



**Committee of Experts on the Transport of Dangerous Goods
and on the Globally Harmonized System of Classification
and Labelling of Chemicals**

**Sub-Committee of Experts on the Globally Harmonized
System of Classification and Labelling of Chemicals**

Twenty-fourth session

Geneva, 12 – 14 December 2012

Item 2 of the provisional agenda

**Updating of the Globally Harmonized System of
Classification and Labelling of Chemicals (GHS)**

**Draft amendments to the GHS adopted by the
Sub-Committee at its twenty-first, twenty-second
and twenty-third sessions**

Note by the secretariat¹

This document contains the draft amendments to the fourth revised edition of the Globally Harmonized System of Classification and Labelling of Chemicals (ST/SG/AC.10/30/Rev.4), adopted by the Sub-Committee of Experts at its twenty-first, twenty-second and twenty-third sessions.

¹ In accordance with the programme of work of the Sub-Committee for 2011-2012 approved by the Committee at its fifth session (refer to ST/SG/AC.10/38, par. 16 and ST/SG/AC.10/C.4/40, Annex II).

Chapter 1.3

- 1.3.3.2.1 Insert a reference to footnote “1” at the end of the first sentence as follows: “.....in the GHS¹.” and add the following related footnote:

¹ *For the purposes of the GHS, the terms “cut-off value” and “concentration limit” are equivalent and are meant to be used interchangeably. Competent authorities may choose whether to use either term to define thresholds that trigger classification.”*

(Ref. Doc: ST/SG/AC.10/C.4/46, Annex I)

Chapter 2.1

- 2.1.3 Add a new note 2 under Table 2.1.2 to read as follows:

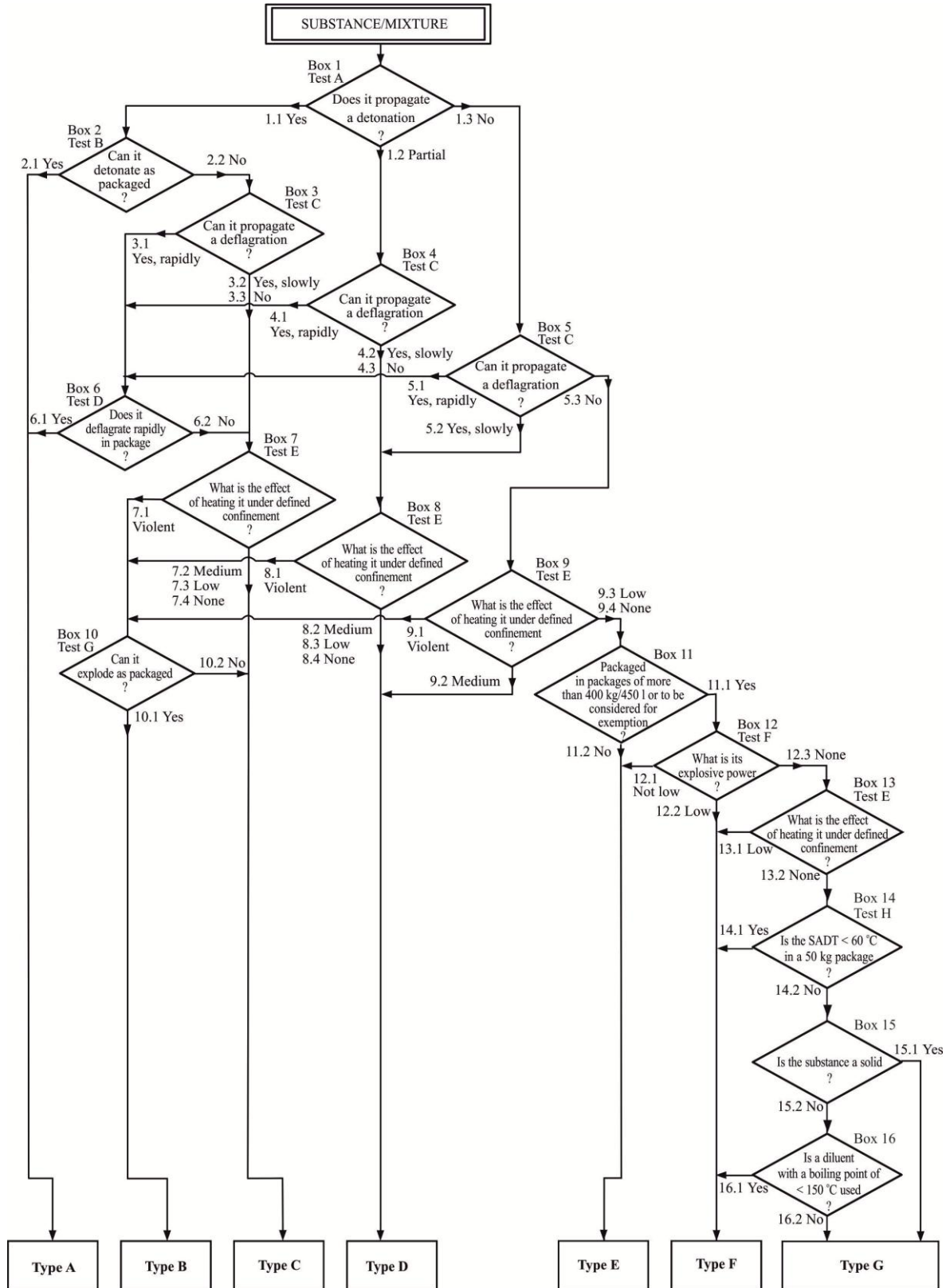
“NOTE 2: Substances and mixtures, as supplied, with a positive result in Test Series 2 in Part I, Section 12, of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, which are exempted from classification as explosives (based on a negative result in Test Series 6 in Part I, Section 16 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria,) still have explosive properties. The user should be informed of these intrinsic explosive properties because they have to be considered for handling – especially if the substance or mixture is removed from its packaging or is repackaged – and for storage. For this reason, the explosive properties of the substance or mixture should be communicated in Section 2 (Hazard identification) and Section 9 (Physical and chemical properties) of the Safety Data Sheet in accordance with Table 1.5.2, and other sections of the Safety Data Sheet, as appropriate.”.

Renumber the current note under the table as NOTE 1.

(Ref. Doc: ST/SG/AC.10/C.4/46, Annex I)

Chapter 2.8

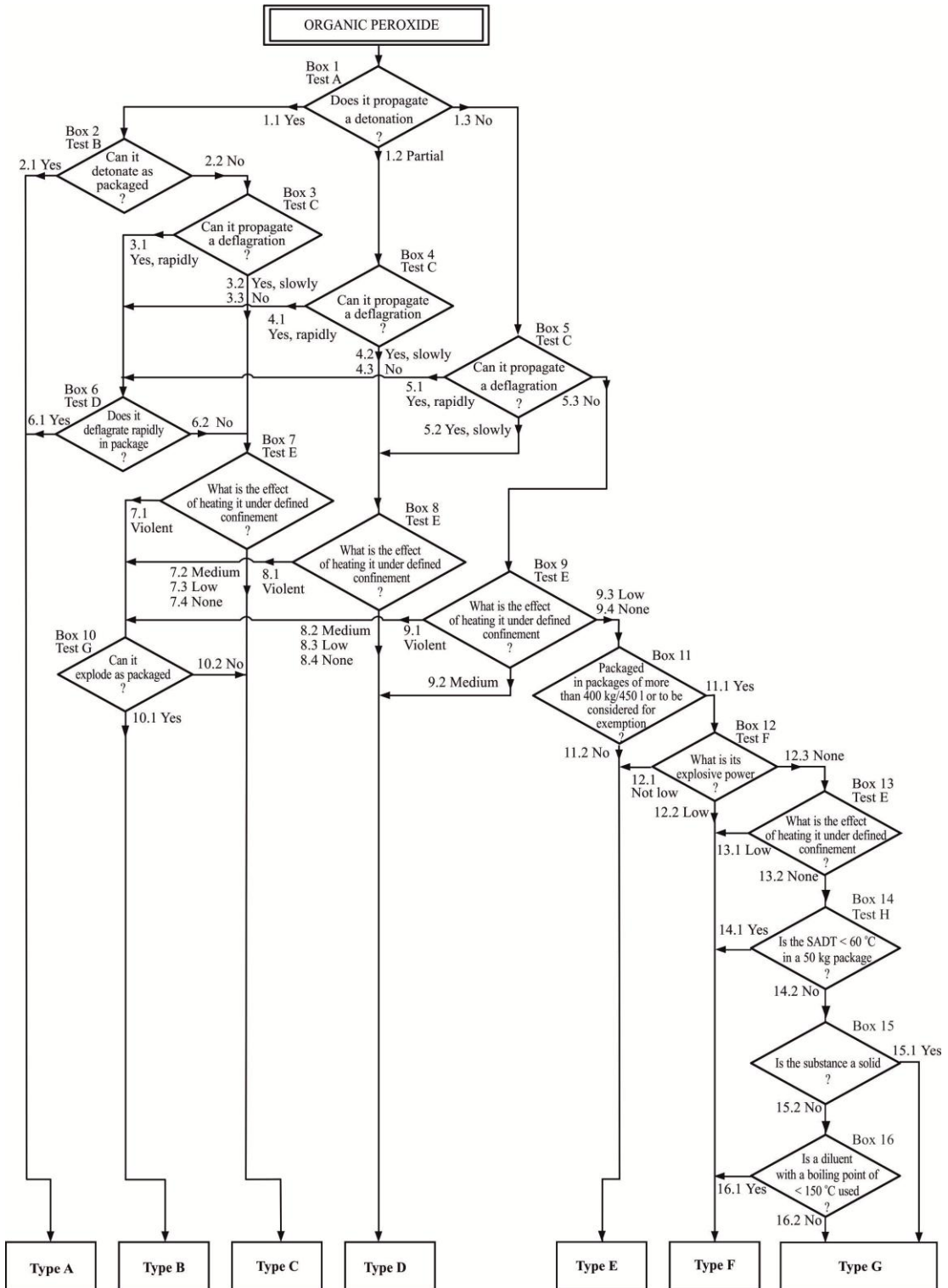
- 2.8.4.1 Replace decision logic 2.8 with the decision logic hereafter:



(Ref. Doc: ST/SG/AC.10/C.4/46, Annex I)

Chapter 2.15

2.15.4.1 Replace decision logic 2.15 with the decision logic hereafter:



(Ref. Doc: ST/SG/AC.10/C.4/46, Annex I)

Chapter 3.1

3.1.2.1 In the first sentence, replace “five toxicity categories” with “five hazard categories”.

(Ref. Doc: ST/SG/AC.10/C.4/46, Annex I)

3.1.2.4 Replace “highest toxicity category” with “highest hazard category”.

(Ref. Doc: ST/SG/AC.10/C.4/46, Annex I)

3.1.2.6.4 Replace “high toxicity categories” with “highest hazard categories”.

(Ref. Doc: ST/SG/AC.10/C.4/46, Annex I)

3.1.3.5.5 In the heading and in the text, replace (3 times) “toxicity category” with “hazard category”.

(Ref. Doc: ST/SG/AC.10/C.4/46, Annex I)

3.1.3.6.1 (a) Replace “acute toxicity categories” with “acute toxicity hazard categories”.

(Ref. Doc: ST/SG/AC.10/C.4/46, Annex I)

3.1.4.1 Replace “acute toxicity categories” with “acute toxicity hazard categories”.

(Ref. Doc: ST/SG/AC.10/C.4/46, Annex I)

Chapter 3.2

3.2.3.2.5 In the heading and in the text, replace (twice) “toxicity category” with “hazard category”.

(Ref. Doc: ST/SG/AC.10/C.4/46, Annex I)

3.2.5 Amend the heading to read: “Decision logics and guidance”.

3.2.5.3 Insert a new sub-section 3.2.5.3 after the decision logics to read as follows²:

[“3.2.5.3 Background guidance

3.2.5.3.1 Classification criteria for the skin and eye hazard classes are detailed in the GHS in terms of a 3-animal test. It has been identified that some older test methods may have used up to 6 animals. However, the GHS does not specify how to classify based on existing data from tests with more than 3 animals. Guidance on how to classify based on existing data from studies with 4 or more animals is given in the following paragraphs.

3.2.5.3.2 Classification criteria based on a 3-animal test are detailed in 3.2.2.4 (skin corrosion) and 3.2.2.5 (skin irritation). Evaluation of a 4, 5 or 6-animal study should follow the criteria in the following paragraphs, depending on the number of animals tested. Scoring for erythema/eschar and oedema should be performed at 24, 48 and 72 hours after exposure or, if reactions are delayed, from grades on 3 consecutive days after the onset of skin reactions.

² **Note by the secretariat:** The text of 3.2.5.3 is reproduced as adopted by the Sub-Committee at its twenty-first session. The text as amended in accordance with the editorial changes which were subsequently proposed by the informal working group on the revision of Chapters 3.2 and 3.3 is reproduced in document ST/SG/AC.10/C.4/2012/12 for consideration by the Sub-Committee.

3.2.5.3.3 In the case of a study with 6 animals the following principles apply:

- (a) The substance or mixture is classified as skin corrosion Category 1 if destruction of skin tissue (that is, visible necrosis through the epidermis and into the dermis) occurs in at least one animal after exposure up to 4 hours in duration;
- (b) The substance or mixture is classified as skin irritation Category 2 if at least 4 out of 6 animals show a mean score per animal of $\geq 2.3 \leq 4.0$ for erythema/eschar or for oedema;
- (c) The substance or mixture is classified as skin irritation Category 3 if at least 4 out of 6 animals show a mean score per animal of $\geq 1.5 < 2.3$ for erythema/eschar or for oedema.

3.2.5.3.4 In the case of a study with 5 animals the following principles apply:

- (a) The substance or mixture is classified as skin corrosion Category 1 if destruction of skin tissue (that is, visible necrosis through the epidermis and into the dermis) occurs in at least one animal after exposure up to 4 hours in duration;
- (b) The substance or mixture is classified as skin irritation Category 2 if at least 3 out of 5 animals show a mean score per animal of $\geq 2.3 \leq 4.0$ for erythema/eschar or for oedema;
- (c) The substance or mixture is classified as skin irritation Category 3 if at least 3 out of 5 animals show a mean score per animal of $\geq 1.5 < 2.3$ for erythema/eschar or for oedema.

3.2.5.3.5 In the case of a study with 4 animals the following principles apply:

- (a) The substance or mixture is classified as skin corrosion Category 1 if destruction of skin tissue (that is, visible necrosis through the epidermis and into the dermis) occurs in at least one animal after exposure up to 4 hours in duration;
- (b) The substance or mixture is classified as skin irritation Category 2 if at least 3 out of 4 animals show a mean score per animal of $\geq 2.3 \leq 4.0$ for erythema/eschar or for oedema;
- (c) The substance or mixture is classified as skin irritation Category 3 if at least 3 out of 4 animals show a mean score per animal of $\geq 1.5 < 2.3$ for erythema/eschar or for oedema.”.]

(*Ref. Doc: ST/AG/AC.10/C.4/2011/2 as amended by ST/SG/AC.10/C.4/42, Annex*)

Chapter 3.3

3.3.3.2.5 In the heading and in the text, replace (twice) “toxicity category” with “hazard category”.

(*Ref. Doc: ST/SG/AC.10/C.4/46, Annex I*)

3.3.5 Amend the heading to read: “Decision logics and guidance”.

3.3.5.3 Insert a new sub-section 3.2.5.3 after the decision logics to read as follows³:

[“3.3.5.3 Background guidance

3.3.5.3.1 Classification criteria for the skin and eye hazard classes are detailed in the GHS in terms of a 3-animal test. It has been identified that some older test methods may have used up to 6 animals. However, the GHS does not specify how to classify based on existing data from tests with more than 3 animals. Guidance on how to classify based on existing data from studies with 4 or more animals is given in the following paragraphs.

3.3.5.3.2 Classification criteria based on a 3-animal test are detailed in 3.3.2.8 (serious eye damage) and 3.3.2.9 (eye irritation). Evaluation of a 4, 5 or 6 animal study should follow the criteria in the following paragraphs, depending on the number of animals tested. Scoring should be done at 24, 48 and 72 hours after instillation of the test material.

3.3.5.3.3 In the case of a study with 6 animals the following principles apply:

- (a) The substance or mixture is classified as serious eye damage Category 1 if:
 - (i) 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
 - (ii) at least 4 out of 6 animals show a mean score per animal of ≥ 3 for corneal opacity and/or > 1.5 for iritis.
- (b) The substance or mixture is classified as eye irritation Category 2A if at least 4 out of 6 animals show a mean score per animal of:
 - (i) ≥ 1 for corneal opacity and/or
 - (ii) ≥ 1 for iritis and/or
 - (iii) ≥ 2 for conjunctival redness and/or
 - (iv) ≥ 2 for conjunctival oedema (chemosis)
 and which fully reverses within an observation period of normally 21 days.
- (c) The substance or mixture is classified as mildly irritating to eyes (Category 2B) if the effects listed in sub-paragraph (b) above are fully reversible within 7 days of observation.

3.3.5.3.4 In the case of a study with 5 animals the following principles apply:

- (a) The substance or mixture is classified as serious eye damage Category 1 if:

³ **Note by the secretariat:** The text of 3.3.5.3 is reproduced as adopted by the Sub-Committee at its twenty-first session. The text as amended in accordance with the editorial changes proposed by the informal working group on the revision of Chapters 3.2 and 3.3 is included in document ST/SG/AC.10/C.4/2012/13 for consideration by the Sub-Committee.

- (i) 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
 - (ii) at least 3 out of 5 animals show a mean score per animal of ≥ 3 for corneal opacity and/or > 1.5 for iritis.
- (b) The substance or mixture is classified as eye irritation Category 2A if at least 3 out of 5 animals show a mean score per animal of:
- (i) ≥ 1 for corneal opacity and/or
 - (ii) ≥ 1 for iritis and/or
 - (iii) ≥ 2 for conjunctival redness and/or
 - (iv) ≥ 2 for conjunctival oedema (chemosis)
- and which fully reverses within an observation period of normally 21 days.
- (c) The substance or mixture is classified as mildly irritating to eyes (Category 2B) if the effects listed in sub-paragraph (b) above are fully reversible within 7 days of observation.

3.3.5.3.5 In the case of a study with 4 animals the following principles apply:

- (a) The substance or mixture is classified as serious eye damage Category 1 if:
- (i) 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
 - (ii) at least 3 out of 4 animals show a mean score per animal of ≥ 3 for corneal opacity and/or > 1.5 for iritis.
- (b) Classification as eye irritation Category 2A if at least 3 out of 4 animals show a mean score per animal of:
- (i) ≥ 1 for corneal opacity and/or
 - (ii) ≥ 1 for iritis and/or
 - (iii) ≥ 2 for conjunctival redness and/or
 - (iv) ≥ 2 for conjunctival oedema (chemosis)
- and which fully reverses within an observation period of normally 21 days.
- (c) The substance or mixture is classified as mildly irritating to eyes (Category 2B) if the effects listed in sub-paragraph (b) above are fully reversible within 7 days of observation.”.]

(Ref. Doc: ST/AG/AC.10/C.4/2011/2 as amended by ST/SG/AC.10/C.4/42, Annex)

Chapter 3.8

3.8.3.3.5 In the heading and in the text, replace (3 times) “toxicity category” with “hazard category”.

(Ref. Doc: ST/SG/AC.10/C.4/46, Annex I)

Chapter 3.9

3.9.3.3.5 In the heading and in the text, replace (3 times) “toxicity category” with “hazard category”.

(Ref. Doc: ST/SG/AC.10/C.4/46, Annex I)

Chapter 3.10

3.10.3.3.5 In the heading and in the text, replace (3 times) “toxicity category” with “hazard category”.

(Ref. Doc: ST/SG/AC.10/C.4/46, Annex I)

Chapter 4.1

4.1.3.4.5 In the heading and in the text, replace (3 times) “toxicity category” with “hazard category”.

(Ref. Doc: ST/SG/AC.10/C.4/46, Annex I)

4.1.5.1.1 At the end of decision logic 4.1.1 1 (page 234 of the English version of the GHS), in the text box starting with “Use all available...”, sub-paragraph (a), replace “toxicity category” with “hazard category”.

(Ref. Doc: ST/SG/AC.10/C.4/46, Annex I)
