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

> Report of the Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals on its twelfth session

Held in Geneva on 6 December 2024

Addendum

**Annex III** 

Amendments to the tenth revised edition of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (ST/SG/AC.10/30/Rev.10)



## Chapter 1.2

In the definition of "Ozone Depleting Potential", delete "(ODP)" in the first sentence and replace "ODP" with "ozone depleting potential" in the second sentence.

Insert the following new definition in the alphabetical order:

"Global warming potential means a metric that compares the ability of a substance or mixture to trap heat in the atmosphere as compared to a benchmark gas (generally carbon dioxide). The formal definition of global warming potential is the cumulative radiative forcing, both direct and indirect effects, over a specified time horizon resulting from the emission of a unit mass of gas relative to that of carbon dioxide (as the reference gas)."

## Chapter 2.2

2.2.2 In note 2 under table 2.2.1, replace "Aerosols" with "Aerosols and chemicals under pressure".

## Chapter 2.3

2.3.1.1 Amend to read as follows:

#### "2.3.1.1 Definition and general considerations

- 2.3.1.1.1 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.
- 2.3.1.1.2 Aerosols do not fall additionally within the scope of section 2.3.2 (chemicals under pressure), chapters 2.2 (flammable gases), 2.5 (gases under pressure), 2.6 (flammable liquids) and 2.7 (flammable solids). Depending on their contents, aerosols may fall within the scope of other hazard classes.

**NOTE:** Some sectors, e.g. transport, may have other specific provisions regarding the applicability of additional hazard classes. For the transport of aerosols, see special provision 63 of the UN Model Regulations.".

### 2.3.1.2.1 Amend table 2.3.1 as follows:

- Row for category 1, column "Criteria":
  - At the end of (b), delete "or".
  - In (c), first sentence, insert "aerosol" before "foam flammability test".
     In (c) (ii), at the end, replace the full stop by "; or".
  - Add the following new subparagraph (d):
    - (d) Any aerosol that contains > 1 % flammable components (by mass) or with a heat of combustion  $\ge 20$  kJ/g, which has not been tested according to 2.3.1.2.1, third indent."
- Row for category 2, column "Criteria":
  - In (a), delete ", based on the results of the ignition distance test,".
     In (a) (ii), replace "along with" by "and in the ignition distance test,".
     In (a) (iii), before "an ignition distance" add "in the ignition distance test,".
  - In (b), replace ", based on the results of the aerosol foam flammability test, does not meet the criteria for Category 1, and which" by "does not

meet the criteria for Category 1 and in the aerosol foam flammability test,".

- Row for category 3, column "Criteria", amend subparagraph (b) to read:
  - "(b) Any other aerosol that does not meet the criteria for Category 1 or Category 2."
- Delete current notes 1, 2 and 3 under the table.

#### 2.3.2.1 Amend to read as follows:

## "2.3.2.1 Definition and general considerations

2.3.2.1.1 *Chemicals under pressure* are liquids or solids (e.g. pastes or powders), pressurized with a gas at a pressure of 200 kPa (gauge) or more at 20 °C in pressure receptacles other than aerosol dispensers and which are not classified as gases under pressure.

**NOTE:** Chemicals under pressure typically contain 50 % or more by mass of liquids or solids whereas mixtures containing more than 50 % gases are typically considered as gases under pressure.

2.3.2.1.2 Chemicals under pressure do not fall additionally within the scope of section 2.3.1 (aerosols), chapters 2.2 (flammable gases), 2.5 (gases under pressure), 2.6 (flammable liquids) and 2.7 (flammable solids). Depending on their contents, chemicals under pressure may fall within the scope of other hazard classes."

**NOTE:** Some sectors, e.g. transport, may have specific provisions regarding the applicability of additional hazard classes. For the transport of chemicals under pressure, see special provision 362 of the UN Model Regulations."

2.3.2.2.2 Delete notes 1 and 2.

## Chapter 2.6

2.6.2 In note 4 under table 2.6.1, replace "Aerosols" with "Aerosols and chemicals under pressure".

## Chapter 2.7

2.7.2 In note 2 under table 2.7.1, replace "Aerosols" with "Aerosols and chemicals under pressure".

## Chapter 2.8

2.8.1.1 Amend the end of the second sentence to read "... as explosives, organic peroxides, or oxidizing liquids or solids in accordance with 2.8.2.1."

## Chapter 2.17

2.17.2.2 Amend the note as follows:

"NOTE: Phlegmatized explosives which do not meet the criteria of 2.17.2.2 should not be classified as a desensitized explosive and should be classified as an explosive in accordance with chapter 2.1.".

- 2.17.2.3 Delete the note ("Nitrocellulose mixtures containing ... of 2.17.2.2 (b)(ii)").
- 2.17.4.1 In decision logic 2.17.1, delete footnote 2 ("Test series 3... other than nitrocellulose.").

## Chapter 3.4

- 3.4.2.2.3.1 In the fourth sentence, replace "in the radioisotopic local lymph node assay" with "in the radioactive local lymph node assay".
- 3.4.2.2.5.1 Replace "3.4.5.3.5" with "3.4.5.3.1.5" in the last sentence.
- 3.4.2.2.5.3 Replace "3.4.5.3.6.2" with "3.4.5.3.1.6.2" in the first sentence and the related footnote 4.
- 3.4.2.2.7.2 Replace "3.4.5.3.2" with "3.4.5.3.1.2" in subparagraphs (a), (b) and (c). Replace "3.4.5.3.3" with "3.4.5.3.1.3" in subparagraph (d), "3.4.5.3.4" with "3.4.5.3.1.4" in subparagraph (e), and "3.4.5.3.5" with "3.4.5.3.1.5" in subparagraph (f).
- 3.4.2.2.7.3 Replace "3.4.5.3.5" with "3.4.5.3.1.5" in subparagraph (a).
- 3.4.3.1 Replace with the following:

# "3.4.3.1 Classification of mixtures when data are available for the complete mixture

- 3.4.3.1.1 In general, the mixture should be classified using the criteria for substances taking into account the tiered approach to evaluate data for this hazard class (see 3.4.3.1.2 and figure 3.4.1). If classification is not possible using the tiered approach, then the approach described in 3.4.3.2 or, if that is not applicable, in 3.4.3.3, should be followed. For supplemental labelling required by some competent authorities, see the note to table 3.4.5 and 3.4.4.2.
- 3.4.3.1.2 Care should be exercised in evaluating data on mixtures that the dose used does not render the results inconclusive and that the test methods used to generate such results are appropriate for predicting the skin sensitizing properties of the mixture (see 3.4.5.3.2). Further, for both standard test methods (in vivo, *in chemico*, in vitro) and defined approaches, data can only be used for classification when all ingredients fall within their applicability domain. Specific limitations regarding applicability domains are described in the respective test methods and defined approaches and should be taken into consideration as well as any further information on such limitations from the published literature. A competent authority may decide which *in chemico/*in vitro test method or defined approach may be accepted for mixtures (see 3.4.5.3.2.4 and 3.4.5.3.2.5). A more detailed overview of factors to consider in the classification of mixtures can be found in guidance section 3.4.5.3.2 and the test methods."
- 3.4.5.3 Insert the following new heading beneath "3.4.5.3 Background guidance":
  - "3.4.5.3.1 Guidance on substances skin sensitization".
- 3.4.5.3.1 to 3.4.5.3.2 Current sections 3.4.5.3.1 to 3.4.5.3.2 become new sections 3.4.5.3.1.1 to 3.4.5.3.1.2.
- 3.4.5.3.1.2 (former 3.4.5.3.2) Replace with the following:
  - "3.4.5.3.1.2 Guidance on the use of human data
  - 3.4.5.3.1.2.1 This guidance is relevant to substances and mixtures.
  - 3.4.5.3.1.2.2 The classification of substances and mixtures can be based on human evidence generated from a variety of sources. These sources include human predictive patch testing, epidemiological studies, case studies, case reports or histories, diagnostic patch testing and medical surveillance reports, and poison control centre information. This data may have been generated for consumers, workers, or the general population. Guidance for evaluating human

evidence and the criteria in 3.4.2.2.2 is provided by some competent authorities (e.g. ECHA Guidance on the Application of the CLP Criteria, 2017). Further valuable information which should be considered for classification purposes (e.g., on use of appropriate concentrations and vehicles, as well as mixture evaluation) is also available (see U.S. Consumer Product Safety Commission (U.S CPSC), 2013; European Society of Contact Dermatitis guidance, 2015; Frosch et al., 2015).

- 3.4.5.3.1.2.3 When evaluating existing data, its quality should be taken into consideration. Criteria for a "well conducted" study would include validated outcomes, relevant dosing and route of administration and use of appropriate controls. Special attention should be applied to ascertain that exposure to the relevant substance or mixture is established with sufficient reliability. Studies should, where applicable, be carried out according to national and/or international test guidelines and according to good laboratory practice (GLP), compliance with good clinical practice (GCP), and good epidemiological practice (GEP) (U.S. CPSC, 2013; Hoffman, 2019; Alba, 2020; World Health Organization, Council for *International* Organizations of Medical Sciences (WHO CIOMS), 2009).
- 3.4.5.3.1.2.4 Positive data from well-run epidemiological studies (in accordance with WHO CIOMS guidelines, 2009) can be used for classifying substances and mixtures for skin sensitization. Some examples of epidemiological studies may include case control studies, cohort studies, cross-sectional studies, or longitudinal studies. These studies should have large sample sizes with well-documented exposures to a substance or a mixture.
- 3.4.5.3.1.2.5 When using human epidemiological data for classification, consideration should be given to available data from a number of sources: (a) well-conducted clinical and diagnostic studies; (b) epidemiological studies, either general population studies or occupational studies; (c) cross-reactivity data; (d) case histories. Positive data from well-run epidemiological studies (which should also comply with WHO CIOMS guidelines, 2009) can be used for classifying substances and mixtures for skin sensitization. The incidence and severity of sensitization in occupational epidemiological studies may be higher than in general population studies due to the higher exposure levels (both in time and concentration). The exposure, the incidence and the severity in the study populations should be taken into account especially when deciding on the subcategory (see 3.4.2.2.2).
- 3.4.5.3.1.2.6 A specific type of epidemiological study (such as randomized control studies or trials) may include information from diagnostic patch testing. Diagnostic patch testing is considered by some competent authorities to be the gold standard in diagnosing contact allergy in dermatitis patients (Johansen et al, 2015; Frosch et al., 2015). Importantly, due consideration needs to be given to the appropriate selection of vehicle, test material composition, and patch test concentrations for the purpose of not causing false negatives, false positives, irritant reactions or inducing contact allergy (skin sensitization). Positive data from experimental, clinical or diagnostic studies in humans and/or well-documented episodes of allergic contact dermatitis may be used to classify substances and mixtures for skin sensitization, when it can be assumed with sufficient confidence that the tested substance or mixture was indeed the most likely cause for induction of sensitization. Therefore, it should be established that there is at least a general likelihood that the respective patient(s) had been previously exposed to the substance or mixture. On the other hand, negative results from such tests are not sufficient to prove that the test substance or mixture should not be classified as a skin sensitizer.
- 3.4.5.3.1.2.7 For some substances and mixtures, predictive patch test data in human volunteers are available (e.g. Strickland et al., 2023). Two test

designs for predicting whether the substance or mixture will induce sensitization are the Human Maximization Test (HMT) and the Human Repeated Insult Patch Tests (HRIPT).

- 3.4.5.3.1.2.8 Positive data from predictive patch testing (HRIPT or HMT) showing allergic contact dermatitis caused by the test substance or mixture can be used to classify for skin sensitization. These studies are generally conducted in controlled clinical settings and in general the study outcome is considered more reliable the larger the test panel size. Criteria for evaluating these data are provided in 3.4.2.2.2.2 and 3.4.2.2.2.3. When evaluating the data from HRIPT, consideration should be given to the appropriate use of vehicle as this can affect the outcome of testing (Johansen et al., 2015; Frosch et al., 2015).
- 3.4.5.3.1.2.9 The HMT is no longer in use, due to ethical concerns about its potential to create adverse health consequences for the person being tested. In cases where such data exist, they can nevertheless be used for classification.
- 3.4.5.3.1.2.10 Special consideration should be given to negative human data as full dose-response information is generally not available. For example, a negative result in an HRIPT or HMT at a low concentration may not allow for the conclusion that the substance or mixture does not have skin sensitizing properties, as such effect at a higher concentration may not be excluded. In addition, negative human data should not necessarily be used to negate positive results from animal studies and/or defined approaches but can be used as part of a weight of evidence assessment. For both animal and human data, consideration should be given to the impact of the vehicle (e.g. Wright et al, 2001 and Kligman, 1966).
- 3.4.5.3.1.2.11 For example, negative results from substances or mixtures tested in a predictive patch test at a DSA (dose per skin area) of < 500 µg/cm<sup>2</sup> imply that a classification for skin sensitization might not be needed at all, however, classification as sub-category 1A or 1B cannot be ruled out, because the concentration tested was not high enough to exclude these possibilities. The same holds for test results for which it is unknown whether the test concentration corresponded to a DSA < 500 μg/cm<sup>2</sup>. Negative results from substances or mixtures tested at a DSA ≥ 500 μg/cm<sup>2</sup> suggest that classification might not be needed. However, while classification as subcategory 1A can be ruled out, classification as sub-category 1B cannot, because a higher test concentration might have resulted in a positive test result. However, a negative test result at a concentration of 100% (i.e. the undiluted substance or mixture) can justify no classification (based on this test). Nevertheless, negative results at low concentrations may be informative for classification of mixtures containing the substance or mixture at similar or lower concentrations.
- 3.4.5.3.1.2.12 Human data not generated in controlled experiments with volunteers for the purpose of hazard classification (e.g. case studies, case reports and case histories, and poison control centre information) can be used with caution. Consideration should be given to the frequency of cases, the inherent properties of the substance or mixture, as well as factors such as the exposure situation, bioavailability, individual predisposition, cross-reactivity and preventive measures taken."
- 3.4.5.3.1.3 to 3.4.5.3.1.6 (new, former 3.4.5.3.3 to 3.4.5.3.6) Current sections 3.4.5.3.3 to 3.4.5.3.6 become new sections 3.4.5.3.1.3 to 3.4.5.3.1.6. Renumber the paragraphs within each section accordingly.
- 3.4.5.3.1.5 (former 3.4.5.3.5) In the second sentence, replace "criteria" with "methods" and insert "for this purpose" at the end of the sentence.
- 3.4.5.3.1.6.1 (former 3.4.5.3.6.1) Replace "3.4.5.3.6.2" with "3.4.5.3.1.6.2".

3.4.5.3.2 (new) Insert the following new section after 3.4.5.3.1.6 (former 3.4.5.3.6):

"3.4.5.3.2 Guidance on mixtures – skin sensitization

#### 3.4.5.3.2.1 General considerations

3.4.5.3.2.1.1 Mechanistic information in the OECD document on the "Adverse Outcome Pathway for skin sensitization" can be helpful in understanding the value of the individual *in chemico* and in vitro methods compared to the in vivo methods (see OECD (2014)).

3.4.5.3.2.1.2 Most of the standard animal test methods, defined approaches, in vitro and *in chemico* methods were developed and formally validated for identifying sensitizing substances and not mixtures. Nevertheless they are technically applicable to mixtures (see 3.4.3.1.2). However, there is limited data indicating whether there is a difference in the predictive capacity between standard animal test methods and defined approaches for the classification of mixtures. Sometimes, standard animal tests (see 3.4.2.2.3) on mixtures are required by competent authorities or applied voluntarily and the results are internationally accepted for classification. Therefore, the results of standard animal test methods can be used for the classification of mixtures. The defined approaches were first introduced in OECD Guideline 497 in 2021 without a clear statement on the applicability of the defined approaches for mixtures (see also 3.4.5.3.2.4.1). Human data can also be used for the classification of mixtures (see 3.4.5.3.2.2).

#### 3.4.5.3.2.2 Guidance on the use of human data

See the guidance on the use of human data in 3.4.5.3.1.2 which is also applicable to mixtures.

- 3.4.5.3.2.3 Guidance on the use of standard animal data
- 3.4.5.3.2.3.1 Animal tests have been developed to identify sensitizing substances and not mixtures. Therefore, the results obtained on mixtures need to be evaluated with care. The following considerations can be relevant for mixtures because of dilution effects, in particular for borderline cases, but can also be applicable for substances.
- 3.4.5.3.2.3.2 For example, a stimulation index of three or more in the radioactive local lymph node assay (LLNA) (OECD Test Guideline 429) should be seen as a regulatory threshold for identification of a sensitizing mixture rather than as a threshold for sensitization as such. If a sensitizing substance is present at a low concentration in a mixture, a stimulation index of three may not be reached in the LLNA, but the substance in that mixture may still act as a sensitizer at population level. For this reason, a conclusion on the absence of sensitizing potential of a mixture based on the negative outcome in a test must be taken with great caution.
- 3.4.5.3.2.3.3 Where the mixture is tested undiluted, contains sensitizing ingredients and there is an increase in positive animals (Buehler, guinea pig maximisation test (GPMT)) or in the response (LLNA) which does not fulfil the criteria for a positive result, an overall weight of evidence assessment is required including the indicators included in tier 3. This should also include available data on the sensitizing ingredient(s) regarding their potency, bioavailability, accumulation in the skin and interaction with the other ingredients. When the result is inconclusive, where applicable the bridging principles should be applied, otherwise the ingredient-based approach should be followed according to the tiered approach for mixtures (see 1.3.2.3).

- 3.4.5.3.2.3.4 Test data on a mixture takes into account effects of possible interactions of its components. For instance, it is known that the presence of a vehicle may significantly influence the skin sensitizing potency, by altering the penetration of the sensitizing component(s) through the skin, (Basketter et al. 2001, Dearman et al. 1996, Heylings et al. 1996) or through other mechanisms involved in the induction of sensitization (Cumberbatch et al. 1993; Dearman et al. 1996). These mechanisms may differ between animals and humans. Especially where differences are known or suspected that could lead to the underestimation of sensitization, negative outcomes may not be reliable.
- 3.4.5.3.2.3.5 If the classification of a mixture based on one or more standard animal tests is inconsistent with the classification based on the concentration and potency (e.g. from one or more standard animal tests or human data) of at least one sensitizing ingredient (see table 3.4.5), additional considerations may need to be taken into account for the classification of the mixture (see OECD Test Guideline 429). This could include, for example, test concentrations, difference in vehicle and purity of the test material.
- 3.4.5.3.2.3.6 Where the mixture contains corrosives or potent irritants resulting in unacceptable irritation in the pilot study with the mixture, either a dilution has to be used or the results may be a false positive. If a dilution is tested, the lower tested dose of the potential sensitizer(s) in the mixture may lead to false negative results for classification. In such cases, where applicable the bridging principles should be applied, otherwise the ingredient-based approach should be followed according to the tiered approach for mixtures (see 1.3.2.3), unless evidence is provided that the negative result is not caused by the dilution. This could for example be shown by testing the mixture without the corrosive or irritant ingredients at the actual concentration. Also, the validity of a well conducted LLNA on a mixture with a negative outcome can scientifically be confirmed by spiking the test mixture with another sensitizer (positive control) at different concentrations, or by showing a dose-response relationship.

#### 3.4.5.3.2.4 Guidance on the use of defined approaches

- 3.4.5.3.2.4.1 Defined approaches may not have been formally validated for mixtures according to international procedures. Several defined approaches require upfront consideration to whether such testing will yield results that are predictive of the skin sensitizing properties of the mixture (see 3.4.5.3.2.4.3). This upfront consideration could include a comparison of the classification based on the results of a defined approach with existing classifications of similar mixtures. Where the comparison shows that the defined approach is predictive of certain types of mixtures, the outcome of the defined approach can be used for other mixtures of the same type for classification.
- 3.4.5.3.2.4.2 *In chemico* and in vitro methods used in defined approaches do not account for dermal penetration. Therefore, results from defined approaches may lead to false positive predictions compared to the standard animal tests that account for dermal penetration.
- 3.4.5.3.2.4.3 Also, it is necessary to exercise care when evaluating whether the dose used will yield results that are predictive of the skin sensitizing properties of the mixture. For example, in some *in chemico* and in vitro methods, the limited solubility of the ingredients of the mixture or limited stability of any suspension formed in the exposure medium or solvent may not allow testing at a dose that corresponds to the test requirements. In such a case, no valid outcome can be obtained for a negative result. Also, where the mixture is tested at lower concentrations in the in vitro methods due to the presence of cytotoxic ingredients, a positive result can be used for classification. However, a negative result is considered inconclusive as the concentration of the sensitizing ingredient(s) could have been too low unless evidence is provided

that the negative result is not caused by the dilution. In such cases, where applicable the bridging principles should be applied, otherwise the ingredient-based approach should be followed according to the tiered approach for mixtures (see 1.3.2.3). Approaches to address cytotoxicity are suggested in the relevant OECD test guidelines 442D and 442E.

3.4.5.3.2.4.4 In some methods, e.g. in silico predictions in the defined approaches for skin sensitization listed in OECD Guideline 497, all ingredients have to be assessed individually and the outcome from the in silico component of the defined approach is considered positive, if one ingredient is positive. However, it is noted that this may provide overly conservative or false positive predictions, as the in silico methods currently do not take into account the concentration at which the ingredient is present in the mixture.

3.4.5.3.2.5 Guidance on the use of non stand-alone *in chemico*/in vitro methods

3.4.5.3.2.5.1 Individual in chemico/in vitro methods such as those reported in OECD test guidelines 442C, 442D and 442E, due to their limited mechanistic coverage, cannot be used on their own to conclude on Category 1 or no classification. In addition, although some of these methods provide quantitative information, these cannot be used for the purposes of subcategorization into sub-categories 1A and 1B since the methods have not been validated according to international procedures for this purpose. Nevertheless, such quantitative information may be accepted by a competent authority when used in a weight of evidence assessment under tier 2 for the purpose of subcategorization. This is also in line with the statement in these test guidelines that "Depending on the regulatory framework, positive results generated with these methods may be used on their own to classify a chemical into UN GHS Category 1." Therefore, the GHS also allows a competent authority to decide that a positive result with one of these non stand-alone in chemico/in vitro methods, may be used on its own to classify in Category 1 and whether test guideline 442C (Appendix III) kinetic Direct Peptide Reactivity Assay (kDPRA) can be used to differentiate between sub-category 1A and no sub-category 1A.

3.4.5.3.2.5.2 *In chemico*/in vitro methods may not have been formally validated for mixtures according to international procedures. Several *in chemico*/in vitro methods require upfront consideration to whether such testing will yield results that are predictive of the skin sensitizing properties of the mixture (see 3.4.5.3.2.5.4). This upfront consideration could include a comparison of the classification based on the results of an *in chemico*/in vitro method with existing classifications of similar mixtures. Where the comparison shows that the *in chemico*/in vitro method is predictive of certain types of mixtures, the outcome of the *in chemico*/in vitro method may be used for other mixtures of the same type for classification.

3.4.5.3.2.5.3 *In chemico/*in vitro methods do not account for dermal penetration. Therefore, results from *in chemico/*in vitro methods may lead to false positive predictions compared to the standard animal tests that account for dermal penetration.

3.4.5.3.2.5.4 Also, it is necessary to exercise care when evaluating whether the dose used will yield results that are predictive of the skin sensitizing properties of the mixture. For example, in some *in chemico* and in vitro methods, the limited solubility of the ingredients of the mixture or limited stability of any suspension formed in the exposure medium or solvent may not allow testing at a dose that corresponds to the test requirements. In such a case, no valid outcome can be obtained for a negative result. Also, where the mixture is tested at lower concentrations in the in vitro methods due to the presence of cytotoxic ingredients, a positive result can be used for classification. However,

a negative result is considered inconclusive as the concentration of the sensitizing ingredient(s) could have been too low unless evidence is provided that the negative result is not caused by the dilution. In such cases, where applicable the bridging principles should be applied, otherwise the ingredient-based approach should be followed according to the tiered approach for mixtures (see 1.3.2.3). Approaches to address cytotoxicity are suggested in the relevant OECD test guidelines 442D and 442E."

3.4.5.3.3 (new, former 3.4.5.3.7) Current section 3.4.5.3.7 becomes new section 3.4.5.3.3. Renumber the paragraphs within the section accordingly.

Insert the following references in the alphabetical order in the current list at the end of the chapter:

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## Chapter 4.2

### Chapter title Amend to read "HAZARDOUS TO THE ATMOSPHERIC SYSTEM"

4.2.1 Amend the heading to read "**Definitions and general considerations**".

Insert a new paragraph beneath the amended title to read:

"This chapter covers substances and mixtures that are hazardous to the atmospheric system due to their ozone depleting and/or global warming potential. For the purposes of this chapter, the following definitions apply:"

Move the existing definition "Montreal Protocol is ..." to place it before the existing definition for "Ozone Depleting Potential"

In the existing definition of "Ozone Depleting Potential" delete: "(ODP)" in the first sentence and replace "ODP" with "ozone depleting potential" in the second sentence.

Insert the following new definition for "Global warming potential" after the definition for "Ozone Depleting Potential" to read:

"Global warming potential is a metric that compares the ability of a substance or mixture to trap heat in the atmosphere as compared to a benchmark gas (generally carbon dioxide). The formal definition of global warming potential is the

cumulative radiative forcing, both direct and indirect effects, over a specified time horizon resulting from the emission of a unit mass of gas relative to that of carbon dioxide (as the reference gas)."

4.2.2 Move footnote reference "1" from the heading of 4.2.2, to the end of the first sentence under the new heading for 4.2.2.1 (see amendment to 4.2.2.1 below).

Insert a new paragraph under the heading "Classification criteria" to read as follows:

"Substances and mixtures are classified into the hazardous to the ozone layer hazard class due to their ozone depleting potential in accordance with 4.2.2.1 and/or hazardous by contributing to global warming hazard class by their global warming potential in accordance with 4.2.2.2, independently."

4.2.2.1 Place the existing sentence under "Classification criteria" ("A substance or mixture...") under a new heading 4.2.2.1 and amend as follows:

### "4.2.2.1 Hazardous to the ozone layer

A substance or mixture shall be classified in Category 1 hazardous to the ozone layer according to the following table: 1"

In the text of footnote 1 (previously assigned to 4.2.2) replace "ozone layer" with "atmospheric system".

Table 4.2.1, column "Criteria":

Replace "listed in annexes to" with "listed with an ozone depleting potential in annexes to" and "listed in the annexes to the" with "listed with an ozone depleting potential in the annexes".

4.2.2.2 Insert the following new section after table 4.2.1:

## "4.2.2.2 Hazardous by contributing to global warming

A substance or mixture shall be classified in Category 1 hazardous to global warming according to the following table:  $^{\rm 1}$ 

Table 4.2.2: Criteria for substances and mixtures that are hazardous by contributing to global warming

Category	Criteria
1	Any of the controlled substances listed with a global warming potential in annexes to the Montreal Protocol; or Any mixture containing at least one ingredient listed with a global warming potential in the annexes to the Montreal Protocol, at a concentration $\geq 0.1 \%$

Footnote 1: Reproduce the text of footnote 1 assigned to 4.2.2.1, as amended.

4.2.3 Renumber the paragraph preceding the table as "4.2.3.1". In the last sentence of that paragraph, replace "Table 4.2.2" with "Table 4.2.3".

Amend current table 4.2.2 (renumbered 4.2.3) and insert a new paragraph 4.2.3.2 to read as follows:

"Table 4.2.3: Label elements for substances and mixtures hazardous to the atmospheric system

	Category 1	Category 1
	Hazardous to the ozone layer	Hazardous by contributing to global warming
Symbol	Exclamation mark	Exclamation mark
Signal word	Warning	Warning
Hazard statement	Harms public health and the environment by destroying ozone in the upper atmosphere	Harms public health and the environment by contributing to global warming

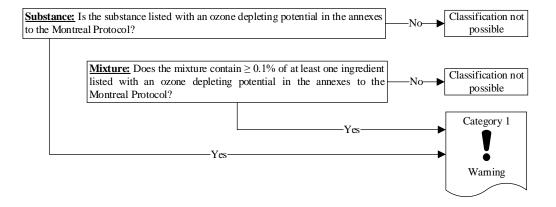
4.2.3.2 Some substances and mixtures meet the criteria for classification as hazardous to the ozone layer and hazardous by contributing to global warming. In these cases, the principles outlined in A3.1.2.5 for combining hazard statements can be used to combine the hazard statements for both hazard classes into a single hazard statement (i.e. "Harms public health and the environment by contributing to global warming and destroying ozone in the upper atmosphere.")."

#### 4.2.4 Amend to read as follows:

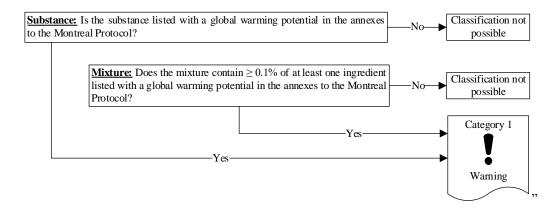
# **"4.2.4** Decision logics for substances and mixtures hazardous to the atmospheric system

The decision logics for hazardous to the ozone layer (see 4.2.2.1) and hazardous by contributing to global warming (see 4.2.2.2) which follow are not part of the harmonized classification system but are provided as additional guidance. It is strongly recommended that the person responsible for classification study the criteria before and during use of these decision logics.

Decision logic 4.2.1 for hazardous to the ozone layer



Decision logic 4.2.2 for hazardous by contributing to global warming



## Annex 1

## **Table A1.30**

Amend to read as follows:

"A1.30 Hazardous to the atmospheric system (see chapter 4.2 for classification criteria)

Classification			Labelling				GHS hazard	
GHS hazard class	GHS hazard category	UN Model Regulations class or division	GHS pictogram	UN Model Regulations pictograms	GHS signal word	GHS hazard statement	statement code	
Hazardous to the ozone layer	1				N		Harms public health and the environment by destroying ozone in the upper atmosphere	H420
Hazardous by contributing to global warming	1	Not applicable		Not applicable	Warning	Harms public health and the environment by contributing to global warming	H421	

# Annex 3, section 1

**Table A3.1.3** 

Insert the following new entry under H420:

(1)	(2)	(3)	(4)
H421	Harms public health and the environment by	Hazardous by contributing to global	1
	contributing to global warming	warming (chapter 4.2)	

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## Annex 3, section 2

#### **Table A3.2.2**

#### P260, column (4)

For "Acute toxicity, inhalation (chapter 3.1)": Insert ", 3" after "1, 2".

For "Specific target organ toxicity, single exposure (chapter 3.8)" and "Specific target organ toxicity, repeated exposure (chapter 3.9)": Delete: ", 2".

#### P261

For "Acute toxicity, inhalation (chapter 3.1)", column (4): delete "3,".

Insert the following new row below the entry for "Skin sensitization (chapter 3.4)":

(1)	(2)	(3)	(4)	(5)
		Specific target organ toxicity, single	2	
		exposure (chapter 3.8)		

Insert the following new row below the entry for "Specific target organ toxicity, single exposure, narcotic effects (chapter 3.8)":

(1)	(2)	(3)	(4)	(5)
		Specific target organ toxicity, repeated	2	
		exposure (chapter 3.9)		

In column (5), at the end of the current condition for use (applicable to all entries), replace "applicable conditions" with "applicable physical state(s)."

## P284, row "Acute toxicity, inhalation (chapter 3.1)", column (4)

Insert ", 3" after "1, 2".

### **Table A3.2.3**

#### P320

In column (2), replace "(see ... on this label)" with "(see information on this label and safety data sheet)".

Insert the following rows before the existing entry for "Acute toxicity, inhalation (chapter 3.1)":

(1)	(2)	(3)	(4)	(5)
		Acute toxicity, oral (chapter 3.1)	1, 2, 3	
		Acute toxicity, dermal (chapter 3.1)	1, 2, 3	

For "Acute toxicity, inhalation (chapter 3.1)", column (4): insert ", 3" after "1, 2".

In column (5) amend the current condition for use (applicable to all entries) to read as follows:

"- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate."

#### P321

In column (2) replace "(see ... on this label)" with "(see information on this label and safety data sheet)".

In column (4):

- For "Acute toxicity, oral (chapter 3.1)": replace "1, 2, 3" with "4".
- For "Acute toxicity, dermal (chapter 3.1)": delete "1, 2, 3".
- For "Acute toxicity, inhalation (chapter 3.1)": replace "3" with "4".

In column (5), replace all conditions for use with the following (applicable to all entries):

"- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate.

- may be omitted if P320 is given on the label."

## P322 and P323 (new)

Insert the following new precautionary statements after P321:

(1)	(2)	(3)	(4)	(5)
P322	urgent (see	Acute toxicity, oral (chapter 3.1)	1, 2, 3	Manufacturer/supplier to reference on the
	information on the safety data sheet).	Acute toxicity, dermal (chapter 3.1)	1, 2, 3	safety data sheet detailed instructions,
		Acute toxicity, inhalation (chapter 3.1)	1, 2, 3	including any training requirements, to administer an antidote or other specific treatment.  - may be omitted if P320 is given on the label.
P323	Specific treatment (see information on	Acute toxicity, oral (chapter 3.1)		Manufacturer/supplier to reference on the safety
	the safety data sheet).	Acute toxicity, dermal (chapter 3.1)	4	data sheet detailed instructions, including
		Acute toxicity, inhalation (chapter 3.1)	4	any training requirements, to administer an antidote or
		Skin corrosion (chapter 3.2)	1 1 A 1 D 1 C	other specific treatment.  - may be omitted if P321
		Skin irritation (chapter 3.2)	2	or P322 is given on the
		Skin sensitization (chapter 3.4)	1, 1A, 1B	label.
		Specific target organ toxicity, single exposure (chapter 3.8)	1	

P340, row "Acute toxicity, inhalation (chapter 3.1)", column (4)

Add ", 5" after "1, 2, 3, 4".

P352, row "Acute toxicity, dermal (chapter 3.1)", column (4)

Add ", 5" after "1, 2, 3, 4".

## P302+P317, column (2)

Replace current text with "[Deleted]" and delete the text under columns (3) and (4).

### P302+P352, row "Acute toxicity, dermal (chapter 3.1)", column (4)

Add ", 5" after "1, 2, 3, 4".

#### P304+P317, column (2)

Replace current text with "[Deleted]" and delete the text under columns (3) and (4).

### P304+P340, row "Acute toxicity, inhalation (chapter 3.1)", column (4)

Add ", 5" after "1, 2, 3, 4".

#### **Table A3.2.5**

### P501, row "Acute toxicity, inhalation (chapter 3.1)", column (4)

Add ", 4" after: "1, 2, 3".

#### P502

Insert the following new row after the existing row for "Hazardous to the ozone layer (chapter 4.2)":

(1)	(2)	(3)	(4)	(5)
		Hazardous by contributing to global warming	1	
		(chapter 4.2)		

## Annex 3, section 3

# Table for "Acute toxicity, oral (chapter 3.1)", hazard categories 1, 2, 3, column "Response"

Delete the P321 entry, and insert the following P320 and P322 entries (current entries for P301+P316 and P330 remain unchanged):

"P320

## Specific treatment is urgent (see information on this label and safety data sheet).

- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment, are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate.

### P322

#### Specific treatment is urgent (see information on the safety data sheet).

Manufacturer/supplier to reference on the safety data sheet detailed instructions, including any training requirements, to administer an antidote or provide other specific treatment.

- may be omitted if P320 is given on the label."

## Table for "Acute toxicity, oral (chapter 3.1)" hazard category 4, column "Response"

Insert the following P321 and P323 entries (current entries for P301+P317 and P330 remain unchanged):

"P321

### Specific treatment (see information on this label and safety data sheet).

- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment, are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate.
- may be omitted if P320 is given on the label.

P323

## Specific treatment (see information on the safety data sheet).

Manufacturer/supplier to reference on the safety data sheet detailed instructions, including any training requirements, to administer an antidote or other specific treatment.

- may be omitted if P321 or P322 is given on the label."

#### Tables for "Acute toxicity, dermal (chapter 3.1)" hazard categories 1, 2 and 3

Delete the current table for category 3.

In the current table for categories 1 and 2, insert a row for category 3 under the existing row for category 2 as follows:

Hazard	Symbol	_	Signal	Hazard	statement
category			word		
3	Skull and crossbones		Danger	H331	Toxic in contact with skin

Column "Response", delete the P321 entry, and insert the following P320 and P322 entries (current entries for P302+P352, P316 and P361+P364 remain unchanged):

"P320

# Specific treatment is urgent (see information on this label and safety data sheet).

- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment, are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate.

P322

## Specific treatment is urgent (see information on the safety data sheet).

Manufacturer/supplier to reference on the safety data sheet detailed instructions, including any training requirements, to administer an antidote or provide other specific treatment.

- may be omitted if P320 is given on the label."

## Table for "Acute toxicity, dermal (chapter 3.1)", hazard category 4, column "Response"

Amend P321 and insert a new entry for P323, to read as follows (current P302+P352, P317 and P362+P364 remain unchanged):

"P321

## Specific treatment (see information on this label and safety data sheet).

- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment, are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate.
- may be omitted if P320 is given on the label.

P323

#### Specific treatment (see information on the safety data sheet).

Manufacturer/supplier to reference on the safety data sheet detailed instructions, including any training requirements, to administer an antidote or other specific treatment.

- may be omitted if P321 or P322 is given on the label".

### Table for "Acute toxicity, dermal (chapter 3.1)" hazard category 5, column "Response"

Amend to read:

"P317

#### Get medical help.

P302+P352

### IF ON SKIN: Wash with plenty of water/...

...Manufacturer/supplier or the competent authority may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate.".

## Tables for "Acute toxicity, inhalation (chapter 3.1)" hazard categories 1, 2 and 3

Delete the current table for category 3.

In the current table for categories 1 and 2, insert a row for category 3 under the existing row for category 2 as follows:

Hazard category	Symbol	$\circ$	Signal word	Hazard	l statement
3	Skull and crossbones		Danger	H331	Toxic if inhaled

Column "Response", amend P320 and insert a new P322 entry as follows (current entries for P304+P340 and P316 remain unchanged):

"P320

## Specific treatment is urgent (see information on this label and safety data sheet).

- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment, are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate.

P322

#### Specific treatment is urgent (see information on the safety data sheet).

Manufacturer/supplier to reference on the safety data sheet detailed instructions, including any training requirements, to administer an antidote or other specific treatment.

- may be omitted if P320 is given on the label."

#### Table for "Acute toxicity, inhalation (chapter 3.1)" hazard category 4

Column "Prevention", for the P261 entry replace ".... to specify applicable conditions." with "... to specify applicable physical state(s)." (current entry P271 remains unchanged).

Column "Response", insert the following new P321 and P323 entries (current entries for P304+P340 and P317 remain unchanged):

"P321

### Specific treatment (see information on this label and safety data sheet).

- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment, are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate.
- may be omitted if P320 is given on the label.

P323

## Specific treatment (see information on the safety data sheet).

Manufacturer/supplier to reference on the safety data sheet detailed instructions, including any training requirements, to administer an antidote or other specific treatment.

- may be omitted if P321 or P322 is given on the label."

Column "Disposal", insert a new entry for P501, to read as follows:

"P501

#### Dispose of contents/container to...

... in accordance with local/regional/national/international regulations (to be specified).

Manufacturer/supplier or the competent authority to specify whether disposal requirements apply to contents, container or both."

# Table for "Acute toxicity, inhalation (chapter 3.1)" hazard category 5, column "Response"

Amend to read:

"P317

Get medical help.

P304+P340

IF INHALED: Remove person to fresh air and keep comfortable for breathing."

# Table for "Skin corrosion/irritation (chapter 3.2)" hazard categories 1, 1A, 1B, 1C, column "Response"

Replace P321 and insert a new P323 entry, as follows (current entries for P301+P330+P331, P302+P361+P354, P363, P304+P340, P316 and P305+P354+P338 remain unchanged):

"P321

## Specific treatment (see information on this label and safety data sheet).

- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment, are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate.
- may be omitted if P320 is given on the label.

P323

## Specific treatment (see information on the safety data sheet).

Manufacturer/supplier to reference on the safety data sheet detailed instructions, including any training requirements, to administer an antidote or other specific treatment.

- may be omitted if P321 or P322 is given on the label."

# Table for "Skin corrosion/irritation (chapter 3.2)" hazard category 2, column "Response"

Amend P321 and insert a new P323 as follows (current entries P302+P352, P332+P317 and P362+P364 remain unchanged):

"P321

#### Specific treatment (see information on this label and safety data sheet).

- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment, are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate.
- may be omitted if P320 is given on the label.

#### P323

#### Specific treatment (see information on the safety data sheet).

Manufacturer/supplier to reference on the safety data sheet detailed instructions, including any training requirements, to administer an antidote or other specific treatment.

- may be omitted if P321 or P322 is given on the label.".

### Table for "Skin sensitization (chapter 3.4)" hazard categories 1, 1A, 1B

Column "Prevention":

For the P261 entry replace ".... to specify applicable conditions." with "... to specify applicable physical state(s)." (current entries P272 and P280 remain unchanged).

## Column "Response":

Amend P321 and insert a new P323 as follows (current entries P302+P352, P333+P317 and P362+P364 remain unchanged):

"P321

#### Specific treatment (see information on this label and safety data sheet).

- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment, are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate.
- may be omitted if P320 is given on the label.

#### P323

#### Specific treatment (see information on the safety data sheet).

Manufacturer/supplier to reference on the safety data sheet detailed instructions, including any training requirements, to administer an antidote or other specific treatment.

- may be omitted if P321 or P322 is given on the label.".

# Table for "Specific target organ toxicity (single exposure) (chapter 3.8)" hazard category 1, column "Response"

Amend P321 and insert a new P323, to read as follows (current entry for P308+P316 remains unchanged):

"P321

#### Specific treatment (see information on this label and safety data sheet).

- if immediate measures that can be easily applied, such as the administration of antidote or other specific treatment, are required. These measures must be specified on the label and safety data sheet, recognizing additional detailed instructions, including any training requirements, should be provided on the safety data sheet, if appropriate.
- may be omitted if P320 is given on the label.

#### P323

#### Specific treatment (see information on the safety data sheet).

Manufacturer/supplier to reference on the safety data sheet detailed instructions, including any training requirements, to administer an antidote or other specific treatment.

- may be omitted if P321 or P322 is given on the label.".

# Table for "Specific target organ toxicity (single exposure) (chapter 3.8)" hazard category 2, column "Prevention"

Delete the P260 entry and insert a new P261 to read as follows (current entries for P264 and P270 remain unchanged):

"P261

### Avoid breathing dust/fume/gas/mist/vapours/spray.

- may be omitted if P260 is given on the label

Manufacturer/supplier or the competent authority to specify applicable physical state(s)."

# Table for "Specific target organ toxicity (single exposure) (chapter 3.8)" hazard category 3, column "Prevention"

For P261 replace ".... to specify applicable conditions." with "... to specify applicable physical state(s)." (current entry for P271 remains unchanged).

# Table for "Specific target organ toxicity (repeated exposure) (chapter 3.9)" hazard category 2, column "Prevention"

Delete the P260 entry and insert a new P261 entry to read as follows:

"P261

## Avoid breathing dust/fume/gas/mist/vapours/spray.

- may be omitted if P260 is given on the label

Manufacturer/supplier or the competent authority to specify applicable physical state(s)."

## Table for "Hazardous to the ozone layer (chapter 4.2)"

# Amend the heading to read as follows: "HAZARDOUS TO THE ATMOSPHERIC SYSTEM (CHAPTER 4.2) (Hazardous to the ozone layer)"

Insert a new matrix table for the new "Hazardous by contributing to global warming" hazard class, after the renamed matrix table for "Hazardous to the atmospheric system (chapter 4.2) (Hazardous to the ozone layer)", to read as follows:

# "HAZARDOUS TO THE ATMOSPHERIC SYSTEM (CHAPTER 4.2)

(Hazardous by contributing to global warming)

Hazard category	Symbol	Signal word	Hazard statement
1	Exclamation mark	Warning	H421 Harms public health and the
			environment by contributing to
			global warming

groom warming			groom warning
Precautionary statements			
Prevention	Response	Storage	Disposal
			P502
			Refer to manufacturer or supplier for
			information on recovery or recycling.

# Annex 7

Amend the introductory sentence to read as follows:

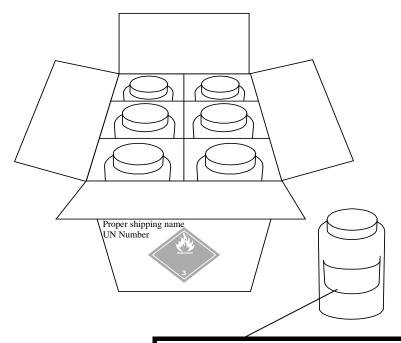
"The following examples are provided for illustrative purposes by arranging the GHS label elements in accordance with sections 1.4.10.4 and 1.4.10.5 and are subject to further discussion and consideration by the GHS Sub-Committee.

## Example 1

Replace with the following:

"Example 1: Combination packaging for a chemical with the classification: Flammable liquids, Category 2

Outer packaging: Box with a Class 3 flammable liquids transport label\* Inner packaging: Plastic bottle with GHS label



Product identifier (see 1.4.10.5.2 (d))



SIGNAL WORD (see 1.4.10.5.2 (a))

Hazard statements (see 1.4.10.5.2 (b))

Precautionary statements (see 1.4.10.5.2 (c)) and annex 3 sections 2 and 3)

Supplemental information as allowed or required by the competent authority as appropriate (see 1.4.10.5.4.2).

Supplier identification (see 1.4.10.5.2 (e))

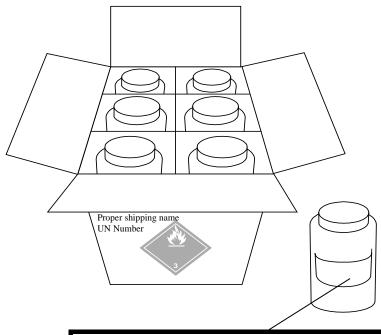
<sup>\*</sup> Only the transport markings and labels as specified in the UN Model Regulations are required for outer packagings.".

Replace with the following:

"Example 2: Combination packaging for a chemical with the classification: Flammable liquids, Category 2 and specific target organ toxicity – single exposure, Category  $\bf 1$ 

Outer packaging: Box with a Class 3 flammable liquids transport label\*

Inner packaging: Plastic bottle with GHS label



Product identifier (see 1.4.10.5.2 (d))



SIGNAL WORD (see 1.4.10.5.2 (a))

Hazard statements (see 1.4.10.5.2 (b))

Precautionary statements (see 1.4.10.5.2 (c)) and annex 3 sections 2 and 3)

Supplemental information as allowed or required by the competent authority as appropriate (see 1.4.10.5.4.2).

Supplier identification (see 1.4.10.5.2 (e))

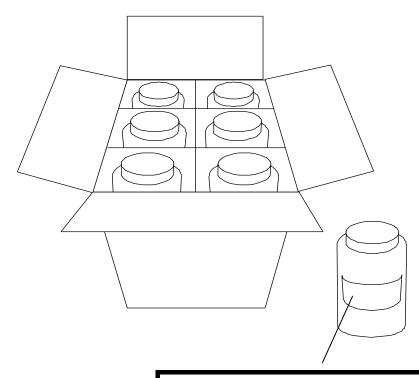
<sup>\*</sup> Only the transport markings and labels as specified in the UN Model Regulations are required for outer packagings.".

Replace with the following:

"Example 3: Combination packaging for a chemical with the classification: skin corrosion/irritation, Category 2 and serious eye damage/eye irritation, Category 2A

Outer packaging: Box with no transport label (not required) \*

Inner packaging: Plastic bottle with GHS label



Product identifier (see 1.4.10.5.2 (d))



**SIGNAL WORD (see 1.4.10.5.2 (a))** 

Hazard statements (see 1.4.10.5.2 (b))

Precautionary statements (see 1.4.10.5.2 (c)) and annex 3 sections 2 and 3)

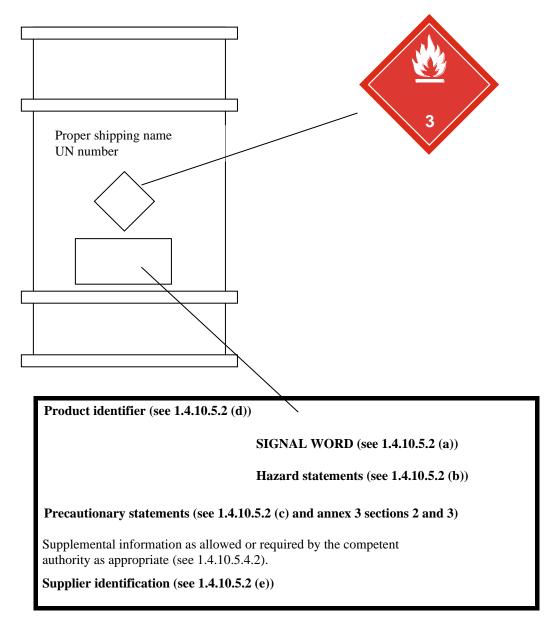
Supplemental information as allowed or required by the competent authority as appropriate (see 1.4.10.5.4.2).

Supplier identification (see 1.4.10.5.2 (e))

<sup>\*</sup> Some competent authorities may require a GHS label on the outer packaging.".

Replace with the following:

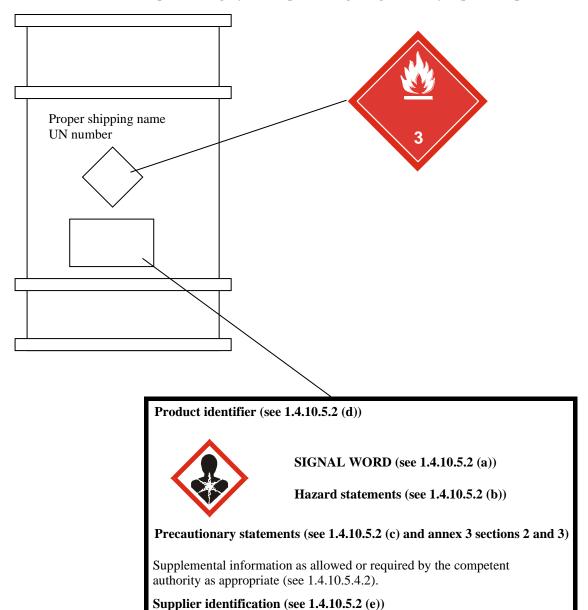
"Example 4: Single packaging (for example a 200 l drum) for a chemical with the classification flammable liquids, Category 2



**Note:** The GHS label and the Class 3 flammable liquid pictogram (commonly referred to as label in transport regulations, see 1.4.10.4) as well as any other markings required by the UN Model Regulations may also be presented in a combined format (see also example 7).".

Replace with the following:

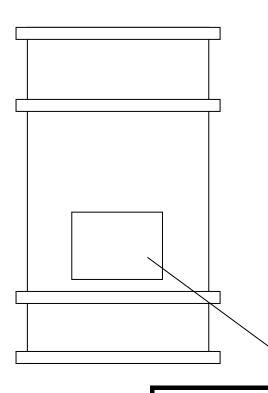
"Example 5: Single packaging (for example a 200 *l* drum) for a chemical with the classification: Flammable liquids, Category 2 and specific target organ toxicity-repeated exposure, Category 1



**Note:** The GHS label and the Class 3 flammable liquid pictogram (commonly referred to as label in transport regulations, see 1.4.10.4) as well as any other markings required by the UN Model Regulations may also be presented in a combined format (see also example 7).".

Replace with the following:

"Example 6: Single packaging (for example, a 200 *l* drum) for a chemical with the classification: Skin corrosion/irritation, Category 2 and serious eye damage/eye irritation, Category 2A"



Product identifier (see 1.4.10.5.2 (d))



**SIGNAL WORD** (see 1.4.10.5.2 (a))

Hazard statements (see 1.4.10.5.2 (b))

Precautionary statements (see 1.4.10.5.2 (c) and annex 3 sections 2 and 3)

Supplemental information as allowed or required by the competent authority as appropriate (see 1.4.10.5.4.2).

Supplier identification (see 1.4.10.5.2 (e))

. .

Replace with the following:

## "Example 7: Additional guidance when transport and other GHS information appear on single packagings

- (a) Where transport and other GHS information appear on a single packaging, consideration must be given to ensure that the label elements are placed in a manner that addresses the needs of the different sectors. The GHS pictogram does not appear on the GHS label when a transport label for the same hazard is already used (see 1.4.10.5.1);
- (b) Transport labels must convey information immediately in an emergency situation. They must be able to be seen from a distance, as well as in conditions that are smoky or otherwise partially obscure the package;
- (c) Transport labels are distinct in appearance from pictograms intended solely for non-transport purposes which helps to distinguish them;
- (d) Transport labels may be placed on a separate panel of a GHS label to distinguish them from the other information or may be placed adjacent to the other GHS information on the packaging; and
- (e) The pictograms may be distinguished by adjusting their size. Generally speaking, the size of the non-transport pictograms should be proportional to the size of the text of the other label elements. This would generally be smaller than the transport labels (the size of which is intentionally regulated), but such size adjustments should not affect the clarity or comprehensibility of the non-transport pictograms.

Following is an example of how such a label may appear for a chemical in a 200 *l* drum for transport and use in the workplace.

This example is not intended to cover all specific requirements which may have been included in national legislation implementing the GHS nor all possible supplemental information which may be voluntarily included (e.g. "Directions of use" or "Filling weight") or which may be required by some competent authorities. It takes account of the required basic GHS label information as described in section 1.4.10.

Single packaging using 3 adjacent panels to convey multiple hazards: A mixture with the classification: Flammable liquids Category 2; Acute toxicity (inhalation) Category 4, and Specific target organ toxicity - repeated exposure, Category 2

PRODUCT identifier (see 1.4.10.5.2 (d))

Supplier identification ((see 1.4.10.5.2 (e))





Danger

Highly flammable liquid and vapour.

Harmful if inhaled.

May cause liver and kidney damage through prolonged or repeated exposure.

Keep container tightly closed.

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Store in a well- ventilated place. Keep cool.

Ground and bond container and receiving equipment.

Use explosion-proof ventilating equipment.

Use non-sparking tools.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse affected

areas with water or shower.

In case of fire: Use dry chemical or carbon dioxide to extinguish.

Take action to prevent static discharges.

Use only outdoors or in a well-ventilated area.

Do not breathe mist, vapours or spray.

Wear protective gloves, protective clothing, eye protection and face protection.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Get medical help.

Dispose of contents/container to the municipal collection point in accordance to

local/national regulations.



UN Number Proper shipping name

Expiration date:

## Annex 11

Insert the following new section A11.3 after A11.2.8.2:

## "A11.3 Simple asphyxiants

This section provides information to facilitate the identification of simple asphyxiant hazards.

### A11.3.1 Scope and applicability

- A11.3.1.1 An asphyxiant is a vapour or gas that can cause unconsciousness and death by suffocation due to lack of oxygen. Asphyxiants can be either chemical asphyxiants or simple asphyxiants. Simple asphyxiants are gases or vapours which are harmful to the body when they become so concentrated that they reduce oxygen in the air (normally about 21 percent) to dangerous levels. When the concentration of a particular gas increases, the fraction of inspired oxygen decreases, causing decreased oxygen in the blood. Thus, the severity and timing of effects are dependent on the fraction of inspired oxygen in the atmosphere. For example, inhaling an atmosphere containing no oxygen causes loss of consciousness in a matter of seconds because such an atmosphere not only fails to provide fresh oxygen, but also removes that already present in the bloodstream. There will be little sense of breathlessness to warn the victim that something is amiss, and they will rapidly lose consciousness. The heart will continue to function for a short time, but will then arrest, causing circulatory failure leading to death.
- A11.3.1.2 Asphyxiation is a well-known hazard in the workplace. Simple asphyxiants frequently contribute to industrial accidents involving loss of life and are of particular concern for those who work in confined spaces.
- A11.3.1.3 Competent authorities and trade associations use various approaches including implementing regulations, reference standards and guidance on safe practices for working in environments where oxygen levels can be reduced. They may also establish a minimum safe level of oxygen. Section A11.3.5 contains examples of regulations, reference standards and guidance documents.
- A11.3.1.4 Chemical asphyxiants cause suffocation by either preventing the uptake of oxygen in the blood or by preventing the normal oxygen transfer from the blood to the tissues or within the cell itself. The specific toxic health effects associated with chemical asphyxiants are covered by acute toxicity (chapter 3.1), specific target organ toxicity- single exposure (chapter 3.8) and specific target organ toxicity repeated exposure (chapter 3.9).

### A11.3.2 Definition

Simple asphyxiant refers to gases or vapours that displace oxygen and can thus cause oxygen deprivation in those who are exposed, which may lead to unconsciousness and death, after exposure to a substance or mixture.

### A11.3.3 Identification of simple asphyxiants

Simple asphyxiants are of particular concern in enclosed spaces. Some examples of well-known simple asphyxiants from experience include: carbon dioxide, hydrogen, nitrogen, helium, neon, argon, krypton, xenon, ethane, ethylene, acetylene, methane, propane, propylene, aliphatic alkanes and the chlorofluorocarbons. Evaluation of other gases and vapours (e.g., some solvents) as simple asphyxiants requires expert judgment to evaluate evidence such as human experience, information from similar substances, and other pertinent data. In cases where a substance or mixture is already classified for acute toxicity via inhalation, then identification as a simple asphyxiant is not warranted.

#### A11.3.4 Supplemental information for hazard communication

- A11.3.4.1 As explained in 1.4.6.3, there are many communication elements which have not been standardized in the harmonized system. Some of these clearly need to be communicated to the downstream user. For substances and mixtures that are simple asphyxiants, information should be provided in section 2 of the safety data sheet (A4.3.2) that addresses hazards that do not result in classification.
- A11.3.4.2 To communicate the simple asphyxiant hazard, competent authorities may require the use of the following phrases on labels, safety data sheets and/or operating instructions or may leave the choice to the manufacturer or supplier.
  - (a) "May displace oxygen and be fatal".
  - (b) In addition, "Danger" and/or "Store in well-ventilated place" may also be used.

## A11.3.5 References

- A11.3.5.1 Examples of regulations, reference standards, and guidance documents on safe practices for working in environments where oxygen levels can be reduced are provided below:
  - (a) U.S. OSHA Respiratory Protection Standard (29 CFR 1910.134);
  - (b) U.S. OSHA Permit Required Confined Spaces (29 CFR 19010.146);
  - (c) U.K. HSE Control of Substances Hazardous to Health (COSHH) Regulations 2002 (as amended). Approved Code of Practice L5 (Sixth edition, 2013) ISBN: 9780717665822;
  - (d) U.K. HSE Confined Spaces Regulation 1997. Approved Code of Practice, Regulations and guidance L101 (Third edition, 2014) ISBN: 978 0 7176 6622 5;
  - (e) German Technical Rules for Hazardous Substances, TRGS 528 Welding Work, GMBI 2020 p. 463 [No. 23] (7 August 2020);
  - (f) U.K. HSE EH40/2005 Workplace exposure limits (fourth edition 2020) ISBN: 9780717667031 EH40/2005;
  - (g) German Working in oxygen reduced atmosphere (DGUV Information 205-006);
  - (h) U.K. HSE Confined spaces: A brief guide to working safely INDG258 (revision 1, 2013) ISBN: 9780717664894 Confined spaces: A brief guide to working safely INDG258;
  - (i) U.K. HSE Guidance on permit-to-work systems A guide for the petroleum, chemical and allied industries HSG 250 (first edition, 2005) ISBN: 978 0 7176 2943 5;
  - (j) Hazards of Oxygen-Deficient Atmospheres, U.S. Compressed Gas Association P-76 (2018);
  - (k) Hazards of Oxygen-Deficient Atmospheres, European Industrial Gas Association Document 44 (2018); and
  - (l) Hazards of Oxygen-Deficient Atmospheres, Asian Industrial Gas Association 008/18".