COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS

Sub-Committee of Experts on the Transport of Dangerous Goods
(Sixteenth session,
Geneva, 3-12 July 2000,
agenda item 6 (b))

GLOBAL HARMONIZATION OF SYSTEMS OF CLASSIFICATION AND LABELLING OF CHEMICALS

Health hazards and hazards to the environment

Environmentally hazardous substances

Transmitted by the Expert from the United Kingdom

Introduction

1. In document ST/SG/AC.10/C.3/R.664 dated 22 September 1995, the expert from the United Kingdom made proposals for the inclusion in the UN Model Regulations of provisions for the transport of packaged environmentally hazardous substances, i.e. water pollutants. These proposals followed from an informal working group of the Committee of Experts held at the International Maritime Organization from 2-4 May 1995 (report in document ST/SG/AC.10/C.3/R.635).

2. After considering the proposals, the Committee preferred to await decisions in the context of the development of the globally harmonized system (GHS) of chemicals under UNCED Agenda 21, Chapter 19. The United Kingdom proposals have since remained in the agendas of the Sub-Committee and Committee.

3. The development of harmonized criteria for the classification of aquatic pollutants has been co-ordinated by the Organization for Economic Co-operation and Development (OECD). The seventh meeting of its Advisory Group on Harmonization of Classification and Labelling Systems met in Paris from 1-2 September 1998 and the eighth high level meeting of the Advisory Group was held from 3-4 September 1998. During those meetings, agreement was reached on the criteria to be used to define a number of biological parameters, including hazardous to the aquatic environment. These have been presented in the OECD paper "Harmonised Integrated Hazard Classification System for Human Health and Environmental Effects of Chemical Substances" as endorsed by the 28th Joint meeting of the Chemicals Committee and the Working Party on Chemicals in November 1998. The OECD table for the Classification Scheme for substances hazardous to the aquatic environment is reproduced at Annex A for ease of reference. It now has to be decided how far the OECD scheme is relevant to the transport of dangerous goods and how that should be included in the Model Regulations.

4. The expert from the United Kingdom therefore submitted Paper INF 10 to the December 1998 Committee of Experts meeting proposing that this subject should be included as a major new agenda item in the future work programme of the Committee for the biennium 1999-2000. This was agreed by the Committee and the expert from the UK invited written comments on the draft proposal.

5. Paper ST/SG/AC.10/C.3/1999/27 replaced document ST/SG/AC.10/C.3/R.664 and took account of the few comments received. It contained a first draft of a new Chapter 2.9 and notes of many points that would need to be taken into account in future *(shown in italics)*. The GHS scheme for this subject includes much explanatory text that will be inappropriate in Model Regulations but will have to be included, probably by means of Notes and Footnotes or, possibly, in the Manual of Tests and Criteria.

6. The following points were noted, in particular:

(a) The text had been kept as close as possible to the agreed text for the GHS. This will facilitate updating and adaptation to technical progress of the transport scheme as the GHS is developed;

(b) There were references in the text to a Guidance Document which is currently being developed under the GHS. The timetable for this Document was understood to be that it should be agreed by December 1999. Its subsequent status would have to be considered;

(c) The proposals at this stage were applicable only to substances and would require amending/updating when the criteria applicable to mixtures/preparations under discussion by the ILO working group are agreed for inclusion in the GHS;

(d) Consideration had been given to existing classification systems in current regulations, including the EU 'Supply and Use' scheme, the revised GESAMP hazard evaluation procedure, the IMO scheme for Marine Pollutants, the European Road and Rail Transport rules (RID/ADR), the Canadian and US pesticides systems and the US land transport requirements. The proposed system was for use for packaged dangerous goods in multimodal transport; elements of it may be used for 'bulk' land transport and for bulk marine transport under MARPOL 73/78 Annex II insofar as this uses aquatic toxicity;

7. Particular attention will have to be paid to developments in the context of the GHS, by the GESAMP and IMO in relation to MARPOL 73/78, Annexes II and III and the IBC Code.

8. It is for consideration whether the proper shipping names for UN 3077 and UN 3082 should be made specific to the aquatic environment, with Basel Convention wastes not otherwise dangerous in transport dealt with differently. Conversely, it should also be considered whether the aquatic environment be deemed the most sensitive and that these proposals automatically read across to substances presenting a hazard to the environment generally.

9. Paper 1999/27 was considered by the Sub-Committee at its sixteenth and seventeenth sessions. At the seventeenth session it was concluded that text based on the United Kingdom proposal be adopted placing the flow chart in square brackets and taking account of editorial comments from the expert from Belgium in paper ST/SG/AC.10/C.3/1999/77. This revised proposal is now presented in a form without explanatory text for adoption in the Model regulations. Some editorial amendments follow from this approach which are shown in bold type face. However, the expert from the United Kingdom does not agree with the expert from Belgium that preparations and mixtures can be included in the proposal at this stage.

Draft proposal

CHAPTER 2.9

2.9.2 CLASSIFICATION OF SUBSTANCES DANGEROUS TO THE ENVIRONMENT BY REASON OF AQUATIC POLLUTION

2.9.2.1 PURPOSE, BASIS AND APPLICABILITY

2.9.2.1.1 The scheme for classifying substances for the hazards they present to the aquatic environment is based on **criteria for the classification of substances hazardous to the aquatic environment presented in the OECD paper "Harmonised Integrated Hazard Classification System for Human Health and Environmental Effects of Chemical Substances" as endorsed by the 28th Joint meeting of the OECD Chemicals Committee and Working Party on Chemicals**. The aquatic environment may be considered in terms of the aquatic organisms that live in the water, and the aquatic ecosystem of which they are part.[1] The basis, therefore, of the identification of hazard is the aquatic toxicity of the substance, although this may be modified by taking account of the degradation and bioaccumulation behaviour.

2.9.2.2.5 This scheme is intended specifically for use with chemical substances **and does not address preparations or other mixtures.**[2] While the scheme is intended to apply to all substances, it is recognised that in some cases, e.g. metals or poorly soluble inorganic compounds, special guidance will be necessary.[3]

2.9.2.2 DEFINITIONS AND DATA REQUIREMENTS

2.9.2.2.1 The basic elements of the scheme are:

acute aquatic toxicity;
potential for or actual bioaccumulation;
degradation (biotic or abiotic) for organic chemicals; and
chronic aquatic toxicity.

2.9.2.2.2 While data from internationally harmonized test methods are preferred, in practice data from national methods may also be used where they are considered as equivalent. In general, it has been agreed that freshwater and marine species toxicity data can be considered as equivalent data and are preferably to be derived using OECD Test Guidelines or equivalent according to the principles of good laboratory practice (GLP). Where such data are not available, classification shall be based on the best available.

2.9.2.2.3 **Acute aquatic toxicity** shall normally be determined using a fish 96 hour LC_{50} (OECD Test Guideline 203 or equivalent), a crustacean species 48 hour EC_{50} (OECD Test Guideline 202 or equivalent) and/or an algal species 72 or 96 hour EC_{50} (OECD Test Guideline 201 or equivalent). These species are considered as surrogates for all aquatic organisms. Data on other species such as Lemna may also be considered if the test methodology is suitable.

---

[1] *This does not address aquatic pollutants for which there may be a need to consider effects beyond the aquatic environment such as the impacts on human health etc.*

[2] *It is intended to extend the Model Regulations at a later stage to cover preparations or other mixtures such as formulated pesticides.*

[3] *This can be found in the OECD Guidance Document.*

2.9.2.2.4 **The potential for or actual bioaccumulation** shall normally be determined by using the octanol/water partition coefficient, usually reported as a log Kow determined according to OECD Test Guideline 107 or 117. While this represents a potential to bioaccumulate, an experimentally determined Bioconcentration Factor (BCF) provides a better measure and shall be used in preference when available. A BCF shall be determined according to OECD Test Guideline 305.

2.9.2.2.5 **Degradation** for organic chemicals may be biotic or abiotic (eg. hydrolysis) and the criteria used reflect this fact (see 2.9.2.4). Ready biodegradation is most easily defined using the OECD biodegradability tests (OECD Test Guideline 301 (A - F)). A pass level in these tests may be considered as indicative of rapid degradation in most aquatic environments. As these are freshwater tests, use of results from OECD Test Guideline 306, which is more suitable for the marine environment, is also included. Where such data are not available, a BOD(5 days)/COD ratio >0.5 is considered as indicative of rapid degradation. Abiotic degradation such as hydrolysis, primary degradation, both abiotic and biotic, degradation in non-aquatic media and proven rapid degradation in the environment may all be considered in defining rapid degradability.[4]

2.9.2.2.6 **Chronic aquatic toxicity** data are less available than acute data and the range of testing procedures less standardised. Data generated according to the OECD Test Guidelines 210 (Fish Early Life Stage), 202 Part 2 or 211 (Daphnia Reproduction) and 201 (Algal Growth Inhibition) may be accepted. Other validated and internationally accepted tests may also be used. The 'no observed effect concentrations' (NOECs) or other equivalent L(E)Cx shall be used.

2.9.2.3 CLASSIFICATION CATEGORIES AND CRITERIA

2.9.2.3.1 Substances meeting the following criteria shall be categorised as 'dangerous to the aquatic environment' for transport purposes, if they satisfy the criteria for Acute I (and Chronic I by default) or Chronic II. These criteria describe in detail the classification categories set out diagrammatically in 2.9.2.6.

[4] *Special guidance on data interpretation is provided in the Guidance Document.*

Acute toxicity

Category: Acute I
Acute toxicity:

96 hr LC_{50} (for fish)	≤ 1 mg/L and/or
48 hr EC_{50} (for crustacea)	≤ 1 mg/L and/or
72 or 96hr ErC_{50} (for algae or other aquatic plants)	≤1 mg/L.

Category: Acute I may be subdivided for some regulatory systems to include a lower band at LC_{50} or EC_{50} ≤ 0.1 mg/L.

Chronic toxicity

Category: Chronic I
Acute toxicity:

96 hr LC_{50} (for fish)	≤ 1 mg/L and/or
48 hr EC_{50} (for crustacea)	≤ 1 mg/L and/or
72 or 96hr ErC_{50} (for algae or other aquatic plants)	≤ 1 mg/L

and the substance is not rapidly degradable and/or the log Kow≥ 4
(unless the experimentally determined BCF <500).

Category: Chronic II
Acute toxicity

96 hr LC_{50} (for fish)	>1 to ≤ 10 mg/L and/or
48 hr EC_{50} (for crustacea)	>1 to ≤ 10 mg/L and/or
72 or 96hr ErC_{50} (for algae or other aquatic plants)	>1 to ≤ 10 mg/L

and the substance is not rapidly degradable and/or the log Kow ≥4 (unless the experimentally determined BCF <500), unless the chronic toxicity NOECs are > 1 mg/L.

NOTES: RATIONALE FOR THE SCHEME

Note 1. *The classification scheme recognises that the core intrinsic hazard to aquatic organisms is represented by both the acute and chronic toxicity of a substance. Distinction is made between the acute hazard and the chronic hazard and therefore separate hazard categories are defined for both properties representing a gradation in the level of hazard identified. The lowest of the available toxicity values shall be used to define the appropriate hazard category(s). There may be circumstances, however, when a weight of evidence approach may be used. Acute toxicity data are the most readily available and the tests used are the most standardised. For that reason, these data form the core of the classification scheme.*

Note 2. *Acute toxicity represents a key property in defining the hazard where transport of large quantities of a substance may give rise to short-term dangers arising from accidents or major spillages. Hazards categories up to LC_{50} or EC_{50} values of 10 mg/L are thus defined, although categories up to 1000 mg/L may be used in certain regulatory frameworks. The Acute category I*

may be further sub-divided to include an additional category for acute toxicity LC_{50} or EC_{50} £0.1 mg/L in certain regulatory systems such as that defined by MARPOL 73/78 Annex II concerning bulk transport by sea.

Note 3. *For packaged substances it is considered that the principal hazard is defined by chronic toxicity, although acute toxicity at LC_{50} or EC_{50} levels £ 1 mg/L is also considered hazardous. Levels of substances up to 1 mg/L are considered to be possible in the aquatic environment following normal use and disposal. At toxicity levels above this, the short-term toxicity itself does not describe the principal hazard, which arises from low concentrations causing effects over a longer time scale. Thus, a number of hazard categories are defined which are based on levels of chronic aquatic toxicity. Chronic toxicity data are not available for many substances and it is necessary to use the available data on acute toxicity to estimate this property. The intrinsic properties of a lack of rapid degradability and/or a potential to bioconcentrate in combination with acute toxicity may be used to assign a substance to a chronic hazard category. Chronic toxicity showing NOECs >1 mg/L indicates that there is no chronic hazard category classification.*

Note 4. *While the current scheme uses acute toxicity data in combination with a lack of rapid degradation and/or a potential to bioaccumulate as the basis for classification for assigning a chronic hazard category, actual chronic toxicity data form a better basis for classification where these data are available. It is thus the intention that the scheme should be further developed to accommodate such data. It is anticipated that in such a further development, the available chronic toxicity data would be used to classify in the chronic hazard in preference to that derived from their acute toxicity in combination with a lack of rapid degradation and/or a potential to bioaccumulate.*

Note 5. *Recognition is given to the classification goals of MARPOL 73/78 Annex II that covers the transport of bulk quantities in ships' tanks, which are aimed at regulating operational discharges from ships and the assigning of suitable ship types. They go beyond protecting aquatic ecosystems, although that clearly is included. Additional hazard categories may thus be used which take account of factors such as physico-chemical properties and mammalian toxicity.*

Note 6. *The organisms fish, crustacea and algae are tested as surrogate species covering a range of trophic levels and taxa, and the test methods are highly standardised. Data on other organisms may also be considered, provided they represent equivalent species and test endpoints. The algal growth inhibition test is a chronic test, but the EC_{50} is treated as an acute value for classification purposes. This EC_{50} is normally based on growth rate inhibition. If only the EC_{50} based on reduction in biomass is available, or it is not indicated which EC_{50} is reported, this value may be used in the same way.*

Note 7. *Aquatic toxicity testing by its nature involves the dissolution of the substance under test in the water media used and the maintenance of a stable bioavailable exposure concentration over the course of the test. Some substances are difficult to test under standard procedures and special guidance will be developed on data interpretation for these substances and how the data should be used when applying the classification criteria.*

Note 8. *It is the bioaccumulation of substances within the aquatic organisms that can give rise to toxic effects over longer time scales even when actual water concentrations are low. The potential to bioaccumulate is determined by the partitioning between n-octanol and water. The relationship between the partition coefficient of an organic substance and its bioconcentration as measured by the BCF in fish has considerable scientific literature support. Using a cut-off value of log Kow (log P(o/w)) ³4 is intended to identify only those substances with a real potential to bioconcentrate. In recognition that the log Kow is only an imperfect surrogate for a measured BCF, such a*

measured value shall always take precedence. A BCF in fish of <500 indicates a low level of bioconcentration.

Note 9. *Substances that rapidly degrade can be quickly removed from the environment. While effects can occur, particularly in the event of a spillage or accident, they will be localised and of short duration. The absence of rapid degradation in the environment can mean that a substance in the water has the potential to exert toxicity over a long period and a wide area. One way of demonstrating rapid degradation utilises the biodegradation screening tests designed to determine whether a substance is 'readily biodegradable'. Thus a substance which passes this screening test is one that is likely to biodegrade 'rapidly' in the aquatic environment, and is thus unlikely to be persistent. However, a failure in the screening test does not necessarily mean that the substance will not degrade rapidly in the environment. Thus a further criterion allows the use of data to show that the substance did actually degrade biotically or abiotically in the aquatic environment by >70% in 28 days. Thus, if degradation is demonstrated under environmentally realistic conditions, then the definition of 'rapid degradability' is met. Many degradation data are available in the form of degradation half-lives and these may also be used in defining rapid degradation. Details regarding the interpretation of these data are further elaborated in the OECD Guidance Document. Some tests measure the ultimate biodegradation of the substance, i.e. full mineralisation is achieved. Primary biodegradation shall not normally qualify in the assessment of rapid degradability unless it can be demonstrated that the degradation products do not fulfil the criteria for classification as dangerous to the aquatic environment.*

Note 10. *The criteria used reflect the fact that environmental degradation may be biotic or abiotic (e.g. hydrolysis). Equally, failing the ready biodegradability criteria in the OECD tests does not mean that the substance will not be degraded rapidly in the real environment. Thus, where such rapid degradation can be shown, the substance shall be considered as rapidly degradable. Hydrolysis may be considered if the hydrolysis products do not fulfil the criteria for classification as dangerous to the aquatic environment. A specific definition of rapid degradability is included at 2.9.2.4. Other evidence of rapid degradation in the aquatic environment may also be considered and may be of particular importance where the substances inhibit microbial activity at the concentration levels used in standard testing. The range of available data and guidance on its interpretation are provided in the OECD Guidance Document.*

Note 11. *For inorganic compounds and metals, the concept of degradability as applied to organic compounds has limited or no meaning. Rather the substance may be transformed by normal environmental processes either to increase or to decrease the bioavailability of the toxic species. Equally the use of bioaccumulation data shall be treated with care. Specific guidance will be provided on how these data for such substances may be used in meeting classification criteria requirements.*

Note 12. *Poorly soluble inorganic compounds and metals may be acutely or chronically toxic in the aquatic environment depending on the intrinsic toxicity of the bioavailable inorganic species and the rate and amount of this species which may enter solution. A protocol for testing these poorly soluble substances is being developed and will be covered further in the OECD Guidance Document.*

Note 13. *While experimentally derived test data are preferred, where no experimental data are available, validated Quantitative Structure Activity Relationships (QSARs) for aquatic toxicity and log Kow may be used in the classification process. Such validated QSARs may be used without modification to the agreed criteria, if restricted to chemicals for which their mode of action and applicability are well characterized. Validity may be judged according to the criteria established*

within the US-EPA/EU/Japan Collaborative Project. Reliable calculated toxicity and log Kow values shall be valuable in a safety net context. QSARs for predicting ready biodegradation are not yet sufficiently accurate to predict rapid degradation.

2.9.2.4 RAPID DEGRADABILITY

2.9.2.4.1 Substances are considered rapidly degradable in the aquatic environment if the following criteria are met:

(a) if in 28-day ready biodegradation studies, the following levels of degradation are achieved;
tests based on dissolved organic carbon: 70%

tests based on oxygen depletion or carbon dioxide generation: 60% of theoretical maxima

These levels of biodegradation shall 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.

or

(b) if, in those cases where only BOD and COD data are available, when the ratio of BOD5/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.

2.9.2.5 CLASSIFICATION SCHEME FOR SUBSTANCES DANGEROUS IN TRANSPORT TO THE AQUATIC ENVIRONMENT[5]

Toxicity		Degradability (note 3)	Bioaccumulation (note 4)	Classification	
Acute (note 1)	Chronic (note 2)			Acute	Chronic
Box 1 value ≤1.00 Box 2 1.0 < value ≤ 10.0	 Box 7 value > 1.00	Box 5 lack of rapid degradability	Box 6 BCF ≥ 500 or, if absent log Kow ≥ 4	<u>Acute I</u> Box 1	<u>Chronic I</u> Boxes 1+5+6 Boxes 1+5 Boxes 1+6 <u>Chronic II</u> Boxes 2+5+6 Boxes 2+5 Boxes 2+6 Unless Box 7

Notes to the table:

Note 1. Acute toxicity band based on LC_{50} or EC_{50} values in mg/L for fish, crustacea and/or algae or other aquatic plants (or QSAR estimation if no experimental data)
Where the algal toxicity ErC_{50} [= EC_{50} (growth rate)] falls more than 100 times below the next most sensitive species and results in a classification based solely on this effect, consideration shall be given to whether this toxicity is representative of the toxicity to aquatic plants. Where it can be shown that this is not the case, professional judgement may be used in deciding if classification shall be applied. Classification shall be based on the ErC_{50}. In circumstances where the basis of the EC_{50} is not specified and no ErC_{50} is recorded, classification shall be based on the lowest EC_{50} available.

Note 2. Chronic toxicity band based on NOEC values in mg/L for fish or crustacea or other recognised measures for long-term toxicity[6].

Note 3. Lack of rapid degradability is based on either a lack of ready biodegradability or other evidence of lack of rapid degradation.

Note 4. Potential to bioaccumulate, based on an experimentally derived BCF ≥ 500 or, if absent, a log Kow ≥ 4 provided log Kow is an appropriate descriptor for the bioaccumulation potential of the substance. Measured log Kow values take precedence over estimated values and measured BCF values take precedence over log Kow values.

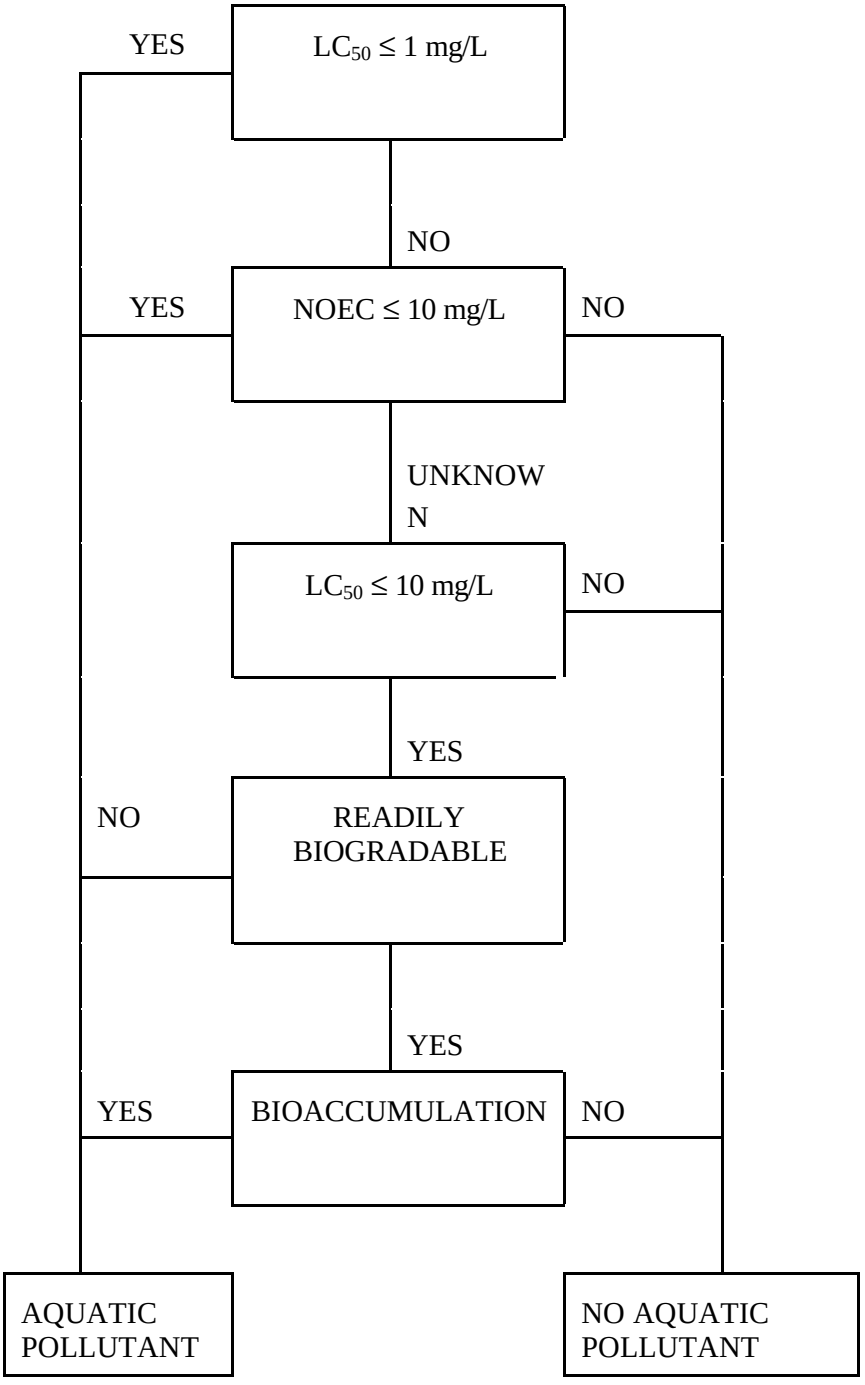
---

[5] *Abridged OECD table*

[6] *It is intended to develop the system further to include chronic toxicity data.*

.

2.9.2.6 PROCEDURE FOR CLASSIFYING A SUBSTANCE DANGEROUS TO THE AQUATIC ENVIRONMENT WHEN TRANSPORTED IN PACKAGES



2.9.2.7 Substances dangerous to the aquatic environment not otherwise classified under these Regulations should be designated:

UN 3077 [ENVIRONMENTALLY HAZARDOUS SUBSTANCE] SOLID, N.O.S. or

UN 3082 [ENVIRONMENTALLY HAZARDOUS SUBSTANCE] LIQUID, N.O.S.

They shall be assigned to packing Group III

Consequential amendments

United Nations Recommendations on the Transport of Dangerous Goods

Amend paragraph 10 to read:

> "Many of the substances listed in Classes 1 to 9 are deemed as being dangerous to the environment. Additional labelling is not always specified except for transport by sea. Criteria for substances dangerous to the aquatic environment are given in Chapter 2.9 of the Model Regulations."

Chapter 3.3

Amend special provision 179 to read:

> "This designation shall be used for substances which are dangerous to the aquatic environment or which are marine pollutants that do not meet the classification criteria of any other class or another substance within Class 9. This designation may also be used for wastes not otherwise subject to these Regulations but which are covered under the Basel Convention."

ANNEX A

Annex 2: Classification scheme for substances hazardous to the aquatic environment

Toxicity		Degradability (note 3)	Bioaccumulation (note 4)	Classification categories	
Acute (note 1)	Chronic (note 2)			Acute	Chronic
Box 1 value £ 1.00		Box 5	Box 6	Class: Acute I Box 1	Class: Chronic I Boxes 1+5+6 Boxes 1+5 Boxes 1+6
Box 2 1.00< value £ 10.0		Lack of rapid degradability	BCF ³ 500 or, if absent log Kow ³4	Class: Acute II Box 2	Class: Chronic II Boxes 2+5+6 Boxes 2+5 Boxes 2+6 Unless Box 7
Box 3 10.0< value £100				Class: Acute III Box 3	Class: Chronic III Boxes 3+5+6 Boxes 3+5 Boxes 3+6 Unless Box 7
Box 4 No acute toxicity (note 5)	Box 7 value>1.00				Class: Chronic IV Boxes 4+5+6 Unless Box 7

Notes to the table:

Note 1a. **Acute toxicity band based on L(E)C-50 values in mg/L for fish, crustacea and/or algae or other aquatic plants (or QSAR estimation if no experimental data)**

Note 1b **Where the algal toxicity ErC-50 [= EC-50 (growth rate)] falls more than 100 times below the next most sensitive species and results in a classification based solely on this effect, consideration should be given to whether this toxicity is representative of the toxicity to aquatic plants. Where it can be shown that this is not the case, professional judgement should be used in deciding if classification should be applied. Classification should be based on the ErC-50. In circumstances where the basis of the EC-50 is not specified and no ErC-50 is recorded, classification should be based on the lowest EC-50 available.**

Note 2a. **Chronic toxicity band based on NOEC values in mg/L for fish or crustacea or other recognised measures for long-term toxicity.**

Note 2b. **It is the intention that the system be further developed to include chronic toxicity data.**

Note 3. **Lack of rapid degradability is based on either a lack of Ready Biodegradability or other evidence of lack of rapid degradation.**

Note 4. **Potential to bioaccumulate, based on an experimentally derived BCF ³ 500 or, if absent, a log Kow ³ 4 provided log Kow is an appropriate descriptor for the bioaccumulation potential of the substance. Measured log Kow values take precedence over estimated values and measured BCF values take precedence over log Kow values.**

Note 5. **"No acute toxicity" is taken to mean that the L(E)C-50 is above the water solubility. Also for poorly soluble substances, (w.s. < 1.00 mg/L), where there is evidence that the acute test would not have provided a true measure of the intrinsic toxicity.**

_____