



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 3 of the provisional agenda

Listing, classification and packing

Proposal for unifying animal species for evaluation test of acute dermal toxicity in GHS and Model Regulations

Transmitted by the expert from China*

Introduction

1. The description about animal species in 3.1.2.3 of *Globally Harmonized System (GHS) of Classification and Labelling of Chemicals* (eighth edition) is given as: "The preferred test species for evaluation of acute toxicity by the oral and inhalation routes is the rat, while the rat or rabbit are preferred for evaluation of acute dermal toxicity."
2. However, the description about animal species in section 2.6.2.1.2 of *UN Model Regulations* (twenty-first edition) is given as: "LD₅₀ for acute dermal toxicity is that dose of the substance which, administered by continuous contact for 24 hours with the bare skin of albino rabbits, is most likely to cause death within 14 days in one half the animals tested."
3. The adult rat, rabbit or guinea pig may be used as test animal in the Organisation for Economic Co-operation and Development (OECD) test guideline 402 (1981) - Acute Dermal Toxicity, while in the 2017 revision of OECD test guideline 402, it is clearly stated that adult rat is the preferred species to be used in acute dermal toxicity test.
4. The preferred animal species for the evaluation test of acute dermal toxicity is "rat" or "rabbit" in GHS, while the animal species for evaluation of acute dermal toxicity is "albino rabbit" in UN Model Regulations. The difference of the animal species between GHS and UN Model Regulations may result in unnecessary potential conflict on the classification of some substances. And many substances only have acute dermal toxicity data on rats, but not on rabbits. For the purpose of the animal welfare and the uniformity of classification in GHS and UN Model Regulations, it is suggested that the acute dermal toxicity data of rats should be added to UN Model Regulations.

* A/75/6 (Sect.20), para. 20.51.

Proposal

5. Amend 2.6.2.1.2 of UN Model Regulations as follows (new text in **bold underlined**):

“2.6.2.1.2 LD₅₀ for acute dermal toxicity is that dose of the substance which, administered by continuous contact for 24 hours with the bare skin of albino rabbits **or rats**, is most likely to cause death within 14 days in one half the animals tested. The number of animals tested shall be sufficient to give a statistically significant result and be in conformity with good pharmacological practice. The result is expressed in milligrams per kg body mass.”
