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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 Globally Harmonized System of Classification and Labelling of Chemicals

(7 (p.m.)-9 December 2004)

SKIN CORROSION/IRRITATION

Solid substances that in contact with water may become corrosive or irritant
(Ref. doc.: ST/SG/AC.10/C.4/2004/23)

Transmitted by the expert from Sweden

Having considered the different views expressed by the sub-committee yesterday, Sweden has elaborated on an alternative proposal on the issue on solid substances that in contact with water may become corrosive or irritant. We hope that this revised proposal is acceptable to the members of the sub-committee.

We propose to include the content of our previous proposal in the text of paragraph 3.2.2.2 but to change the wording in order to leave out the reference to testing, (see bold text below).

3.2.2.2 Several factors should be considered in determining the corrosion and irritation potential of chemicals before testing is undertaken. ***Solid substances (powders) may become corrosive or irritant when moistened or in contact with moist skin or mucous membranes.*** Existing human experience and data including from single or repeated exposure and animal observations and data should be the first line of analysis, as they give information directly relevant to effects on the skin. In some cases enough information may be available from structurally related compounds to make classification decisions. Likewise, pH extremes like < 2 and > 11.5 may indicate skin effects, especially when buffering capacity is known, although the correlation is not perfect. Generally, such agents are expected to produce significant effects on the skin. It also stands to reason that if a chemical is highly toxic by the dermal route, a skin irritation/corrosion study may not be practicable since the amount of test substance to be applied would considerably exceed the toxic dose and, consequently, would result in the death of the animals. When observations are made of skin irritation/corrosion in acute toxicity studies and are observed up through the limit dose, additional testing would not be needed, provided that the dilutions used and species tested are equivalent. *In vitro* alternatives that have been validated and accepted may also be used to help make classification decisions.

All the above information that is available on a chemical should be used in determining the need for *in vivo* skin irritation testing. Although information might be gained from the evaluation of single parameters within a tier (see 3.2.2.3), e.g. caustic alkalis with extreme pH should be considered as skin corrosives, there is merit in considering the totality of existing information and making an overall weight of evidence determination. This is especially true when there is information available on some but not all parameters. Generally, primary emphasis should be placed upon existing human experience and data, followed by animal experience and testing data, followed by other sources of information, but case-by-case determinations are necessary.
