

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

2 July 2021

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Item 2 (c) of the provisional agenda

**Classification criteria and related hazard communication:
use of non-animal testing methods for classification of health hazards**

Amendments to section 3.2.2.3 in ST/SG/AC.10/2021/5

**Transmitted by the experts from the United Kingdom and the Netherlands
on behalf of the informal working group**

Introduction

1. This informal document proposes a revised section 3.2.2.3 following the outcome of the discussions of the informal working group on the proposed revision of Chapter 3.3¹ which is also being presented at the fortieth session. The revised section 3.2.2.3 is reproduced in paragraph 6 of this document and takes account of the amendments proposed in ST/SG/AC.10/C.4/2021/5 and INF.4 for section 3.2.2.3.

Background

2. As planned, the informal working group held a meeting on 1 July 2021 after the formal proposals to revise Chapter 3.3¹ and the consequential amendments to Chapter 1.2 and 3.2² had been submitted for discussion at the fortieth session. A key purpose of the meeting was to undertake a final review of the submitted documents.

3. However, a few minor editorial changes to section 3.2.2.3 and paragraph 3.2.2.7.2 were agreed.

4. New text is proposed to be added to the beginning of paragraph 3.2.2.3.2, prior to the text that is proposed to be deleted from the current paragraph 3.2.2.3.2 in ST/SG/AC.10/C.4/2021/5 and INF.4. In addition, it is proposed to move the last sentence of the current 3.2.2.3.2 into a new paragraph 3.2.2.3.3, which necessitates the renumbering of the remaining paragraphs within 3.2.2.3. These amendments are proposed in full in paragraph 6 below, with new text (including the renumbered paragraphs) shown in **red**, and deleted text shown in ~~strike through~~ for clarity. Text shown in **blue** is the text previously proposed in ST/SG/AC.10/C.4/2021/5 and INF.4 that remains unchanged.

5. In addition, a typographical error was also identified in the reference provided within brackets in paragraph 3.2.2.7.2 where the reference to Tier 4 which should read ‘..see 3.2.2.5)’. This proposed correction is provided in paragraph 7 below, and is shown in **red**.

¹ See ST/SG/AC.10/C.4/2021/4 and informal document INF.3

² See ST/SG/AC.10/C.4/2021/5 and informal document INF.4

Proposed new changes to section 3.2.2.3

6. Replace section 3.2.2.3 with:

“3.2.2.3 Classification based on *in vitro/ex vivo* data (Tier 2 in Figure 3.2.1)

3.2.2.3.1 The currently available individual *in vitro/ex vivo* test methods address either skin irritation or skin corrosion, but do not address both endpoints in one single test. Therefore, classification based solely on *in vitro/ex vivo* test results may require data from more than one method. For authorities implementing Category 3 it is important to note that the currently available internationally validated and accepted *in vitro/ex vivo* test methods do not allow identification of substances classified as Category 3.

3.2.2.3.2 ~~The classification criteria for the currently available *in vitro/ex vivo* test methods adopted by the OECD in test guidelines 430, 431, 435, and 439 are described in Tables 3.2.6 and 3.2.7 (see 3.2.5.3.4). Other validated *in vitro/ex vivo* test methods accepted by some competent authorities may also be considered. A competent authority may decide which classification criteria, if any, should be applied for other test methods to conclude on classification, including that a substance is not classified for effects on the skin. Wherever possible classification should be based on data generated using internationally validated and accepted *in vitro/ex vivo* test methods, and the classification criteria provided in these test methods needs to be applied.~~

3.2.2.3.3 *In vitro/ex vivo* data can only be used for classification when the tested substance is within the applicability domain of the test method(s) used. Additional limitations described in the published literature should also be taken into consideration.

3.2.2.3.4 *Skin corrosion*

3.2.2.3.4.1 Where tests have been undertaken in accordance with OECD test guidelines 430, 431, or 435, a substance is classified for skin corrosion in Category 1 (and, where possible and required into sub-categories 1A, 1B or 1C) based on the criteria in Table 3.2.6 (see 3.2.5.3.4).

3.2.2.3.4.2 Some *in vitro/ex vivo* methods do not allow differentiation between sub-categories 1B and 1C (see Table 3.2.6). Where sub-categories are required by competent authorities and existing *in vitro/ex vivo* data cannot distinguish between the sub-categories, additional information has to be taken into account to differentiate between these two sub-categories. Where no or insufficient additional information is available, Category 1 is applied.

3.2.2.3.4.3 A substance identified as not corrosive should be considered for classification as skin irritant.

3.2.2.3.5 *Skin irritation*

3.2.2.3.5.1 Where classification for corrosivity can be excluded and where tests have been undertaken in accordance with OECD Test Guideline 439, a substance should be considered for classification as skin irritant in Category 2 based on the criteria in Table 3.2.7 (see 3.2.5.3.4).

3.2.2.3.5.2 Where competent authorities adopt Category 3, it is important to note that currently available *in vitro/ex vivo* test methods for skin irritation (e.g. OECD Test Guideline 439) do not allow for classification of substances in Category 3. ~~In this situation, if the classification criteria for either category 1 or 2 are not fulfilled, additional information is required to differentiate between category 3 and no classification.~~

3.2.2.3.6 *No classification for effects on the skin*

3.2.2.3.6.14.3 Where competent authorities do not adopt Category 3, a negative result in an ~~internationally accepted and validated~~ *in vitro/ex vivo* test method for skin irritation that is validated according to international procedures, e.g. OECD Test Guideline 439, can be used to conclude as not classified for skin irritation. Where competent authorities adopt Category 3, additional information is required to differentiate between Category 3 and no classification.”

7. 3.2.2.7.2 In the first sentence within the second set of brackets, replace “see 3.2.2.7” with “see 3.2.2.5”

Action and next steps

8. The Sub-Committee is invited to agree the proposed changes to Chapter 3.2 as provided above in paragraphs 6 and 7 of this document in addition to those provided in ST/SG/AC.10/C.4/2021/5 and INF.4 on proposals to Chapters 1.2 and 3.2.
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