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**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

Thirty-second session
Geneva, 3-12 (a.m.) December 2007
Item 3 of the provisional agenda

LISTING, CLASSIFICATION AND PACKING

Skin corrosion tests

Transmitted by the International Council of Chemical Associations (ICCA) ^{*/}

Background

1. When assigning the packing group to a substance of class 8, subsection 2.8.2.4 of the Model Regulations requires that in the absence of human experience the grouping shall be based on data obtained from experience in accordance with OECD Guideline 404 “*OECD Guidelines for testing of chemicals No. 404 “Acute Dermal Irritation / Corrosion” 1992*. Said guideline 404 describes an “In Vivo” method using albino rabbits. Due to animal protection laws in certain countries, the application of this guideline can be difficult.

2. In recent years, OECD has developed new guidelines for “In Vitro” Skin Corrosion Tests as alternatives for the standard “In Vivo” rabbit skin procedure:

^{*/} In accordance with the programme of work of the Sub-Committee for 2007-2008 approved by the Committee at its third session (refer to ST/SG/AC.10/C.3/60, para. 100 and ST/SG/AC.10/34, para. 14) (classification).

- OECD-Guideline 430 – “In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)”
- OECD-Guideline 431 – “In Vitro Skin Corrosion: Human Skin Model Test”
- OECD-Guideline 435 – “In Vitro Membrane Barrier Test Method for Skin Corrosion”

3. In footnote (e) to Figure 3.2.1 of GHS (Tiered testing and evaluation of skin corrosion and irritation potential) reference is already made to the OECD Test Guidelines 430 and 431 as “Examples of internationally accepted validated in vitro test methods for skin corrosion”.

Proposal

4. It is therefore proposed to amend paragraph 2.8.2.4 as follows: (new text is underlined)

“2.8.2.4 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 Guideline 404 ¹, 430 ², 431 ³ or 435 ⁴.”

¹ OECD Guidelines for testing of chemicals No. 404 “Acute Dermal Irritation/Corrosion” 1992

² OECD Guideline for the testing of chemicals No. 430 “In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)”

³ OECD Guideline for the testing of chemicals No. 431 “In Vitro Skin Corrosion: Human Skin Model Test”

⁴ OECD Guideline for the testing of chemicals No. 435 “In Vitro Membrane Barrier Test Method for Skin Corrosion”.”.

Justification

5. This amendment will take into account technological developments.

6. For reference purposes, OECD guidelines 430, 431 and 435 are reproduced in informal documents INF. 4, INF. 5 and INF. 6.
