

**Committee of Experts on the Transport of Dangerous Goods
and on the Globally Harmonized System of Classification
and Labelling of Chemicals**

3 July 2018

**Sub-Committee of Experts on the Transport
of Dangerous Goods**

Fifty-third session

Geneva, 25 June-4 July 2018

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

**Sub-Committee of Experts on the Globally Harmonized
System of Classification and Labelling of Chemicals**

Thirty-fifth session

Geneva, 4-6 July 2018

Item 2 of the provisional agenda

**Joint work with the Sub-Committee of Experts on the
Transport of Dangerous Goods (TDG Sub-Committee)**

**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 Dangerous Goods Advisory Council (DGAC)

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 because it adds additional flexibility to the classification options. DGAC offers an enhancement of their proposal and the paper submitted by CEFIC (UN/SCETDG/53/INF.34).

Discussion

2. In addition to the changes offered by the EU and CEFIC, DGAC thinks that the following changes in the proposed language provide clear guidance when determining packing group by:

- (a) emphasizing the role of human experience as preeminent data over in vitro testing;
- (b) explicitly stating that if in vitro testing confirms a substance is not corrosive, there is no need to perform exhaustive in vivo testing;
- (c) stating clearly that if in vitro testing is performed using one OECD Test Guideline that does not allow discrimination between packing groups, a default (conservative) packing group may be used.

Proposal

3. Amend the proposal in UN/SCETDG/53/INF.34 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 classification shall be based on data obtained from experiments in accordance with OECD Test Guidelines 4041 (preferably existing data), 4312 (default packing group II in case differentiation between packing group II and III not possible) or 43523. A substance or mixture which is determined not to be

corrosive in accordance with an *in vitro* OECD Test Guideline^{1,2,3,4} ~~4041, 43034, or 43142 or 4353~~ may be considered not to be corrosive to skin for the purposes of these Regulations without further *in vivo* testing. If it is not possible, based on existing *in vitro* testing, to discriminate between packing groups I, II and III, packing group I shall be applied. If it is not possible to discriminate between packing groups II and III, packing group II shall be applied.

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. 430 "In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test Method (TER)" 2015

⁴ OECD Guideline for the testing of chemicals No. 431 "In Vitro Skin Corrosion: Reconstructed Human Skin Model Epidermis (RhE) Test Methode" 20152016"