



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

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Work on the Globally Harmonized System of Classification and Labelling of Chemicals: Improvement of annexes 1 to 3 and further rationalization of precautionary statements

Proposed amendments to precautionary statements in Annex 3 due to the respiratory sensitization hazard class

Transmitted by the expert from the United Kingdom on behalf of the informal working group on improving annexes 1, 2 and 3 of the GHS*

1. In line with its mandate for the 2021-2022 biennium the informal working group has taken forward work under its focus area (a): “to develop proposals to rationalise and improve the comprehensibility of hazard and precautionary statements for users, while taking into account usability for labelling practitioners.”
2. This document, together with informal document INF.4, presents the outcome of work under item 3 in the group’s workplan for the 2021-2022 biennium¹ where the issue was to review the precautionary statements in the tables of Annex 3 in relation to respiratory sensitization categories 1, 1A, 1B to identify where potential improvements could be made.

Discussion

3. Respiratory sensitisation may result from exposure via either the dermal or inhalation exposure route. However, for many chemicals it is not always known that it has occurred specifically via the dermal exposure route whereas for other chemicals, such as beryllium, there is a known link to respiratory sensitisation via dermal exposure.
4. Currently, the following precautionary statements are applied to the respiratory sensitization hazard class:
 - (a) P261 “**Avoid breathing dust/fume/gas/mist/vapours/spray.**”
 - (b) P284 “[**In case of inadequate ventilation**] **wear respiratory protection.**”

* A/75/6 (Sect.20), para. 20.51.

¹ See informal document INF.21, thirty-ninth session.

- (c) P304 **“IF INHALED:”**
- (d) P316 **“Get emergency medical help immediately.”**
- (e) P340 **“Remove person to fresh air and keep comfortable for breathing.”**
- (f) P342 **“If experiencing respiratory symptoms:”**
- (g) P501 **“Dispose of contents/container to ...”**
- (h) P304 + P340 **“IF INHALED: Remove person to fresh air and keep comfortable for breathing”**
- (i) P342 + P316 **“If experiencing respiratory symptoms: Get emergency medical help immediately.”**

5. Since there are no response precautionary statements that provide information on what specific immediate treatment should be provided to alleviate symptoms following exposure to a respiratory sensitizer, initially the group considered whether the application of the following response precautionary statements could potentially provide such information for this hazard class:

- (a) P320 **“Specific treatment is urgent (see ... on this label).”** which is accompanied by conditions for use that refers to administration of an antidote.
- (b) P321 **“Specific treatment (see ... on this label).”** which is accompanied by various conditions for use that refer to the administration of an antidote; specific measures; or use of a cleansing agent, depending on the specific hazard class.

6. However, following extensive considerations, the group concluded that it would not be appropriate to apply either P320 or P321 for respiratory sensitizers for reasons detailed in paragraphs 15 to 32 of informal document INF.19 from the forty-first session which include:

- (a) sensitized person issues;
- (b) availability of in-date medical treatment (e.g., epi-pens, inhalers) on site and trained persons to administer the treatment;
- (c) First aid and legal considerations;
- (d) Target audience and reference to specific treatment on the label;
- (e) Reference to the use of an antidote in the conditions for use is not considered appropriate; and
- (f) Order of action/treatment following exposure to respiratory sensitizers via inhalation would be to immediately remove the exposed person to fresh/clean air and then if they are experiencing any respiratory symptoms to get emergency medical help immediately, and this order of actions are already expressed in the combination statements: P304+P340 and P342+P316.

7. The group considered that it was fundamentally important to prevent exposure to respiratory sensitizers and reviewed relevant preventative and storage precautionary statements that could be utilized for this hazard class, whilst also cognisant of the potential number of additional statements that may be applied, particularly for those jurisdictions that require all precautionary statements for a hazard class to be applied.

8. The review concluded that respiratory sensitizers should be listed beneath a number of additional precautionary statements (P233; P260; P271; and P280); removed from beneath one precautionary statement (P261); and that amendments should be made to the text of two statements (P271 and P284) and several conditions of use for some precautionary statements (P260; P271 and P284), as follows:

- (a) **P233 “Keep container tightly closed.”**
- (i) Although this precautionary statement is more relevant to the inhalation route rather than the dermal route of exposure, it is important to note that the exact route of exposure from respiratory sensitizers is often not known.
 - (ii) In addition, even though the conditions of use for the current health hazard classes listed under P233 (Acute toxicity, inhalation (1-3); Specific target organ toxicity, single exposure respiratory tract irritation (3); and Specific target organ toxicity, single exposure narcotic effects (3)), indicates that P233 is applied only if the chemical is volatile and may generate a hazardous atmosphere, the group considered that similar conditions for use were not necessary for respiratory sensitizers.
 - (iii) This means that P233 would apply to all respiratory sensitizers not just those that are volatile, which would need to be determined through additional testing if it was not already known.
 - (iv) Consequently, to help prevent exposure to respiratory sensitizers, particularly via the inhalation exposure route, the group propose to place this hazard class under P233 without any conditions for use, as detailed in paragraph 12 below.
- (b) **P260 “Do not breathe dust/fume/gas/mist/vapours/spray.” versus P261 “Avoid breathing dust/fume/gas/mist/vapours/spray.”**
- (i) Given that a primary aim is to prevent the inhalation of respiratory sensitizers, the group considered that the words “**Do not breathe...**” in **P260** would provide a stronger message compared to the words “**Avoid breathing..**” in **P261** and as a consequence propose that respiratory sensitization hazard class should be deleted from beneath P261 and instead be placed beneath P260, as proposed in paragraphs 13 and 14 below.
 - (ii) In addition, the group considered that it would be appropriate to apply the same conditions of use for the new respiratory sensitization entry to that which is applied to several other health hazard classes listed under P260 for: Acute toxicity, inhalation (1-2); Specific target organ toxicity, single exposure (1-2); and Specific target organ toxicity, repeated exposure (1-2) which currently reads:
“...Manufacturer/supplier or the competent authority to specify applicable conditions.”
 - (iii) However, upon reflection the group considered that current conditions for use entry for these health hazard classes should be amended to replace the word: “**conditions**” with: “**physical state(s)**” on the grounds that the words “dust/fume/gas/vapour/spray” in the precautionary statement are more accurately described as physical states rather than conditions.
 - (iv) Hence the group propose to amend the conditions for use for all health hazard classes listed in paragraph (ii) above for P260, and for the proposed new entry for respiratory sensitizers, as detailed in paragraph 13 below.
- (c) **P271 “Use only outdoors or in a well-ventilated area.”**
- (i) To help prevent exposure to respiratory sensitizers via the inhalation route, the group considered that it would be appropriate to place this hazard class under P271.

- (ii) Working group members had different interpretations of what was meant by “**a well-ventilated area.**” Some members interpreted “a well-ventilated area” as simply having a window and/or door open, while other members interpreted it as using fans to extract or circulate the air. It was also noted that P284 refers to “inadequate ventilation.”. The group therefore agreed that the precautionary statement should be revised to make clearer what type of ventilation was adequate.
 - (iii) To provide the necessary clarity, the group propose to replace the words “**in a well-ventilated areas**” in P271 with the words “**with adequate ventilation**” which would also provide greater consistency with the text used in P284 which would be particularly beneficial where both P271 and P284 were used on the same product label.
 - (iv) Hence, the proposed amended P271 would read: “**Use only outdoors or with adequate ventilation**” which would apply to the proposed new entry for respiratory sensitizers and all current health hazards listed under P271 (Acute toxicity, inhalation (1-4); Specific target organ toxicity, single exposure respiratory tract irritation (3); and Specific target organ toxicity, single exposure narcotic effects (3)), as detailed in paragraph 15 below.
 - (v) In addition, the group considered that further explanation should be provided in the conditions for use for all the health hazard classes listed under P271 to ensure that the type of ventilation that is considered adequate is provided in the safety instructions that are provided to users, as proposed in paragraph 15 below.
- (d) **P280 “Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...”**
- (i) In terms of reducing potential dermal exposure from respiratory sensitiser chemicals, the group considered that the use of protective gloves was the most important preventative action that a user could take to help prevent dermal exposure.
 - (ii) Hence, the group propose to place the respiratory sensitization hazard class under P280, with the same conditions of use that are used for acute toxicity dermal (1-4) which is already listed under P280, as proposed in paragraph 16 below.
- (e) **P284 “[In case of inadequate ventilation] wear respiratory protection.”**
- (i) P284 is currently applied to respiratory sensitization and acute toxicity, inhalation (1-2) hazard classes with the following conditions for use:

“– text in square brackets may be used if additional information is provided with the chemical at the point of use that explains what type of ventilation would be adequate for safe use.

Manufacturer/supplier or the competent authority to specify equipment.”
 - (ii) However, the group considered that both the text of the precautionary statement and the conditions of use required amendment to provide clarity because:
 - a. The operative word: “may” in the current conditions for use implies that provision of information on adequate ventilation is optional;
 - b. If no information is provided on what is deemed adequate ventilation, or the ventilation type available on-site is different or inadequate according to the information provided by the manufacturer/supplier, then by default the user is directed to “Wear respiratory protection” whilst they are using the product, which is contrary to the hierarchy of controls;

- c. The manufacturer/supplier should always know what type of ventilation and/or respiratory equipment should be used with their products to ensure safe use and hence they should always be able to convey such information, though currently there is no requirement for them to do so;
 - d. It should not be up to the user to decide what type of ventilation and/or respiratory equipment should be used for safe use. If the user is not provided with this information, there is a danger that users may implement inadequate ventilation and/or respiratory protective equipment;
 - e. If, in accordance with the safety information provided, the ventilation type is considered adequate, then respiratory protective equipment does not need to be worn. However, the manufacturer/supplier must specify if both ventilation and respiratory protection are needed
- (iii) As a consequence, to help remove the current ambiguity and ensure that information is always provided on the type of ventilation that is adequate and respiratory protective equipment may be required for safe use, the group propose to amend the text of P284, and its conditions for use, as detailed in paragraph 17 below. These proposed changes would also be more consistent with the control measure hierarchy for using hazardous chemicals such as respiratory sensitizers.
- (f) **P403 “Store in a well-ventilated place.”**

Similar to P233 above, although this precautionary statement is more relevant to the inhalation route rather than the dermal route of exposure, since the exact route of exposure is not always known the group considered it would be good practice to place all respiratory sensitizers, regardless of volatility, under P403, without any conditions of use, as proposed in paragraph 18 below.

9. In addition, the group considered two further prevention precautionary statements P262 (“**Do not get in eyes, on skin, or on clothing.**”) and P264 (“**Wash hands [and ...] thoroughly after handling.**”) to help prevent dermal exposure to respiratory sensitizers. However, the group could not reach a consensus on whether or not to apply these precautionary statements to respiratory sensitizers. The group considered the number of new statements that the group are proposing to be added under this hazard class, including P280 (“**Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...**”) which was considered would provide a stronger message on protection from dermal exposure than would be achieved through P262 and/or P264. The last consideration was that in some jurisdictions there is a requirement to place all precautionary statements onto the label. Given all the considerations, the group agreed not to take forward P262 and/or P264 into the formal proposals in this document.

10. Further, due to the proposed amendments to P284, and its conditions for use, the group identified that a consequential amendment would be required to paragraph A3.2.4.4 regarding the application of square brackets [...] around text of a precautionary statement and propose to replace the existing example given on P284 with an alternative example for P264 “**Wash hands [and ...] thoroughly after handling.**”, as proposed in paragraph 11 below.

Proposed amendments to Section 2:

11. In A3.2.4.4, replace with:

“A3.2.4.4 Where square brackets [...] appear around some text in a precautionary statement, this indicates that the text in square brackets is not appropriate in every case and should be used only in certain circumstances. In these cases, conditions for use explaining when the text should be used are given in column (5) of the tables. For example, P264 states: **“Wash hands [and ...] thoroughly after handling.”**. This statement is given with the condition for use: *“- text in square brackets to be used when the manufacturer/supplier or the competent authority specify other parts of the body to be washed after handling.”*. The application of the condition for use should be interpreted as follows: If additional information is provided with the chemical explaining what other part(s) of the body is to be washed following handling, then the text in brackets is to be used followed by the name of the relevant body part(s). However, if other part(s) of the body do not need to be specified, the text in square brackets should not be used, and the precautionary statement should read: **“Wash hands thoroughly after handling.”**”

12. In Table A.3.2.2, Section 2, for the P233 entry:

Under column 3 “Hazard class (3)”, after line 5 for “Acute toxicity, inhalation (chapter 3.1)” insert a new line 6: “Respiratory sensitization (chapter 3.4)”.

Under column 4 “Hazard category (4)”, after line 5 for “Acute toxicity, inhalation (chapter 3.1)”, in the new line 6 for “Respiratory sensitization (chapter 3.4)”, insert: “1, 1A, 1B”.

Under column 5 “Conditions for use (5)”, for all the listed health hazard classes and categories²:

- Delete: **“– if the chemical is volatile and may generate a hazardous atmosphere.”**.
- Split the merged conditions of use entries for all the listed health hazard classes and categories, and the new Respiratory sensitization (categories 1, 1A, 1B) entry into four rows.

Under column 5 “Conditions for use (5)”, for Acute Toxicity, inhalation (categories 1, 2, 3):

- Insert: **“– if the chemical is volatile and may generate a hazardous atmosphere.”**.

Under column 5 “Conditions for use (5)”, for Specific target organ toxicity, single exposure respiratory tract irritation (category 3); and Specific target organ toxicity, single exposure narcotic effects (category 3):

- Insert a merged conditions of use entry: **“– if the chemical is volatile and may generate a hazardous atmosphere.”**.

13. In Table A.3.2.2, Section 2, for the P260 entry:

Under column 3 “Hazard class (3)”, after line 1 for “Acute toxicity, inhalation (chapter 3.1)” insert a new line 2: “Respiratory sensitization (chapter 3.4)”:

Under column 4 “Hazard category (4)”, after line 1 for “Acute Toxicity, inhalation (chapter 3.1)”, in the new line 2 for “Respiratory sensitization (chapter 3.4)”, insert: “1, 1A, 1B”.

Under column 5 “Conditions for use (5)”, for Acute Toxicity, inhalation (categories 1, 2); Specific target organ toxicity, single exposure (categories 1, 2); Specific target

² Acute Toxicity, inhalation (categories 1, 2, 3); Specific target organ toxicity, single exposure respiratory tract irritation (category 3); and Specific target organ toxicity, single exposure narcotic effects (category 3)

organ toxicity, repeated exposure (categories 1, 2); and the new Respiratory sensitization (categories 1, 1A, 1B) entries:

- Delete: **“Manufacturer/supplier or the competent authority to specify applicable conditions.”**
- Insert: **“Manufacturer/supplier or the competent authority to specify applicable physical state(s).”**

14. In Table A.3.2.2, Section 2, for the P261 entry:

Under column 3 “Hazard class (3)”, line 2, delete the entry: “Respiratory sensitization (chapter 3.4)”.

Under column 4 “Hazard category (4)”, line 2, delete the entry: “1, 1A, 1B”.

15. In Table A.3.2.2, Section 2, for the P271 entry:

Under column 2 “Prevention precautionary statement (2)”:

- Delete: **“Use only outdoors or in a well-ventilated area.”**
- Insert: **“Use only outdoors or with adequate ventilation.”**

Under column 3 “Hazard class (3)”, after line 1 for “Acute toxicity, inhalation (chapter 3.1)” insert a new line 2: “Respiratory sensitization (chapter 3.4)”.

Under column 4 “Hazard category (4)”, after line 1 for “Acute toxicity, inhalation (chapter 3.1)”, in the new line 2 for “Respiratory sensitization (chapter 3.4)”, insert: “1, 1A, 1B”.

Under column 5 “Conditions for use (5)”, for Acute toxicity, inhalation (categories 1, 2, 3, 4); Specific target organ toxicity, single exposure respiratory tract irritation (category 3); Specific target organ toxicity, single exposure narcotic effects (category 3); and the new Respiratory sensitization (categories 1, 1A, 1B) entries:

- Insert: **“Manufacturer/supplier to specify what type of ventilation would be adequate for safe use on the safety data sheet and in any supplemental safety instructions provided to consumers.”**

16. In Table A.3.2.2, Section 2, for the P280 entry:

Under column 3 “Hazard class (3)”: after line 19 for “Eye irritation (chapter 3.3)” insert a new line 20: “Respiratory sensitization (chapter 3.4)”:

Under column 4 “Hazard category (4)”, after line 19 for “Eye irritation (chapter 3.3)”, in the new line 20 for “Respiratory sensitization (chapter 3.4)”, insert: “1, 1A, 1B”.

Under column 5 “Conditions for use (5)” after line 19 for Eye irritation (categories 2/2A), in the new line 20 for Respiratory sensitization (categories 1, 1A, 1B):

- Insert: **“– *Specify protective gloves/clothing.* Manufacturer/supplier or the competent authority may further specify type of equipment where appropriate”**

17. In Table A.3.2.2, Section 2, for the P284 entry:

Under column 2 “Prevention precautionary statement (2)”:

- Delete: **“[In case of inadequate ventilation] wear respiratory protection.”**
- Insert: **“In case of inadequate ventilation wear respiratory protection.”**

Under column 5 “Conditions for use (5)”, for Acute Toxicity, inhalation (categories 1, 2, 3, 4) and Respiratory sensitization (categories 1, 1A, 1B) entries:

- Delete: **“– *text in square brackets may be used if additional information is provided with the chemical at the point of use that explains what type of ventilation would be adequate for safe use.* Manufacturer/supplier or the competent authority to specify equipment.”**

- Insert: **“Manufacturer/supplier to specify on the safety data sheet what type of ventilation would be adequate for safe use and provide additional information with the chemical at the point of use that explains what type of respiratory equipment may also be needed.”**

18. In Table A.3.2.4, Section 2, for the P403 entry:

Under column 3 “Hazard class (3)”, after line 8 for “Acute toxicity, inhalation (chapter 3.1)” insert a new line 9: “Respiratory sensitization (chapter 3.4)”.

Under column 4 “Hazard category (4)”, after line 8 for “Acute toxicity, inhalation (chapter 3.1)”, in the new line 9 for “Respiratory sensitization (chapter 3.4)”, insert: “1, 1A, 1B”.

Under column 5 “Conditions for use (5)”, for all the listed health hazard classes and categories³:

- Delete: **“– if the chemical is volatile and may generate a hazardous atmosphere.”**.
- Split the merged conditions of use entries for all the listed health hazard classes and categories, and the new Respiratory sensitization (categories 1, 1A, 1B) entry into four rows.

Under column 5 “Conditions for use (5)”, for Acute toxicity, inhalation (categories 1, 2, 3):

- Insert: **“– if the chemical is volatile and may generate a hazardous atmosphere.”**.

Under column 5 “Conditions for use (5)”, for Specific target organ toxicity, single exposure respiratory tract irritation (category 3); and Specific target organ toxicity, single exposure narcotic effects (category 3):

- Insert a merged conditions of use entry: **“– if the chemical is volatile and may generate a hazardous atmosphere.”**.

Proposed amendments to the matrix tables in Section 3:

19. In Annex 3, Section 3, matrix table for “Acute toxicity, inhalation (chapter 3.1)”, hazard categories 1, 2, column “Prevention”, replace the entire column entry with:

“P260

Do not breathe dust/fume/gas/mist/ vapours/spray.

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

P271

Use only outdoors or with adequate ventilation.

Manufacturer/supplier to specify what type of ventilation would be adequate for safe use on the safety data sheet and in any supplemental safety instructions provided to consumers.

P284

In case of inadequate ventilation wear respiratory protection

Manufacturer/supplier to specify on the safety data sheet what type of ventilation would be adequate for safe use and provide additional information with the chemical at the point of use that explains what type of respiratory equipment may also be needed.”

³ Acute toxicity, inhalation (categories 1, 2, 3); Specific target organ toxicity, single exposure respiratory tract irritation (category 3); and Specific target organ toxicity, single exposure narcotic effects (category 3)

20. In Annex 3, Section 3, matrix table for “Acute toxicity, inhalation (chapter 3.1)”, hazard category 3, column “Prevention”, replace the P271 entry with:

“P271

Use only outdoors or with adequate ventilation.

Manufacturer/supplier to specify what type of ventilation would be adequate for safe use on the safety data sheet and in any supplemental safety instructions provided to consumers.”

21. In Annex 3, Section 3, matrix table for “Acute toxicity, inhalation (chapter 3.1)”, hazard category 4, column “Prevention”, replace the P271 entry with:

“P271

Use only outdoors or with adequate ventilation.

Manufacturer/supplier to specify what type of ventilation would be adequate for safe use on the safety data sheet and in any supplemental safety instructions provided to consumers.”

22. In Annex 3, Section 3, matrix table for “Sensitization - Respiratory (chapter 3.4)”, hazard category 1, 1A, 1B, column “Prevention”, replace the entire column entry with:

“P233

Keep container tightly closed.

P260

Do not breathe dust/fume/gas/mist/ vapours/spray.

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

P271

Use only outdoors or with adequate ventilation.

Manufacturer/supplier to specify what type of ventilation would be adequate for safe use on the safety data sheet and in any supplemental safety instructions provided to consumers.

P280

Wear protective gloves/protective clothing.

Manufacturer/supplier or the competent authority may further specify type of equipment where appropriate.

P284

In case of inadequate ventilation wear respiratory protection.

Manufacturer/supplier to specify on the safety data sheet what type of ventilation would be adequate for safe use and provide additional information with the chemical at the point of use that explains what type of respiratory equipment may also be needed.”

23. In Annex 3, Section 3, matrix table for “Sensitization - Respiratory (chapter 3.4)”, hazard category 1, 1A, 1B, column “Storage” insert:

“P403

Store in a well-ventilated place.”

24. In Annex 3, Section 3, matrix table for “Specific target organ toxicity (single exposure) (chapter 3.8)”, hazard category 1, column “Prevention”, replace the P260 entry with:

“P260

Do not breathe dust/fume/gas/mist/ vapours/spray.

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

25. In Annex 3, Section 3, matrix table for “Specific target organ toxicity (single exposure) (chapter 3.8)”, hazard category 2, column “Prevention”, replace the P260 entry with:

“P260

Do not breathe dust/fume/gas/mist/ vapours/spray.

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

26. In Annex 3, Section 3, matrix table for “Specific target organ toxicity (single exposure) (chapter 3.8)”, hazard category 3, column “Prevention”, replace the P271 entry with:

“P271

Use only outdoors or with adequate ventilation.

Manufacturer/supplier to specify what type of ventilation would be adequate for safe use on the safety data sheet and in any supplemental safety instructions provided to consumers.”

27. In Annex 3, Section 3, matrix table for “Specific target organ toxicity (repeated exposure) (chapter 3.9)”, hazard category 1, column “Prevention”, replace the P260 entry with:

“P260

Do not breathe dust/fume/gas/mist/ vapours/spray.

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

28. In Annex 3, Section 3, matrix table for “Specific target organ toxicity (repeated exposure) (chapter 3.9)”, hazard category 2, column “Prevention”, replace the P260 entry with:

“P260

Do not breathe dust/fume/gas/mist/ vapours/spray.

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

Action requested

29. The Sub-Committee is invited to agree the proposed amendments to sections 2 and 3 of Annex 3 of the GHS as set out in this document in the following paragraphs and shown in full in informal document INF.4:

- Section 2 proposed amendments are provided in paragraphs 11 to 18.
- Section 3 proposed amendments are provided in paragraphs 19 to 28.
