



Ecotox classification under GHS in the EU

H. Waeterschoot

Classification drivers for the environment under GHS and DSD

Classification drivers for ecotoxicity:

- ✓ Toxicity : short or long term toxicity
- ✓ Absence of "degradability"
- ✓ Potential for "bioaccumulation"

Classification drivers for the environment under GHS and DSD

How is this measured ?



✓ Toxicity :

- × **Lowest EC50** for reference species representing the different trophic levels (fish, daphnia and algae)
- × **Lowest NOEC** for reference species



✓ Absence of degradation :

- × $\frac{1}{2}$ Lifetime of Bio- or photodegradation



✓ Bioaccumulation :

- × Bioaccumulation Factor (BCF) (often as $\log K_{ow} > 4$)

DSD classification scheme

EC50 Mg/l	EU and DPD R-Code	Hazard Label
< 1	R50	Very Toxic to Aquatic Env.
< 1 Not rapidly biodegradable and/or BCF>500	R50/53	Very Toxic to Aquatic Env Can cause long term effects
> 1 < 10 Not rapidly biodegradable and/or BCF>500	R51/R53	Toxic to Aquatic Env. Can cause long term effects
> 10 < 100 Not rapidly biodegradable and/or BCF>500	R52/R53	Harmful to Aquatic Env. Can cause long term effects
Expected chronic effects	R53	Can cause long term effects

UN-GHS Classification Categories

GHS Class	EU DSD and R-Code	Hazard Label in the EU
Acute I	R50	Very Toxic to Aquatic Env.
Acute I & Chronic I	R50/53	Very Toxic to Aquatic Env Can cause long term effects
OECD ADOPTED IN 2008		
CHRONIC toxicity assessment CRITERIA based on NOECS		
Acute III & Chronic III	R52/R53	Harmful to Aquatic Env. Can cause long term effects
Chronic I, II or III	R53	Can cause long term effects
Chronic IV (safety net)	R53 (not in EU)	Can cause long term effects

EU-GHS Classification Categories

GHS Class	EU DSD and R-Code	Hazard Label in the EU
Acute I	R50	Very Toxic to Aquatic Env.
Chronic I	R50/53	Very Toxic to Aquatic Env Can cause long term effects
Chronic II	R51/R53	Toxic to Aquatic Env. Can cause long term effects
Chronic III	R52/R53	Harmful to Aquatic Env. Can cause long term effects
Chronic IV	R53	Can cause long term effects

Chronic toxicity is substituted by “acute toxicity” AND lack of rapid degradation and/or potential for BCF

The M-factor for highly ecotoxic substances

Annex I: 4.1.3.5.5.1.

Table 4.1.3

Multiplying factors for highly toxic components of mixtures

L(E)C ₅₀ value mg/l	Multiplying factor (M)
$0.1 < L(E)C_{50} \leq 1$	1
$0.01 < L(E)C_{50} \leq 0.1$	10
$0.001 < L(E)C_{50} \leq 0.01$	100
$0.0001 < L(E)C_{50} \leq 0.001$	1 000
$0.00001 < L(E)C_{50} \leq 0.0001$	10 000
(continue in factor 10 intervals)	

M-factor is used to classify preparations and must be communicated through the SDS

M-factor

→ Application :

- ✓ Metal ion "X" has an acute reference toxicity of 5 µg/L
- ✓ An M factor of "100" will be applied
- ✓ Preparations will be classified as of 0,25 ; 0,025 ; 0,0025 %

→ Consequences :

- ✓ Cut off value for classification of preparations may decrease significantly (eg for ores and concentrates)

Labelling

ACUTE 1
CHRONIC 1 and 2



WARNING
(not for C2)

CHRONIC 3 and 4

No pictogram

Hazard statements



A1 Very toxic to aquatic life (H400)



C1 Very toxic to aquatic life with long lasting effects (H410)



C2 Toxic to aquatic life with long lasting effects (H411)



C3 Harmful to aquatic life with long lasting effects (H412)



C4 May cause long lasting harmful effects to aquatic life (H413)



Precautionary statements

★
★
★
★ Avoid release to the environment (P273)

★
★ Collect spillage (P391)

★
★ Dispose of contents/container to ... (P501)



How to classify preparations?

- By testing the preparations :
 - ✓ Expensive and not possible for alloys and SSMC's since nominal testing is NOT allowed
- By bridging principles :
- By applying calculation rules

How to classify preparations?

Classification of a mixture for chronic (long term) hazards, based on summation of classified components

Sum of components classified as:	Mixture is classified as:
Chronic Category ≥ 25 %	Chronic Category 1
$(10 \times \text{Chronic Category 1}) +$ Chronic Category 2 ≥ 25 %	Chronic Category 2
$(100 \times \text{Chronic Category 1}) + (10 \times$ Chronic Category 2) + Chronic Category 3 ≥ 25 %	Chronic Category 3
Chronic Category 1 + Chronic Category 2 + Chronic Category 3 + Chronic Category 4 ≥ 25 %	Chronic Category 4

★ M-factor application to preparations

Classification of a mixture for chronic (long term) hazards, based on summation of classified components

Sum of components classified as:	Mixture is classified as:
Chronic Category 1 $\times M \geq 25\%$	Chronic Category 1
$(M \times 10 \times \text{Chronic Category 1}) + \text{Chronic Category 2} \geq 25\%$	Chronic Category 2
$(M \times 100 \times \text{Chronic Category 1}) + (10 \times \text{Chronic Category 2}) + \text{Chronic Category 3} \geq 25\%$	Chronic Category 3
Chronic Category 1 + Chronic Category 2 + Chronic Category 3 + Chronic Category 4 $\geq 25\%$	Chronic Category 4

Issues for metals

→ Metals are **data rich** :

- ✓ Scientifically unfair to take to “lowest toxicity reference”

→ The **“ion”** causes often the toxicity

- ✓ Nominal testing of insoluble substances not allowed

→ Metals have **specific particularities**

- ✓ Solubility differs for different “physical forms”
- ✓ “Metal surface” corresponds with moadings

→ Need for **specific approaches** :

- ✓ Measure release rate and equilibrium to read across between ion and SSMC or metal

Classification strategy for metals

1. Assessment approach for *effects data*
2. Guidance on interpreting *BCF and rapid degradation*
3. *Assessment tool* for release rate and equilibrium
4. *Classification strategy* for metals and metal compounds

Classification strategy for metals

These 4 critical issues including examples will be explained in the next presentations

