

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

30 October 2014

Forty-sixth session

Geneva, 1 – 9 December 2014

Item 8 (g) of the provisional agenda

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

Applicability of in vitro tests for the assessment of substances and preparations to be assigned to Class 8

Transmitted by the European Chemical Industry Council (CEFIC)

Introduction

1. According to 2.8.2.4 of the UN Model Regulations Rev. 18 (2013) the applicability of in vitro test results based on OECD Test Guideline 431 is limited to distinguish between substances or preparations whether they have to be considered as corrosive to skin or not, but not to assign a packing group accordingly. On the other hand, data obtained from experiments in accordance with OECD Test Guideline 435 shall be only used to assign the packing group, but it is not established to use these test results to differentiate between substances or preparations to be classified as corrosive to skin or not.

2. Based on a thorough examination of the OECD Guidelines for the Testing of Chemicals, CEFIC comes to the conclusion that paragraph 2.8.2.4 deserves adjustment. The provisions currently do not consider the full content of information provided by in vitro test results according to OECD Test Guideline 435. Additionally, improvements published in revision 2013 of the OECD Test Guideline 431 offer the opportunity to extend the ambit of the respective test results.

Discussion

3. Improvements recently documented in the OECD Test Guideline 431 (2013) do not only allow to clearly identify substances or preparations as corrosive to skin but additionally allow assignment to sub-category 1A according to the provisions of the Globally Harmonized System (GHS) in case the classification criteria are fulfilled under the test conditions prescribed in the guideline. For the purpose of Transport Regulations this partial sub-categorization based on the test results may serve to assign Packing Group I. However, in vitro tests according to OECD Test Guideline 431 do not give the opportunity of a complete sub-categorization and hence, further evidence for a grouping into Packing Group II or III is not provided.

4. The OECD Test Guideline 435 describes a membrane barrier test which is established for sub-categorization of skin corrosive substances into the three sub-categories according to the provisions of GHS and serves for the assignment of packing groups for the purpose of Transport Regulations. The test method also allows making decisions on the corrosivity and non-corrosivity, i.e. the identification of skin corrosive substances and preparations, provided the prescribed conditions of compatibility with the applied chemical detection system are fulfilled. However, for aqueous substances and preparations with a pH

in the range of 4.5 to 8.5 significant limitation for the applicability of the test method has to be considered.

Proposal

5. Based on the above considerations 2.8.2.4 of the UN Model Regulations should be amended as follows:

2.8.2.4I In assigning the packing group to a substance in accordance with 2.8.2.2, 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 404¹ or 435². In case a substance is determined to be corrosive in accordance with OECD Test Guideline 431³ and the test results fulfill the criteria to allocate the severest sub-category of corrosivity according to the Globally Harmonized System (GHS), the substance shall be assigned to Packing Group I.

A substance which is determined not to be corrosive in accordance with OECD Test Guideline 430⁴ or 431³ may be considered not to be corrosive to skin for the purposes of these Regulations without further testing. A substance with a pH below or above the range of 4.5 to 8.5 which is determined not to be corrosive in accordance with OECD Test Guideline 435² may be considered not to be corrosive to skin for the purposes of these Regulations without further testing.

Justification

6. The proposal aims to raise awareness of the full potential of in vitro tests described in the OECD Guidelines for the Testing of Chemicals in regard to the assessment of corrosivity to skin for the purpose of Transport Regulations. Recognition of the full set of information provided by each individual test method will serve to further reduce the amount of tests required for classification, while at the same time the specific limitations of the test methods are considered.

¹ OECD Guideline for the testing of chemicals No. 404 "Acute Dermal Irritation/Corrosion" 2002.

² OECD Guideline for the testing of chemicals No. 435 "In Vitro Membrane Barrier Test Method for Skin Corrosion" 2006.

⁴³ OECD Guideline for the testing of chemicals No. 431 "In Vitro Skin Corrosion: Human Skin Model Test" ~~2004~~ 2013.

³⁴ OECD Guideline for the testing of chemicals No. 430 "In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)" 2004.