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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

Sixteenth session,
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Item 2 (c) of the agenda

UPDATING OF THE SECOND REVISED EDITION OF THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS)

Environmental hazards

I Revised Proposed Amendment to Chapter 4.1.2.10.3 (a) in response to opinions expressed on
10th Dec 2008

II Subsequent Proposed Amendment to Annex 9.4.2.2.3 Time window

Transmitted by the European Chemical Industry Council (CEFIC),
the International Association for Soaps, Detergents and Maintenance Products (A.I.S.E.)
and the Soap and Detergent Association (SDA)

I. 4.1.2.10.3 Substances are considered rapidly degradable in the environment if the following criteria hold true:

- (a) If in 28-day ready biodegradation studies, the following levels of degradation are achieved:
 - (i) tests based on dissolved organic carbon: 70%;
 - (ii) tests based on oxygen depletion or carbon dioxide generation: 60% of theoretical maxima;

These levels of biodegradation must be achieved within ten days of the start of degradation which point is taken as the time when 10% of the substance has been degraded, unless the substance is identified as a complex, multi-component substance with structurally similar constituents. In this case, and where there is sufficient justification, the ten-day window condition may be waived and the pass level is applied at 28 days as explained in Annex 9.4.2.2.3;

II Proposed Amendment to A9.4.2.2.3 Time window

New wording (amendments underlined):

The harmonized criteria (4.1.2.10.3) include a general requirement for all of the ready biodegradability tests on achievement of the pass level within ten days. This is not in line with the OECD Test Guideline 301 in which the ten-days time window applies to the OECD ready biodegradability tests except to the MITI I test (OECD Test Guideline 301C). In the Closed Bottle test (OECD Test Guideline 301D), a 14-days window may be used instead when measurements have not been made after ten days. Moreover, often only limited information is available in references of biodegradation tests. Thus, as a pragmatic approach the percentage of degradation reached after 28 days may be used directly for assessment of ready biodegradability when no information on the ten-days time window is available. This should, however, only be accepted for existing test data or for data where the ten-days window does not apply.

Where there is sufficient justification, the ten-day window condition may be waived for complex, multi-component substances and the pass level is applied at 28 days. The constituents of such substances may have different chain-lengths, degree and/or site of branching or stereo-isomers, even in their most purified commercial forms. Testing of each individual component may be costly and impractical. If a test on the complex, multi-component substance is performed and it is anticipated that a sequential biodegradation of the individual structures is taking place, then the ten-day window should not be applied to interpret the results of the test. A case by case evaluation should however take place on whether a biodegradability test on such a substance would give valuable information regarding its biodegradability as such (i.e. regarding the degradability of all the constituents) or whether instead an investigation of the degradability of carefully selected individual components of the complex, multi-component substance is required.
