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, 3-7 December 2007
Item 3 of the provisional agenda

LISTING, CLASSIFICATION AND PACKING

Comments on ST/SG/AC.10/C.3/2007/50 – Skin Corrosion Tests (ICCA)

Transmitted by the Expert from the United States of America

Background

The Expert from the United States has reviewed the proposal from ICCA related to the adoption of several "In Vitro" skin corrosion test methods recently published by OECD. The specific methods proposed for adoption include:

- 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"

In principle the expert from the United States agrees that these methods should be referenced within the UN Model Regulations. The value of providing alternative test methods not requiring the use of live animals is fully apparent and in vitro methods have proven to be effective in practice for many years. However it has been noted that with respect to achieving a proper classification for transport, only method 435 provides test results which provide for the assignment of a Packing Group. As such, the only method which should be authorized as a "stand alone" procedure for a corrosive determination within the Model Regulations for transport classification purposes is method 435.

It is recognized however that there is value in including a reference to methods 430 and 431 as they could be used to preclude further testing in accordance with methods 404 or 435 if a negative result is obtained. For example, a company which has obtained negative results from method 430 or 431 to satisfy the requirements of other sectors would not have to test the material again for transport purposes using a method which assigns a packing group. A close review of the methods in question by technical experts has shown that a substance which produces a negative result in accordance with methods 430 and 431 should not produce a positive result in accordance with methods 404 or 435.

In order to account for the above considerations, it is proposed that slight amendments be made to the text proposed in ST/SG/AC.10/C.3/2007/50. A revised text is proposed below.

Proposal

Amend 2.8.2.4 to read as follows:

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] or 435[4]. A substance which is determined not to be corrosive in accordance with OECD Test Guideline 430[2] or OECD Test Guideline 431[3] may be considered to be not corrosive for the purposes of these Regulations without further testing.

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)" 2004

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

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