the 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).

2.5.2.6.2.3 *Additional considerations (weight of evidence)*: beyond the determination of the strength of evidence for carcinogenicity, a number of other factors should be considered that influence the overall likelihood that an agent may pose a carcinogenic hazard in humans. The full list of factors that influence this determination is very lengthy, but some of the important ones are considered here.

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

(a) Tumor type and background incidence;

(b) Multisite responses;
(c) Progression of lesions to malignancy;

(d) Reduced tumor latency;

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

(e) Whether responses are in single or both sexes;

(f) Whether responses are in a single species or several species;

(g) Structural similarity or not to a substance (s) for which there is good evidence of carcinogenicity;

(h) Routes of exposure;

(i) Comparison of absorption, distribution, metabolism and excretion between test animals and humans;

(j) The possibility of a confounding effect of excessive toxicity at test doses;

(k) Mode of action and its relevance for humans, such as mutagenicity, cytotoxicity with growth stimulation, mitogenesis, immunosuppression.

#### 2.5.2.6.3 Data availability

2.5.2.6.3.1 Descriptions of carcinogenicity are found frequently in hazard-related reviews or data collections.

2.5.2.6.3.2 Several organizations have reported ranking of carcinogenicity, which should be useful for classification:

(a) (WHO International Agency for Research on Cancer (IARC)

(b) Classification results in Annex I of EU 7th Amendment to Council Directive

(c) National Toxicology Program (NTP)

(d) Carcinogens in "Recommendations for allowable concentrations" by Japan Society for Occupational Health,

(e) Carcinogenicity notes in "TLV and BEIs" by ACGIH

(f) US-EPA Integrated Risk Information System (IRIS)

(g) Carcinogenicity notes in "List of MAK and BAT values" by German DFG

2.5.2.6.3.3 Evaluation by IARC and EU represents a consensus of many expert opinions and therefore shall be given the 1st priority.

2.5.2.6.3.4 Refer to any information released by the Japan Society for Occupational Health, US-EPA, US-NTP, ACGIH, or German DGF, which is given the next priority.

2.5.2.6.3.5 OECD Test Guidelines include the following test methods in relation to Carcinogenicity:

| | |
|---|---|
| OECD TG 451 | Carcinogenicity studies |
| OECD TG 453 | Combined chronic toxicity/ carcinogenicity studies |

2.5.2.6.3.6 When multiple data exists for Carcinogenicity given the high reliability of data, and when they fall under multiple categories, basis for the selection and judgment of data for the determination of category will be determined according to Section 5.5.1.3.

### 2.5.2.6.4 Comparison with conventional classification systems

2.5.2.6.4.1 The principles of GHS classification for Carcinogenicity are in accordance with those of the IARC Carcinogenicity group classification and the Carcinogenicity category classification of EU classification.

2.5.2.6.4.2 The GHS classification categories are generally the same as those in conventional classification systems.

**Table 2.5.2.6.4.2 Correspondence table between GHS classification and classifications by other organizations on Carcinogenicity**

| GHS | IARC | JSOH | ACGIH | EPA 1986 | EPA 1996 | EPA 2005 | NTP | EU |
|---|---|---|---|---|---|---|---|---|
| **1A** | 1 | 1 | A1 | A | K/L | CaH | K | 1 |
| **1B** | 2A | 2A | A2 | B1,<br>B2 | | L | R | 2 |
| **2** | 2B | 2B | A3 | C | | S | | 3 |
| **Classification not possible** | 3 | 3 | A4 | D | CBD | I | | |
| **Not classified** | 4 | 4 | A5 | E | NL | NL | | |

**Note 1:** When classification for carcinogenicity is performed according to the above table, data need not to be input into other items such as toxicity information or epidemiological/ occupational exposure/

When EU classification alone is available, however, searching for evidence supporting the classifications is needed.

**Note 2:** Note that the abbreviations of EPA classification change from year to year.

**Abbreviations in the 1986 Guideline:**

A: Human carcinogen

B1: Probably human carcinogen 9Limited human evidence of carcinogenicity in human)

B2: Probably human carcinogen (sufficient animal evidence, but inadequate human evidence for carcinogenicity)

C: Possible human carcinogen (human data are inadequate and animal data demonstrate limited evidence of carcinogenicity)

D: Not classifiable as to human carcinogenicity

E: Evidence of non-carcinogenicity for human

**Abbreviations in the 1996 Guideline:**

K: Known human carcinogens

L: Likely to produce cancer in humans

CBD: Cannot be determined

NL: Not likely to be carcinogenic in humans

**Abbreviations in the 2005 Guideline:**

CaH: Carcinogenic to humans

L: Likely to be carcinogenic in humans

S: Suggestive evidence of carcinogenic potential

I: Inadequate information to assess carcinogenic potential

NL: Not likely to be carcinogenic to humans

### Abbreviations in the IARC classification:

Group 1: Carcinogen To humans

Group 2A: Probably carcinogenic to humans

Group 2B: Possibly carcinogenic to humans

Group 3: Not classifiable as to carcinogenicity to humans

Group 4: Probably not carcinogenic to humans

### Abbreviations in the Japan Society for Occupational Health classification:

Group 1: Carcinogenic to humans

Group 2A: Probably carcinogenic to humans

Group 2B: Possibly carcinogenic to humans

### Abbreviations in the ACGIH classification:

A1: Confirmed human carcinogen

A2: Suspected human carcinogen

A3: Confirmed animal carcinogen with unknown relevance to humans

A4: Not classifiable as a human carcinogen

A5: Not suspected as a human carcinogen

### Abbreviations in the National Toxicology Program (NTP) classification:

K: Known

R: Reasonably suspected

### 2.5.2.6.5 Guidance for classification

2.5.2.6.5.1 Data verified by credible agencies, such as those derived from the materials specified in “Priority 1”. Evaluation by IARC and EU represents a consensus of many expert opinions and therefore shall be given a high priority. Refer to any information released by Japan Society for Occupational Health, US-EPA, US-NTP, ACGIH or German DGF, which is given the next priority.

2.5.2.6.5.2 Data that are deemed reliable, such as those obtained by GLP-conforming laboratories or those whose scientific basis is available and verified.

2.5.2.6.5.3 Data obtained from other information sources, such as those derived from the materials specified in “Priority 2” and “Priority 3”.

### 2.5.2.6.6 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labeling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.5.2.6.1 Label elements for carcinogenicity**

| | **Category 1 (Category 1A, 1B)** | **Category 2** |
|---|---|---|
| **Symbol** | Health hazard | Health hazard |
| **Signal word** | Danger | Warning |
| **Hazard statement** | May cause cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard) | Suspected of causing cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard) |

# SECTION 2.5.2.7

# REPRODUCTIVE TOXICITY

## 2.5.2.7.1 Definition

2.5.2.7.1.1 Reproductive toxicity includes adverse effects on sexual function and fertility in adult males and females, as well as developmental toxicity in the offspring. The definitions presented below are adapted from those agreed as working definitions in IPCS/EHC Document N◦225 Principles for evaluating health risks to reproducyion associated with exposure to chemicals. For classification purposes, the known induction of genetically based inheritable effects in the offspring is addressed in Germ Cell Mutagenicity since in the present classification system it is considered more appropriate to address such effects under the separate hazard class of germ cell mutagenicity.

2.5.2.7.1.2 In this classification system, reproductive toxicity is subdivided under two main headings:

(a) Adverse effects on sexual function and fertility;

(b) Adverse effects on development of the offspring

2.5.2.7.1.3 Adverse effects on sexual function and fertility

Any effect of chemicals that would interfere with sexual function and fertility. This may include, but not limited to, alterations to the female and male reproductive system, adverse effects on onset of puberty, gamete production and transport, reproductive cycle normality, sexual behavior, fertility, parturition, pregnancy outcomes, premature reproductive senescence, or modifications in other functions that are dependent on the integrity of the reproductive systems.

Adverse effects on or via lactation are also included in reproductive toxicity, but for classification purposes, such effects are treated separately. This is because it is desirable to be able to classify chemicals specifically for an adverse effect on lactation so that a specific hazard warning about this effect can be provided for lactating mothers.

### 2.5.2.7.1.4 Adverse effects on development of the offspring

Taken in its widest sense, developmental toxicity includes any effect which interferes with normal development of the conceptus, either before or after birth, and resulting from exposure of either parent prior to conception, or exposure of the developing offspring during prenatal development, or post natally, to the time of sexual maturation. However, it is considered that classification under the heading of developmental toxicity is primarily intended to provide a hazard warning for pregnant women and men and women of reproductive capacity. Theredore, for pragmatic purposes of classification, developmental toxicity essentially means adverse effects induced during pregnancy, or as a result of parental exposure. These effects can be manifested at any point in the life span of the organism. The major manifestations of developmental toxicity include death of the developing organism, structural abnormality, altered growth and functional deficiency.

### 2.5.2.7.2 Classification criteria

**Table 2.5.2.7.1 Hazard categories of reproductive toxicants**

| |
|---|
| **Category 1:Known or presumed human reproductive toxicant**<br>This category includes substances which are known to have produced an adverse effect on sexual function and fertility or on development in humans or for which there is evidence from animal studies, possibly supplemented with other information, to providea strongpresumption that the substance has the capacity to interfere with reproduction in humans. For regulatory purposes, a substance can be further distinguished on the basis of whether the evidence for classification is primarily from human data (Category 1A) or from animal data (Category 1B).<br>**Category 1A**: **Known human reproductive toxicant**<br>The placing of the substance in this category is largely based on evidence from humans.<br>**Category 1B: Presumed human reproductive toxicant**<br>The placing of the substance in this category is largely based on evidence from experimental animals. Data from animal studies should provide clear evidence of adverse effect on sexual function and fertility or on development in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of other toxic effects. However, when there is |

mechanistic information that raises doubt about the relevance of the effect for humans, classification in Category 2 may be more appropriate.

**Category 2: Suspected human reproductive toxicant**

This category includes substances for which there is some evidence from humans or experimental animals, possibly supplemented with other information, of adverse effect on sexual function and fertility, or on development, in the absence of other toxic effects, or if occurring together with other toxic effects, adverse effects on reproduction is considered not to be a secondary non-specific consequence of the other toxic effects, and where the evidence is not sufficiently convincing to place the substance in Category 1. For instance, deficiencies in the study may make the quality of evidence less convincing, and in view of this Category 2 could be the more appropriate classification.

**Table 2.5.2.7.2 Hazard categoriy for effects on or via lactation**

**EFFECTS ON OR VIA LACTATION**

**Effects on or via lactation** are allocated to a separate single category. It is appreciated that for many substances there is no information on the potential to cause adverse effects on the offspring via lactation. However, substances which are absorbed by women and have been shown to interfere with lactation, or which may be present (including metabolites) in breast milk in amounts sufficient to cause concern for the health of a breastfed child, should be classified to indicate this property hazardous to breastfed babies. This classification can be assigned on the basis of:

(a) absorption, metabolism, distribution and excretion studies that would indicate the likelihood the substance would bepresent in potentially toxic level in breast milk; and/or
(b) results of one or twogeneration studies in animals which provide clear evidence of adverse effect in the offspring due to the transfer in the milk or adverse effect on the quality of the milk; and/or
(c) human evidence indicating a hazard to babies during the lactation period.

### 2.5.2.7.3 Data availability

2.5.2.7.3.1 Evaluation of reproductive toxicity has been reported in "Chemical Substance Hazard Data" prepared by CERI, EHC, ECETOC, SIDS, etc.

2.5.2.7.3.2 A large amount of data is available from reports on reproductive toxicity, but whether they meet the criteria must be checked by experts by tracing back to their original publication.

2.5.2.7.3.3 Testing methods (OECD Test Guidelines include the following testing methods in relation to Reproductive Toxicity)

| | |
|---|---|
| OECD TG 414 | Prenatal development toxicity study |
| OECD TG 415 | One-generation reproduction toxicity study |
| OECD TG 416 | Two-generation reproduction toxicity |
| OECD TG 421 | reproduction/ developmental toxicity screening test |
| OECD TG 422 | Combined repeated does toxicity study with the reproduction/ developmental toxicity screening test |

2.5.2.7.3.4 When multiple data exists for Reproductive Toxicity given the high reliability of data, and when they fall under multiple categories, basis for the selection and judgment of data for the determination of category will be determined according to Section 8.5.1.3.

### 2.5.2.7.4 Comparison with conventional classification systems

2.5.2.7.4.1 The concept of the EU category classification on reproductive toxicity is in accordance with that of the GHS category classification.

2.5.2.7.4.2 Substances classified as Category 1 in EU DSD classification with R60, R61 fall under GHS classification Category 1A.

2.5.2.7.4.3 Substances classified as Category 2 in EU DSD classification with R60, R61 fall under GHS classification Category 1B.

2.5.2.7.4.4 Substances classified as category 3 in EU DSD classification with R62, R63 fall under GHS classification Category 2.

2.5.2.7.4.5 Substances in EU DSD classification R64 (May be hazardous for breastfed children) fall under “the additional category for effects on or via lactation”.

2.5.2.7.4.6 EU CLP classification H360D and H360F are in accordance with Category 1A or Category 1B, and H361d and H361f are in accordance with Category 2. H360FD, H360Fd and H360Df are in accordance with Category 1A or 7

### 2.5.2.7.5 Guidance for classification

The following shall be given a high priority:

2.5.2.7.5.1 Data verified by credible agencies, such as those derived from the materials specified in “Priority 1”.

2.5.2.7.5.2 If appropriate information sources based on data cannot be obtained easily, classification is performed based on the evaluation by the EU, the only organization performing evaluation on reproductive toxicity.

2.5.2.7.3 Data that are deemed reliable, such as those obtained by GLP-conforming laboratories or those whose scientific basis is available and verified.

2.5.2.7.4 Data obtained from other information sources, such as those derived from the materials specified in "Priority 2" and "Priority 3".

### 2.5.2.7.6 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labeling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.5.2.7.1 Label elements for reproductive toxicity**

| | **Category 1 (Category 1A, 1B)** | **Category 2** | **Additional category for effects on or via lactation** |
|---|---|---|---|
| **Symbol** | Health hazard | Health hazard | No symbol |
| **Signal word** | Danger | Warning | No signal word |
| **Hazard statement** | May damage fertility or the unborn child (state specific effect if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard) | Suspected of damaging fertility or the unborn child (state specific effect if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard) | May cause harm to breast-fed children |

# SECTION 2.5.2.8

# SPECIFIC TARGET ORGAN TOXICITY
# SINGLE EXPOSURE

## 2.5.2.8.1 Definition

2.5.2.8.1.1 The purpose of this chapter is to provide a means of classifying substances that produce specific, non-lethal target organ toxicity arising from a single exposure. All significant health effects that can impair function, reversible and irreversible, immediate and/or delayed and not specifically addressed in section 2.5.2.1 to 2.5.2.7 and 2.5.2.10 are included.

2.5.2.8.1.2 Classification identifies the substance as being a specific target organ toxicant and, as such, it may present a potential for adverse health effects in people who are exposed to it.

2.5.2.8.1.3 Classification depends upon the availability of reliable evidence that a single exposure to the substance has produced a consistent and identifiable toxic effects in humans, or, in experimental animals, toxicologically significant changes which have affected the function or morphology of a tissue/organ, or has produced serious changes to the biochemistry or hematology of the organism and these changes are relevant for human health. It is recognized that human data will be the primary source of evidence for this hazard class.

2.5.2.8.1.4 Assessment should take into consideration not only significant changes in a single organ or biological system but also generalized changes of a less severe nature involving several organs.

2.5.2.8.1.5 Specific target organ toxicity can occur by any route that is relevant for humans, i.e. principally oral, dermal or inhalation.

2.5.2.8.1.6 Specific target organ toxicity following a repeated exposure is classified in the GHS as described in Specific target organ toxicity- repeated exposure (Section 5.5.2.9) and is therefore excluded from the present section. Other specific toxic effects, listed below are assessed separately in the GHS and consequently are not included here:

(a) Acute toxicity (Section 2.5.2.1);

(b) Skin corrosion/ irritation (Section 2.5.2.2)

(c) Serious eye damage/ eye irritation (Section 5.5.2.3)

(d) Respiratory or skin sensitization (Section 2.5.2.4)

(e) Germ cell mutagenicity (Section 2.5.2.5)

(f) Carcinogenicity (Section 2.5.2.6)

(g) Reproductive toxicity (Section 2.5.2.7)

(h) Aspiration toxicity (Section 2.5.2.10)

### 2.5.2.8.2 Classification criteria

2.5.2.8.2.1 Criteria for respiratory tract irritation

The criteria for respiratory tract irritation are:

(a) Respiratory irritant effects characterized by localized redness, edema, pruritis and/or pain) that impair function with symptoms such as cough, pain, choking, and breathing difficulties are included. It is recognized that this evaluation is based primarily on human data;

(b) Subjective human observations could be supported by objective measurements for clear respiratory tract irritation (RTI) (e.g. electrophysiological responses, biomarkers of inflammation in nasal or bronchoalveolar lavage fluids);

(c) The symptoms observed in humans should also be typical of those that would be produced in the exposed population rather than being an isolated idiosyncratic reaction or response triggered only in individuals with hypersensisitive airways. Ambiguous reports simply of "irritation" should be excluded as this term is commonly used to describe a wide range of sensations including those such as smell, unpleasant taste, a tickling sensation, and dryness, which are outside the scope of this classification endpoint;

(d) There are currently no validated animal tests that deal specifically with RTI, however, useful information may be obtained from the single and repeated inhalation toxicity tests. For example, animal studies may provide useful information in terms of clinical signs of toxicity (dyspnoea, rhinitis etc) and hispathology (e.g. hyperemia, edema, minimal inflammation, and thickened mucous layer) which are reversible and may be reflective of the characteristic clinical symptoms described above. Such animal studies can be used as part of weight of evidence evaluation;

(e) This special classification would occur only when more severe organ effects including in the respiratory system are not observed.

2.5.2.8.2.2 Criteria for narcotic effects

The criteria narcotic effects are:

(a) Central nervous system depression including narcotic effects in humans such as drowsiness, narcosis, reduced alertness, loss of reflexes, lack of coordination, and vertigo are included. These effects can also be manifested as severe headache or nausea, and can lead to reduce judgment, dizziness, irritability, fatigue, impaired memory function, deficits in perception and coordination, reaction time, or sleepiness;

(b) Narcotic effects observed in animal studies may include lethargy, lack of coordination righting reflex, narcosis, and ataxia. If these effects are not transient in nature, then they should be considered for classification as Category 1 and 2.

**Table 2.5.2.8.1 Hazard categories for specific target organ toxicity following single exposure**

| | |
|---|---|
| <u>Category 1</u>: | **Substances that have produced significant toxicity in humans or that, on the basis of evidence from studies in experimental animals, can be presumed to have the potential to produce significant toxicity in humans following a single exposure**<br>Placing a substance in Category 1 is done on the basis of:<br>(a) reliable and goodquality evidence from human cases or epidemiological studies; or<br>(b) observations from appropriate studies in experimental animals in which significant and/or severe toxic effects of relevance to human health were produced at generally low exposure concentrations. Guidance dose/ concentration values are provided below to be used as part of weight-of evidence evaluation. |
| <u>Category 2</u>: | **Substances that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to be harmful to human health following a single exposure**<br>Placing a substance in Category 2 is done on the basis of |

observations from appropriate studies in experimental animals in which significant toxic effects, of relevance to human health, were produced at generally moderate exposure concentrations. Guidance dose/ concentration values are provided below in order to help in classification.

In exceptional cases, human evidence can also be used to place a substance in Category 2.

**Category 3:Transient target organs effects**

There are target organ effects for which a substance may not meet the criteria to be classified in Categories 1 or 2 indicated above. These are effects which adversely alter human function for a short duration after exposure and from which humans may recover in a reasonable period without leaving significant alteration of structure or function. This category also includes narcotic effects and respiratory tract irritation. Substances may be classified specifically for these effects as discussed in 3.8.2.2 of the UN GHS.

*Note: For these categories, the specific target organ/system that has been primarily affected by the classified substance may be identified, or the substance may be identified as a general toxicant. Attempts should be made to determine the primary target organ of toxicity and classify for that purpose, e.g. as hepatotoxicants, neurotoxicants. One should carefully evaluate the data and, where possible, not include secondary effects, e.g. a hepatotoxicant can produce secondary effects in the nervous or gastro-intestinal systems.*

**Table 2.5.2.8.2 Guidance value ranges for single-dose exposures**

| | | **Guidance value ranges for:** | | |
|---|---|---|---|---|
| Routes of exposure | Units | Category 1 | Category 2 | Category 3 |
| Oral (rat) | mg/kg body weight | C ≤ 300 | 300 < C ≤ 2000 | Guidance values do not apply |
| Dermal (rat or rabbit) | mg/kg body weight | C ≤1000 | 1000 < C ≤ 2000 | |
| Inhalation (rat) gas | Ppm | C ≤2500 | 2500 < C ≤ 20000* | |
| Inhalation (rat) vapor | mg/L | C ≤10 | 10< C ≤ 20 | |
| Inhalation (rat) dust/mist/fume | mg/L 4h | C ≤1.0 | 1.0< C ≤5.0 | |

### 2.5.2.8.3 Data availability

2.5.2.8.3.1 When utilizing descriptions in existing MSDSs, the quoted original reports must be reviewed. Even if MSDSs according to GHS classification are utilized, for confirmation of the classification, the original reports shall be reviewed.

2.5.2.8.3.2 Sufficient information for classification cannot be obtained from the brief descriptions in existing SDSs. A literature search shall be conducted to obtain solid information from reviews or primary information concerning toxicity.

2.5.2.8.3.3Substances with R-Phrases (R39, R68 R37 and R67) in EU DSD classification are feared to possess specific target organ toxicity (single exposure)

2.5.2.8.3.4 T+, R39 and T, R39 correspond to Category 1. R68 corresponds to Category 2. R37 and R67 correspond to Single Exposure Category 3 respiratory tract irritation and narcotic effects, respectively.

2.5.2.8.3.5 When multiple data exists for Specific Target Organ Toxicity (STOT) given the high reliability of data, and when they fall under multiple categories, basis for the selection and judgment of data for the determination of category will be determined according to Section 5.5.1.3.

### 2.5.2.8.4 Comparison with conventional classification systems

2.5.2.8.4.1 Systems in accordance with GHS include R-Phrases (R39, R68, R37 and R67) in EU DSD classification.

2.5.2.8.4.2 EU CLP classification H370 accords with Category 1, H371 accords with Category 2 and H335 or H336 accord with Category 3.

### 2.5.2.8.5 Guidance for classification

2.5.2.8.5.1 If information concerning specific, non-lethal, specific organ/systemic toxicity arising from a single is obtained, whether the toxicity is significant to human health shall be determined through expert judgment.

2.5.2.8.5.2 The relevant route of exposure by which the classified substance has produced damage shall be identified.

2.5.2.8.5.3 Examples of toxic effects in humans or experimental animals that must be taken into consideration in the classification of specific organ/systemic toxicity are provided below:

(a) Morbidity resulting from single exposure;

(b) Significant functional changes, more than transient in nature, in the respiratory system, central or peripheral nervous systems, or other organ systems, including signs of central nervous system depression and effects on special senses (e.g. sight, hearing and sense of smell);

(c) Any consistent and significant adverse change in clinical biochemistry, hematology or urinalysis parameters;

(d) Significant organ damage that may be noted at necropsy and/or confirmed at microscopic examination;

(e) Multifocal or diffuse necrosis, fibrosis or granuloma formation in vital organs with regenerative capacity;

(f) Morphological changes that are potentially reversible but provide clear evidence of marked organ dysfunction;

(g) Evidence of appreciable cell death (including cell degeneration and reduced cell number) in vital organs incapable of regeneration.

2.5.2.8.5.4 Hazards listed below are treated separately in the UN GHS fourth revised edition hence are not included in specific target organ toxicity.

(a) Acute toxicity (Section 2.5.2.1);

(b) Skin corrosion/ irritation (Section 2.5.2.2)

(c) Serious eye damage/ eye irritation (Section 2.5.2.3)

(d) Respiratory or skin sensitization (Section 2.5.2.4)

(e) Germ cell mutagenicity (Section 2.5.2.5)

(f) Carcinogenicity (Section 2.5.2.6)

(g) Reproductive toxicity (Section 2.5.2.7)

(h) Aspiration toxicity (Section 2.5.2.10)

### 2.5.2.8.6 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labeling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.5.2.8.1 Label elements for specific target organ toxicity after single exposure**

| | **Category 1** | **Category 2** | **Category 3** |
|---|---|---|---|
| **Symbol** | Health hazard | Health hazard | Exclamation mark |
| **Signal word** | Danger | Warning | Warning |
| **Hazard statement** | Causes damage to organs (or state all organs affected, if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard) | May cause damage to organs (or state all organs affected, if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard) | May cause respiratory irritation;<br>or<br>May cause drowsiness or dizziness |

# SECTION 2.5.2.9

# SPECIFIC TARGET ORGAN TOXICITY
# REPEATED EXPOSURE

## 2.5.2.9.1 Definition

2.5.2.9.1.1 The purpose of this chapter is to provide a means of classifying substances that produce specific target organ toxicity arising from a repeated exposure. All significant health effects that can impair function, reversible and irreversible, immediate and/or delayed are included.

2.5.2.9.1.2 Classification identifies the substance as being a specific target organ toxicant and, as such, it may present a potential for adverse health effects in people who are exposed to it.

2.5.2.9.1.3 Classification depends upon the availability of reliable evidence that a repeated exposure to the substance has produced a consistent and identifiable toxic effects in humans, or, in experimental animals, toxicologically significant changes which have affected the function or morphology of a tissue/organ, or has produced serious changes to the biochemistry or hematology of the organism and these changes are relevant for human health. It is recognized that human data will be the primary source of evidence for this hazard class.

2.5.2.9.1.4 Assessment shall be taken into consideration not only significant changes in a single organ or biological system but also generalized changes of a less severe nature involving several organs.

2.5.2.9.1.5 Specific target organ toxicity can occur by any route that is relevant for humans, i.e. principally oral, dermal or inhalation.

## 2.5.2.9.2 Classification criteria

**Table 2.5.2.9.1 Hazard categories for specific target organ toxicity following repeated exposure**

| | |
|---|---|
| Category 1: | **Substances that have produced significant toxicity in humans or that, on the basis of evidence from studies in experimental animals, can be presumed to have the potential to produce significant toxicity in humans following a repeated exposure** |

Placing a substance in Category 1 is done on the basis of:

(a) reliable and good quality evidence from human cases or epidemiological studies; or

(b) observations from appropriate studies in experimental animals in which significant and/or severe toxic effects of relevance to human health were produced at generally low exposure concentrations. Guidance dose/ concentration values are provided below to be used as part of weight-of evidence evaluation.

Category 2:**Substances that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to be harmful to human health following a repeated exposure**

Placing a substance in Category 2 is done on the basis of observations from appropriate studies in experimental animals in which significant toxic effects, of relevance to human health, were produced at generally moderate exposure concentrations. Guidance dose/ concentration values are provided below inorder to help in classification.

In exceptional cases, human evidence can also be used to place a substance in Category 2.

*Note: For these categories, the specific target organ/system that has been primarily affected by the classified substance may be identified, or the substance may be identified as a general toxicant. Attempts should be made to determine the primary target organ of toxicity and classify for that purpose, e.g. as hepatotoxicants, neurotoxicants. One should carefully evaluate the data and, where possible, not include secondary effects, e.g. a hepatotoxicant can produce secondary effects in the nervous or gastro-intestinal systems.*

**Table 2.5.2.9.2 Guidance value ranges for toxicity - repeated exposures**

| | | **Guidance values (dose/concentration)** | |
|---|---|---|---|
| Routes of exposure | Units | Category 1 | Category 2 |
| Oral (rat) | mg/kg body weight | 10 | 10 – 100 |
| Dermal (rat or rabbit) | mg/kg body weight | 20 | 20 – 500 |
| Inhalation (rat) gas | PpmV/6h/d | 50 | 50 – 250 |

| | | | |
|---|---|---|---|
| Inhalation (rat) vapor | mg/L/6h/d | 0.2 | 0.2 – 1.0 |
| Inhalation (rat) dust/mist/fume | mg/L 6h/ d | 0.02 | 0.02 – 0.2 |

### 2.5.2.9.3 Data availability

2.5.2.9.3.1 When utilizing descriptions in existing SDSs, the quoted original reports must be reviewed. Even if SDSs according to GHS classification are utilized, for confirmation of the classification, the original reports should be reviewed.

2.5.2.9.3.2 Sufficient information for classification cannot be obtained from the brief descriptions in existing SDSs. In often cases, especially information on the target organs is not described, and a literature search should be carried out for reliable reviews and primary information relevant to toxicity.

2.5.2.9.3.3 Substances with R-Phrases (R39, R48 or combination of these) in EU DSD classification are feared to possess specific target organ toxicity (repeated exposure)

2.5.2.9.3.4 T+, R48 correspond to Category 1. R33 and Xn, R48 correspond to Category 2.

2.5.2.9.3.5 When multiple data exists for Specific Target Organ Toxicity (STOT) given the high reliability of data, and when they fall under multiple categories, basis for the selection and judgment of data for the determination of category will be determined according to Section 5.5.1.3.

### 2.5.2.9.4 Comparison with conventional classification systems

2.5.2.9.4.1 Systems in accordance with GHS include R-Phrase R48 in EU DSD classification.

2.5.2.9.4.2 EU CLP classification H372 accords with Category 1, H373 accords with Category 2.

### 2.5.2.9.5 Guidance for classification

2.5.2.9.5.1 If information concerning specific, non-lethal, specific organ/systemic toxicity arising from a single is obtained, whether the toxicity is significant to human health shall be determined through expert judgment.

2.5.2.9.5.2 The relevant route of exposure by which the classified substance has produced damage shall be identified.

2.5.2.9.5.3 Examples of toxic effects in humans or experimental animals that must be taken into consideration in the classification of specific organ/systemic toxicity are provided below:

(a) Morbidity resulting from single exposure;

(b) Significant functional changes, more than transient in nature, in the respiratory system, central or peripheral nervous systems, or other organ systems, including signs of central nervous system depression and effects on special senses (e.g. sight, hearing and sense of smell);

(c) Any consistent and significant adverse change in clinical biochemistry, hematology or urinalysis parameters;

(d) Significant organ damage that may be noted at necropsy and/or confirmed at microscopic examination;

(e) Multifocal or diffuse necrosis, fibrosis or granuloma formation in vital organs with regenerative capacity;

(f) Morphological changes that are potentially reversible but provide clear evidence of marked organ dysfunction;

(g) Evidence of appreciable cell death (including cell degeneration and reduced cell number) in vital organs incapable of regeneration.

2.5.2.9.5.4 Hazards listed below are treated separately in the UN GHS fourth revised edition hence are not included in specific target organ toxicity.

(a) Acute toxicity (Section 2.5.2.1);

(b) Skin corrosion/ irritation (Section 2.5.2.2)

(c) Serious eye damage/ eye irritation (Section 2.5.2.3)

(d) Respiratory or skin sensitization (Section 2.5.2.4)

(e) Germ cell mutagenicity (Section 2.5.2.5)

(f) Carcinogenicity (Section 2.5.2.6)

(g) Reproductive toxicity (Section 2.5.2.7)

### 2.5.2.9.6 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labeling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.5.2.9.1 Label elements for specific target organ toxicity following repeated exposure**

| | **Category 1** | **Category 2** |
|---|---|---|
| **Symbol** | Health hazard | Health hazard |
| **Signal word** | Danger | Warning |
| **Hazard statement** | Causes damage to organs (or state all organs affected, if known) through prolonged or repeated exposure (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard) | May cause damage to organs (or state all organs affected, if known) through prolonged or repeated exposure (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard) |

# SECTION 2.5.2.10

# ASPIRATION HAZARD

## 2.5.2.10.1 Definition

2.5.2.10.1.1 Aspiration means the entry of a liquid or solid chemical directly through the oral or nasal cavity, or directly from vomiting, into the trachea and lower respiratory system.

2.5.2.10.1.2 Aspiration toxicity includes severe acute effects such as chemical pneumonia, varying degrees of pulmonary injury or death following aspiration.

2.5.2.10.1.3 Aspiration is initiated at the moment of inspiration, in the time required to take one breath, as the causative material lodges at the crossroad of the upper respiratory and digestive tracts in the laryngopharyngeal region.

2.5.2.10.1.4 Aspiration of a substance can occur as it is vomited following ingestion. This may have consequences for labeling, particularly where, due to acute toxicity, a recommendation may be considered to induce vomiting after ingestion. However, if the substance also presents an aspiration toxicity hazard, the recommendation to induce vomiting may need to be modified.

2.5.2.10.1.5 Specific considerations

2.5.2.10.1.5.1 A review of the medical literature on chemical aspiration revealed that some hydrocarbons (petroleum distillates) and certain chlorinated hydrocarbons have been shown to pose an aspiration hazard in humans. Primary alcohols and ketones have been shown to pose an aspiration hazard only in animal studies.

2.5.2.10.1.5.2 While a methodology for determination of aspiration hazard in animals has been utilized, it has not been standardized. Positive experimental evidence with animals can only serve as a guide to possible aspiration toxicity in humans. Particular care must be taken in evaluating animal data for aspiration hazards.

2.5.2.10.1.5.3 The classification criteria refer to kinematic viscosity. The following provides the conversion between dynamic and kinematic viscosity:

$$\frac{\text{Dynamic viscosity (mPa.s)}}{\text{Density (g/cm}^3\text{)}} = \text{Kinematic viscosity (mm}^2\text{/s)}$$

2.5.2.10.1.6 Classification of aerosol/mist products

Aerosol and mist products are usually dispensed in containers such as self-pressurized containers trigger and pump sprayers. The key to classifying these products is whether a pool of product is formed in the mouth, which then may be aspirated. If the mist or aerosol from a pressurized container is fine, a pool may not be formed. On the other hand, if a pressurized container dispenses product in a stream, a pool may be formed that may be aspirated. Usually, the mist produced by trigger and pump sprayers is coarse and therefore, a pool may be formed that then may be aspirated. When the pump mechanism may be removed and contents are available to be swallowed then the classification of the products should be considered.

### 2.5.2.10.2 Classification criteria

**Table 2.5.2.10.1 Hazard categories for aspiration toxicity**

| Categories | Decision criteria |
|---|---|
| **Category 1:** Chemicals known to cause human aspiration toxicity hazards or to be regarded as if they cause human aspiration toxicity hazard | A substance is classified as Category 1:<br>(a) based on reliable and goodquality human evidence (see note 1); or<br>(b) if it is a hydrocarbon and has a kinematic viscosity of ≦20.5 mm$^2$/s measured at 40℃. |

**Note 1:** Examples of substances included in Category 1 are certain hydrocarbons, turpentine and pine oil.

### 2.5.2.10.3 Data availability

2.5.2.10.3.1 Aspiration toxicity is a severe acute effect that induces chemical pneumonitis or lung injuries of various severities after aspiration, or death. The term “aspiration” refers to invasion of a liquid or solid chemical into the trachea or the lower respiratory tract, either directly through the mouth or the nasal cavity or indirectly through vomiting.

2.5.2.10.3.2 Although some methodologies for determining aspiration toxicity in animals exist, none has been standardized. Positive evidence from animal tests merely serves as a guideline for the potential to induce effects classified as aspiration toxicity in humans.

2.5.2.10.3.3When multiple data exists for Aspiration Hazard given the high reliability of data, and when they fall under multiple categories, basis for the selection and judgment of data for the determination of category will be determined according to Section 2.5.1.3.

### 2.5.2.10.4 Comparison with conventional classification systems

2.5.2.10.4.1 This class represents a new concept for classification, but R65 in EU DSD classification is in accordance with it.

2.5.2.10.4.2 In EU CLP classification, H304 is in accordance with Category 1.

### 2.5.2.10.5 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labeling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.5.2.10.1 Label elements for aspiration toxicity**

| | **Category 1** |
|---|---|
| **Symbol** | Health hazard |
| **Signal word** | Danger |
| **Hazard statement** | May be fatal if swallowed and enter airways |

# SECTION 2.6

# ENVIRONMENTAL HAZARDS

## SECTION 2.6.1

## HAZARDOUS TO THE AQUATIC ENVIRONMENT

### 2.6.1.1 Definitions

2.6.1.1.1 Acute aquatic toxicity means the intrinsic property of a substance to be injurious to an organism in a short-term aquatic exposure to that substance.

2.6.1.1.2 Acute (short-term) hazard, for classification purposes, means the hazard of a chemical caused by its acute toxicity to an organism during short-term aquatic exposure to that chemical.

2.6.1.1.3 Availability of a substance means the extent to which this substance becomes a soluble or disaggregates species. For metal availability, the extent to which the metal ion portion of a metal ($M^{\circ}$) compound can disaggregate from the rest of the compound (molecule).

2.6.1.1.4 Bioavailability (or biological availability) means the extent to which a substance is taken up by an organism, and distributed to an area within the organism. It is dependent upon physic-chemical properties of the substance, anatomy and physiology of the organism, pharmacokinetics, and route of exposure. Availability is not a prerequisite for bioavailability.

2.6.1.1.5 Bioaccumulation means net result of uptake, transformation and elimination of a substance in an organism due to all routes of exposure (i.e air, water, sediment/ soil and food).

2.6.1.1.6 Bioconcentration means net result of uptake, transformation and elimination of a substance in an organism due to waterborne exposure.

2.6.1.1.7 Chronic aquatic toxicity means the intrinsic property of a substance to cause adverse effects to aquatic organisms during aquatic exposures which are determined in relation to the life-cycle of the organism.

2.6.1.1.8 Degradation means the decomposition of organic molecules to smaller molecules eventually to carbon dioxide, water and salts.

2.6.1.1.9 ECx means the concentration associated with x% response.

2.6.1.1.10 NOEC (No Observed Effect Concentration) means the test concentration immediately below the lowest tested concentration with statistically significant adverse effect. The NOEC has no statistically significant adverse effect compared to the control.

### 2.6.1.2 Basic elements

2.6.1.2.1 The basic elements for use within the harmonized system are:

(a) Acute aquatic toxicity

(b) Chronic aquatic toxicity

(c) Potential for or actual bioaccumulation ; and

(d) Degradation (biotic or abiotic) for organic chemicals

### 2.6.1.3 Acute aquatic toxicity

Acute aquatic toxicity would normally be determined using a fish 96 hour $LC_{50}$ (OECD Test Guideline 203 or equivalent), a crustacean species 48 hour $EC_{50}$ (OECD Test Guideline 202 or equivalent) and/ or algal species 72 or 96 hour $EC_{50}$ (OECD Test Guideline 201 or equivalent). These species are considered as surrogate for all aquatic organisms and data on other species such as Lemna may also be considered if the test methodology is suitable.

### 2.6.1.4 Chronic aquatic toxicity

Chronic toxicity data are less available than acute data and the range of testing procedures less standardized. Data generated according the OECD Test Guidelines 210 (fish Early Life Stage), or 211 (Daphnia Reproduction) and 201 (Algal Growth Inhibition) can be accepted. Other validated and internationally accepted test could also be used. The NOECs or other equivalent ECx should be used.

### 2.6.1.5 Bioaccumulation potential

The potential for bioaccumulation would normally be determined by using the octanol/ water partition coefficient, usually reported as a log Kow determined by OECD Test Guideline 107 or 117. While this represents a potential to bioaccumulate, an experimentally determined Bioconcentration Factor (BCF) provides a better measure and should be used in preference when available. A BCF should be determined according to OECD Test Guideline 305.

### 2.6.1.6 Rapid degradability

Environmental degradation may be biotic or abiotic (e.g. hydrolysis) and the criteria used reflect this fact. Ready biodegradation can most easily be defined using the biodegradability tests (A-F) of OECD Test Guideline 301. A pass level in these tests can be considered as indicative or rapid degradation in most environments. These are freshwater tests and thus the use of the results from OECD Test Guideline 306 which is more suitable for marine environments has also been included. Where such data are not available, a BOD (5 days)/ CO ratio $\geq$ 0.5 is considered as indicative of rapid degradation.

### 2.6.1.7 Classification criteria. Categories for substances hazardous to the aquatic environment (Note 1)

#### 2.6.1.7.1Acute (short-term) aquatic hazard

**Category Acute 1: (Note 2)**

96 hr $LC_{50}$(for fish) $\leq$ 1 mg/L and/or
48 hr $EC_{50}$(for crustacea) $\leq$ 1 mg/L and/or
72 or 96 hr $ErC_{50}$(for algae or other aquatic plants) $\leq$ 1 mg/L(Note 3)

#### 2.6.1.7.2Long-term aquatic hazard

**(a) Non-rapidly degradable substances (Note 4) for which there are adequate chronic toxicity data available**

**Category Chronic 1: (Note 2)**

Chronic NOEC or ECx (for fish) $\leq$ 0.1 mg/L and/or
Chronic NOEC or ECx (for crustacea) $\leq$ 0.1 mg/L and/or
Chronic NOEC or ECx (for algae or other aquatic plants) $\leq$ 0.1 mg/L

**Category Chronic 2:**

Chronic NOEC or ECx (for fish) $\leq$ 1 mg/L and/or
Chronic NOEC or ECx (for crustacea) $\leq$ 1 mg/L and/or
Chronic NOEC or ECx (for algae or other aquatic plants) $\leq$ 1 mg/L

**(b) Rapidly degradable substances for which there are adequate chronic toxicity data available**

**Category Chronic 1: (Note 2)**

Chronic NOEC or ECx (for fish) $\leq$ 0.01 mg/L and/or
Chronic NOEC or ECx (for crustacea) $\leq$ 0.01 mg/L and/or
Chronic NOEC or ECx (for algae or other aquatic plants) $\leq$ 0.01 mg/L

**Category Chronic 2:**

| | |
|---|---|
| Chronic NOEC or ECx (for fish) | $\leq$ 0.1 mg/L and/or |
| Chronic NOEC or ECx (for crustacea) | $\leq$ 0.1 mg/L and/or |
| Chronic NOEC or ECx (for algae or other aquatic plants) | $\leq$ 0.1 mg/L |

**(c) Substances for which adequate chronic toxicity are not available**

**Category Chronic 1: (Note 2)**

| | |
|---|---|
| Chronic NOEC or ECx (for fish) | $\leq$ 1 mg/L and/or |
| Chronic NOEC or ECx (for crustacea) | $\leq$ 1 mg/L and/or |
| Chronic NOEC or ECx (for algae or other aquatic plants) | $\leq$ 1 mg/L (Note 3) |

and the substance is not rapidly degradable and/or the experimentally determined BCF is $\geq$ 500 (or, if absent, the log Kow $\geq$ 4). (Notes 4 and 5)

**Category Chronic 2:**

| | |
|---|---|
| 96 hr $LC_{50}$(for fish) | >1 but $\leq$ 10 mg/L and/or |
| 48 hr $EC_{50}$(for crustacea) | >1 but $\leq$ 10 mg/L and/or |
| 72 or 96 hr $ErC_{50}$(for algae or other aquatic plants) | >1 but $\leq$ 10 mg/L (Note 3) |

and the substance is not rapidly degradable and/or the experimentally determined BCF is $\geq$ 500 (or, if absent, the log Kow $\geq$ 4). (Notes 4 and 5)

### 2.6.1.7.3 "Safety net" classification

**Category Chronic 4**

Poorly soluble substances for which no acute toxicity is recorded at levels up to the water solubility, and which are not rapidly degradable and have a log Kow $\geq$ 4, indicating a potential to bioaccumulate, will be classified in this category unless other scientific evidence exists showing classification to be unnecessary. Such evidence would include an experimentally determined BCF < 500, or a chronic toxicity NOECs > 1 mg/L, or evidence of rapid degradation in the environment.

Note 1: The organism fish, crustacean and algae are tested as surrogate species covering a range of trophic levels and taxa, and the test methods are highly standardized. Data on other organisms may also be considered, however, provided they represent equivalent species and test endpoints.

Note 2: When classifying substances as Acute 1 and/or Chronic 1 it is necessary at the same time to indicate an appropriate M factor to apply the summation method.

Note 3: Where the algal toxicity $ErC_{50}$ [ = $EC_{50}$ (growth rate)] falls more than 100 times below the next most sensitive species and results in a classification based solely on this effect, consideration should be given to whether this toxicity is representative of the toxicity to aquatic plants. Where it can be shown that this is not the case, professional judgment should be used in deciding if classification should be applied. Classification should be based on the $ErC_{50}$. In circumstances where the basis of the $EC_{50}$ is not specified and no $ErC_{50}$is recorded, classification should be based on the lowest $EC_{50}$ available.

Note 4: lack of rapid degradability is based on either a lack of ready biodegradability or other evidence of lack of rapid degradation. When no useful data on degradability are available, either experimentally determined or estimated data, the substance should be regarded as not rapidly degradable.

Note 5: Potential to bioaccumulate, based on an experimentally derived BCF $\geq$ 500 or, if absent, a log Kow $\geq$ 4, provided log Kow is an appropriate descriptor for the bioaccumulation potential of the substance. Measured log Kow values take precedence over estimated values and measured BCF values take precedence over log Kow values.

### 2.6.1.8 Data availability

2.6.1.8.1Data for classification on acute aquatic toxicity, bioconcentration (Bioconcentration factor, octanol/ water partition coefficient), rapid degradability (biotic or abiotic), and chronic aquatic toxicity can be easily accessed from websites.

2.6.1.8.2 EU classification results, which are similar to GHS classification, are also available but as a reference information only. Mainly because, results cannot be used directly for GHS classification since the classification criteria for chronic aquatic toxicity is slightly different from EU classification compared to GHS classification.

### 2.6.1.9 Data to be collected and utilized for acute aquatic toxicity hazard

2.6.1.9.1 Tests shall be conducted by using fish, crustacean and algae (or other aquatic plants) especially those organisms recommended by standard test methods such as OECD Test Guidelines and ASTM.

The test period and endpoints (effect indicators) are as follows:

(a) Fish : 96 hour $LC_{50}$ (lethal)

(b) Crustacea : 24 or 48 hour $EC_{50}$ (immobile), $LC_{50}$ (lethal)

(c) Daphnia : 24 or 48 hour $EC_{50}$ (immobile), $LC_{50}$ (lethal)

(d) Decapoda, Amphipoda, Mysidacea : 24, 48 or 96 hour $EC_{50}$ (immobile), $LC_{50}$ (lethal)

(e) Algae (or other aquatic plants): 72 or 96 hour with Algae, 7 day or 14 day with $ErC_{50}$ (growth rate method: the concentration at which mean growth rate during test period is inhibited by 50%) and other higher aquatic plants.

2.6.1.9.2 TLm (median Tolerance Limit) is treated as the same with $LC_{50}$ and $IC_{50}$ (50% inhibition concentration) with EC50.

2.6.1.9.3 Data according to GLP shall be used in the classification for aquatic environment hazard. However, even if the test result is not based on GLP, if an expert judgment states that the result is reliable, the data can be used for categorization judgment.

2.6.1.9.4 Similarly, even if the test results is based on GLP, if an expert judgment concludes that there is doubt about the test procedure, the data from the test shall not be used as a basis of classification especially for values of aquatic toxicity levels above the water solubility.

2.6.1.9.5 Acceptable test guidelines for acute aquatic toxicity are as follows:

(a) Fish : 96 hour $LC_{50}$ according to OECD TG 203 or corresponding test methods

(b) Crustacea: 48 hour $EC_{50}$ according to OECD TG 202 (Daphnia Acute Immobilization test) or corresponding test methods should be the standard test. If 48 hour $EC_{50}$ is not available, 24 hour $EC_{50}$ (according to the previous OECD TG 202) may be referred.

(c) Algae, Cyanobacteria and higher aquatic plants: OECD TG 201 includes growth inhibition tests for Algae and Cyanobacteria.

(d) Other higher aquatic plants: OECD Test Guideline 221 (approved 2004) showing a growth inhibition test method using a higher plant, Lemna, and acute $EC_{50}$ according to US EPA850.4400 may be utilized.

### 5.6.1.10 Data to be collected and utilized for chronic aquatic toxicity hazard

2.6.1.10.1 Tests shall be conducted by using fish, crustacean and algae (or other aquatic plants) especially those organisms recommended by standard test methods such as OECD Test Guidelines and ASTM.

The test period and endpoints (effect indicators) are as follows:

(a) Fish : in early life stage test, 28 days or more, NOEC 9hatching success rate, growth (change of length and weight), spawning success rate and survival rate)

(b) Crustacea : 7 days or more, NOEC (the period up to the first spawning, number of eggs per female, growth and survival rate)

(c) Algae (or other aquatic plants):

a. Algae : 72 or 96 hours, NOEC (growth inhibition)

b. Other aquatic plants, no available long-term chronic toxicity test

2.6.1.10.2 Data above the water solubility shall not be used for classification for aquatic environmental hazard.

2.6.1.10.3 Data according to GLP shall be used in the classification for aquatic environment hazard. However, even if the test result is not based on GLP, if an expert judgment states that the result is reliable, the data can be used for categorization judgment.

2.6.1.10.4 Similarly, even if the test results is based on GLP, if an expert judgment concludes that there is doubt about the test procedure, the data from the test shall not be used as a basis of classification.

2.6.1.10.5 Chronic or long term toxicity test using fish shall be conducted according to OECD TG 210 (Fish early life stage test), Fish Life Cycle Test (US EPA 850.1500).

5.6.1.10.6 Chronic toxicity tests using crustacean shall be conducted in accordance with OECD TG 211 (Daphnia Magna Reproduction Test), US EPA OPPTS 850.1035 (Mysidaccea Chronic Toxicity), or corresponding test methods (NOECs of 21 days for Daphnia, NOECs of 7 days or more for Ceriodaphnia).

2.6.1.10.7 For algae, since OECD TG 201 (Algae growth inhibition test, 72 or 96 hours) is not a long-term test, its NOEC are not generally used as evidence for exclusion from chronic aquatic toxicity. When NOECs exceed 1 mg/L for other species of algae, NOECs may be used as evidence for exclusion.

**2.6.1.11 Acceptable test guidelines bioaccumulation and rapid degradability are as follows:**

2.6.1.11.1 Test methods for bioaccumulation (BCF, log Kow), rapid degradability (bio degradability, hydrolysis) shall be based on the methods prescribed by OECD test Guidelines, ASTM Standard Test Methods or other appropriate test guidelines.

(a) Bioaccumulation acceptable test methods

OECD TG 305 and the former 305A-D (BCF)
OECD TG 107 and 117 (Kow)

(b) Rapid degrability acceptable methods

When data on rapid degradability are not available, the substance is assumed to be without rapid degradability.

OECD TG 301A-F (readily degradability test)

(c) When test results using OECD TG 301A-F are not available, results from the following test methods may be adopted and used.

OECD TG 302A, 302B, 302C, 303A, 303B, 304A, 306, 307, 308 and 309
OECD TG 310 and 311

**2.6.1.12 Precedence of data**

2.6.1.12.1 Data derived from OECD Test Guidelines and GLP shall be used.

2.6.1.12.2 When data are not available using the OECD TG or GLP, data from tests conducted according to internationally recognized test guidelines but whose compliance to GLP is not clear take precedence.

2.6.1.12.3 Where data cannot be derived using the above principles, the latest data take precedence.

2.6.1.12.4 In the presence of multiple data, the smallest concentration for aquatic environment hazards, the highest value for bioaccumulation and the lowest value for rapid degradability shall be adopted which are considered the safer data.

**2.6.1.13 Comparison with conventional classification systems**

2.6.1.13.1 EU DSD classifications are almost in accordance with the GHS categories:

R50 : Very toxic to aquatic organisms

R51 : Toxic to aquatic organisms

R52 : Harmful to aquatic organisms

R53 : May cause long-term adverse effects in the aquatic environment

Based on the relevant R-phrases mentioned above, the following categories from GHS may be estimated:

Category : Acute 1 = R50 (and R50/R53)

Category : Acute 2 = R51 (and R51/ R53)

Category : Acute 3 = R52 (and R52/ R53)

Category : Chronic 1 ≠ R50/53

Category : Chronic 2 ≠ R51/ 53

Category : Chronic 3 ≠ R52/ 53

5.6.1.13.2 EU CLP classifications are almost in accordance with the GHS categories:

Category : Acute 1 = CLP H400

Category : Chronic 1 = CLP H400

Category : Chronic 2 = CLP H410

Category : Chronic 3 = CLP H411

Category : Chronic 4 = CLP H413

### 2.6.1.14 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labeling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

**Table 2.6.1.14.1 Label elements for hazardous to the aquatic environment**

**ACUTE**

| | **Category 1** |
|---|---|
| **Symbol** | Environment |
| **Signal word** | Warning |
| **Hazard statement** | Very toxic to aquatic life |

**CHRONIC**

| | **Category 1** | **Category 2** |
|---|---|---|
| **Symbol** | Environment | Environment |
| **Signal word** | Warning | No signal word |
| **Hazard statement** | Very toxic to aquatic life with long lasting effects | Toxic to aquatic life with long lasting effects |

# SECTION 2.6.2

# HAZARDOUS TO THE OZONE LAYER

## 2.6.2.1 Definitions

2.6.2.1.1 Ozone Depleting Potential (ODP) is an integrative quantity, distinct for each halocarbon sources species, that represents the extent of ozone depletion in the stratosphere expected from the halocarbon on a mass-for-mass basis relative to CFC-11.

2.6.2.1.2 Ozone Depleting Potential (ODP) is the ratio of integrated perturbations to total ozone, for a differential mass emission of a particular compound relative to an equal emission of CFC-11.

2.6.2.1.3 Montreal Protocol is the Montreal Protocol on Substances that Deplete the Ozone Layer as either adjusted and/ or amended by the Parties to the Protocol.

## 2.6.2.2 Classification criteria

A substance or mixture shall be classified as Category 1 according to the following table:

**Table 2.6.2 Criteria for substances and mixtures hazardous to the ozone layer**

| Category | Criteria |
|---|---|
| **1** | Any of the controlled substances listed in Annexes to the Montreal Protocol; or<br>Any mixture containing at least one ingredient listed in the Annexes to the Montreal Protocol, at a concentration $\geq$ 0.1%. |

## 2.6.2.3 Hazard communication

General and specific considerations concerning labeling requirements are provided in Hazard communication: Labeling (Chapter 1.4) of the UN Purple Book. Annex 2 contains summary tables about classification and labeling. Annex 3 contains examples of precautionary statements and pictograms which can be used where allowed by the competent authority.

### Table 2.6.2.3 Label elements for substances and mixtures hazardous to the ozone layer

| | **Category 1** |
|---|---|
| **Symbol** | Exclamation mark |
| **Signal word** | Warning |
| **Hazard statement** | Harms public health and the environment by destroying ozone in the upper atmosphere |

## B. INITIAL LIST OF SINGLE SUBSTANCES AND COMPOUNDS COVERED UNDER CHEMICAL CONTROL ORDER (CCO) AND PRIORITY CHEMICAL LIST (PCL)

| No. | CAS No. | PICCS Name |
|---|---|---|
| 1. | 106-93-4 | 1,2-Dibromoethane |
| 2. | 95-50-1 | 0-Dichlorobenzene |
| 3. | 106-46-7 | 1,4-Dichlorobenzene |
| 4. | 107-06-2 | 1,2-Dichloroethane |
| 5. | 122-66-7 | 1,2 Diphenylhydrazine |
| 6. | 108-46-3 | 3-Hydroxyphenol |
| 7. | 7647-18-9 | Antimony pentachloride |
| 8. | 7778-39-4 | Arsenic Acid |
| 9. | 22441-45-8 | Arsenic pentachloride |
| 10. | 1303-28-2 | Arsenic pentoxide |
| 11. | 7784-34-1 | Arsenic trichloride |
| 12. | 1327-53-3 | Arsenic trioxide |
| 13. | 1332-21-4 | Asbestos |
| 14. | 71-43-2 | Benzene |
| 15. | 13327-32-7 | Beryllium hydroxide |
| 16. | 7787-49-7 | Beryllium fluoride |
| 17. | 1304-56-9 | Beryllium oxide |
| 18. | 13510-49-1 | Beryllium sulfate |
| 19. | 543-90-8 | Cadmium acetate |
| 20. | 10108-64-2 | Cadmium chloride |
| 21. | 10325-94-7 | Cadmium nitrate |
| 22. | 10124-36-4 | Cadmium sulfate |
| 23. | 1306-23-6 | Cadmium sulfide |
| 24. | 67-66-3 | Chloroform |
| 25. | 76-06-2 | Chloropicrin |
| 26. | 100025-73-7 | Chromium chloride |
| 27. | 7789-02-8 | Chromium nitrate |
| 28. | 1333-82-0 | Chromium trioxide |
| 29. | 7789-00-6 | Potassium Chromate |
| 30. | 7775-11-3 | Sodium Chromate |
| 31. | 74-90-8 | Hydrogen Cyanide |

| | | |
|---|---|---|
| 32. | 143-33-9 | Potassium Cyanide |
| 33. | 151-50-8 | Sodium Cyanide |
| 34. | 64-67-5 | Diethyl sulfate |
| 35. | 106-93-4 | Ethylene dibromide |
| 36. | 75-21-8 | Ethylene Oxide |
| 37. | 50-00-0 | Formaldehyde |
| 38. | 111-30-8 | Glutaraldehyde |
| 39. | 9002-83-9 | Halons |
| 40. | 67-72-1 | Hexachloroethane |
| 41. | 302-01-2 | Hydrazine |
| 42. | 598-63-0 | Lead carbonate |
| 43. | 1309-60-0 | Lead dioxide |
| 44. | 15245-44-0 | Lead styphnate |
| 45. | 1314-91-6 | Lead telluride |
| 46. | 1314-41-6 | Lead tetroxide |
| 47. | 1317-36-8 | Lead (II) oxide |
| 48. | 10099-74-8 | Lead (II) nitrate |
| 49. | 149-30-4 | MBT (2-Mercaptobenzothiazole) |
| 50. | 594-42-3 | Mercaptan, Perchloromethyl |
| 51. | 7774-29-0 | Mercury(II) iodide |
| 52. | 592-85-8 | Mercury thiocyanate |
| 53. | 7439-97-6 | Mercury metal |
| 54. | 7783-34-8 | Mercuric nitrate monohydrate |
| 55. | 74-87-3 | Methyl Chloride |
| 56. | 75-09-2 | Methylenechloride |
| 57. | 87-86-5 | Pentachlorophenol |
| 58. | 127-18-4 | Perchloroethylene |
| 59. | 108-95-2 | Phenic Acid |
| 60. | 75-44-5 | Phosgene |
| 61. | 85-44-9 | Phthalic Anhydride |
| 62. | 7782-49-2 | Selenium |
| 63. | 79-01-6 | Trichloroethylene |
| 64. | 75-01-4 | Vinyl Chloride |

## C. GHS PICTOGRAMS

Explosives
Organic peroxides
Self-reactive
substances

Flammable subs.
Self reactive
Pyrophoric & self-
Heating substances
Organic peroxides

Oxidizers
Organic peroxides

Compressed gas
(Gases under
Pressure)

Corrosive to metal
Skin corrosion
Serious eye damage

Acute
Toxicity
(Severe)

Irritant (skin and eye)
Acute Toxicity (harmful)
Dermal Sensitizer
Target Organ toxicity
(narcotics or respiratory

Carcinogen
Respiratory Sensitive
Mutagenicity
Reproductive Toxicity
Target Organ Toxicity
Aspiration Hazard.

Oxidizing
Solids

Compressed gas

Environmental
Hazard

Sensitization
(Respiratory)
Mutagenicity
Carcinogenicity
Reproductive
Toxicity
Target Organ
Toxicity
Aspiration
Hazard.

Eye irritation
Acute Toxicity
Skin irritation
Eye irritation
Sensitization
(Dermal)
Target Organ
toxicity

# D. Guidance Manual on the Preparation of GHS Labels

## 1.0 General rules, requirements and procedures

This Section shall provide specific guidance to be observed and followed in labeling or re-labelling to comply with the requirements of the Department Administrative Order (DAO): Rules and Procedures for the Safety Data Sheet (SDS), Labeling Requirements and Hazards Classification under DENR Administrative Order No. 29, Series of 1992 of Republic Act 6969 for the Adoption and Implementation of the Globally Harmonized System (GHS).

### 1.1 General rules

1.1.1 Label, tag or mark each container within the workplace.

1.1.2 Labels shall clearly covey the hazards and risks associated with the substances or mixtures.

1.1.3 Place appropriate pictograms, signal words, hazard and precautionary statements at the storage facility/ premise and on transport.

1.1.4 Importer, manufacturer, supplier and distributor of chemicals and mixtures shall conduct appropriate education and training for GHS for the different target audiences.

### 1.2 Specific rules

1.2.1 Label elements

1.2.1.1 Label elements are composed of the symbol, signal word and hazard statement. A summary of the allocation of label elements is provided in Annex A- Allocation of Label Elements.

1.2.1.2 The GHS hazard pictograms, signal word and hazard statements should be located together on the label.

1.2.2 Reproduction of the symbol

1.2.2.1 Use the standard symbols in the GHS, except for the exclamation mark symbol, all other symbols are part of the UN Recommendations on the Transport of Dangerous Goods, Model Regulations.

| Flame | Flame over circle | Exploding bomb |
|---|---|---|
|  |  |  |
| Corrosion | Gas cylinder | Skull and crossbones |
|  |  |  |
| Exclamation mark | Environment | Health Hazard |
|  |  |  |

## 1.2.3 Pictograms and reproduction of the hazard pictograms

### 1.2.3.1 Shape and color

1.2.3.1.1 Hazard pictograms used in the GHS shall be in the shape of a square set at point.

1.2.3.1.2 Transport pictograms prescribed by the UN Recommendations on the Transport of Dangerous Goods, Model Regulations shall be used for chemicals for transport.

1.2.3.1.3 Transport pictograms shall be in the require minimum dimensions of 100 mm by 100 mm, with some exceptions for allowing smaller pictograms for very small packagings and for gas cylinders.

Example:

Pictogram for flammable liquid in the UN Model Regulations
(Symbol: black or white; Background: Red;
Figure 3 in bottom corner; minimum dimensions: 100mm x 100mm)

1.2.3.1.4 The transport pictogram shall be printed or affixed to a packaging on a background of contrasting color.

1.2.3.1.5 Pictograms prescribed by the GHS shall have a black symbol on a white background with a red frame.

Example:

Pictogram for skin irritant

1.2.3.1.6 Packaging of materials which are not to be exported or for local use only, can use the black border.

Example:

Pictogram for hazardous to aquatic life

## 1.2.4 Allocation of Label Elements

1.2.4.1 Where a UN Model Regulations on the Transport of Dangerous Goods pictogram appears on the label, a GHS pictogram for the same hazard shall not appear.

1.2.4.2 GHS pictograms not required for the transport of dangerous goods shall not be displayed on freight containers, road vehicles or railway wagons/ tanks.

1.2.4.3 The following GHS label elements shall appear on the packaging of chemicals:

1.2.4.3.1Signal words to be used shall be “Danger” or “Warning”.

1.2.4.3.2“Danger” shall be used for the more severe hazard categories, while “Warning” shall be used for the less severe.

1.2.4.4 Hazard statements

1.2.4.4.1 A complete hazard statement shall consist of hazard statement and a hazard statement code (H-Code).

1.2.4.4.2 A hazard statement shall be appropriate with the degree of hazard.

1.2.4.4.3 A hazard statement code shall be consistent with the hazard statement and shall be used as a reference only.

1.2.4.5 Precautionary statement

1.2.4.5.1 A complete precautionary statement shall consist of precautionary statement and a precautionary statement code (P-Code).

1.2.4.5.2 Precautionary statement shall include appropriate precautionary information.

1.2.4.5.3 A precautionary statement code shall be consistent with the precautionary statement and shall be used as a reference only.

1.2.4.6 Product identifier/ declaration of ingredients/ chemical identity

1.2.4.6.1 Product identifier used in the label shall be consistent with the product identifier used in the SDS.

1.2.4.6.2 UN proper shipping shall be used on the package if a substance or mixture is covered under UN Model Regulations on the Transport of Dangerous Goods.

1.2.4.6.3 The label of a substance shall include the chemical identity of the substance, also consistent with the composition declared in the SDS.

1.2.4.6.4 The labels for containers of hazardous chemical substances or mixtures must clearly indicate the ingredients unless covered by the CBI agreement.

1.2.4.7 Supplier identification

1.2.4.7.1 The name, address and telephone number of the manufacturer or supplier of the substance or mixture shall be indicated on the label consistent with the information used in the SDS.

1.2.5 Precedence for the allocation of symbols

1.2.5.1The precedence of symbols for physical hazards shall follow the rules of the UN Model Regulations if a substance and mixture are covered by the UN Recommendations on the Transport on Dangerous Goods.

1.2.5.2 For health hazards, the following precedence shall apply:

1.2.5.2.1 If the skull and crossbones applies, the exclamation mark should not appear;

1.2.5.2.2 If the corrosive symbol applies, the exclamation mark should not appear where it is used for skin or eye irritation;

1.2.5.2.3 If the health hazard symbol appears for respiratory sensitization, the exclamation mark should not appear where it is used for skin sensitization or for skin or eye irritation.

1.2.6 Precedence for the allocation of signal words

1.2.6.1 If the signal word “Danger” applies, the signal word “Warning” should not appear.

1.2.7 Precedence for the allocation of hazard statements

1.2.7.1 All assigned hazard statements should appear on the label, except for the following conditions:

1.2.7.1.1 If the statement H410 “Very toxic to aquatic life with long lasting effects” is assigned, the statement H400 “Very toxic to aquatic life” may be omitted;

1.2.7.1.2 If the statement H411 “Toxic to aquatic life with long lasting effects” is assigned, the statement H401 “Toxic to aquatic life” may be omitted;

1.2.7.1.3 If the statement H412 “Harmful to aquatic life long lasting effects” is assigned, the statement H402 “Harmful to aquatic life” may be omitted;

1.2.7.1.4 If the statement H314 “Causes severe skin burns and eye damage” is assigned, the statement H318 “Causes serious eye damage” may be omitted.

1.2.8 Arrangements for presenting the GHS label elements

1.2.8.1 Location of GHS information on the label

1.2.8.1.1 The GHS hazard pictograms, signal word and hazard statements shall be located together on the label.

1.2.8.2 Supplemental information

1.2.8.2.1The placement of the supplemental information shall not impede identification of GHS information.

1.2.8.3 Use of color outside pictograms

1.2.8.3.1 Color can be used on other areas of the label to implement special labeling requirements such as the use of the pesticide bands in the FAO Labeling Guide.

1.2.9 Packaging specification

1.2.9.1 Chemicals shall be packed in good quality packagings, which shall be strong enough to withstand the shocks and loadings encountered during transport, storage or manual or mechanical handling.

1.2.9.2 Inner packagings shall be packed in an outer packaging in such a way that they cannot break, be punctured or leak their contents into the outer packaging.

1.2.10 Label sizes and specification

1.2.10.1 All the applicable GHS label elements should appear on the immediate container of a hazardous substance or mixture.

1.2.10.1.1 GHS Pictogram

1.2.10.1.2 Signal word

1.2.10.1.3 Hazard statement

1.2.10.1.4 Precautionary statement

1.2.10.1.5 Product identifier/ declaration of ingredients/ chemical identity

1.2.10.1.6 Supplier identification

1.2.10.1.7 Supplemental information

1.2.10.2 GHS label sizes and requirements depend on the size of the container. The minimum label dimensions based on the container size are given below:

| **Container Capacity** | **Required GHS Label Dimensions** |
|---|---|
| Less than 1 liter | No size specification required but label should be readable. |
| Greater than 1 - 4 liters<br>(0.066 – 0.792 gallons) | 52 mm x 74 mm<br>(2.04” x 2.91”) |
| Greater than 4 – 50 liters<br>(3.17 – 13.2 gallons) | 74 mm x 105 mm<br>(2.91” x 4.133”) |
| Greater than 50 – 500 liters<br>(13.2 – 132 gallons) | 105 mm x 148 mm<br>(4.133” x 5.82”) |
| Greater than 500 liters<br>($\geq$132 gallons) | 148 mm x 210 mm<br>(5.82” x 8.26”) |

# E. Guidance Manual for the Preparation of Safety Data Sheet (SDS)

## 1.0 General rules, requirements and procedures

This Section provides the specific guidance to be observed and followed in the preparation of the Safety Data Sheet (SDS) to comply with the requirements of the Department Administrative Order (DAO): Rules and Procedures for the Safety Data Sheet (SDS), Labeling Requirements and Hazards Classification under DENR Administrative Order No. 29, Series of 1992 of Republic Act 6969 for the Adoption and Implementation of the Globally Harmonized System (GHS).

### 1.1 General rules

1.1.1 SDS shall be composed of sixteen (16) sections in the order of arrangement and presentation within the SDS document based on GHS.

1.1.2 English shall be used as the primary language in preparing the SDS.

1.1.3 Safety Data Sheet shall be termed as such instead of Material Safety Data Sheet (MSDS) or Chemical Safety Data Sheet (CSDS).

1.1.4 SDS shall be written in a simple, clear and precise manner that is understandable by all stakeholders.

1.1.5 Avoid using vague and misleading expressions such as “may be dangerous”, “no health effects” “safe under most conditions of use” or “harmless”.

1.1.6 Indicate the date of issuance of SDS, it must be visible and clearly stated in the document. The date of issue is the date of the SDS version when it was made public.

1.1.7 All pages of the SDS shall be numbered indicating if there are following pages or end of pages.

1.1.8 Update SDS every 5 years or earlier where there are known changes in product composition that may affect the classification of the substance and/or product.

1.1.9 SDS shall be prepared by a competent person in the company to assure the accuracy of information of the document.

1.1.10 SDS shall be made available and accessible to all workers at all times.

1.1.11 Training on the use of SDS shall be conducted by a competent person within the company to ensure that all information is properly understood by the workers.

1.2 SDS format

### 1.2.1 Section 1. Identification

This section shall describe the GHS information requirements for SDSs.

1.2.1.1 Identify the substance name or mixture

1.2.1.1.1 The identity of the substance or mixture shall be exactly the same as found on the label.

1.2.1.1.2 All names and variants shall be listed on the SDS if an SDS is used to cover several minor variants of a substance or mixture.

1.2.1.1.3 Alternative names, numbers, company products codes or other unique identifiers shall also be used as an alternative to GHS product identifier.

1.2.1.2 Provide the name of the supplier

1.2.1.2.1 Name of the supplier

1.2.1.2.2 Complete address

1.2.1.3 Provide the recommended uses of the chemical, mixtures or product

1.2.1.3.1 Provide a brief description of what the chemical or mixture actually does.

1.2.1.3.2 Provide restrictions on use

1.2.1.3.3 State non-statutory recommendations of the chemical or mixture

1.2.1.4 Provide the contact detail information of the supplier

1.2.1.4.1 Telephone number

1.2.1.5 Provide the emergency contact number

1.2.1.5.1 References to emergency information services

1.2.1.5.2 Include restrictions such as hours of operation (e.g Monday – Friday 0800 am – 05:00 pm)

1.2.1.5.3 Limits of specific types of information (e.g. medical emergencies, or transportation emergencies)

1.2.1.5.4 If the principal supplier or the manufacturer is a foreign company, and is most likely that contact numbers are from the said supplier, provide emergency contact numbers of the local distributor and/ or importer.

### 1.2.2 Section 2. Hazard identification

This section shall include a brief summary and/ or conclusion of the data given, that even non-experts in the can identify all the hazards for the hazardous substance or mixture.

1.2.2.1 Hazard of the substance or mixture

1.2.2.1.1 Indicate the appropriate hazard class and category/ sub-category if a substance or mixture is classified in accordance with physical, health and environmental hazards of GHS.

1.2.2.1.2 When classification is differentiated within a hazard class and resulted in unique hazard statements, the difference in classification shall also be reflected e.g route of exposure differentiates the acute toxicity classification: oral, dermal and inhalation

1.2.2.1.3 If a substance or mixture is classified into more than one category in a hazard class that is differentiated, all classifications shall be indicated and communicated in the SDS.

1.2.2.2 Appropriate signal word, hazard statements and precautionary statements associated with identified hazards

1.2.2.2.1 Provide appropriate label elements as indicated in Annexes A, B and C of the Guidance Manual

1.2.2.2.2 Pictograms (or hazard symbols) shall be provided as a graphical reproduction of the symbols in black and white or the name of the symbol, e.g. “flame”, “skull and crossbones”.

1.2.2.2.3 Provide information on other hazards which do not result in classification but may contribute to the overall hazards of the material, e.g. formation of air contaminants during hardening or dust explosion hazards

### 1.2.3 Section 3. Composition/ information on ingredients

This section shall identify the ingredients of the product.

1.2.3.1 Chemical identity of the substance

1.2.3.1.1 Common chemical name

1.2.3.1.1.1 Chemical Abstract Service (CAS) registry number

1.2.3.1.1.2 European Community (EC) number can be used as other unique identifiers

1.2.3.1.1.3 International Union of Pure and Applied Chemistry (IUPAC) name

1.2.3.1.1.4 Trade name

1.2.3.1.1.5 Brand name

1.2.3.1.1.6 Product code

1.2.3.1.1.7 Impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance.

1.2.3.2 Mixture

1.2.3.2.1 Chemical identity

1.2.3.2.2 Identification number

1.2.3.2.3 Concentration or concentration ranges of all hazardous ingredients, hazardous to health or the environment within the context of GHS, and are present above their cut-off levels.

1.2.3.2.3.1 Exact percentages in descending order by mass or volume or;

1.2.3.2.3.2 Ranges of percentages in descending order by mass or by volume

### 1.2.4 Section 4. First-aid measures

This section shall describe the initial care that can be given by an untrained responder without the use of sophisticated equipment and without a wide selection of medications available.

1.2.4.1 Description of necessary first-aid measures

1.2.4.1.1 Provide first-aid instructions by relevant routes of exposure.

1.2.4.1.2 Provide advice whether:

1.2.4.1.2.1 Immediate medical attention is required and if delayed effects can be expected after exposure;

1.2.4.1.2.2 Movement of the exposed individual from the area to fresh air is recommended;

1.2.4.1.2.3 Removal and handling of clothing and shoes from the individual is recommended;

1.2.4.1.2.4 Personal protective equipment (PPE) for first-aid responders is recommended.

1.2.4.2 Most important symptoms / effects, acute and delayed

1.2.4.2.1 Provide information on the most important symptoms / effects, acute and delayed, from exposure

1.2.4.3 Indication of immediate medical attention and special treatment needed, if necessary

1.2.4.3.1 Provide information on clinical testing and medical monitoring for delayed effects, specific details on antidotes (if known) and contraindications.

### 1.2.5 Section 5. Fire-fighting measures

This section shall cover the requirements for fighting a fire caused by the substance or mixture, or arising in its vicinity.

1.2.5.1 Suitable extinguishing media

1.2.5.1.1 Provide information on the appropriate extinguishing media.

1.2.5.1.2 Indicate whether any extinguishing media are inappropriate for a particular situation involving the substance or mixture.

1.2.5.2 Specific hazards arising from the chemical

1.2.5.2.1 Provide advice on specific hazards that may arise from the chemical, such as hazardous combustion products that form when the substance or mixture burns.

1.2.5.2.1.1 “may produce toxic fumes of carbon monoxide if burning”; or

1.2.5.2.1.2 “produces oxides of sulphur and nitrogen on combustion”

1.2.5.3 Special protective actions for fire fighters

1.2.5.3.1 Provide advice on any protective actions to be taken during fire fighting. E.g “keep containers cool with water spray”.

### 1.2.6 Section 6. Accidental release measures

This section shall recommend the appropriate response to spills, leaks, or releases in order to minimize the adverse effects on persons, property and the environment. In this section, distinguish the response to small and large spills.

1.2.6.1 Personal precautions, protective equipment and emergency procedures for non-emergency personnel

1.2.6.1.1 Provide advice related to accidental spills and release of the substance or mixture such as:

1.2.6.1.1.1 The wearing of suitable protective equipment (including PPE) to prevent any contamination of skin, eyes and personal clothing;

1.2.6.1.1.2 Removal of ignition sources and provision of sufficient ventilation;

1.2.6.1.1.3 Emergency procedures such as the necessity to evacuate the danger area or to consult an expert.

1.2.6.2 Personal precautions, protective equipment and emergency procedures for emergency responders

1.2.6.2.1 Provide advice related to suitable fabric for personal protective clothing (e.g. “appropriate: butylenes; not appropriate: PVC”)

1.2.6.3 Environmental precautions

1.2.6.3.1 Provide advice on any environmental precautions related to accidental spills and release of the substance or mixture, such as keeping away from drains, surface or ground water.

1.2.6.4 Methods and materials for containment and cleaning up

1.2.6.4.1 Provide appropriate advice on how to contain and clean up a spill.

1.2.6.4.2 Appropriate containment techniques include the following:

1.2.6.4.2.1 Bunding, covering of drains; and

1.2.6.4.2.2 Capping procedures

1.2.6.4.3 Appropriate clean up techniques include the following:

1.2.6.4.3.1 Neutralization;

1.2.6.4.3.2 Decontamination;

1.2.6.4.3.3 Use of adsorbent materials;

1.2.6.4.3.4 Cleaning techniques;

1.2.6.4.3.5 Vacuuming; and

1.2.6.4.3.6 Equipment required for containment/ clean up which include non-spark producing tools and equipment

1.2.6.4.4 Provide any other issues relating to spills and releases. E.g advice on inappropriate containment or clean up techniques.

### 1.2.7 Section 7. Handling and storage

This section shall describe the guidance on safe handling practices that minimize the potential hazards to people, property and the environment from the substance or mixture.

1.2.7.1 Precautions for safe handling

1.2.7.1.1 Provide advice that:

1.2.7.1.1.1 Allows safe handling of the substance or mixture;

1.2.7.1.1.2 Prevents handling of incompatible substances or mixtures; and

1.2.7.1.1.3 Minimizes the release of the substance or mixture to the environment.

1.2.7.1.2 Provide advice on general hygiene:

1.2.7.1.2.1 “Eating, drinking and smoking in work areas is prohibited”;

1.2.7.1.2.2 “Wash hands after use”; and

1.2.7.1.2.3 “remove contaminated clothing and protective equipment before entering eating areas”.

1.2.7.2 Conditions for safe storage, including any incompatibilities

1.2.7.2.1 Provide advice that is consistent with the physical and chemical properties of the substances or mixture as discussed in Section 9 of the SDS:

- 1.2.7.2.1.1 How to avoid:
  - 1.2.7.2.1.1.1 Explosive atmospheres;
  - 1.2.7.2.1.1.2 Corrosive conditions;
  - 1.2.7.2.1.1.3 Flammability hazards;
  - 1.2.7.2.1.1.4 Incompatible substances or mixtures;
  - 1.2.7.2.1.1.5 Evaporative conditions;
  - 1.2.7.2.1.1.6 Potential ignition sources including electrical equipment.
- 1.2.7.2.1.2 How to control the effects of:
  - 1.2.7.2.1.2.1 Weather conditions;
  - 1.2.7.2.1.2.2 Ambient pressure;
  - 1.2.7.2.1.2.3 Temperature;
  - 1.2.7.2.1.2.4 Sunlight;
  - 1.2.7.2.1.2.5 Humidity; and
  - 1.2.7.2.1.2.6 Vibration.
- 1.2.7.2.1.3 How to maintain the integrity of the substance or mixture by the use of:
  - 1.2.7.2.1.3.1 Stabilizers; and
  - 1.2.7.2.1.3.2 Anti-oxidants.
- 1.2.7.2.1.4 Other advice including:
  - 1.2.7.2.1.4.1 Ventilation requirements;
  - 1.2.7.2.1.4.2 Specific designs for storage rooms/ vessels;
  - 1.2.7.2.1.4.3 Quantity limits under storage conditions; and

1.2.7.2.1.4.4 Packaging compatibilities.

### 1.2.8 Section 8. Exposure controls / personal protection

This section shall provide guidance on “occupational exposure limits” and exposure controls necessary to minimize worker and environmental exposure.

1.2.8.1 Control parameters

1.2.8.1.1 Provide list of occupational exposure and biological (if available) limits including notations, for a substance or mixture and for each ingredients of a mixture.

1.2.8.1.2 Occupational limits and biological limits (if available) for a substance or mixture and for each ingredients of a mixture for the country or region in which SDS is being supplied.

1.2.8.1.3 Sources of occupational exposure limits and biological limits

1.2.8.1.4 List of occupational exposure and biological limits of the ingredients listed in Section 3 of the SDS.

1.2.8.2 Appropriate engineering controls

1.2.8.2.1 Description of appropriate exposure control measures related to the intended modes of use of the substance or mixture

1.2.8.2.1.1 “maintain air concentrations below occupational exposure standards”, using engineering controls;

1.2.8.2.1.2 “use local exhaust ventilation when”;

1.2.8.2.1.3 “use only in an enclosed system”;

1.2.8.2.1.4 “use only in spray paint booth or enclosure”;

1.2.8.2.1.5 “use mechanical handling to reduce human contact with materials”; or

1.2.8.2.1.6 “use explosive dust handling controls”.

1.2.8.2.2 Advices in this section shall complement the information provided under Section 7 of the SDS.

1.2.8.3 Individual protection measures, such as personal protective equipment (PPE)

1.2.8.3.1 PPE shall be in consistent with occupational hygiene practices, and in conjunction with other control measures including engineering controls, ventilation and isolation.

1.2.8.3.2 Identify the PPE needed to minimize the potential for illness or injury due to exposure from the substance or mixture:

1.2.8.3.2.1 Eye/ face protection: specify the type of eye protection and/or face shield required, based on the hazard of the substance or mixture and potential for contact;

1.2.8.3.2.2 Skin protection: specify the protective equipment to be worn (e.g. type of gloves, boots and body suit) based on the hazard of the substance or mixture and potential for contact;

1.2.8.3.2.3 Respiratory protection: specify the appropriate types of respiratory protection based on the hazard of the substance or mixture and potential for exposure, including air-purifying respirators and the proper purifying element (cartridge or canister) or breathing apparatus; and

1.2.8.3.2.4 Thermal hazards: when specifying protective equipment to be worn for materials that represent a thermal hazard, special consideration shall be given to the construction of the PPE.

1.2.8.3.3 Clearly specify the type of PPE where special requirements may exist such as the type of gloves or other protective clothing to prevent skin, eye or lung exposure. E.g "PVC gloves" or "nitrile gloves".

### 1.2.9 Section 9. Physical and chemical properties

This section shall describe the empirical data of the substance or mixture (if possible).

1.2.9.1 Identify the properties and specify appropriate units of measure and/or reference conditions.

1.2.9.2 The method of determination for the interpretation of the numerical value shall be provided.

1.2.9.2.1 Appearance (physical state, color, etc);

1.2.9.2.2 Odor;

1.2.9.2.3 Odor threshold;

1.2.9.2.4 pH;

1.2.9.2.5 melting point/ freezing point;

1.2.9.2.6 initial boiling point and boiling range;

1.2.9.2.7 flash point;
1.2.9.2.8 evaporation rate;

1.2.9.2.9 flammability (solid, gas);

1.2.9.2.10 upper/lower flammability or explosive limits;

1.2.9.2.11 vapor pressure;

1.2.9.2.12 vapor density;

1.2.9.2.13 relative density;

1.2.9.2.14 solubilites;

1.2.9.2.15 partition coefficient: n-octanol / water

1.2.9.2.16 auto-ignition temperature;

1.2.9.2.17 decomposition temperature;

1.2.9.2.18 viscosity

1.2.9.3 If specific characteristics do not apply or not available, they shall still be listed on the SDS with a statement that they “do not apply” or “data not available”.

1.2.9.4 Other physical or chemical properties in addition to those listed above may also be included in this section of SDS.

### 1.2.10 Section 10. Stability and reactivity

This section shall describe the reactivity hazards of the substance or mixture.

1.2.10.1 Reactivity

1.2.10.1.1 Provide specific test data for the substance or mixture as a whole.

1.2.10.1.2 Information may also be based on general data for the class or family of chemical if such data adequate represent the anticipated hazard of the substance or mixture.

1.2.10.2 Chemical stability

1.2.10.2.1 Indicate if the substance or mixture is stable or unstable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

1.2.10.2.2 Describe any stabilizers which are, or may need to be, used to maintain the product.

1.2.10.2.3 Indicate the safety significance of any changes in the physical appearance of the product.

1.2.10.3 Possibility of hazardous reactions

1.2.10.3.1 State if the substance or mixture will react or polymerize, releasing excess pressure or heat, or creating other hazardous conditions.

1.2.10.3.2 Describe under what conditions the hazardous reactions may occur.

1.2.10.4 Conditions to avoid

1.2.10.4.1 List conditions such as heat, pressure, shock, static discharge, vibrations or other physical stresses that might result in hazardous situation.

1.2.10.5 Incompatible materials

1.2.10.5.1 List classes of chemicals or specific substances with which the substance or mixture could react to produce a hazardous situation.

1.2.10.6 Hazardous decomposition products

1.2.10.6.1 List known reasonably anticipated hazardous decomposition products produces as a result of use, storage and heating.

### 1.2.11 Section 11. Toxicological information

This section shall provide information to be used by medical professionals, occupational health and safety professionals and toxicologists.

1.2.11.1 Describe various toxicological health effects from relevant hazards derived from GHS classification:

1.2.11.1.1 Acute toxicity;

1.2.11.1.2 Skin corrosion / irritation;

1.2.11.1.3 Serious eye damage/ irritation;

1.2.11.1.4 Respiratory or skin sensitization;

1.2.11.1.5 Germ cell mutagenicity;

1.2.11.1.6 Carcinogenicity;

1.2.11.1.7 Reproductive toxicity;

1.2.11.1.8 STOT- single exposure;

1.2.11.1.9 STOT- repeated exposure; and

1.2.11.1.10 Aspiration hazard.

1.2.11.2 If data from the GHS classification is not available, they shall still be listed in the SDS with a statement that “data is not available”

1.2.11.3 Information on the likely routes of exposure

1.2.11.3.1 Provide information on the likely routes of exposure and the effects of the substance or mixture via each possible route of exposure, that is, through ingestion, inhalation or skin/ eye exposure.

1.2.11.3.2 A statement should be made if health effects are not known.

1.2.11.4 Symptoms related to the physical, chemical and toxicological characteristics

1.2.11.4.1 Describe the potential adverse health effects and symptoms associated with exposure to the substance or mixture and its ingredients or known by-products.

1.2.11.4.2 Provide information on the symptoms related to the physical, chemical and toxicological characteristics of the substance or mixture following exposure to intended uses.

1.2.11.4.3 Describe the first symptoms at the lowest exposures through to the consequences of severe exposures.

1.2.11.5 Delayed and immediate effects and also chronic effects from short and long term exposure

1.2.11.5.1 Provide information on whether delayed or immediate effects can be expected after short or long term exposure.

1.2.11.5.2 Provide information on acute and chronic health effects relating to human exposure to the substance or mixture.

1.2.11.5.3 If human data are not available. Animal data should be summarized. Identify if the data is from human or animal data.

1.2.11.6 Numerical measures of toxicity (such as acute toxicity estimates)

1.2.11.6.1 Provide information on the dose, concentration or conditions of exposure that may cause adverse health effect.

1.2.11.6.2 Doses shall be linked to symptoms and effects, including period of exposure likely to cause harm.

### 1.2.12 Section 12. Ecological information

This section shall provide information to evaluate the environmental impact of the substances or mixture if it is released to the environment.

1.2.12.1 Provide information available for assisting user in:

1.2.12.1.1 Handling spills;

1.2.12.1.2 Evaluating waste treatment practices;

1.2.12.1.3 Provide summary of data given under toxicity and other adverse effects

1.2.12.2 Provide information on toxicity using data from tests performed on aquatic and/or terrestrial organisms and relevant data on both acute and chronic aquatic toxicity.

1.2.12.3 Provide test results that can assess persistence and degradability.

1.2.12.3.1 Indicate whether half-lives refer to mineralization or to primary degradation.

1.2.12.3.2 Degradation in sewage treatment plants shall be mentioned.

1.2.12.4 Provide test results that can assess bioaccumulative potential.

1.2.12.4.1 Octanol-water coefficient ($K_{ow}$);

1.2.12.4.2 Bioconcentration factor (BCF);

1.2.12.5 Provide information on mobility from related mobility data such as:

1.2.12.5.1 Adsorption studies;

1.2.12.5.2 Leaching studies;

1.2.12.6 Provide information on any other adverse effects to the environment:

1.2.12.6.1 Environmental fate;

1.2.12.6.2 Ozone depletion potential;

1.2.12.6.3 Photochemical ozone creation potential;

1.2.12.6.4 Endocrine disrupting potential; and / or

1.2.12.6.5 Global warming potential

### 1.2.13 Section 13. Disposal consideration

This section shall provide information for proper disposal, recycling or reclamation of the substance or mixture and/ or its container to assist in the determination of safe and environmentally preferred waste management options, consistent with the requirements of the national competent authority.

1.2.13.1 Specify disposal containers and methods;

1.2.13.2 Discuss physical/ chemical properties that may affect disposal options;

1.2.13.3 Discourage sewage disposal;

1.2.13.4 Identify any special precautions for incineration or landfill.

### 1.2.14 Section 14. Transport information

This section shall provide basic classification information for the transporting shipment of hazardous substance or mixture by road, rail, sea or air.

1.2.14.1 Provide UN number (four-figure identification number of the substance or article0 from the UN Model Regulations.

1.2.14.2 Provide the UN proper shipping name from the UN Model Regulations.

1.2.14.3 Provide the transport hazard class (and subsidiary risks) assigned to the substances or mixtures according to the most predominant hazard that may be present in accordance with the UN Model Regulations.

1.2.14.4 Provide the packing group number from the UN Model Regulations if applicable. The packing group number is assigned to certain substances in accordance with their degree of hazard.

1.2.14.5 Indicate whether the substance or mixture is known marine pollutant according to the IMDG Code, and if so, whether it is “marine pollutant” or a “severe marine pollutant”.

1.2.14.6 Indicate whether the substance or mixture is environmentally hazardous according to the UN Model Regulations, ADR, RID and ADN.

1.2.14.7 Provide information on any special precautions, which a user needs to be aware of, or needs to comply with in connection with transport.

1.2.14.8 Provide sub-section when cargoes are intended to be carried in bulk according to the IMO instruments: Annex II of MARPOL 73/78 and the IBC Code.

### 1.2.15 Section 15. Regulatory information

This section shall describe any other regulatory information on the substance or mixture that is not provided elsewhere in the SDS.

1.2.15.1 Specify if the substance or mixture is covered under Montreal Protocol, Stockholm Convention or the Rotterdam Convention.

1.2.15.2 Specify if the product is under Chemical Control Order (CCO), Priority Chemical List (PCL) for local chemical substance or mixtures.

1.2.15.3 Provide safety, health and environmental regulations specific for the product in question

### 1.2.16 Section 16. Other information

This section shall provide information relevant to the preparation of the SDS. It shall incorporate other information that does not belong in Sections 1 to 15 of the SDS.

1.2.16.1 The date of preparation of the latest revision of the SDS. When revisions are made to an SDS, indicate clearly where the changes have been made to the previous version of the SDS.

1.2.16.1.1 Suppliers shall maintain an explanation of the changes and be willing to provide to the requesting party upon request;

1.2.16.2 Key / legend to abbreviations and acronyms used in the SDS; and

1.2.16.3 Key literature references and sources for data used to compile the SDS.

1.3 Submission of SDS

1.3.1 An importer, distributor, supplier and manufacturer shall submit a hard copy of the latest revision SDS in the GHS format as an additional requirement in securing the necessary Permits/ Licenses and Clearances from DENR-EMB.

1.3.2 Electronic copy of the latest revision of SDS shall be submitted to DENR-EMB for compilation of SDS. The SDS shall be used to:

1.3.2.1 monitor the inventory of chemicals in the country;

1.3.2.2 update the information in the existing Philippine Inventory of Chemicals and Chemical Substances (PICCS);

1.3.2.3 provide information during emergency situations involving the chemicals and/ or mixtures;

1.3.2.4 gather information for future establishment of a comprehensive chemical database.

1.3.3 An importer, distributor, supplier and manufacturer shall submit to DENR-EMB an updated revision of the SDS every 5 years of submission or any changes in the product composition.

1.4 Maintenance of SDS

1.4.1 DENR-EMB GHS Review Committee shall review the completeness of the sixteen (16) sections of the submitted SDS upon submission of SDS.

1.4.2 DENR-EMB shall allocate resources and designate an individual for the maintenance of these SDSs.

1.4.3 DENR-EMB shall compile the electronic copies of SDS.