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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
Geneva, 10-12 (a.m.) December 2008
Item 2 (c) of the provisional agenda

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

Environmental hazards

Proposed change to paragraph 4.1.2.10.3

Transmitted by the European Chemical Industry Council (CEFIC),
the International Association for Soaps, Detergents and Maintenance Products (AISE)
and the Soap and Detergent Association (SDA)[1]

Introduction

1. At the fifteenth session of the Sub-Committee in July 2008 informal document UN/SCEGHS/15/INF.35 was introduced, setting out the background and justification for amending paragraph 4.1.2.10.3 in Chapter 4.1 of the GHS, which specifies the criteria which substances have to meet in order to be considered rapidly degradable in the environment.

[1] 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.4/24, Annex 2 and ST/SG/AC.10/34, para. 14).

2. The Sub-Committee had not had sufficient time to consider informal document INF.35 before the fifteenth session but a number of experts were able to provide useful comments. These comments are each addressed below and a new revision of 4.1.2.10.3 is provided, with a short explanation.

Responses to comments from the fifteenth session (presented in the order in which they arose)

3. AISE and CEFIC are grateful for the comments supplied. They are repeated below, as noted by the AISE and CEFIC representatives, with a response to each.

(a) Spain

The European Union Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE)[2] had indeed prepared an opinion on the value of the 10-day window but its conclusions must be seen as based only on the case of surfactants, a well-studied group of complex substances. This did not necessarily mean that the concept of the 10-day window was inappropriate for other complex substances but the case had not yet been made.

Response:

The studies on surfactants identified by the expert from Spain highlighted a theoretical problem in the 10-day window concept recognised by the Guideline. If the phenomenon arises for reasons of chemical structure, as is widely accepted, it would be hard to argue that this only applied to surfactants as a class.

Therefore the new proposal emphasises that it must be clear that the substance is a multi-component substance and has been sufficiently characterised as to its composition of related isomers and homologues to allow the 10-day window criterion to be waived.

(b) Organisation for Economic Co-operation and Development (OECD)

The representative of the OECD pointed to the detail given in their guidelines and included as footnote 6 in INF.35. This specified the requirement that for the 10-day window to be set aside was that the substance/s had to be structurally similar.

Response:

The point is accepted. It illustrates the need to bring consistency between OECD methods and GHS guidelines. Certainly in the case of those surfactants which can be described as multi-component substances, the structural similarity is assured (see also response to Spain). The various components do, as the OECD guideline indicates, consist of "constituents with different chain-lengths, degree and/or site of branching or stereo-isomers, even in their most purified commercial forms" but the substance under consideration would not be a 'mixture' or a preparation of several distinct substances.

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[2] *Replaced in 2004 by the "Scientific Committee on Health and Environment Risks" (SCHER).*

(c) Soap and Detergent Association (SDA)

The representative of SDA stated that INF.35 had the support of the SDA and was an example of where data were to be obtained and interpreted in a meaningful manner.

Response: This opinion is endorsed.

(d) France

The expert from France considered that the proposed modification was not needed as item (c) in 4.1.2.10.3 (other convincing evidence) was adequate to cover the situation where complex substances failed the 10-day window but could be shown to degrade to >70%.

Response:

It may be appropriate to indicate that item (c) relates to "other scientific evidence".

"Other scientific evidence" is clearly defined in Annex 9 (paragraph A9.4.2.4.1) as "Rapid degradation in the aquatic environment may be demonstrated by other data than referred to in Chapter 4.1, paragraph 4.1.2.10.3, items (a) and (b)". These are, respectively the ready biodegradability test (a) and the BOD/COD ratio (b). Item (c) relates primarily to results from aquatic simulation tests and/or field investigations (see GHS Annex 9, paragraphs A9.4.2.4.5 and A9.4.2.4.6).

Such tests providing other scientific evidence are conducted in a less well defined environment than the ready tests for which the ten-day window was introduced. There will be additional organic material and micro-organisms present in a simulation test, giving more opportunities for degradation e.g. *via* co-metabolism and adapted micro-organisms.

As a result of this possible confusion, instead of using a new clause (d) as in INF.35, the amendment proposed below is placed within item (a), so that it clearly relates only to the stringent ready test. No modification of item (c) is proposed.

(d) United States of America

The expert from the United States of America referred to the importance of conforming strictly to the GHS definitions of substance and mixture.

Response:

This point is accepted absolutely and the proposed new wording in (a) uses the term *multi-component substance* to emphasize that this proposal should not be extended to cases such as mixtures (as defined in GHS Chapter 1.2).

(e) European Commission

The representative of the European Commission recommended that the Sub-Committee should proceed with caution before extending the concept of waiving the

10-day window beyond its application for surfactants. The OECD Guidance could be used as a means of giving a degree of flexibility.

Response:

It is hoped that the proposed new wording in (a) fully addresses the concern expressed by the representative from the European Commission.

(f) The Netherlands

Annex 9 could be used to provide any guidance on interpreting the results of tests with complex substances. Guidance was needed. This could be by adding the proposed (d) in INF.35 to 4.2.1.10.3 or by using the Annex.

Response:

It seems a useful suggestion to amplify the guidance given in the Annex, while at the same time using a modified (a), as proposed below. The guidance in Annex 9 could be used to clarify that only substances demonstrated to be of a multi-component nature may be subject to a waiving of the 10-day window. But, for the time being, such substances can only be exemplified for surfactants.

Proposed revision of 4.1.2.10.3

4. As a result of all the comments received at the fifteenth session of the Sub-Committee in July 2008 the following revision to 4.1.2.10.3 is proposed. From the text above it may be seen where the particular concerns of the experts have all been addressed.

Amend current paragraph 4.1.2.10.3 to read as follows (new text is underlined):

"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 10 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 multi-component substance e.g. a UVCB[3] such as most surfactants, where the 10-day window condition can be waived and the pass level is applied at 28 days; or

[3] *UVCBs*: *Substances of unknown or variable composition, complex reaction products or biological materials.*

(b) if, in those cases where only BOD and COD data are available, when the ratio of BOD_5/COD is ≥ 0.5; or

(c) if other convincing scientific evidence is available to demonstrate that the substance can be degraded (biotically and/or abiotically) in the aquatic environment to a level >70% within a 28-day period.
