

ECONOMIC COMMISSION FOR EUROPE

INLAND TRANSPORT COMMITTEE

Working Party on the Transport of Dangerous Goods

Joint Meeting of the RID Safety Committee and the
Working Party on the Transport of Dangerous Goods
(Bern, 24-28 March 2003)

HARMONIZATION WITH THE UNITED NATIONS
MODEL REGULATIONS ON THE TRANSPORT OF DANGEROUS GOODS

Draft proposal of amendments to Part 2 of RID/ADR/ADN

Prepared by the UNECE secretariat

NOTE: The proposal is based on ST/SG/AC.10/29/Add.1.
Stricken out text means that the amendment does not seem relevant for RID/ADR/ADN.
Text in square brackets means that the relevance of the text for RID/ADR/ADN should be discussed by the Working Group of the Joint Meeting.

PART 2

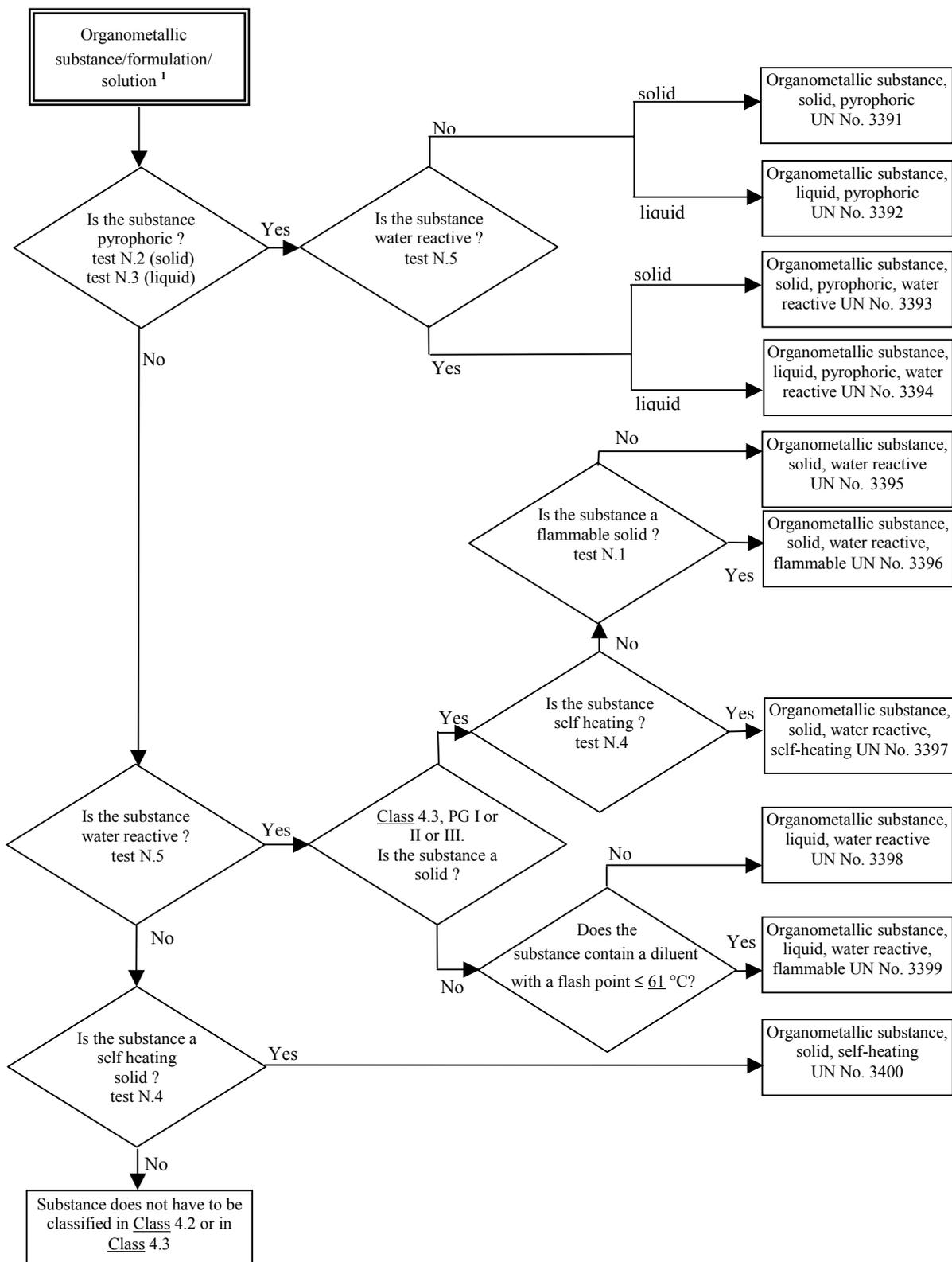
~~2.4.52.1.5~~ Add a new paragraph ~~2.4.5~~ and a new figure ~~2.4.2-2.1.5~~ as follows:

"~~2.4.5~~ 2.1.5 Classification of organometallic substances

Depending on their properties, organometallic substances may be classified in ~~divisions~~ Classes 4.2 or 4.3, as appropriate, in accordance with the flowchart scheme given in figure ~~2.4.2~~ 2.1.5.

[NOTE: Flammable solutions with organometallic compounds in concentrations which are not liable to spontaneous combustion or, in contact with water, do not emit flammable gases, are substances of Class 3.]

Figure 2.4.2 2.1.5: Flowchart scheme for organometallic substances²



¹ If applicable and testing is relevant, taking into account reactivity properties, class 6.1 and 8 properties should be considered according to the precedence of hazard table 2.0.3.3.

² Test methods N.1 to N.5 can be found in the Manual of Tests and Criteria, Part III, Section 33.

2.2.3.3 [In the “liquefied gases” table, Classification code 2F, add the following text at the end of the existing name for UN No. 1010 “or BUTADIENES AND HYDROCARBON MIXTURE, STABILIZED, containing more than 40% butadienes”.]

In the table for “other Articles containing gas under pressure”, Classification code 6A, add the UN No 2857 as follows: “2857 REFRIGERATING MACHINES containing non-flammable, non-toxic gases or ammonia solutions (UN 2672)”.

Chapter Section 2.2.3

~~2.3.1.4~~2.2.3.1.1 In the last sentence of the third paragraph, replace “and UN 3357” with “, UN-3357 and UN-3379”.

2.2.3.3 Classification code D: add a new entry as follows “3379 DESENSITIZED EXPLOSIVE, LIQUID, N.O.S.”.

Chapter Section 2.2.41

Add a new introductory note to read as follows:

~~“NOTE 3: Since organometallic substances can be classified in divisions 4.2 or 4.3 with additional subsidiary risks, depending on their properties, a specific classification flow chart for these substances is given in 2.4.5.”~~

~~2.4.2.3.2.2~~ 2.2.41.1.12 Amend the two first sentences of this paragraph to read as follows:

“Self-reactive substances permitted for ~~transport~~ carriage in packagings are listed in ~~2.4.2.3.2.3~~ 2.2.41.4, those permitted for ~~transport~~ carriage in IBCs are listed in packing instruction IBC520 and those permitted for ~~transport~~ carriage in portable tanks are listed in portable tank instruction T23. For each permitted substance listed, the appropriate generic entry of the Dangerous Goods List (UN Nos. 3221 to 3240) is assigned, and appropriate subsidiary risks and remarks providing relevant transport information are given.”.

2.2.41.3 Classification code D: add a new entry as follows “3380 DESENSITIZED EXPLOSIVE, SOLID, N.O.S.”.

~~2.4.2.3.2.3~~ 2.2.41.4 ~~In the title, add at the end: “in packages”:~~ Amend the title to read “list of currently assigned self-reactive substances in packagings”.

Add the following text before the existing Note 1:

“In the column “Packing Method” codes “OP1” to “OP8” refer to packing methods in packing instruction P520 (see also 4.1.7.1). Self-reactive substances to be transported shall fulfil the classification and the control and emergency temperatures (derived from the SADT) as listed.”.

Delete note 4 2. As a consequence, “NOTE 1” becomes “NOTE”.

~~2.4.2.3.2.4~~ 2.2.41.1.13 Amend the beginning of the first sentence to read: “Classification of self-reactive substances not listed in ~~2.4.2.3.2.3~~ 2.2.41.4, packing instruction IBC520 or portable tank instruction T23 and assignment to...”.

~~2.4.2.4.1~~ 2.2.41.1.18 Add UN No. 3380 to the list of UN numbers.

Section 2.2.42

2.2.42.1.5 Add a **NOTE 3** to read: "**NOTE 3:** *Since organometallic substances can be classified in Classes 4.2 or 4.3 with additional subsidiary risks, depending on their properties, a specific classification flow chart for these substances is given in 2.1.5.*"

2.2.42.3 [For the substances without subsidiary risk, create a new Classification code S5, "organometallic" and assign it the following entries
"3391 ORGANOMETALLIC SUBSTANCE, SOLID, PYROPHORIC
3392 ORGANOMETALLIC SUBSTANCE, LIQUID, PYROPHORIC
3400 ORGANOMETALLIC SUBSTANCE, SOLID, SELF-HEATING".]

Classification code SW, delete the entries for UN Nos 3049, 3050 and 3203 (2 entries each) and the related notes. Insert new entries as follows:

"3393 ORGANOMETALLIC SUBSTANCE, SOLID, PYROPHORIC, WATER REACTIVE
3394 ORGANOMETALLIC SUBSTANCE, LIQUID, PYROPHORIC, WATER REACTIVE
3433 LITHIUM ALKYL, SOLID".

Section 2.2.43

2.2.43.1.5 Add a **NOTE** to read: "**NOTE:** *Since organometallic substances can be classified in Classes 4.2 or 4.3 with additional subsidiary risks, depending on their properties, a specific classification flow chart for these substances is given in 2.1.5.*"

2.2.43.3 insert ", LIQUID" at the end of UN Nos 1389 and 1392 (Classification code W2) and move them to Classification code W1.

Classification code W1, insert new entries as follows:

"1420 POTASSIUM METAL ALLOYS, LIQUID
1422 POTASSIUM SODIUM ALLOYS, LIQUID".

Classification code W2, insert new entries as follows:

"3395 ORGANOMETALLIC SUBSTANCE, SOLID, WATER REACTIVE
3401 ALKALI METAL AMALGAM, SOLID
3402 ALKALINE EARTH METAL AMALGAM, SOLID
3403 POTASSIUM METAL ALLOYS, SOLID
3404 POTASSIUM SODIUM ALLOYS, SOLID".

Classification code WF1, delete all the existing entries and insert a new entry as follows:

"3399 ORGANOMETALLIC SUBSTANCE, LIQUID, WATER REACTIVE, FLAMMABLE".

Classification code WF2, delete the entry for UN No. 3132 and insert a new entry as follows:

"3396 ORGANOMETALLIC SUBSTANCE, SOLID, WATER REACTIVE, FLAMMABLE".

Classification code WS, insert a new entry as follows:

"3397 ORGANOMETALLIC SUBSTANCE, SOLID, WATER REACTIVE, SELF HEATING".

Chapter Section 2.2.52

~~2.5.3.2.3~~ 2.2.52.1.4 Amend the two first sentences of this paragraph to read as follows:

"Organic peroxides permitted for transport in packagings are listed in ~~2.5.3.2.4~~ 2.2.52.4, those permitted for transport in IBCs are listed in packing instruction IBC520 and those permitted for transport in portable tanks are listed in portable tank instruction T23. For each permitted substance listed, the generic entry of the Dangerous Goods List (UN Nos. 3101 to 3120) is assigned, appropriate subsidiary risks and remarks providing relevant transport information are given."

~~2.5.3.2.4~~ 2.2.52.4 In the title add, at the end: "in packagings".

Replace the existing note under the title with the following text:

"Packing Method" codes "OP1" to "OP8" refer to packing methods in packing instruction P520 (see 4.1.4.1, packing instruction P520 and 4.1.7.1). Peroxides to be transported shall fulfill the classification and the control and emergency temperatures (derived from the SADT) as listed. For substances permitted in IBCs see packing instruction IBC520 and, for those permitted in tanks, see portable tank instruction T23."

In the table:

In the column "Subsidiary risks and remarks", delete "30)".

Amend the entries listed below as follows:

| Organic peroxide | | Column | Amendment |
|---|---|--|--|
| ACETYL BENZOYL PEROXIDE | | | Delete |
| tert-AMYL PEROXYACETATE | | Packing method Number | Replace "OP8" with "OP7" Replace "3107" with "3105" |
| tert-BUTYL CUMYL PEROXIDE | (1 st row) | Packing method Number | Replace "OP7" with "OP8" Replace "3105" with "3107" |
| | (2 nd row) | Concentration Inert solid Packing method Number | Replace " ≤ 42 " with " ≤ 52 " Replace " ≥ 58 " with " ≥ 48 " Replace "OP7" with "OP8" Replace "3106" with "3108" |
| n-BUTYL-4,4-DI-(tert-BUTYLPEROXY)VALERATE | (2 nd row) | | Delete |
| | (3 rd row) | Concentration Inert solid | Replace " ≤ 42 " with " ≤ 52 " Replace " ≥ 58 " with " ≥ 48 " |
| tert-BUTYL HYDROPEROXIDE | (4 th row) | Packing method | Delete ",N,M" |
| tert-BUTYL MONOPEROXYPHthalate | | | Delete |
| tert-BUTYL PEROXYACETATE | (3 rd row) | Diluent type A Diluent type B Packing method | Delete " ≥ 68 " Add " ≥ 68 " Delete ",N" |
| | (4 th and 5 th rows) | | Delete |
| tert-BUTYL PEROXYBENZOATE | (1 st row) | Diluent type A | Delete "< 22" |

| Organic peroxide | | Column | Amendment |
|--|---|--------------------------|--|
| tert-BUTYL PEROXYDIETHYLACETATE + tert-BUTYL PEROXYBENZOATE | | Delete | |
| tert-BUTYL PEROXY-2-ETHYLHEXANOATE | 5 th and 6 th rows | Delete | |
| tert-BUTYL PEROXYISOBUTYRATE | (1 st row) | Diluent type B | Replace ">23" with "≥23" |
| | (2 nd row) | Diluent type B | Replace ">48" with "≥48" |
| tert-BUTYL PEROXYNEODECANOATE | (3 rd row) | Delete | |
| | (4 th row) | Number | Replace "3117" with "3119" |
| | (6 th row) | Packing method | Delete ",N" |
| tert-BUTYL PEROXYPIVALATE | (4 th and 5 th rows) | Delete | |
| 3-tert-BUTYLPEROXY-3-PHENYLPHTHALIDE | | Delete | |
| tert-BUTYL PEROXY-3,5,5-TRIMETHYLHEXANOATE | (2 nd row) | Diluent type A | Delete "≥ 68" |
| | | Diluent type B | Add "≥ 68" |
| | | Packing method | Delete ", N" |
| | (3 rd row) | Delete | |
| CUMYL HYDROPEROXIDE | (2 nd row) | Packing method | Delete ", M, N" |
| CUMYL PEROXYNEODECANOATE | (3 rd row) | Delete | |
| DIBENZOYL PEROXIDE | (8 th row) | Delete | |
| | (11 th row) | Packing method | Delete ",N" |
| DIBENZYL PEROXYDICARBONATE | | Delete | |
| DI-(4-tert-BUTYLCYCLOHEXYL) PEROXYDICARBONATE | (2 nd row) | Packing method | Delete ",N" |
| DI-tert-BUTYL PEROXIDE | (1 st row) | Concentration | Replace ">32" with ">52" |
| | (2 nd row) | Packing method | Delete ",N" |
| | (3 rd row) | Delete | |
| 1,1-DI-(tert-BUTYLPEROXY) CYCLOHEXANE | (5 th row) | Diluent type A | Replace "≥ 36" with "≥ 25" |
| | (6 th row) | Packing method | Delete ",N" |
| 1,1-DI-(tert-BUTYLPEROXY)-3,3,5-TRIMETHYLCYCLOHEXANE | (3 rd row) | Packing method Number | Replace "OP7" with "OP5" Replace "3105" with "3103" |
| | (4 th row) | Packing method Number | Replace "OP7" with "OP8" Replace "3106" with "3110" |
| DICETYL PEROXYDICARBONATE | (2 nd row) | Packing method | Delete ",N" |
| DICUMYL PEROXIDE | (1 st row) | Concentration | Replace "42" with "52" |
| | | Packing method | Delete ",M" |
| DICYCLOHEXYL PEROXYDICARBONATE | (1 st and 2 nd rows) | Control temperature | Replace "+5" with "+10" |
| | | Emergency temperature | Replace "+10" with "+15" |

| Organic peroxide | | Column | Amendment |
|--|--|---|---|
| DI-(2-ETHYLHEXYL) PEROXYDICARBONATE | (3 rd row) | Organic peroxide | This amendment does not apply to the English version |
| | (5 th row) | Delete | |
| | (6 th row) | Concentration Number | Replace "42" with "52" Replace "3118" with "3120" |
| DIETHYL PEROXYDICARBONATE | | Delete | |
| DIISOTRIDECYL PEROXYDICARBONATE | | Delete | |
| DILAUROYL PEROXIDE | (2 nd row) | Packing method | Delete ",N" |
| 2,5-DIMETHYL-2,5-DI-(tert-BUTYLPEROXY)HEXANE | (2 nd row) | Delete | |
| DIMYRISTYL PEROXYDICARBONATE | (3 rd row) | Delete | |
| DIPEROXY AZELAIC ACID | | Delete | |
| DIPEROXY DODECANE DIACID | | Delete | |
| DISTEARYL PEROXYDICARBONATE | | Delete | |
| DI-(3,5,5-TRIMETHYLHEXANOYL) PEROXIDE | (2 nd row) | Packing method | Delete ", N" |
| | (4 th and 5 th rows) | Delete | |
| DI-(3,5,5-TRIMETHYL-1,2-DIOXOLANYL-3) PEROXIDE | | Delete | |
| 3,3,6,6,9,9-HEXAMETHYL-1,2,4,5-TETRAOXACYCLONONANE | | Delete | |
| ISOPROPYLCUMYL HYDROPEROXIDE | | Packing method | Delete ", M, N" |
| p-MENTHYL HYDROPEROXIDE | (2 nd row) | Packing method | Delete ", M, N" |
| METHYL ETHYL KETONE PEROXIDE(S) | (1 st row) | Concentration | Replace "≤ 52" with "see remark 8)" |
| | (2 nd row) | Concentration | Replace "≤ 45" with "see remark 9)" |
| | (3 rd row) | Concentration | Replace "≤ 40" with "see remark 10)" |
| | (4 th row) | Delete | |
| PEROXYACETIC ACID, TYPE F, stabilized | (1 st row) | Packing method | Delete ", N" |
| | (2 nd row) | Delete | |
| PINANYL HYDROPEROXIDE | (1 st row) | Concentration | Replace "56" with ">56" |
| | (2 nd row) | Concentration Diluent type A Packing method | Replace "<56" with "≤ 56" Replace ">44" with "≥44" Delete ", M" |
| TETRAHYDRONAPHTHYL HYDROPEROXIDE | | Delete | |
| 1,1,3,3-TETRAMETHYLBUTYL PEROXY-2 ETHYLHEXANOATE | | Control temperature Emergency temperature | Replace "+20" with "+15" Replace "+25" with "+20" |
| 1,1,3,3-TETRAMETHYLBUTYL PEROXYPHENOACETATE | | Delete | |

Insert the following new entries:

| Organic peroxide | (2) | (3) | (4) | (5) | (6) | (7) | (8) | (9) | (10) | (11) |
|---|--------------------------------------|------|------|-----|-----|-----|-----|-----|------|------|
| tert-AMYLPEROXY ISOPROPYL CARBONATE | ≤ 77 | ≥ 23 | | | | OP5 | | | 3103 | |
| tert-BUTYL PEROXYNEO-HEPTANOATE <i>(new second row)</i> | ≤ 42 as a stable dispersion in water | | | | | OP8 | 0 | +10 | 3117 | |
| 1,6-Di-(tert-BUTYLPEROXY-CARBONYLOXY) HEXANE | ≤ 72 | ≥ 28 | | | | OP5 | | | 3103 | |
| DICYCLOHEXYL PEROXYDICARBONATE <i>(new third row)</i> | ≤ 42 as a stable dispersion in water | | | | | OP8 | +15 | +20 | 3119 | |
| 1-(2-ETHYLHEXANOYL-PEROXY)-1,3-DIMETHYLBUTYL PEROXYPIVALATE | ≤ 52 | ≥ 45 | ≥ 10 | | | OP7 | -20 | -10 | 3115 | |
| PEROXYLAURIC ACID | ≤ 100 | | | | | OP8 | +35 | +40 | 3118 | |
| POLYETHER POLY-tert-BUTYLPEROXY-CARBONATE | ≤ 52 | | ≥ 23 | | | OP8 | | | 3107 | |
| 1,1,3,3-TETRAMETHYL-BUTYL PEROXYPIVALATE | ≤ 77 | ≥ 23 | | | | OP7 | 0 | +10 | 3315 | |

2.5.3.2.4 2.2.52.4 Notes after the table:

Note 1): Add the following sentence at the end: "*Boiling point diluent type B should be at least 60°C higher than the SADT of the organic peroxide.*".

~~Note 3): Add at the end: "*(Model No. 1, see 5.2.2.2.2).*".~~

Note 8): Amend to read as follows: "*Available oxygen > 10% and ≤ 10.7%, with or without water.*".

Note 9): Amend to read as follows: "*Available oxygen ≤ 10%, with or without water.*".

Note 10): Amend to read as follows: "*Available oxygen ≤ 8,2%, with or without water.*".

~~Note 13): Add at the end: "*(Model No. 8, see 5.2.2.2.2).*".~~

Note 21): Amend to read as follows: "*With ≥ 25% diluent type A by mass, and in addition ethylbenzene.*".

Note 22): Amend to read as follows: "*With ≥ 19% diluent type A by mass, and in addition methyl isobutyl ketone.*".

~~Note 27): Add at the end: "*(Model No. 8, see 5.2.2.2.2).*".~~

~~Note 29): Replace "*regulations*" with "*Model Regulations*".~~

Note 30): Delete

~~2.5.3.2.5~~ 2.2.52.1.8 Amend the beginning of the first sentence to read: "Classification of organic peroxides not listed in ~~2.5.3.2.4~~ 2.2.52.4, packing instruction IBC520 or portable tank instruction T23 and assignment to...".

Chapter Section 2.2.6x

~~2.6.1(b)~~ 2.2.62.1.1 Replace in the last sentence of the first paragraph "or recombinant micro-organisms (hybrid or mutant), that are known or reasonably expected to cause infectious disease in animals or humans." with "and other agents such as prions, which can cause disease in humans or animals."

~~2.6.2.1.1~~ 2.2.61.1.3 Replace the existing definition for " *LD₅₀ for acute oral toxicity*" with the following text:

"*LD₅₀ (median lethal dose) for acute oral toxicity* is the statistically derived single dose of a substance that can be expected to cause death within 14 days in 50 per cent of young adult albino rats when administered by the oral route. The *LD₅₀* value is expressed in terms of mass of test substance per mass of test animal (mg/kg)."

~~2.6.2.2.4.3~~ 2.2.61.1.7 In table footnote "a", replace "Tear gases" with "Tear gas substances".

2.2.61.3 Classification code T1, amend the following entries to read:

"3276 NITRILES, TOXIC, LIQUID, N.O.S.";

"3278 ORGANOPHOSPHORUS COMPOUND, TOXIC, LIQUID, N.O.S.";

[Insert new entries as follows:

"3381 TOXIC BY INHALATION LIQUID, N.O.S. with an inhalation toxicity lower than or equal to 200 ml/m³ and saturated vapour concentration greater than or equal to 500 LC₅₀

3382 TOXIC BY INHALATION LIQUID, N.O.S. with an inhalation toxicity lower than or equal to 1000 ml/m³ and saturated vapour concentration greater than or equal to 10 LC₅₀."]

Classification code T2, delete the entry for UN No. 3278.

Classification code T3, amend liquid entries for UN Nos 3280, 3281 and 3282 as follows:

"3280 ORGANOARSENIC COMPOUND, LIQUID, N.O.S.";

"3281 METAL CARBONYLS, LIQUID, N.O.S.";

"3282 ORGANOMETALLIC COMPOUND, LIQUID, TOXIC, N.O.S.".

Delete the solid entries of UN Nos 3280, 3281 and 3282.

Insert new entries as follows:

"3465 ORGANOARSENIC COMPOUND, SOLID, N.O.S.

3466 METAL CARBONYLS, SOLID, N.O.S.

3467 ORGANOMETALLIC COMPOUND, TOXIC, SOLID, N.O.S.".

Classification code T4, [insert new entries as follows:

"3381 TOXIC BY INHALATION LIQUID, N.O.S. with an inhalation toxicity lower than or equal to 200 ml/m³ and saturated vapour concentration greater than or equal to 500 LC₅₀

3382 TOXIC BY INHALATION LIQUID, N.O.S. with an inhalation toxicity lower than or equal to 1000 ml/m³ and saturated vapour concentration greater than or equal to 10 LC₅₀."]

Insert a new entry as follows:

"3440 SELENIUM COMPOUND, LIQUID, N.O.S.".

Classification code T5, amend the entry for UN No. 3283 to read:

“3283 SELENIUM COMPOUND, SOLID, N.O.S.”.

Classification code T8, amend the entry for UN No. 3315 to read:

“3315 CHEMICAL SAMPLE, TOXIC”.

Classification code FT1, insert new entries as follows:

“3383 TOXIC BY INHALATION LIQUID, FLAMMABLE, N.O.S. with an inhalation toxicity lower than or equal to 200 ml/m³ and saturated vapour concentration greater than or equal to 500 LC₅₀

3384 TOXIC BY INHALATION LIQUID, FLAMMABLE, N.O.S. with an inhalation toxicity lower than or equal to 1000 ml/m³ and saturated vapour concentration greater than or equal to 10 LC₅₀”.

Classification code TW1, insert new entries as follows:

“3385 TOXIC BY INHALATION LIQUID, WATER-REACTIVE, N.O.S. with an inhalation toxicity lower than or equal to 200 ml/m³ and saturated vapour concentration greater than or equal to 500 LC₅₀

3386 TOXIC BY INHALATION LIQUID, WATER-REACTIVE, N.O.S. with an inhalation toxicity lower than or equal to 1000 ml/m³ and saturated vapour concentration greater than or equal to 10 LC₅₀”.

Classification code TO1, insert new entries as follows:

“3387 TOXIC BY INHALATION LIQUID, OXIDIZING, N.O.S. with an inhalation toxicity lower than or equal to 200 ml/m³ and saturated vapour concentration greater than or equal to = 500 LC₅₀

3388 TOXIC BY INHALATION LIQUID, OXIDIZING, N.O.S. with an inhalation toxicity lower than or equal to 1000 ml/m³ and saturated vapour concentration greater than or equal to 10 LC₅₀”.

[Classification code TC1, insert new entries as follows:

“3389 TOXIC BY INHALATION LIQUID, CORROSIVE, N.O.S. with an inhalation toxicity lower than or equal to 200 ml/m³ and saturated vapour concentration greater than or equal to = 500 LC₅₀

3390 TOXIC BY INHALATION LIQUID, CORROSIVE, N.O.S. with an inhalation toxicity lower than or equal to 1000 ml/m³ and saturated vapour concentration greater than or equal to 10 LC₅₀”.]

[Classification code TC3, insert new entries as follows:

“3389 TOXIC BY INHALATION LIQUID, CORROSIVE, N.O.S. with an inhalation toxicity lower than or equal to 200 ml/m³ and saturated vapour concentration greater than or equal to = 500 LC₅₀

3390 TOXIC BY INHALATION LIQUID, CORROSIVE, N.O.S. with an inhalation toxicity lower than or equal to 1000 ml/m³ and saturated vapour concentration greater than or equal to 10 LC₅₀”.]

~~2.6.3-2.2.62~~ Replace the existing text with the following:

~~2.6.3 2.2.62~~ Division Class 6.2 - Infectious substances

2.2.62.1 Criteria

~~2.6.3.1~~ — *Definitions*

For the purposes of these Regulations:

~~2.6.3.1.1~~ 2.2.62.1.1 The heading of Class 6.2 covers infectious substances. For the purposes of RID/ADR/ADN, infectious substances are substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals.

NOTE 1 (Existing **NOTE 3**)

NOTE 2 (Existing **NOTE 4**)

2.2.62.1.2 (unchanged)

Definitions

2.2.62.1.3 For the purposes of RID/ADR/ADN,

~~2.6.3.1.2~~ *Biological products* are those products derived from living organisms which are manufactured and distributed in accordance with the requirements of appropriate national authorities, which may have special licensing requirements, and are used either for prevention, treatment, or diagnosis of disease in humans or animals, or for development, experimental or investigational purposes related thereto. They include, but are not limited to, finished or unfinished products such as vaccines;

~~2.6.3.1.3~~ *Cultures* (laboratory stocks) are the result of a process by which pathogens are amplified or propagated in order to generate high concentrations, thereby increasing the risk of infection when exposure to them occurs. This definition refers to cultures prepared for the intentional generation of pathogens and does not include cultures intended for diagnostic and clinical purposes;

~~2.6.3.1.4~~ *Genetically modified micro-organisms and organisms* are micro-organisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally;

~~2.6.3.1.5~~ *Medical or clinical wastes* are wastes derived from the medical treatment of animals or humans or from bio-research.

~~2.6.3.2~~ — *Classification of infectious substances*

Classification

~~2.6.3.2.1~~ 2.2.62.1.4 Infectious substances shall be classified in ~~Division~~ **Class 6.2** and assigned to UN Nos 2814, UN-2900 or UN-3373, as appropriate.

~~2.6.3.2.3~~ **NOTE 1:** *Substances which do not contain infectious substances or substances which are unlikely to cause disease in humans or animals are not subject to ~~these Regulations~~ the provisions of RID/ADR/ADN unless they meet the criteria for inclusion in another class.*

~~2.6.3.2.4~~ **NOTE 2:** *Blood or blood components which have been collected for the purposes of transfusion or for the preparation of blood products to be used for transfusion or transplantation and any tissues or organs intended for use in transplantation are not subject to ~~these Regulations~~ the provisions of RID/ADR/ADN.*

~~2.6.3.2.5~~ **NOTE 3:** *Substances for which there is a low probability that infectious substances are present, or where the concentration is at a level naturally encountered, are not subject to ~~these Regulations~~ the provisions of RID/ADR/ADN. Examples are: foodstuffs, water samples, living persons and substances which have been treated so that the pathogens have been neutralized or deactivated.*

~~2.6.3.2.2~~ Infectious substances are divided into the following categories:

~~2.6.3.2.2.1~~ ~~2.2.62.1.4.1~~ **Category A:** An infectious substance which is ~~transported~~ carried in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease to humans or animals. Indicative examples of substances that meet these criteria are given in the table in this paragraph.

NOTE : *An exposure occurs when an infectious substance is released outside of the protective packaging, resulting in physical contact with humans or animals.*

- (a) Infectious substances meeting these criteria which cause disease in humans or both in humans and animals shall be assigned to UN No. 2814. Infectious substances which cause disease only in animals shall be assigned to UN No. 2900.
- (b) Assignment to UN No. 2814 or UN No. 2900 shall be based on the known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgement concerning individual circumstances of the source human or animal.

NOTE 1: *The proper shipping name for UN No. 2814 is INFECTIOUS SUBSTANCE, AFFECTING HUMANS. The proper shipping name for UN No. 2900 is INFECTIOUS SUBSTANCE, AFFECTING ANIMALS only.*

NOTE 2: *The following table is not exhaustive. Infectious substances, including new or emerging pathogens, which do not appear in the table but which meet the same criteria shall be assigned to Category A. In addition, if there is doubt as to whether or not a substance meets the criteria it shall be included in Category A.*

NOTE 3: *In the following table, the micro-organisms written in italics are bacteria, mycoplasmas, rickettsia or fungi.*

**INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES INCLUDED IN CATEGORY A
IN ANY FORM UNLESS OTHERWISE INDICATED
(2.6.3.2.2.1 2.2.62.1.5 (a))**

| UN Number and proper shipping name | Micro-organism |
|--|---|
| <p>UN No. 2814 Infectious substances affecting humans</p> | <p><i>Bacillus anthracis (cultures only)</i> <i>Brucella abortus (cultures only)</i> <i>Brucella melitensis (cultures only)</i> <i>Brucella suis (cultures only)</i> <i>Burkholderia mallei - Pseudomonas mallei – Glanders (cultures only)</i> <i>Burkholderia pseudomallei – Pseudomonas pseudomallei (cultures only)</i> <i>Chlamydia psittaci - avian strains (cultures only)</i> <i>Clostridium botulinum (cultures only)</i> <i>Coccidioides immitis (cultures only)</i> <i>Coxiella burnetii (cultures only)</i> Crimean-Congo hemorrhagic fever virus Dengue virus (cultures only) Eastern equine encephalitis virus (cultures only) <i>Escherichia coli</i>, verotoxigenic (cultures only) Ebola virus Flexal virus <i>Francisella tularensis (cultures only)</i> Guanarito virus Hantaan virus Hantaviruses causing hantavirus pulmonary syndrome Hendra virus Hepatitis B virus (cultures only) Herpes B virus (cultures only) Human immunodeficiency virus (cultures only) Highly pathogenic avian influenza virus (cultures only) Japanese Encephalitis virus (cultures only) Junin virus Kyasanur Forest disease virus Lassa virus Machupo virus Marburg virus Monkeypox virus <i>Mycobacterium tuberculosis (cultures only)</i> Nipah virus Omsk hemorrhagic fever virus Poliovirus (cultures only) Rabies virus <i>Rickettsia prowazekii (cultures only)</i> <i>Rickettsia rickettsii (cultures only)</i> Rift Valley fever virus Russian spring-summer encephalitis virus (cultures only) Sabia virus <i>Shigella dysenteriae type 1 (cultures only)</i> Tick-borne encephalitis virus (cultures only) Variola virus</p> |

| INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES INCLUDED IN CATEGORY A IN ANY FORM UNLESS OTHERWISE INDICATED (2.6.3.2.2.1 2.2.62.1.5 (a)) | |
|--|---|
| UN Number and proper shipping name | Micro-organism |
| | Venezuelan equine encephalitis virus West Nile virus (cultures only) Yellow fever virus (cultures only) <i>Yersinia pestis</i> (cultures only) |
| UN No. 2900 Infectious substances affecting animals only | African horse sickness virus African swine fever virus Avian paramyxovirus Type 1 - Newcastle disease virus Bluetongue virus Classical swine fever virus Foot and mouth disease virus Lumpy skin disease virus <i>Mycoplasma mycoides</i> - Contagious bovine pleuropneumonia Peste des petits ruminants virus Rinderpest virus Sheep-pox virus Goatpox virus Swine vesicular disease virus Vesicular stomatitis virus |

~~2.6.3.2.2.2~~ 2.2.62.1.4.2 **Category B:** An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B shall be assigned to UN No. 3373 except that cultures, as defined in 2.6.3.1.3, shall be assigned to UN No. 2814 or UN No. 2900 as appropriate.

NOTE: *The proper shipping name of UN No. 3373 is "DIAGNOSTIC SPECIMENS" or "CLINICAL SPECIMENS."*

~~2.6.3.3~~ 2.2.62.1.5 **Biological products**

~~2.6.3.3.1~~ For the purposes of ~~these Regulations~~ RID/ADR/ADN, biological products are divided into the following groups:

- (a) those which are manufactured and packaged in accordance with the requirements of appropriate national authorities and transported for the purposes of final packaging or distribution, and use for personal health care by medical professionals or individuals. Substances in this group are not subject to ~~these Regulations~~ the provisions of RID/ADR/ADN.
- (b) those which do not fall under paragraph (a) and are known or reasonably believed to contain infectious substances and which meet the criteria for inclusion in Category A or Category B. Substances in this group shall be assigned to UN No. 2814, UN No. 2900 or UN No. 3373, as appropriate.

NOTE: *Some licensed biological products may present a biohazard only in certain parts of the world. In that case, competent authorities*

may require these biological products to be in compliance with local requirements for infectious substances or may impose other restrictions.

2.6.3.4 2.2.62.1.6 Genetically modified micro-organisms and organisms

2.6.3.4.1 Genetically modified micro-organisms not meeting the definition of infectious substance shall be classified according to ~~Chapter 2.9~~ section 2.2.9.

2.6.3.5 2.2.62.1.7 Medical or clinical wastes

2.6.3.5.1 2.2.62.1.7.1 Medical or clinical wastes containing Category A infectious substances or containing Category B infectious substances in cultures shall be assigned to UN No. 2814 or UN No. 2900 as appropriate. Medical or clinical wastes containing infectious substances in Category B, other than cultures, shall be assigned to UN No. 3291 (Packing group II).

2.6.3.5.2 2.2.62.1.7.2 Medical or clinical wastes which are reasonably believed to have a low probability of containing infectious substances shall be assigned to UN No. 3291 (Packing group II).

NOTE 1: *The proper shipping name for UN No. 3291 is "CLINICAL WASTE, UNSPECIFIED, N.O.S." or "(BIO) MEDICAL WASTE, N.O.S." or "REGULATED MEDICAL WASTE, N.O.S."*

2.6.3.5.3 **NOTE 2:** Decontaminated medical or clinical wastes which previously contained infectious substances are not subject to ~~these Regulations~~ the provisions of RID/ADR/ADN unless they meet the criteria for inclusion in another class."

2.2.62.2 Substances not accepted for carriage

2.6.3.2.6 A life animal which has been intentionally infected and is known or suspected to contain an infectious substance shall only be ~~transported~~ carried under terms and conditions approved by the competent authority [in accordance with the relevant regulations governing the carriage of animals*].

2.2.62.3 Classification code I4, amend the entry for UN No
"3373 DIAGNOSTIC or CLINICAL SPECIMENS".

Chapter 2.7 Section 2.2.7

Except for the definition in 2.2.7.2, replace, all throughout the chapter, "Industrial package Type 1 (Type IP-1)" with "Type IP-1 package", "Industrial package Type 2 (Type IP-2)" with "Type IP-2 package" and "Industrial package Type 3 (Type IP-3)" with "Type IP-3 package".

2.2.7.1.2 In (e), insert the following text after "naturally occurring radionuclides":
"which are either in their natural state, or have only been processed for purposes other than for extraction of the radionuclides, and"

* Existing footnote to 2.2.62.2

Add a new (f) as follows:

"(f) Non-radioactive solid objects with radioactive substances present on any surfaces in quantities not in excess of the limit defined in 2.2.7.2".

2.2.7.2 In the definition of "package", add "package" after "Type IP-1", "Type IP-2" and "Type IP-3" in b), c) and d).

2.2.7.6.1.1 Amend the title of the table to read: "Multiplication factor for tanks, freight containers and unpackaged LSA-I and SCO-I".

2.2.7.6.2.2 Amend to read: "The criticality safety index for each overpack or freight container shall be determined as the sum of the CSIs of all the packages contained. The same procedure shall be followed for determining the total sum of the CSIs in a consignment or aboard a conveyance."

2.2.7.7.2.1 In the table, for "Cf-252", replace " 5×10^{-2} " with " 1×10^{-1} " under the heading A_1 .

2.2.7.8.3 Insert the words "or overpack" after "package".

2.2.7.9.3 (b) Amend to read as follows:

" (b) Each instrument or article bears the marking "RADIOACTIVE" except:

- i) radioluminescent time-pieces or devices;
- ii) consumer products that either have received regulatory approval according to 2.2.7.1.2(d) or do not individually exceed the activity limit for an exempt consignment in Table 2.2.7.7.2.1 (column (5)), provided such products are transported in a package that bears the marking "RADIOACTIVE" on an internal surface in such a manner that warning of the presence of radioactive material is visible on opening the package, and "

Chapter Section 2.2.8

~~2.8.2.5 (e) (ii)~~ 2.2.8.1.6 (c) second indent Replace the two last sentences of this subparagraph with the following text:

"For the purposes of testing steel, type S235JR+CR (1.0037 resp. St 37-2), S275J2G3+CR (1.0144 resp. St 44-3), ISO 3574, Unified Numbering System (UNS) G10200 or SAE 1020, and for testing aluminium, non-clad, types 7075-T6 or AZ5GU-T6 shall be used. An acceptable test is prescribed in the *Manual of Tests and Criteria*, Part III, Section 37".

Chapter Section 2.2.9

2.2.9.10 Replace “2.3.5” with “2.9.5”.

Replace the existing text with the following:

~~“CHAPTER 2.9~~

~~CLASS 9 MISCELLANEOUS DANGEROUS SUBSTANCES AND ARTICLES~~

~~2.9.1 Definitions~~

~~2.9.1.1 Class 9 substances and articles (miscellaneous dangerous substances and articles) are substances and articles which, during transport present a danger not covered by other classes.~~

~~2.9.1.2~~ 2.2.9.1.11 Amend to read “*Genetically modified micro-organisms (GMMOs) and genetically modified organisms (GMOs) are micro-organisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.*

~~2.9.2 Assignment to Class 9~~

~~2.9.2.1 Class 9 includes, inter alia:~~

- ~~a) environmentally hazardous substances;~~
- ~~b) elevated temperature substances (i.e. substances that are transported or offered for transport at temperatures equal to or exceeding 100°C in a liquid state or at temperatures equal or exceeding 240°C in a solid state);~~
- ~~e) GMMOs or GMOs which do not meet the definition of infectious substances (see 2.6.3) but which They are capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction. They shall be assigned to UN No. 3245.”~~

NOTE 1: (unchanged)

NOTE 2: amend to read “*GMMOs or GMOs are not subject to ~~these Regulations~~ the provisions of RID/ADR/ADN when authorized for use by the competent authorities of the Governments of the countries of origin, transit and destination.*”

NOTE 3: ([unchanged] [delete])

~~2.9.3 Environmentally hazardous substances (aquatic environment)~~

Add a new sub-section 2.2.9.5 to read:

~~2.3.5.1 Add a new sub-section which reads as follows and renumber accordingly the following sub-sections:~~

2.2.9.5 Criteria for pollutants to the aquatic environment

~~2.9.3.1~~ 2.2.9.5.1 General definitions

~~2.9.3.1.1~~ 2.2.9.5.1.1 Environmentally hazardous substances include, *inter alia*, liquid or solid substances pollutant to the aquatic environment and solutions and mixtures of such substances (such as preparations and wastes).

~~2.9.3.1.2~~ 2.2.9.5.1.2 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[†]. The basis, therefore, of the identification of hazard is the aquatic toxicity of the substance or mixture, although this may be modified by further information on the degradation and bioaccumulation behaviour.

~~2.9.3.1.3~~ 2.2.9.5.1.3 While the following classification procedure is intended to apply to all substances and mixtures, it is recognised that in some cases, e.g. metals or poorly soluble inorganic compounds, special guidance will be necessary[‡].

~~2.9.3.1.4~~ 2.2.9.5.1.4 The following definitions apply for acronyms or terms used in this section:

- BCF: Bioconcentration Factor;
- BOD: Biochemical Oxygen Demand;
- COD: Chemical Oxygen Demand;
- GLP: Good Laboratory Practices;
- EC₅₀: the effective concentration of substance that causes 50% of the maximum response;
- ErC₅₀ IC_{50r}: EC₅₀ in terms of reduction of growth;
- K_{ow} P_{ow}: octanol/water partition coefficient;
- LC₅₀ (50% lethal concentration): the concentration of a substance in water which causes the death of 50% (one half) in a group of test animals;
- L(E)C₅₀: LC₅₀ or EC₅₀;
- NOEC: No Observed Effect Concentration;

[†] 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.

[‡] This can be found in Annex 9 of the GHS.

- OECD Test Guidelines: Test guidelines published by the Organization for Economic Cooperation and Development (OECD).

2.9.3.2 2.2.9.5.2 Definitions and data requirements

2.9.3.2.1 2.2.9.5.2.1 The basic elements for classification of environmentally hazardous substances (aquatic environment) are:

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

2.9.3.2.2 2.2.9.5.2.2 While data from internationally harmonised test methods are preferred, in practice, data from national methods may also be used where they are considered as equivalent. In general, 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 Practices (GLP). Where such data are not available, classification shall be based on the best available data.

2.9.3.2.3 2.2.9.5.2.3 **Acute aquatic toxicity** shall normally be determined using a fish 96 hour LC₅₀ (OECD Test Guideline 203 or equivalent), a crustacea species 48 hour EC₅₀ (OECD Test Guideline 202 or equivalent) and/or an algal species 72 or 96 hour EC₅₀ (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.

2.9.3.2.4 2.2.9.5.2.4 **Bioaccumulation** means net result of uptake, transformation and elimination of a substance in an organism due to all routes of exposure (i.e. air, water, sediment/soil and food).

The potential for bioaccumulation shall normally be determined by using the octanol/water partition coefficient, usually reported as a log K_{ow} 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.

2.9.3.2.5 2.2.9.5.2.5 **Environmental degradation** may be biotic or abiotic (eg. hydrolysis) and the criteria used reflect this fact. 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[§].

[§] *Special guidance on data interpretation is provided in Chapter 3.10 and Annex 8 of the GHS.*

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

(a) 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 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) 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 or mixture can be degraded (biotically and/or abiotically) in the aquatic environment to a level above 70% within a 28 day period.

~~2.9.3.2.6~~ ~~2.2.9.5.2.6~~ **Chronic 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) 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.

~~2.9.3.3~~ ~~2.2.9.5.3~~ **Substance classification categories and criteria**

~~2.9.3.3.1~~ ~~2.2.9.5.3.1~~ Substances shall be classified as "environmentally hazardous substances (aquatic environment)", if they satisfy the criteria for Acute I, Chronic I or Chronic II, according to the following tables:

Acute toxicity

| | |
|--|-----------------|
| <u>Category: Acute I</u> | |
| 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 |

Chronic toxicity

Category: Chronic I

Acute toxicity:

96 hr LC₅₀ (for fish) ≤ 1 mg/l and/or

48 hr EC₅₀ (for crustacea) ≤ 1 mg/l and/or

72 or 96hr ErC₅₀ (for algae or other aquatic plants) ≤ 1 mg/l

and the substance is not rapidly degradable and/or the log K_{ow} ≥ 4 (unless the experimentally determined BCF < 500)

Category: Chronic II

Acute toxicity:

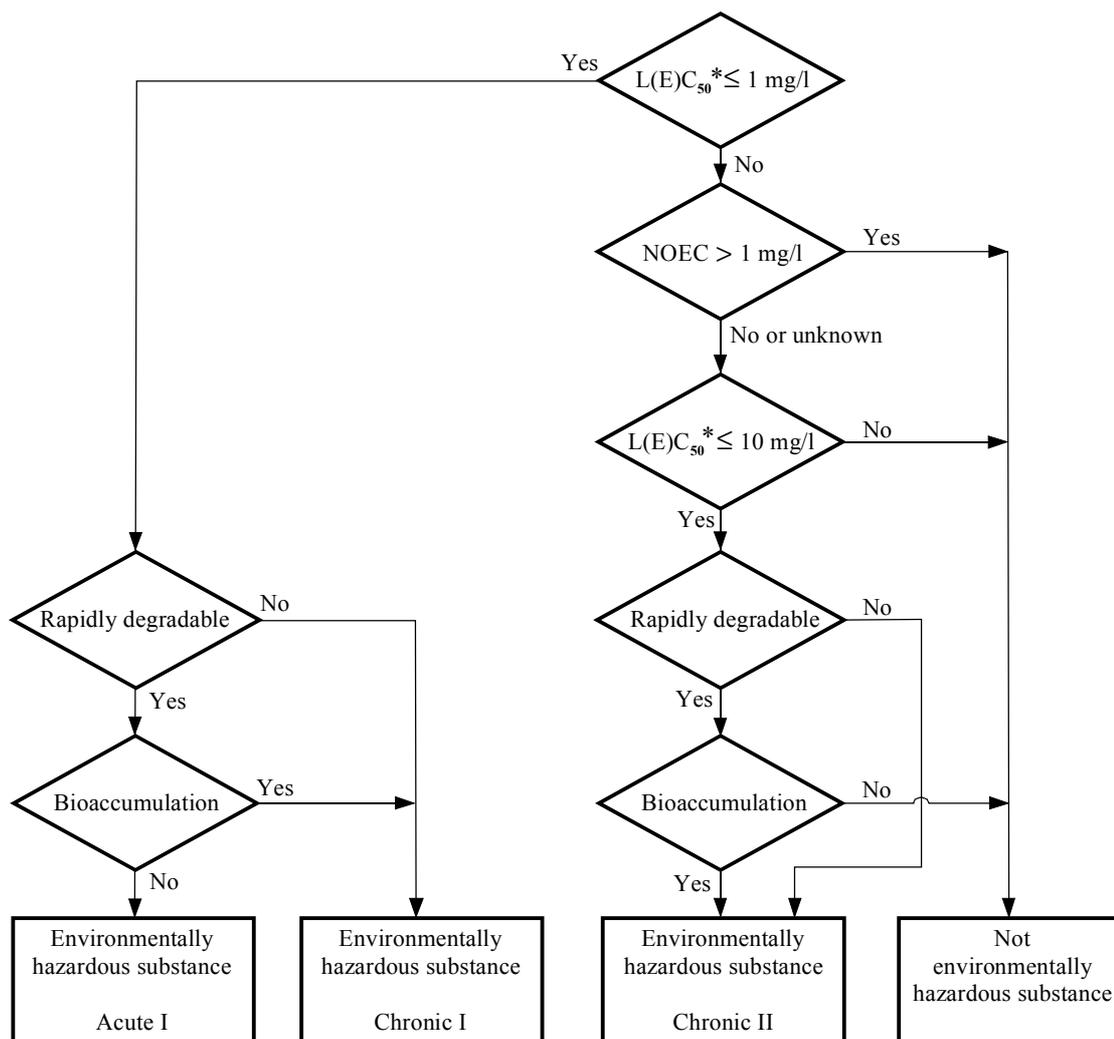
96 hr LC₅₀ (for fish) >1 to ≤ 10 mg/l and/or

48 hr EC₅₀ (for crustacea) >1 to ≤ 10 mg/l and/or

72 or 96hr ErC₅₀ (for algae or other aquatic plants) >1 to ≤ 10 mg/l

and the substance is not rapidly degradable and/or the log K_{ow} ≥ 4 (unless the experimentally determined BCF < 500), unless the chronic toxicity NOECs are > 1 mg/l

The classification flowchart below outlines the process to be followed.



* *Lowest value of 96-hour LC₅₀, 45-hour EC₅₀ or 72-hour IC₅₀ as appropriate.*

2.9.3.4 2.3.9.5.4 Mixtures classification categories and criteria

2.9.3.4.1 2.2.9.5.4.1 The classification system for mixtures covers the classification categories which are used for substances meaning acute category I and chronic categories I and II. In order to make use of all available data for purposes of classifying the aquatic environmental hazards of the mixture, the following assumption is made and is applied where appropriate:

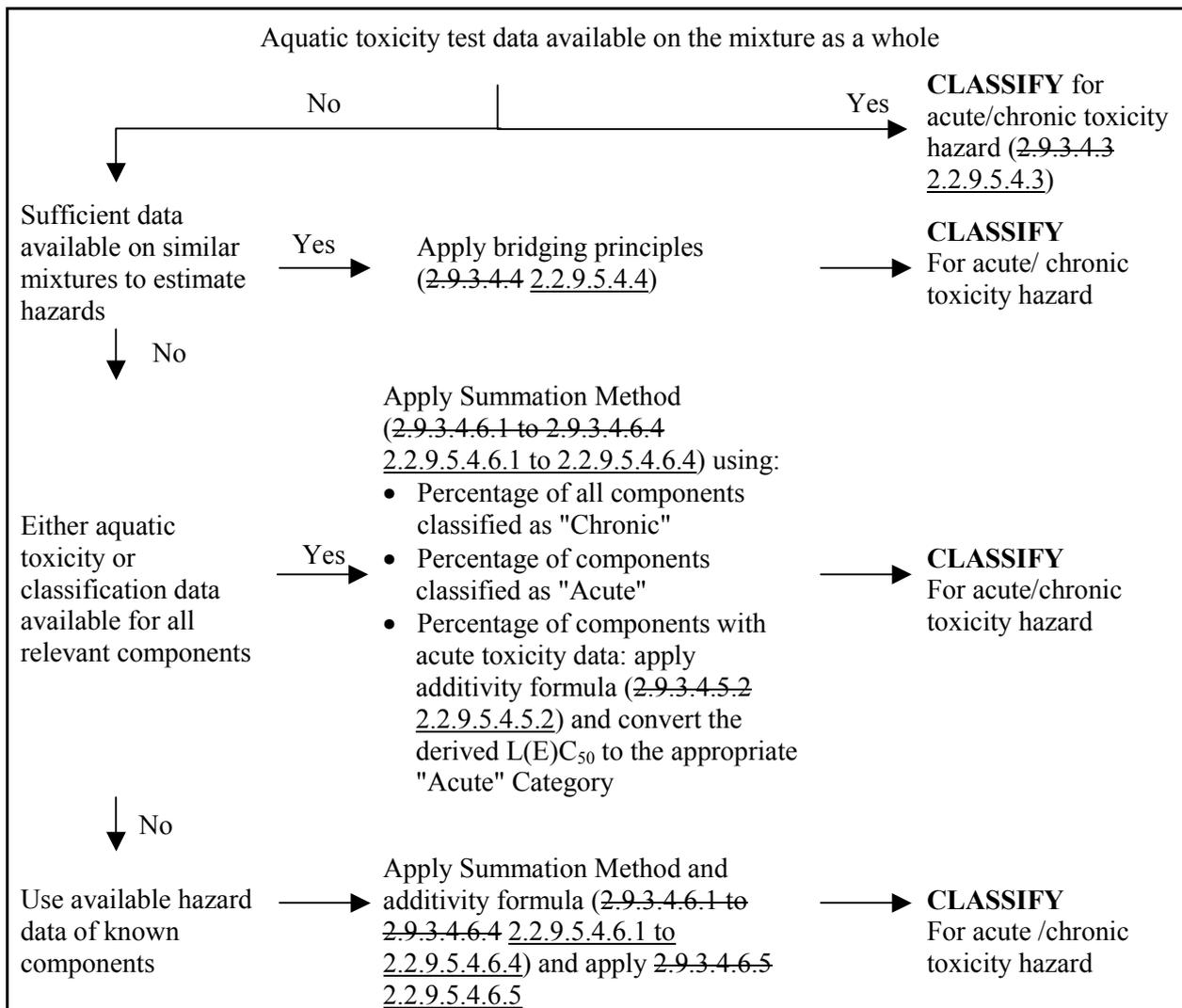
The "relevant components" of a mixture are those which are present in a concentration of 1% (w/w) or greater, unless there is a presumption (e.g. in the case of highly toxic components) that a component present at less than 1% can still be relevant for classifying the mixture for aquatic environmental hazards.

2.9.3.4.2 2.2.9.5.4.2 The approach for classification of aquatic environmental hazards is tiered, and is dependent upon the type of information available for the mixture itself and for its components. Elements of the tiered approach include:

- a) classification based on tested mixtures;
- b) classification based on bridging principles;
- c) the use of "summation of classified components" and /or an "additivity formula".

Figure 2.9.1 2.2.9.5.4.2 below outlines the process to be followed.

Figure 2.9.1 2.2.9.5.4.2: Tiered approach to classification of mixtures for acute and chronic aquatic environmental hazards



~~2.9.3.4.3~~ 2.2.9.5.4.3 Classification of mixtures when data are available for the complete mixture

~~2.9.3.4.3.1~~ 2.2.9.5.4.3.1 When the mixture as a whole has been tested to determine its aquatic toxicity, it shall be classified according to the criteria that have been agreed for substances, but only for acute toxicity. The classification is based on the data for fish, crustacea and algae/plants. Classification of mixtures by using LC₅₀ or EC₅₀ data for the mixture as a whole is not possible for chronic categories since both toxicity data and environmental fate data are needed, and there are no degradability and bioaccumulation data for mixtures as a whole. It is not possible to apply the criteria for chronic classification because the data from degradability and bio-accumulation tests of mixtures cannot be interpreted; they are meaningful only for single substances.

~~2.9.3.4.3.2~~ 2.2.9.5.4.3.2 When there is acute toxicity test data (LC₅₀ or EC₅₀) available for the mixture as a whole, this data as well as information with respect to the classification of components for chronic toxicity shall be used to complete the classification for tested mixtures as follows. When chronic (long term) toxicity data (NOEC) is also available, this shall be used in addition.

- (a) L(E)C₅₀ (LC₅₀ or EC₅₀) of the tested mixture \leq 1mg/l and NOEC of the tested mixture \leq 1.0 mg/l or unknown:
 - classify mixture as category acute I;
 - apply summation of classified components approach (see ~~2.9.3.4.6.3 and 2.9.3.4.6.4~~ 2.2.9.5.4.6.3 and 2.2.9.5.4.6.4) for chronic classification (chronic I, II, or no need of chronic classification).
- (b) L(E)C₅₀ of the tested mixture \leq 1 mg/l and NOEC of the tested mixture $>$ 1.0 mg/l:
 - classify mixture as category acute I;
 - apply summation of classified components approach (see ~~2.9.3.4.6.3 and 2.9.3.4.6.4~~ 2.2.9.5.4.6.3 and 2.2.9.5.4.6.4) for classification as Category Chronic I. If the mixture is not classified as Category Chronic I, then there is no need for chronic classification.
- (c) L(E)C₅₀ of the tested mixture $>$ 1mg/l, or above the water solubility, and NOEC of the tested mixture \leq 1.0mg/l or unknown:
 - no need to classify for acute toxicity;
 - apply summation of classified components approach (see ~~2.9.3.4.6.3 and 2.9.3.4.6.4~~ 2.2.9.5.4.6.3 and 2.2.9.5.4.6.4) for chronic classification or no need for chronic classification.
- (d) L(E)C₅₀ of the tested mixture $>$ 1mg/l, or above the water solubility, and NOEC of the tested mixture $>$ 1.0 mg/l:
 - No need to classify for acute or chronic toxicity.

2.9.3.4.4 2.2.9.5.4.4 *Bridging principles*

2.9.3.4.4.1 2.2.9.5.4.4.1 Where the mixture itself has not been tested to determine its aquatic environmental hazard, but there are sufficient data on the individual components and similar tested mixtures to adequately characterise the hazards of the mixture, this data shall be used in accordance with the following agreed bridging rules. This ensures that the classification process uses the available data to the greatest extent possible in characterising the hazards of the mixture without the necessity for additional testing in animals.

2.9.3.4.4.2 2.2.9.5.4.4.2 Dilution

2.9.3.4.4.2.1 2.2.9.5.4.4.2.1 If a mixture is formed by diluting another classified mixture or a substance with a diluent which has an equivalent or lower aquatic hazard classification than the least toxic original component and which is not expected to affect the aquatic hazards of other components, then the mixture shall be classified as equivalent to the original mixture or substance.

2.9.3.4.4.2.2 2.2.9.5.4.4.2.2 If a mixture is formed by diluting another classified mixture or a substance with water or other totally non-toxic material, the toxicity of the mixture shall be calculated from the original mixture or substance.

2.9.3.4.4.3 2.2.9.5.4.4.3 Batching

2.9.3.4.4.3.1 2.2.9.5.4.4.3.1 The aquatic hazard classification of one production batch of a complex mixture shall be assumed to be substantially equivalent to that of another production batch of the same commercial product and produced by or under the control of the same manufacturer, unless there is reason to believe there is significant variation such that the aquatic hazard classification of the batch has changed. If the latter occurs, new classification is necessary.

2.9.3.4.4.4 2.2.9.5.4.4.4 Concentration of mixtures which are classified with the most severe classification categories (chronic I and acute I)

2.9.3.4.4.4.1 2.2.9.5.4.4.4.1 If a mixture is classified as chronic I and/or acute I, and components of the mixture which are classified as chronic I and/or acute I are further concentrated, the more concentrated mixture shall be classified with the same classification category as the original mixture without additional testing.

2.9.3.4.4.5 2.2.9.5.4.4.5 Interpolation within one toxicity category

2.9.3.4.4.5.1 2.2.9.5.4.4.5.1 If mixtures A and B are in the same classification category and mixture C is made in which the toxicologically active components have concentrations intermediate to those in mixtures A and B, then mixture C shall be in the same category as A and B. Note that the identity of the components is the same in all three mixtures.

2.9.3.4.4.6 2.2.9.5.4.4.6 Substantially similar mixtures

2.9.3.4.4.6.1 2.2.9.5.4.4.6.1 Given the following:

(a) Two mixtures:

- i) A + B
- ii) C + B

- (b) The concentration of component B is the same in both mixtures;
- (c) The concentration of component A in mixture (i) equals that of component C in mixture (ii);
- (d) Classification for A and C are available and are the same, i.e. they are in the same hazard category and are not expected to affect the aquatic toxicity of B,

then there shall be no need to test mixture (ii) if mixture (i) is already characterised by testing and both mixtures are classified in the same category.

2.9.3.4.5 2.2.9.5.4.5 *Classification of mixtures when data are available for all components or only for some components of the mixture*

2.9.3.4.5.1 2.2.9.5.4.5.1 The classification of a mixture shall be based on summation of the classification of its components. The percentage of components classified as "Acute" or "Chronic" will feed straight into the summation method. Details of the summation method are described in 2.9.3.4.6.1 2.2.9.5.4.6.1 to 2.9.3.4.6.4.1 2.2.9.5.4.6.4.1.

2.9.3.4.5.2 2.2.9.5.4.5.2 Mixtures are often made of a combination of both components that are classified (as Acute I and/or Chronic I, II) and those for which adequate test data is available. When adequate toxicity data is available for more than one component in the mixture, the combined toxicity of those components shall be calculated using the following additivity formula, and the calculated toxicity shall be used to assign that portion of the mixture an acute toxicity hazard which is then subsequently used in applying the summation method.

$$\frac{\sum C_i}{L(E)C_{50m}} = \sum \frac{C_i}{L(E)C_{50i}}$$

where:

- C_i = concentration of component i (weight percentage);
- $L(E)C_{50i}$ = (mg/L) LC_{50} or EC_{50} for component i;
- n = number of components, and i is running from 1 to n;
- $L(E)C_{50m}$ = $L(E)C_{50}$ of the part of the mixture with test data

2.9.3.4.5.3 2.2.9.5.4.5.3 When applying the additivity formula for part of the mixture, it is preferable to calculate the toxicity of this part of the mixture using for each substance toxicity values that relate to the same species (i.e. fish, daphnia or algae) and then to use the highest toxicity (lowest value) obtained (i.e. use the most sensitive of the three species). However, when toxicity data for each component are not available in the same species, the toxicity value of each component shall be selected in the same manner that toxicity values are selected for the classification of substances, i.e. the higher toxicity (from the most sensitive test organism) is used. The calculated acute toxicity shall then be used to classify this part of the mixture as Acute I using the same criteria described for substances.

2.9.3.4.5.4 2.2.9.5.4.5.4 If a mixture is classified in more than one way, the method yielding the more conservative result shall be used.

2.9.3.4.6 2.2.9.5.4.6 *Summation method*

2.9.3.4.6.1 2.2.9.5.4.6.1 Classification procedure

2.9.3.4.6.1.1 2.2.9.5.4.6.1.1 In general a more severe classification for mixtures overrides a less severe classification, e.g. a classification with chronic I overrides a classification with chronic II. As a consequence the classification procedure is already completed if the results of the classification is chronic I. A more severe classification than chronic I is not possible and it is not necessary therefore to undergo the further classification procedure.

2.9.3.4.6.2 2.2.9.5.4.6.2 Classification for the acute category I

2.9.3.4.6.2.1 2.2.9.5.4.6.2.1 All components classified as acute I shall be considered. If the sum of these components is greater than 25% the whole mixture shall be classified as category acute I. If the result of the calculation is a classification of the mixture as category acute I, the classification process is completed.

2.9.3.4.6.2.2 2.2.9.5.4.6.2.2 The classification of mixtures for acute hazards based on this summation of classified components, is summarised in Table 2.9.1 2.2.9.5.4.6.2.2 below.

Table ~~2.9.1~~ 2.3.5.8.6.2.2: Classification of a mixture for acute hazards, based on summation of classified components

| Sum of components classified as: | Mixture is classified as: |
|-------------------------------------|---------------------------|
| Acute I $\times M^{\dagger a}$ >25% | Acute I |

^{† a} For explanation of the M factor, see 2.9.3.4.6.4 2.2.9.5.4.6.4.

2.9.3.4.6.3 2.2.9.5.4.6.3 Classification for the chronic categories I, II

2.9.3.4.6.3.1 2.2.9.5.4.6.3.1 First, all components classified as chronic I are considered. If the sum of these components is greater than 25% the mixture shall be classified as category chronic I. If the result of the calculation is a classification of the mixture as category chronic I the classification procedure is completed.

2.9.3.4.6.3.2 2.2.9.5.4.6.3.2 In cases where the mixture is not classified as chronic I, classification of the mixture as chronic II is considered. A mixture shall be classified as chronic II if 10 times the sum of all components classified as chronic I plus the sum of all components classified as chronic II is greater than 25%. If the result of the calculation is classification of the mixture as chronic II, the classification process is completed.

2.9.3.4.6.3.3 2.2.9.5.4.6.3.3 The classification of mixtures for chronic hazards, based on this summation of classified components, is summarised in Table 2.9.2 2.2.9.5.4.6.3.3 below.

Table 2.9.2 2.2.9.5.4.6.3.3: Classification of a mixture for chronic hazards, based on summation of classified components

| Sum of components classified as: | Mixture is classified as: |
|--|---------------------------|
| Chronic I \times M ^{1a} >25% | Chronic I |
| (M \times 10 \times Chronic I)+Chronic II >25% | Chronic II |

^{1a} For explanation of the M factor, see 2.9.3.4.6.4 2.3.5.8.6.4.

2.9.3.4.6.4 2.2.9.5.4.6.4 Mixtures with highly toxic components

2.9.3.4.6.4.1 2.2.9.5.4.6.4.1 Acute category 1 components with toxicities well below 1 mg/l may influence the toxicity of the mixture and are given increased weight in applying the summation of classification approach. When a mixture contains components classified as acute or chronic category I, the tiered approach described in 2.9.3.4.6.2 2.2.9.5.4.6.2 and 2.9.3.4.6.3 2.2.9.5.4.6.3 shall be applied using a weighted sum by multiplying the concentrations of acute category 1 components by a factor, instead of merely adding up the percentages. This means that the concentration of "Acute I" in the left column of Table 2.9.1 2.2.9.5.4.6.2.2 and the concentration of "Chronic I" in the left column of Table 2.9.2 2.2.9.5.4.6.3.3 are multiplied by the appropriate multiplying factor. The multiplying factors to be applied to these components are defined using the toxicity value, as summarised in Table 2.9.3 2.2.9.5.4.6.4.1 below. Therefore, in order to classify a mixture containing acute I and/or chronic I components, the classifier needs to be informed of the value of the M factor in order to apply the summation method. Alternatively, the additivity formula (2.9.3.4.5.2 2.2.9.5.4.5.2) may be used when toxicity data are available for all highly toxic components in the mixture and there is convincing evidence that all other components, including those for which specific acute toxicity data are not available, are of low or no toxicity and do not significantly contribute to the environmental hazard of the mixture.

Table 2.9.3 2.2.9.5.4.6.4.1: Multiplying factors for highly toxic components of mixtures

| L(E)C ₅₀ value | Multiplying factor (M) |
|--|------------------------|
| 0.1 < L(E)C ₅₀ ≤ 1 | 1 |
| 0.01 < L(E)C ₅₀ ≤ 0.1 | 10 |
| 0.001 < L(E)C ₅₀ ≤ 0.01 | 100 |
| 0.0001 < L(E)C ₅₀ ≤ 0.001 | 1000 |
| 0.00001 < L(E)C ₅₀ ≤ 0.0001 | 10000 |
| (continue in factor 10 intervals) | |

~~2.9.3.4.6.5~~ 2.2.9.5.4.6.5 Classification of mixtures with components without any useable information

~~2.9.3.4.6.5.1~~ 2.2.9.5.4.6.5.1 In the event that no useable information on acute and/or chronic aquatic hazard is available for one or more relevant components, it is concluded that the mixture cannot be attributed (a) definitive hazard category(ies). In this situation the mixture shall be classified based on the known components only with the additional statement that: "x percent of the mixture consists of component(s) of unknown hazards to the aquatic environment."

2.2.9.5.4

~~2.9.3.5~~ 2.2.9.5.4 ***Substances or mixtures dangerous to the aquatic environment not otherwise classified under these Regulations RID/ADR/ADN***

~~2.9.3.5.1~~ 2.2.9.5.4.1 Substances or mixtures dangerous to the aquatic environment not otherwise classified under ~~these Regulations~~ RID/ADR/ADN shall be designated:

UN No. 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. or

UN No. 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

They shall be assigned to Packing Group III."

2.2.9.6 Existing 2.2.9.3 with the following amendments:

Classification code M2, amend the entry for UN No. 2315 as follows:

"2315 POLYCHLORINATED BIPHENYLS LIQUID".

Insert a new entry as follows:

"3432 POLYCHLORINATED BIPHENYLS, SOLID".

2.3.5 Delete 2.3.5.