

## 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

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Item 10 (c) of the provisional agenda

### Issues relating to the Globally Harmonized System of Classification and Labelling of Chemicals:

Updating of references to OECD Guidelines

## Applicability of OECD Test Guidelines for the assessment of substances or mixtures on corrosivity to skin: comments on ST/SG/AC.10/C.3/2018/30

Transmitted by the European Chemical Industry Council (CEFIC)

### Introduction

1. The initiative of the experts of the European Union on the revision of the applicability of OECD Test Guidelines for the assessment of corrosivity to skin (ST/SG/AC.10/C.3/2018/30) is very much appreciated.
2. At the forty-sixth session of the Sub-Committee, also CEFIC draw attention to continuous improvements of the OECD Test Guidelines offering further opportunities regarding the assessment of corrosivity to skin for the purpose of transport regulations (see INF.13, 46<sup>th</sup> session).

### Discussion

3. After the basic revision of Chapter 2.8 published in Rev. 20 (2017) of the UN Model Regulations, it is now consequent to consider a systematic and comprehensive approach to review the applicability of the results of experiments according to the OECD Test Guidelines and to adjust their ambit in 2.8.3.2 of the UN Model Regulations.
4. The OECD Guidance Document No. 203 (OECD, 2014) "New Guidance Document on an Integrated Approach on Testing and Assessment for Skin Corrosion and Irritation" provides information how and to which extend the results of experiments based on the different OECD Test Guidelines may be used for classification according to the provisions of the Globally Harmonized System. In the following a short summary according to the Guidance Document and the description of the Test Guidelines (TG) on skin corrosion adopted by the OECD is provided:

- (a) *The OECD TG 404 on "Acute Dermal Irritation/Corrosion" describes an in vivo test method performed on albino rabbits.*

*Classification of the full irritation and corrosion potency, i.e., No Cat., Cat. 3, Cat. 2, Sub-cat. 1C, Sub-cat. 1B or Sub-cat. 1A, has been based on this test, so that it can provide classifications over the entire spectrum. It should be used only as a last option after in vitro testing when the test chemical cannot be tested due to limitations or non-applicability. It may in exceptional cases also be used, when in vitro testing is not feasible or reliable.*

- (b) *The OECD TG 430 on “In vitro skin corrosion: Transcutaneous Electrical Resistance test method” describes a test method where the test material is applied to the epidermal surfaces of rat skin discs in a two-compartment test system in which the skin discs function as the separation between the compartments.*

*The test method may be used as a stand-alone test method for the detection or exclusion of corrosive effects of test chemicals. If corrosive sub-categorization is required other test methods should be considered.*

- (c) *The OECD TG 431 on “In vitro skin corrosion: Reconstructed human epidermis test method” describes a test method where the test material is applied to reconstructed human epidermis, which in its overall design closely mimics the biochemical and physiological properties of the upper parts of the human skin, i.e. the epidermis.*

*The test method may be used as a stand-alone test method for the detection or exclusion of corrosive effects of test chemicals. It also allows for the sub-categorization of corrosive chemicals into Cat. 1A or Cat. 1B/1C but does not permit the distinction of the latter into Cat. 1B and Cat. 1C. In this case a cautious default classification as 1B if the test results in 1B/1C could be decided.*

- (d) *The OECD TG 435 on “In vitro Membrane Barrier test method for skin corrosion” describes a test method that detects membrane barrier damage caused by corrosive test chemicals after the application of the test chemical to the surface of the artificial membrane barrier, presumably by the same mechanism(s) of corrosion that operate on living skin.*

*The test method is accepted to identify non-corrosive and skin corrosive chemicals and allows full sub-categorization into Sub-cat 1A, 1B and 1C. It is often not applicable to chemicals with  $4.5 < \text{pH} < 8.5$  which may not qualify for testing, based on the results of the initial compatibility test for the chemical detection system used to detect passage of chemicals through the bio-barrier. The test method may therefore be particularly useful to sub-categorize corrosive chemicals identified on the basis of extreme pH.*

5. Following the approach of the Globally Harmonized System the guidance on sub-categorization should be adopted for the assignment of packing groups to provide the adequate conditions for transport. Recognition of the full set of information derived by each individual test method, while at the same time considering its specific limitations, will serve to further reduce the number of required tests.

## Proposal

6. Amend the proposal in ST/SG/AC.10/C.3/2018/30 for 2.8.3.2 to read as follows (deleted text is struck through; new text is underlined):

“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, the grouping shall be based on data obtained from experiments in accordance with OECD Test Guideline 404<sup>1</sup> (preferably existing data), 431<sup>2</sup> (default packing group II in case differentiation between packing group II and III not possible) or 435<sup>23</sup>. A substance or mixture which is determined not to be corrosive in accordance with OECD Test Guideline 404<sup>1</sup>, 430<sup>24</sup>, ~~or 431<sup>42</sup>~~ or 435<sup>3</sup> may be considered not to be corrosive to skin for the purposes of these Regulations without further testing.

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<sup>1</sup> OECD Guideline for the testing of chemicals No. 404 "Acute Dermal Irritation/Corrosion" 2015

<sup>23</sup> OECD Guideline for the testing of chemicals No. 435 "In Vitro Membrane Barrier Test Method for Skin Corrosion" 2015

<sup>34</sup> OECD Guideline for the testing of chemicals No. 430 "In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test Method (TER)" 2015

<sup>42</sup> OECD Guideline for the testing of chemicals No. 431 "In Vitro Skin Corrosion: Reconstructed Human Skin Model Epidermis (RhE) Test Methode" ~~2015~~2016"

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