



**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 Transport of Dangerous Goods****Fifty-fifth session**

Geneva, 1-5 July 2019

Item 10 (c) of the provisional agenda

Updating of references to OECD Guidelines**Revision of paragraph 2.8.3.2****Transmitted by the European Union*****Introduction**

1. The European Commission wishes to thank all delegates that contributed to finalise and agreed to the adoption of paragraph 2.8.3.2 based on the proposal in document ST/SG/AC.10/C.3/2018/70 considered at the fifty-fourth session.

2. In Annex I to the report of the Sub-Committee of Experts on the Transport of Dangerous Goods on its fifty-fourth session (ST/SG/AC.10/C.3/108/Add.1) the following amendments to paragraph 2.8.3.2 to the twentieth revised edition of the Recommendations on the Transport of Dangerous Goods, Model Regulations (ST/SG/AC.10/1/Rev.20), were included:

“2.8.3.2 In the second sentence, replace “the grouping” by “classification” and replace “OECD Test Guideline 404¹, or 435^{2,3,4}.” By “OECD Test Guidelines^{1,2,3,4}”.

In the third sentence replace “OECD Test Guideline 430³, or 431⁴.” By “OECD Test Guidelines^{1,2,3,4}”.

Delete the existing footnote 4 and renumber the current footnote 3 to 4. In the renumbered footnote, add “Method” between “Test” and “(TER)”. Insert a new footnote 3 as follows: “³ OECD Guideline for the testing of chemicals No. 431 “In vitro skin corrosion: reconstructed human epidermis (RHE) test method” 2016”

* In accordance with the programme of work of the Sub-Committee for 2019-2020 approved by the Committee at its ninth session (see ST/SG/AC.10/C.3/108, paragraph 141 and ST/SG/AC.10/46, paragraph 14).

At the end of the paragraph, add the following new sentence: “If the in vitro test results indicate that the substance or mixture is corrosive and not assigned to packing group I, but the test method does not allow discrimination between packing groups II and III, it shall be considered to be packing group II.”.

3. During the discussions at the fifty-fourth session on the revision of paragraph 2.8.3.2, the following observations were made:

(a) A substance or mixture resulting as non-classified based on OECD Test Guideline (TG) No 439 "In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method" may also be considered as non-corrosive to skin for the purposes of these Regulations without further new testing. The TG provides an *in vitro* procedure that may be used for the hazard identification of irritant chemicals (substances and mixtures) in accordance with GHS Category 2. Non-classified chemicals identified using this TG can be considered as non-corrosive to skin;

(b) It was also suggested that it would be useful to allow the possibility to classify in packing group (PG) I if a test method identifies a substance or mixture as skin corrosive, but does not allow discrimination between PG I, II and III without requiring additional testing. This is then following the same philosophy as classification in PG II if a test method discriminates between PG I and II, but not between PG II and III, which was the provision agreed at the fifty-fourth session.

4. The addition of the 5th OECD Guideline in section 2.8.3.2 is likely to create confusion if the numbers of the documents are not comprised in the regulatory text. We therefore propose to the Sub-Committee to reconsider inserting the numbers in the texts for the existing Guidelines and add the number for the newly proposed reference (No. 439). It is our opinion that strict references to the Guidelines increase legal certainty and prevent misuse of the Model Regulations provisions. Furthermore, considering the long series of OECD Guidelines for the Testing of Chemicals indicating the numbers in the text provide a quick reference to avoid confusion.

Proposal 1

5. Paragraph 2.8.3.2 is therefore suggested to be further revised as follows (~~stricken out~~ text is deleted, underlined text is added):

“2.8.3.2 In assigning the packing group in accordance with 2.8.2.3, account shall be taken of human experience in instances of accidental exposure. In the absence of human experience classification shall be based on data obtained from experiments in accordance with OECD Test Guidelines Nos. 404¹, 435², 431³ and 430⁴. A substance or mixture which is determined not to be corrosive in accordance with ~~OECD Test Guidelines~~ one of these or non-classified in accordance with OECD Test Guideline No. 439⁵, may be considered not to be corrosive to skin for the purposes of these Regulations without further testing. If the in vitro test results indicate that the substance or mixture is corrosive and not assigned to packing group I, but the test method does not allow discrimination between packing groups II and III, it shall be considered to be packing group II. If the in vitro test results indicate that the substance or mixture is corrosive, but the test method does not allow discrimination between packing groups I, II and III, it shall be considered to be packing group I.”

¹ OECD Guideline for the testing of chemicals No. 404 "Acute Dermal irritation/Corrosion" 2015

² OECD Guideline for the testing of chemicals No. 435 "In Vitro Membrane Barrier Test Method for Skin Corrosion" 2015

³ *OECD Guideline for the testing of chemicals No. 431 "In Vitro Skin Corrosion: reconstructed human epidermis (RHE) test method" 2016*

⁴ *OECD Guideline for the testing of chemicals No. 430 "In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test Method (TER)" 2015*

⁵ *OECD Guideline for the testing of chemicals No. 439 "In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method" 2015*

Proposal 2

6. As an alternative to the proposal in paragraph 5, we suggest the Sub-Committee to consider to re-format footnotes 1 to 4 and include the four references in one common footnote to avoid the long list of footnotes and partly repeated text:

“2.8.3.2 In assigning the packing group in accordance with 2.8.2.3, account shall be taken of human experience in instances of accidental exposure. In the absence of human experience classification shall be based on data obtained from experiments in accordance with OECD Test Guidelines Nos. 404, 435, 431 and 430¹. A substance or mixture which is determined not to be corrosive in accordance with ~~OECD Test Guidelines~~ one of these or non-classified in accordance with OECD Test Guideline No. 439², may be considered not to be corrosive to skin for the purposes of these Regulations without further testing. If the in vitro test results indicate that the substance or mixture is corrosive and not assigned to packing group I, but the test method does not allow discrimination between packing groups II and III, it shall be considered to be packing group II. If the in vitro test results indicate that the substance or mixture is corrosive, but the test method does not allow discrimination between packing groups I, II and III, it shall be considered to be packing group I.”

¹ *OECD Guidelines for the testing of chemicals No. 404 "Acute Dermal irritation/Corrosion" 2015; No. 435 "In Vitro Membrane Barrier Test Method for Skin Corrosion" 2015; No. 431 "In Vitro Skin Corrosion: reconstructed human epidermis (RHE) test method" 2016; and No. 430 "In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test Method (TER)" 2015*

² *OECD Guideline for the testing of chemicals No. 439 "In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method" 2015*