DGP-WG/02-WP/12 16/8/02

#### DANGEROUS GOODS PANEL

#### Frankfurt, 16 to 20 September 2002

# Agenda Item 2: Development of recommendations for amendments to the Technical Instructions for incorporation in the 2005/2006 edition

# DRAFT AMENDMENTS TO THE TECHNICAL INSTRUCTIONS TO ALIGN TO THE UN RECOMMENDATIONS — PART 2

(Presented by the Secretary)

# SUMMARY

Below are the draft amendments to Part 2 Chapters 3,4,5, 6, 7, 8, and 9 to reflect the decisions taken by the UN Subcommittee of Experts at the nineteenth, twentieth and twenty first sessions.

# Chapter 3

# CLASS 3 — FLAMMABLE LIQUIDS

# 3.1 DEFINITION AND GENERAL PROVISIONS

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3.1.4 Liquid desensitized explosives are explosive substances which are dissolved or suspended in water or other liquid substances, to form a homogeneous liquid mixture to suppress their explosive properties (see 2.1.3.5.3). Entries in the Dangerous Goods List (Table 3-1) for liquid desensitized explosives are: UN 1204, UN 2059, UN 3064 and UN 3343 and UN 3379.

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# 3.3 DETERMINATION OF

#### FLASH POINT

The following is a list of documents describing methods for determining the flash point of substances in Class 3:

France (Association française de normalisation, AFNOR, Tour Europe, 92049 Paris La Défense)

- French Standard NF M 07 019
- French Standard NF M 07 036

*Germany* (<del>DIN</del> Deutsches Institut fur Normung, Burggrafenstrasse 6, D-10787 Berlin) (Deutscher Normenausschuss)

- Standard DIN 51755 (flash points below 65EC)
- Standard DIN 51758 EN 22719 (flash point above 65EC to 165EC)
- Standard DIN 53213 (for varnishes, lacquers and similar viscous liquids with flash points below 65EC)

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#### Chapter 4

# CLASS 4 — FLAMMABLE SOLIDS; SUBSTANCES LIABLE TO SPONTANEOUS COMBUSTION; SUBSTANCES WHICH, IN CONTACT WITH WATER, EMIT FLAMMABLE GASES

#### **INTRODUCTORY NOTES**

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Note 1.— Where the term 'water-reactive' is used in these Instructions, it refers to a substance which, in contact with water, emits flammable gas.

Note 2.— Because of the different properties exhibited by the dangerous goods within Divisions 4.1 and 4.2, it is impracticable to establish a single criterion for classification in either of these divisions. Tests and criteria for assignment to the three divisions of Class 4 are addressed in this chapter and in the Manual of Tests and Criteria, Part III, section 33.

Note 3.—Because organometallic substances can be classified in division 4.2 or 4.3 with additional subsidiary risks, depending on the properties of the substance, a specific classification flow chart for these substances is given in Figure 2-2

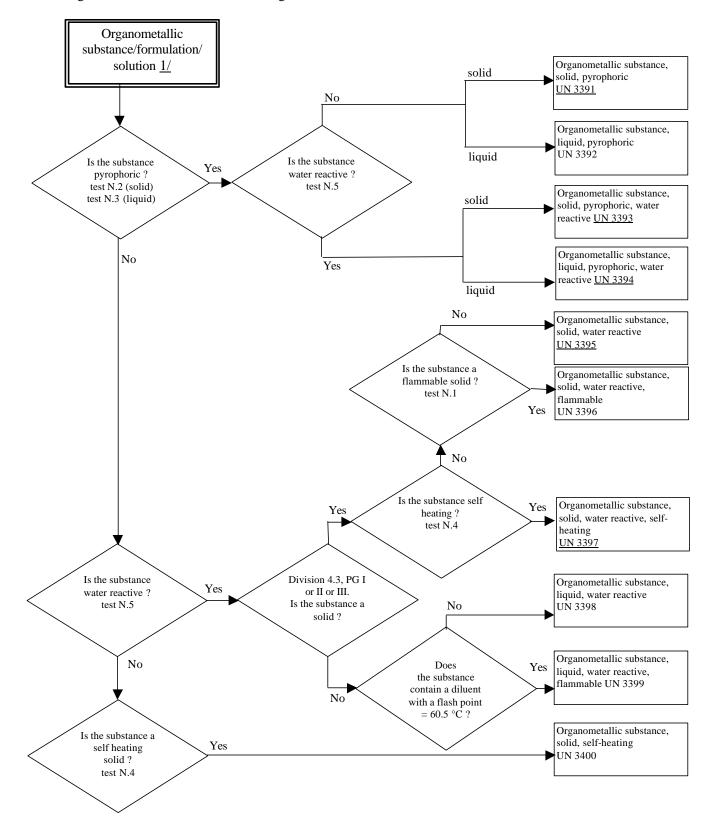
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#### 4.2.4 DIVISION 4.1 — SOLID DESENSITIZED EXPLOSIVES

4.2.4.1 Definition

Solid desensitized explosives are explosive substances which are wetted with water or alcohols or are diluted with other substances to form a homogeneous solid mixture to suppress their explosive properties. Entries in the Dangerous Goods List for solid desensitized explosives are UN Nos. 1310,1320, 1321, 1322, 1336, 1337, 1344, 1347, 1348, 1349, 1354,1355, 1356, 1357, 1517, 1571, 2555, 2556, 2557, 2852, 2907, 3317, 3319, 3344 and 3376 and UN 3380.

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Editorial note: Insert the following new flowchart in new 2.4.5 Figure 2-2: Flowchart scheme for organometallic substances

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# Chapter 5

# CLASS 5 - OXIDIZING SUBSTANCES AND ORGANIC PEROXIDES

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# 5.3.4 DESENSITIZATION OF ORGANIC PEROXIDES

**Table 2-7.** List of currently assigned organic peroxides in packages. Peroxides to be transported should fulfil the classification and the control and emergency temperatures (derived from the SADT) as listed.

Organic peroxide	Concentration (%)	Diluent type A (%)	Diluent type B (%) (Note 1)	Inert solid (%)	Water (%)	Control tempera- ture (EC)	Emergency tempera- ture (EC)	UN Generic Entry	Notes
Acetyl benzoyl peroxide	<del>#45</del>	<del>\$55</del>						<del>3105</del>	
tert-Amyl peroxyacetate	#62	\$38						<del>3.1e+07</del>	
tert-Amyl peroxy isopropyl carbonate	#77	\$23						3103	
tert-Butyl cumyl peroxide	>42-100							<del>3.1e+07</del>	
tert-Butyl cumyl peroxide	<del>#42</del>			<del>\$58</del> \$48				<del>3106</del> 3108	
n-Butyl-4,4-di-(tert-butylperoxy) valerate	>52-100							3103	
n-Butyl-4,4-di-(tert-butylperoxy) valerate	<del>#52</del>			<del>\$48</del>				<del>3106</del>	
n-Butyl-4,4-di-(tert-butylperoxy) valerate	<del>#42-#</del> 52			<del>\$58</del> \$48				3108	
tert-Butyl monoperoxyphthalate	<del>#100</del>							<del>3102</del>	3
tert-Butyl peroxyacetate	#32	<del>\$68</del>	\$68					3109	
tert-Butyl peroxybenzoate	>77-100	<del>&lt;22</del>						3103	
tert-Butyl peroxydiethylacetate + tert-Butyl peroxybenzoate	<del>#33 + #33</del>	<del>\$33</del>						<del>3105</del>	
tert-Butyl peroxyneodecanoate	#52 as a stable dispersion in water					0	+10	<del>3.1e+07</del>	
tert-Butyl peroxyneoheptanoate	#42 as a stable dispersion in water					0	10	3117	
3-tert-Butylperoxy-3-phenylphthalide	#100							<del>3106</del>	
tert-Butyl peroxy-3,5,5- trimethyl- hexanoate	#32	<del>\$68</del>	\$68					3109	
Dibenzoyl peroxide	<del>&gt;36-42</del>	<del>\$58</del>						<del>3107</del>	
Dibenzyl peroxydicarbonate	<del>#87</del>				<del>\$13</del>	+25	+30	<del>3112</del>	<del>3</del>

Organic peroxide	Concentration (%)	Diluent type A (%)	Diluent type B (%) (Note 1)	Inert solid (%)	Water (%)		Emergency tempera- ture (EC)	UN Generic Entry	Notes
Di-tert-butyl peroxide	<del>&gt;32-100</del> >52-100							3107	
1,6-Di-(tert-butylperoxycarbonyloxy) hexane	#72	\$28						3103	
1,1-Di-(tert-butylperoxy)cyclohexane	#27	<del>\$36</del> \$25						3107	21
1,1-Di-(tert-butylperoxy)-3,3,5- trimethylcyclohexane	#77		\$23					<del>3.1e+07</del>	
1,1-Di-(tert-butylperoxy)-3,3,5- trimethylcyclohexane	#57			\$43				<del>3.1c+07</del>	
Dicumyl peroxide	> <del>42-100</del> >52-100			#57				3110	
Dicyclohexyl peroxydicarbonate	>91-100					510	1015	3112	3
Dicyclohexyl peroxydicarbonate	#91				\$9	510	1015	3114	
Dicyclohexyl peroxydicarbonate	#42 as a stable disper- sion in water					15	20	3119	
Di-(2-ethylhexyl)peroxydicarbonate	#42 52 as a stable disper- sion in water (frozen)					-15	-5	<del>3.1e+07</del>	
Diethyl peroxydicarbonate	<del>#27</del>		<del>\$73</del>			<del>-10</del>	θ	<del>3115</del>	
Diisotridecyl peroxydicarbonate	<del>#100</del>					<del>-10</del>	θ	<del>3115</del>	
<del>2,5-Dimethyl-2,5-di-(tert- butylperoxy)hexane</del>	<del>#52</del>			<del>\$48</del>				<del>3106</del>	
Diperoxy azelaie acid	<del>#27</del>			<del>\$73</del>		+35	+40	<del>3116</del>	
Diperoxy dodecane diacid	<del>&gt;13-42</del>			<del>\$58</del>		+40	+45	<del>3116</del>	
Diperoxy dodecane diacid	<del>#13</del>			<del>\$87</del>				Exempt	
Distearyl peroxydicarbonate	<del>#87</del>			<del>\$13</del>				<del>3106</del>	
<del>Di-(3,5,5-trimethylhexanoyl) peroxide</del>	#52 as a stable disper- sion in water					+10	<del>+15</del>	<del>3117</del>	
1-(2-Ethylhexanoylperoxy)-1,3-dimethyl- butyl peroxypivalate	#52	\$45	\$10			-20	-10	3115	
<del>3,3,6,6,9,9-Hexamethyl-1,2,4,5-</del> tetraoxacyclononane	<del>&gt;52-100</del>							<del>3102</del>	<del>3</del>
<del>3,3,6,6,9,9-Hexamethyl-1,2,4,5-</del> tetraoxacyclononane	<del>#52</del>	<del>\$48</del>						<del>3105</del>	
<del>3,3,6,6,9,9-Hexamethyl-1,2,4,5-</del>	<del>#52</del>			<del>\$48</del>				<del>3106</del>	

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Organic peroxide	Concentration (%)	Diluent type A (%)	Diluent type B (%) (Note 1)	Inert solid (%)	Water (%)	Control tempera- ture (EC)	Emergency tempera- ture (EC)	, UN Generic Entry	Notes
+ Methyl ethyl ketone peroxide(s)	<del>#37</del>	<del>\$55</del>			<del>\$8</del>			<del>3105</del>	<del>9</del>
Peroxyacetic acid, type F, stabilized	<del>#41</del>					<del>30</del>	<del>35</del>	<del>3119</del>	<del>1330</del>
Peroxylauric acid	#100					35	40	3118	
Polyether poly -tert-butylperoxycarbonate	#52		\$23					3107	
Tetrahydronaphthyl hydroperoxide	#100							<del>3106</del>	
1,1,3,3-Tetramethylbutylperoxy-2 ethylhexanoate	#100					2015	2520	3115	
<del>1,1,3,3-Tetramethylbutyl</del> peroxyphenoxyacetate	<del>#37</del>		<del>\$63</del>			<del>-10</del>	θ	<del>3115</del>	
1,1,3,3-Tetramethylbutyl peroxypivalate	#77	\$23				0	10	3115	

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# Notes:

- 1. Diluent type B may always be replaced by diluent type A. Boiling point diluent type B should be at least 60 C higher than the SADT of the organic peroxide.
- 2. Available oxygen #4.7%.
- 3. 'EXPLOSIVE' subsidiary risk label required.
- 4. Diluent may be replaced by Di-tert-butyl peroxide.
- 5. Available oxygen #9%.
- 6. With #9% hydrogen peroxide; available oxygen #10%.
- 7. Only non-metallic packagings allowed.
- 8. Available oxygen >10% and #10.7%, with or without water.
- 9. Available oxygen #10%, with or without water.
- 10. Available oxygen #8.2%, with or without water.
- 11. See 5.3.2.5.1.
- 13. 'CORROSIVE' subsidiary risk label required.
- 14. Peroxyacetic acid formulations which fulfil the criteria of 5.3.2.5.
- 15. Peroxyacetic acid formulations which fulfil the criteria of 5.3.2.5.
- 16. Peroxyacetic acid formulations which fulfil the criteria of 5.3.2.5.
- 17. Addition of water to this organic peroxide will decrease its thermal stability.
- 18. No 'CORROSIVE' subsidiary risk label required for concentrations below 80%.
- 19. Mixtures with hydrogen peroxide, water and acid(s).
- 20. With diluent type A, with or without water.
- 21. With \$25 36% diluent type A by mass, and in addition Ethylbenzene in addition to diluent type A.
- 22. With \$19% diluent type A by mass, and in addition Methyl isobutyl ketone in addition to diluent type A.
- 23. With <6% di-tert-butyl peroxide.
- 24. With #8% 1-isopropylhydroperoxy-4-isopropylhydroxybenzene.
- 25. Diluent type B with boiling point >110EC.
- 26. With <0.5 per cent hydroperoxides content.
- 27. For concentrations more than 56 per cent, 'CORROSIVE' subsidiary risk label required.
- 28. Available active oxygen #7.6% in diluent type A having a 95% boil-off point in the range of 220-260EC.
- 29. Not subject to the requirements of these Instructions for Division 5.2
- 30. Formulations derived from distillation of peroxyacetic acid originating from peroxyacetic acid in concentration of not more than 41% with water, total active oxygen (Peroxyacetic acid + H<sub>2</sub>O<sub>2</sub>)

#9.5%, which fulfills the criteria of 2.5.3.3.(f) of the UN Recommendations on the Transport of Dangerous Goods.

#### CLASS 6 — TOXIC AND INFECTIOUS SUBSTANCES

#### **INTRODUCTORY NOTES**

Note 1.— Genetically modified micro-organisms and organisms which do not meet the definition of an infectious substance should be considered for classification in Class 9 and assignment to UN 3245.

Note 1 2.— Toxins from plant, animal or bacterial sources which do not contain any infectious substances or toxins that are not contained in substances which are infectious substances should be considered for classification in Division 6.1 and assignment to UN 3172.

#### 6.1 DEFINITIONS

Class 6 is divided into two divisions as follows:

a) Division 6.1 — Toxic substances.

Substances liable either to cause death or injury or to harm human health if swallowed, if inhaled or by skin contact.

Note.— In these Instructions 'poisonous' has the same meaning as 'toxic'.

b) Division 6.2 — Infectious substances.

Substances known to contain, or reasonably expected to contain, pathogens. Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsia, parasites, fungi) or recombinant micro-organisms (hybrid or mutant), that are known or reasonably expected to cause infectious disease in animals or humans and other agents such as prions, which can cause disease in humans or animals.

#### 6.2 TOXIC SUBSTANCES

#### 6.2.1 Definitions

For the purposes of these Instructions:

6.2.1.1 LD<sub>50</sub> (median lethal dose) for acute oral toxicity is that the statistically derived single dose of the a substance administered which is most likely that can be expected to cause death within 14 days inhalf of both male and female 50 per cent of young adult albino rats when administered by the oral route. The LD<sub>50</sub> value is expressed in terms of mass of test substance per mass of test animal (mg/kg). The number of animals tested must be sufficient to give a statistically significant result and be in conformity with good pharmacological practices. The result is expressed in mg/kg body mass.

6.2.1.2  $LD_{50}$  for acute dermal toxicity is that dose of the substance which, administered by continuous contact for 24 hours with the bare skin of albino rabbits, is most likely to cause death within 14 days in half of the animals tested. The number of animals tested must be sufficient to give a statistically significant result and be in conformity with good pharmacological practices. The result is expressed in mg/kg body mass.

6.2.1.3 LC<sub>50</sub> for acute toxicity on inhalation is that concentration of vapour, mist or dust which, administered by continuous inhalation for one hour to both male and female young adult albino rats, is most likely to cause death within 14 days in half of the animals tested. A solid substance should be tested if at least 10 per cent (by mass) of its total mass is likely to be dust in a respirable range, e.g. the aerodynamic diameter of that particle-fraction is 10  $\mu$ m or less. A liquid substance should be tested if a mist is likely to be generated in a leakage of the transport containment. Both for solid and liquid substances more than 90 per cent (by mass) of a specimen prepared for inhalation toxicity should be in the respirable range as defined above. The result is expressed in mg/L of air for dusts and mists or in mL/m<sup>3</sup> of air (parts per million) for vapours.

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Editorial note: Replace 6.3 with the following new text.

# 6.3 Division 6.2 - Infectious substances

**6.3.1** *Definitions* 

For the purposes of these Instructions:

**6.3.1.1** *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.

**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.

**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 does not include specimens for diagnostic or clinical purposes in growth or non-growth promoting medium.

**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.

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

# 6.3.2 Classification of infectious substances

**6.3.2.1** Infectious substances must be classified in Division 6.2 and assigned to UN 2814, UN 2900 or UN 3373, as appropriate.

**6.3.2.2** Infectious substances are divided into the following categories.

**6.3.2.2.1** Category A: An infectious substance which is transported 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 must be assigned to UN 2814. Infectious substances which cause disease only in animals must be assigned to UN 2900.
- (b) Assignment to UN 2814 or UN 2900 must 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 2814 is Infectious substance, affecting humans. The proper shipping name for UN 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 should be assigned to Category A. In addition, if there is doubt as to whether or not a substance meets the criteria it must 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 (6.3.2.2.(a))				
UN Number and Proper Shipping Name	Micro-organism			
UN 2814 Infectious substances affecting humans	Bacillus anthracis (cultures only)         Brucella abortus (cultures only)         Brucella suis (cultures only)         Brucella suis (cultures only)         Burkholderia mallei - Pseudomonas mallei – Glanders         (cultures only)         Burkholderia pseudomallei – Pseudomonas pseudomallei         (cultures only)         Burkholderia pseudomallei – Pseudomonas pseudomallei         (cultures only)         Chlamydia psittaci - avian strains (cultures only)         Clostridium botulinum (cultures only)         Coccidioides immitis (cultures only)         Coxiella burnetii (cultures only)         Coxiella burnetii (cultures only)         Crimean-Congo hemorrhagic fever virus         Dengue virus (cultures only)         Eastern equine encephalitis virus (cultures only)         Escherichia coli, verotoxigenic (cultures only)         Ebola virus         Flexal virus         Flexal virus         Francisella tularensis (cultures only)         Guanarito virus         Hantaan virus         Hantaan virus			

	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)			
INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES INCLUDED IN CATEGORY A IN ANY FORM UNLESS OTHERWISE INDICATED (Continued) (6.3.2.2.(a))				
UN Number and	Micro-organism			
Proper Shipping Name				
UN 2814	Junin virus			
Infectious	Kyasanur Forest disease virus			
substances affecting	Lassa virus			
humans	Machupo virus			
	Marburg virus			
	Monkeypox virus			
	Mycobacterium tuberculosis (cultures only)			
	Nipah virus			
	Omsk hemorrhagic fever virus			
	Poliovirus (cultures only)			
	Rabies virus			
	Rickettsia prowazekii (cultures only)			
	Rickettsia rickettsii (cultures only)			
	Rift Valley fever virus			
	Russian spring-summer encephalitis virus (cultures only)			
	Sabia virus			
	Shigella dysenteriae type 1 (cultures only)			
	Tick-borne encephalitis virus (cultures only)			
	Variola virus			
	Venezuelan equine encephalitis virus			
	West Nile virus (cultures only)			
	Yellow fever virus (cultures only)			
	Yersinia pestis (cultures only)			

INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES INCLUDED IN CATEGORY A IN ANY FORM UNLESS OTHERWISE INDICATED (End) (6.3.2.2.(a))					
UN Number and Proper Shipping Name	Micro-organism				
UN 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				

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Lumpy skin disease v	irus	
Mycoplasma mycoide	es - Contagious bovine pleuropneumonia	
Peste des petits rumin	ants virus	
Rinderpest virus		
Sheep-pox virus		
Goatpox virus		
Swine vesicular diseas	se virus	
Vesicular stomatitis vi	rus	

6.3.2.2.2 <u>Category B</u>: An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B must be assigned to UN 3373 except that cultures as defined in 6.3.1.3 must be assigned to UN 2814 or UN 2900 as appropriate.

#### Note.- The proper shipping name of UN 3373 is Diagnostic specimens or Clinical specimens

6.3.2.3 Substances which do not contain infectious substances or substances which are unlikely to cause disease in humans or animals are not subject to these Instructions unless they meet the criteria for inclusion in another class.

6.3.2.4 Blood which has been collected for the purpose of blood transfusion or for the preparation of blood products, blood products, and any tissues or organs intended for use in transplants are not subject to these Instructions.

6.3.2.5 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 Instructions. Examples are: foodstuffs, water samples, living persons and substances which have been treated so that the pathogens have been neutralized or deactivated.

#### 6.3.3 **Biological products**

6.3.3.1 For the purposes of these Instructions, 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 Instructions.

**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.

(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 must be assigned to UN 2814, UN 2900 or UN 3373, as appropriate.

#### 6.3.4 **Genetically modified micro-organisms and organisms**

6.3.4.1 Genetically modified micro-organisms not meeting the definition of infectious substances must be classified according to Chapter 2.9.

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# 6.3.5 Medical or clinical wastes

6.3.5.1 Medical or clinical wastes containing Category A infectious substances or containing Category B infectious substances in cultures must be assigned to UN 2814 or UN 2900 as appropriate. Medical or clinical wastes containing infectious substances in Category B, other than cultures, must be assigned to UN 3291.

6.3.5.2 Medical or clinical wastes which are reasonably believed to have a low probability of containing infectious substances must be assigned to UN 3291.

**NOTE**: The proper shipping name for UN 3291 is CLINICAL WASTE, UNSPECIFIED, N.O.S. or (BIO) MEDICAL WASTE, N.O.S. or REGULATED MEDICAL WASTE, N.O.S.

6.3.5.3 Decontaminated medical or clinical wastes which previously contained infectious substances are not subject to these Instructions unless they meet the criteria for inclusion in another class.

# CLASS 7 — RADIOACTIVE MATERIAL

# 7.1 DEFINITION OF CLASS 7

7.1.1 Radioactive material means any material containing radionuclides where both the activity concentration and the total activity in the consignment exceed the values specified in 7.7.2.1 to 7.7.2.6.

7.1.2 The following radioactive materials are not included in Class 7 for the purposes of these Instructions:

- a) radioactive material implanted or incorporated into a person or live animal for diagnosis or treatment;
- b) radioactive material in consumer products which have received regulatory approval, following their sale to the end user;
- c) natural material and ores containing 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 not intended to be processed for use of these radionuclides, provided the activity concentration of the material does not exceed 10 times the values specified in 7.7.2;
- d) Non-radioactive solid objects with radioactive substances present on nay surfaces in quantities not in excess of the limit defined in 7.2.

Size of load*	Multiplication factor			
size of load # 1 m <sup>2</sup> 1 m <sup>2</sup> < size of load # 5 m <sup>2</sup> 5 m <sup>2</sup> < size of load # 20 m <sup>2</sup> 20 m <sup>2</sup> < size of load	1 2 3 10			
* Largest cross-sectional area of the load being measured.				

# Table 2-10. Multiplication factors forlarge dimension loads freight containers

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7.6.2 Determination of criticality safety index (CSI)

7.6.2.1 The criticality safety index (CSI) for packages containing fissile material must be obtained by dividing the number 50 by the smaller of the two values of N derived in 6;7.10.11 and 6;7.10.12 (i.e. CSI = 50/N). The value of the criticality safety index may be zero, provided that an unlimited number of packages is subcritical (i.e. N is effectively equal to infinity in both cases).

7.6.2.2 The criticality safety index for each <del>consignment</del> overpack or freight container must be determined as the sum of the CSIs of all the packages contained in that consignment. The same procedure mist be followed for determining the total sum of CSIs in a consignment or aboard an aircraft.

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Table 2-12. Basic radionuclide	s values for individua	l radionuclides
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			Activity concentration	Activity limit for an exempt
Radionuclide	$A_{I}$	$A_2$	for exempt material	consignment
(atomic number)	(TBq)	(TBq)	(Bq/g)	(Bq)
Cf-252	$\frac{5 \times 10^{-2}}{1 \times 10^{-1}}$	$3 \times 10^{-3}$	$1 \times 10^1$	$1 \times 10^4$

#### Chapter 8

# CLASS 8 — CORROSIVES

#### 8.2 ASSIGNMENT OF PACKING GROUPS

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- a) *Packing Group I* is assigned to substances that cause full thickness destruction of intact skin tissue within an observation period of up to 60 minutes starting after an exposure time of 3 minutes or less.
- b) *Packing Group II* is assigned to substances that cause full thickness destruction of intact skin tissue within an observation period of up to 14 days starting after an exposure time of more than 3 minutes but not more than 60 minutes.
- c) *Packing Group III* is assigned to substances that:
  - i) cause full thickness destruction of intact skin tissue within an observation period of up to 14 days starting after an exposure time of more than 60 minutes but not more than 4 hours;
  - are judged not to cause full thickness destruction of intact skin tissue but which exhibit a corrosion rate on steel or aluminium surfaces exceeding 6.25 mm a year at a test temperature of 55EC. For the purposes of testing steel, type P235 (ISO 9328 (II): 1991) S275J2G3+CR (1.0144 resp. St 44-3). ISO 3574 or Unified Numbering System (UNS) G10200 or a similar type, and for testing aluminium, non-clad types 7075-T6 or AZ5GU-T6, must be used. An acceptable test is prescribed in ASTM G31-72 (Reapproved 1990) the UN Manual of Tests and Criteria, Part III, Section 37.

# Chapter 9

# CLASS 9 — MISCELLANEOUS DANGEROUS SUBSTANCES AND ARTICLES

Editorial note: - 9.1 to be revised by UN

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# 9.2 Environmentally hazardous substances (aquatic environment)

# 9.2.1 General Definition

9.2.1.1 Environmentally hazardous substances include, <u>inter alia</u>, liquid or solid substances pollutant to the aquatic environment and solutions and mixtures of such substances (including preparations and wastes)

9.2.1.2. 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.<sup>1</sup> 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.

9.2.1.2 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.<sup>2</sup>

# 9.2.2 DEFINITIONS AND DATA REQUIREMENTS

9.2.2.1 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.

9.2.2.2 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 practice (GLP). Where such data are not available, classification must be based on the best available data.

9.2.2.3 **Acute aquatic toxicity** must normally be determined using a fish 96 hour  $LC_{50}$  (OECD Test Guideline 203 or equivalent), a crustacea 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.

<sup>&</sup>lt;sup>1</sup> 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 the Annexes 2 and 3 of the OECD Document ENV/JM/MONO(2001)6.

**9.2.2.4** The potential for bioaccumulation must 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 must be used in preference when available. A BCF must be determined according to OECD Test Guideline 305.

**9.2.2.5** Environmental Degradation for organic chemicals may be biotic or abiotic (eg. hydrolysis) and the criteria used reflect this fact (see 9.2.5). 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.<sup>3</sup>

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 must be used.

# 9.2.3 SUBSTANCE CLASSIFICATION CATEGORIES AND CRITERIA

9.2.3.1 Substances must be classified as"environmentally hazardous substances (aquatic environment), if they satisfy the criteria for <u>Acute I, Chronic I or Chronic II, according to the following tables</u>.

# Acute toxicity

#### **Category: Acute I**

Acute toxicity: 96 hr  $LC_{50}$  (for fish) 48 hr  $EC_{50}$  (for crustacea) 72 or 96hr  $ErC_{50}$  (for algae or other aquatic plants)

# 1 mg/L and/or # 1 mg/L and/or # 1 mg/L.

#### **Chronic toxicity**

**Category: Chronic I** 

Acute toxicity:

<sup>&</sup>lt;sup>3</sup> Special guidance on data interpretation is provided in the Annex 2 of the OECD Document ENV/JM/MONO(2001)6.

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 $\text{ErC}_{50}$ (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 $\text{ErC}_{50}$ (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.	

# 9.2.4 MIXTURES CLASSIFICATION CATEGORIES AND CRITERIA

9.2.4.1 The classification scheme 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.

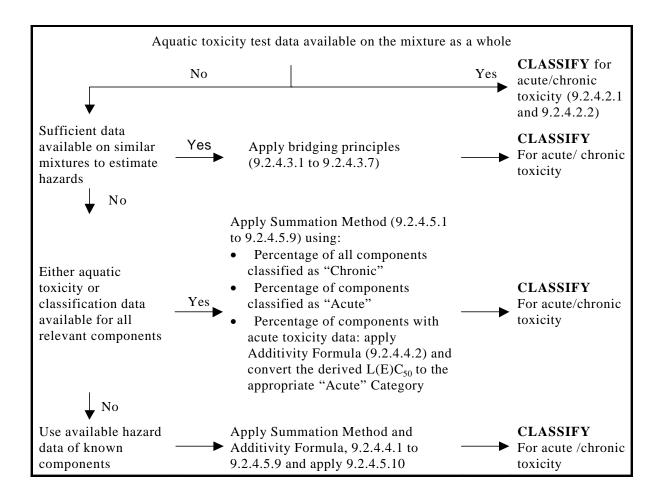
The "relevant components" of a mixture are those which are present in a concentration of 1% (w/w) or greater, unless there is a presumption (e.g. in the case of highly toxic components) that a component present at less than 1% can still be relevant for classifying the mixture for aquatic environmental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

9.2.4.1.1 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:

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

Figure 1 outlines the process to be followed.

# Figure 1: Tiered Approach to Classification of Mixtures for Acute and Chronic Aquatic Environmental Hazards



# 9.2.4.2 Classification of Mixtures when Data is Available for Complete Mixture.

9.2.4.2.1 When the mixture as a whole has been tested to determine its aquatic toxicity, it must be classified according to the criteria that have been agreed for substances in 9.2.3, but only for acute toxicity. The classification is based on the data for: fish, crustacea and algae/plants. Classification of mixtures by using  $LC_{50}$  or  $EC_{50}$  data for the mixture as a whole is not possible for chronic categories

9.2.4.2.2 When there is acute toxicity test data  $(LC_{50} \text{ or } EC_{50})$  available for the mixture as a whole, this data as well as information with respect to the classification of components for chronic toxicity must be used to complete the classification for tested mixtures as follows. When chronic (long term) toxicity data (NOEC) is also available, this must be used in addition.

 $L(E)C_{50}$  (LC<sub>50</sub> or EC<sub>50</sub>) of the tested mixture £ 1mg/L and NOEC of the tested mixture £ 1.0 mg/L or unknown:

unknown:

- ÷ Classify mixture as Category Acute I
- + Apply Summation of Classified Components approach (see 9.2.4.5.6 to 9.2.4.5.9) for chronic classification (Chronic I, II, or no need of chronic classification).
- C L(E)C<sub>50</sub> of the tested mixture £ 1mg/L and NOEC of the tested mixture > 1.0 mg/L:
  - ÷ Classify mixture as Category Acute I
  - Apply Summation of Classified Components approach (see 9.2.4.5.6 to 9.2.4.5.9) for classification as Category Chronic I. If the mixture is not classified as Category Chronic I, then there is no need for chronic classification.
- $L(E)C_{50}$  of the tested mixture >1mg/L, or above the water solubility, and NOEC of the tested mixture # 1.0mg/L or unknown:
  - + No need to classify for acute toxicity
  - + Apply Summation of Classified Components approach (see 9.2.4.5.6 to 9.2.4.5.9) for Chronic classification or no need for chronic classification.
- $L(E)C_{50}$  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

# 9.2.4.3 Classification of Mixtures When Data is not Available for Complete Mixture.

# **Bridging Principles**

9.2.4.3.1 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 must 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.

# **Dilution**

9.2.4.3.2 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 must be classified as equivalent to the original mixture or substance.

9.2.4.3.3 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 must be calculated from the original mixture or substance.

# **Batching**

9.2.4.3.4 The aquatic hazard classification of one production batch of a complex mixture must 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.

# <u>Concentration of Mixtures which are classified with the most severe classification categories</u> (<u>Chronic I and Acute I</u>)

9.2.4.3.5 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 must be classified with the

#### same classification category as the original mixture without additional testing. Interpolation within One Toxicity Category

9.2.4.3.6 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 must be in the same category as A and B. Note that the identity of the components is the same in all three mixtures.

#### **Substantially Similar Mixtures**

- 9.2.4.3.7 Given the following:
  - (a) Two mixtures: i.) A + Bii.) 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 is no need to test mixture (ii) if mixture (i) is already characterised by testing and both mixtures are classified in the same category.

# 9.2.4.4 <u>Classification of Mixtures When Data are Available for All Components or Only for Some</u> <u>Components of the Mixture.</u>

9.2.4.4.1 The classification of a mixture must 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 9.2.4.5.1 to 9.2.4.5.9.

9.2.4.4.2 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 must be calculated using the following additivity formula, and the calculated toxicity must be used to assign that portion of the mixture an acute toxicity category which is then subsequently used in applying the summation method.

$$\frac{\sum Ci}{L(E)C_{50m}} = \sum_{\mathbf{h}} \frac{Ci}{L(E)C_{50m}}$$

where:

9.2.4.4.3 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 (viz., 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 must 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 must then be used to classify this part of the mixture as Acute I, if appropriate, using the same criteria described for substances in 9.2.3.

9.2.4.4.4 If a mixture is classified in more than one way, the method yielding the more conservative result must be used.

#### 9.2.4.5 **Summation Method**

#### **Classification Procedure**

9.2.4.5.3 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.

# Classification for the Acute Category I

9.2.4.5.4 All components classified as Acute I must be considered. If the sum of these components is greater than 25% the whole mixture must be classified as Category Acute I.

9.2.4.5.5 The classification of mixtures for acute hazards based on this summation of classified components, is summarised in Table 2 below.

# Table 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 $\bigwedge$ M <sup>1)</sup>	>25%	Acute I	

1) for explanation of the M factor, see 9.2.4.5.9

# Classification for the Chronic Categories I, II

9.2.4.5.6 First all components classified as Chronic I are considered. If the sum of these components is greater than 25% the mixture must 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.

9.2.4.5.7 In cases where the mixture is not classified as Chronic I, classification of the mixture as Chronic II is considered. A mixture must 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.

9.2.4.5.8 The classification of mixtures for chronic hazards, based on this summation of classified components, is summarised in Table 3 below.

#### Table 3: Classification of a mixture for chronic hazards, based on summation of classified components

Sum of components classified	Mixture is classified as:	
Chronic I $\stackrel{\sim}{}$ M <sup>1)</sup>	>25%	Chronic I
(M ´ 10 ´ Chronic I)+Chronic II	>25%	Chronic II

1) for explanation of the M factor, see 9.2.4.5.9

#### Mixtures with highly toxic components

9.2.4.5.9 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 9.2.4.5.4 to 9.2.4.5.8 must 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 and the concentration of "Chronic I" in the left column of Table 3 are multiplying factor. The multiplying factors to be applied to these components are defined using the toxicity value, as summarised in Table 4 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 (9.2.4.4.2) 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.

L(E)C50 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)		

# Table 4: Multiplying factors for highly toxic components of mixtures

# Classification of Mixtures With Components Without Any Useable Information

**9.2.4.5.10** In the event that no useable information on acute and/or chronic aquatic toxicity 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 must be classified based on the known components only.

# 9.2.5 RAPID DEGRADABILITY

9.2.5.1 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;
- C tests based on dissolved organic carbon: 70%

C 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.

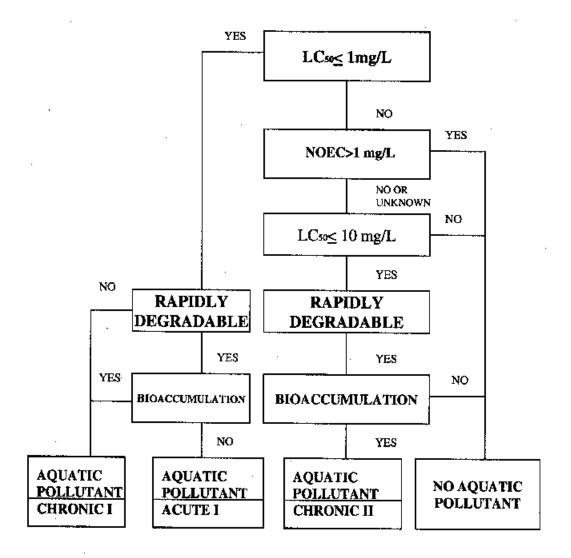
(b) if, in those cases where only BOD and COD data are available, when the ratio of BOD5/COD is \$ 0.5

or

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 >70% within a 28 day period.

9.2.7 Classification Flow Chart



Procedure for classifying a substance dangerous to the aquatic environment when transported in packages

9.2.8 Substances or mixtures dangerous to the aquatic environment not otherwise classified under these Instructions must be designated:

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

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

They must be assigned to packing Group III.

**9.3** Genetically modified micro-organisms (GMMOs) and Genetically modified organisms (GMOs) 9.3.1 Genetically modified micro-organisms and genetically modified organisms which do not meet the definition of infectious substances but which are capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction must be classified in Class 9 and assigned to UN 3245.

9.3.2 When authorized for use by the competent authorities of the Governments of the countries of origin, transit and destination, GMMOs or GMOs are not subject to these Instructions.