



Criteria for Classification and Labelling of Substances and Mixtures

ENVIRONMENTAL HAZARDS

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Coverage

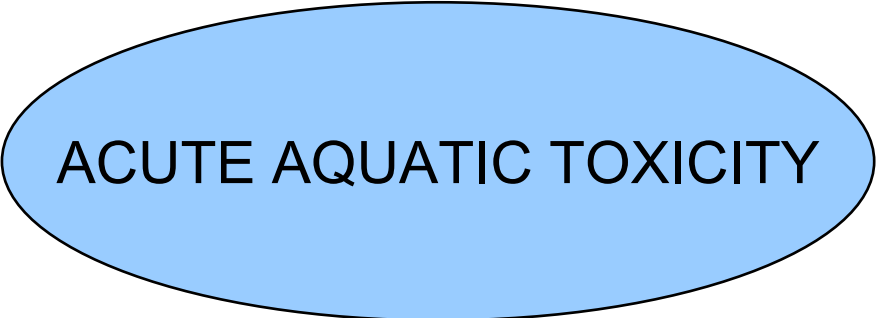
- Mainly focus on short term and long term effects on the aquatic compartment including:
 - How to derive and how to use M-factors
 - Changes from 'current scheme'
- Also
 - Effects on the ozone layer
 - Guidance - Hazardous to the aquatic env.

Rationale of criteria

- Largely based on the current EU system
- Should use standard tests where available (e.g. OECD or other internationally recognised test methods)
- Criteria should be simple and easy to understand
- Should cover short-term and long-term aquatic effects
- Should distinguish by severity of hazard

Criteria are built by 'basic elements'

(Hazardous to the aquatic environment)



ACUTE AQUATIC TOXICITY

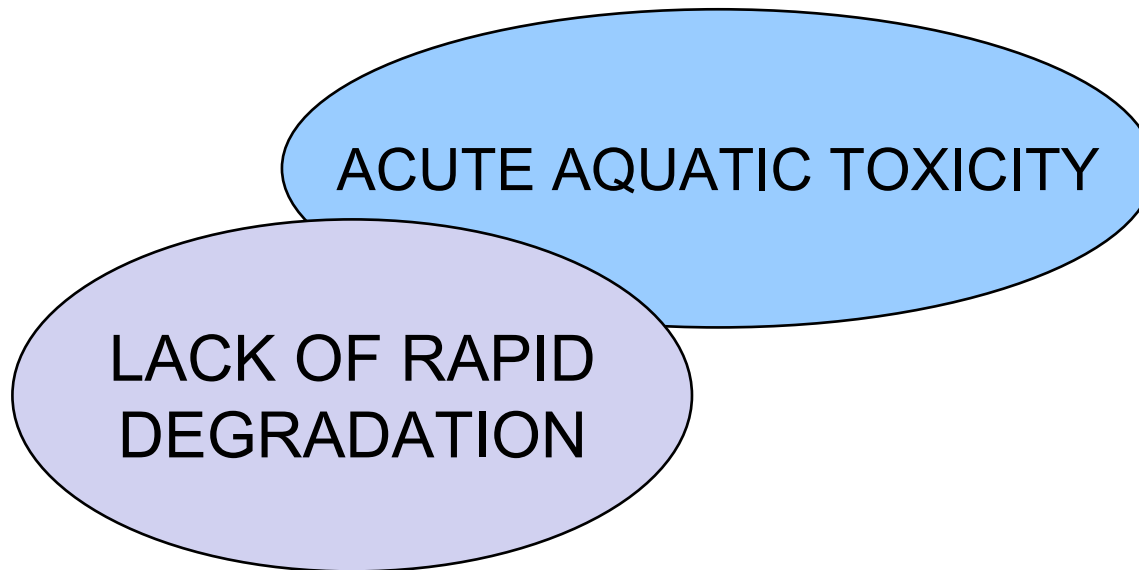
Acute toxicity to

- **Fish** (96 h LC₅₀)
- **Crustacea** (eg 48 h *Daphnia magna* EC₅₀)
- **Algae / aquatic plant** (eg 72/96 h algal growth inhibition EC₅₀)

cover a range of trophic levels and taxa

Criteria are built by 'basic elements'

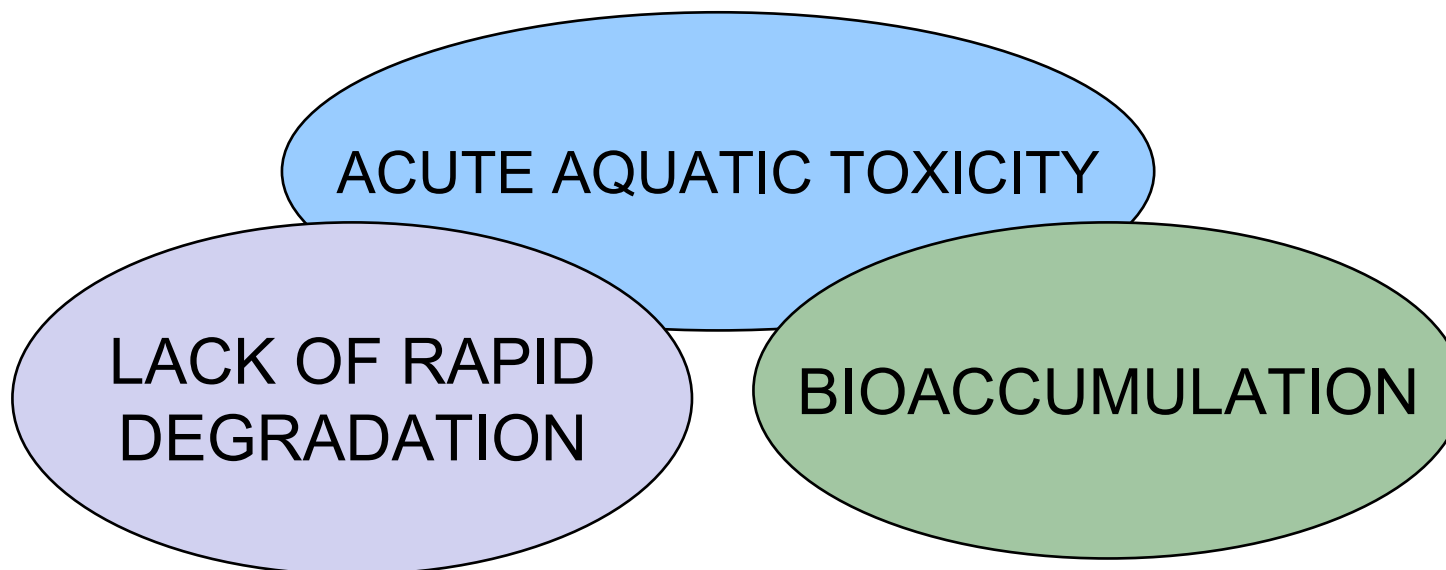
(Hazardous to the aquatic environment)



Lack of rapid degradability
=
Not Readily Biodegradable
or
Not Abiotically Degradable

Criteria are built by 'basic elements'

(Hazardous to the aquatic environment)



Bioconcentration factor (BCF)

≥ 500

or, if absent, partition coef.

$\text{LOG } K_{ow} \geq 4$

Criteria for Acute (short-term) aquatic hazard
Cut-off value of 1 mg/l

ACUTE AQUATIC TOXICITY

Acute toxicity to

Fish

and/or

Crustacea

and/or

Aquatic plant

$\leq 1 \text{ mg/l}$

**ACUTE
CATEGORY 1**

Acute (short-term) aquatic hazard - Category 1

ACUTE TOXICITY TO FISH
CRUSTACEA OR AQUATIC PLANT
 ≤ 1 mg/l

**ACUTE
CATEGORY 1**

~~ACUTE TOXICITY TO FISH
CRUSTACEA OR AQUATIC PLANT~~

~~ACUTE
CATEGORY 2~~

~~*CRUSTACEA OR AQUATIC PLANT*
 > 10 to ≤ 100 mg/l~~

~~ACUTE
CATEGORY 3~~

**Acute categories 2 and 3 are not implemented
since not for Supply & Use, but mainly for
transport of bulk-quantities**

Labelling elements for Acute (short-term) aquatic hazard - Category 1

Pictogram



Signal
word

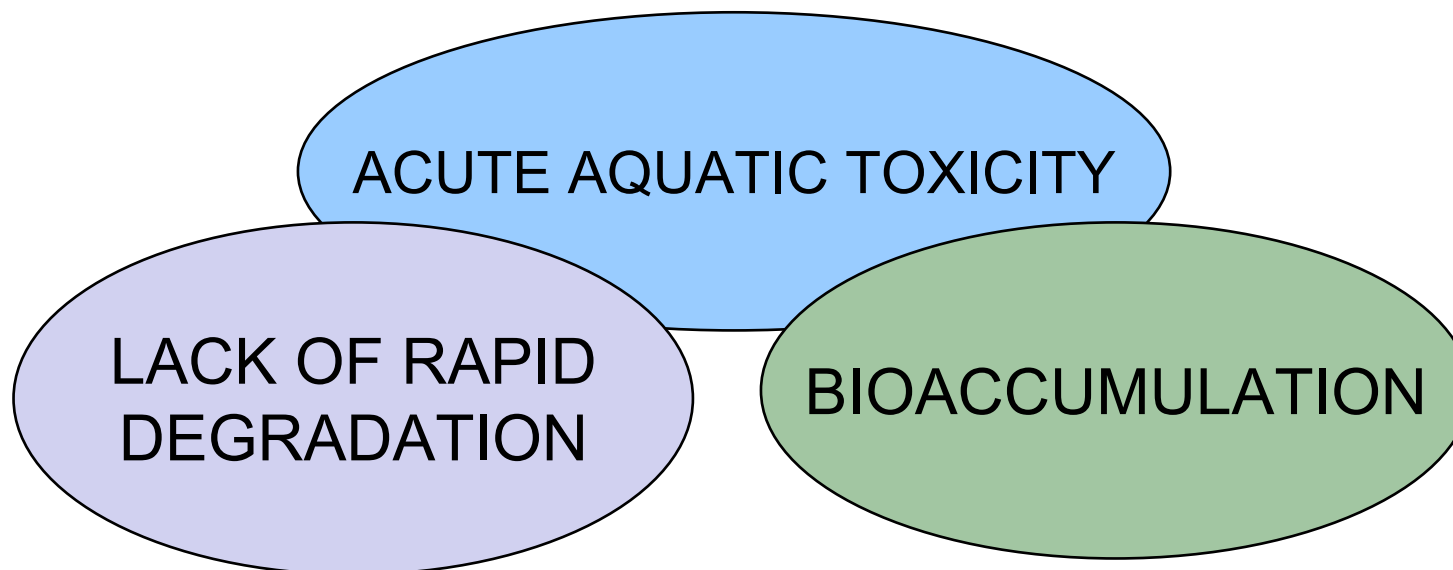
Warning

Hazard
Statement

**Very toxic to
aquatic life**

Substance criteria for Long-term aquatic hazard

Combined elements

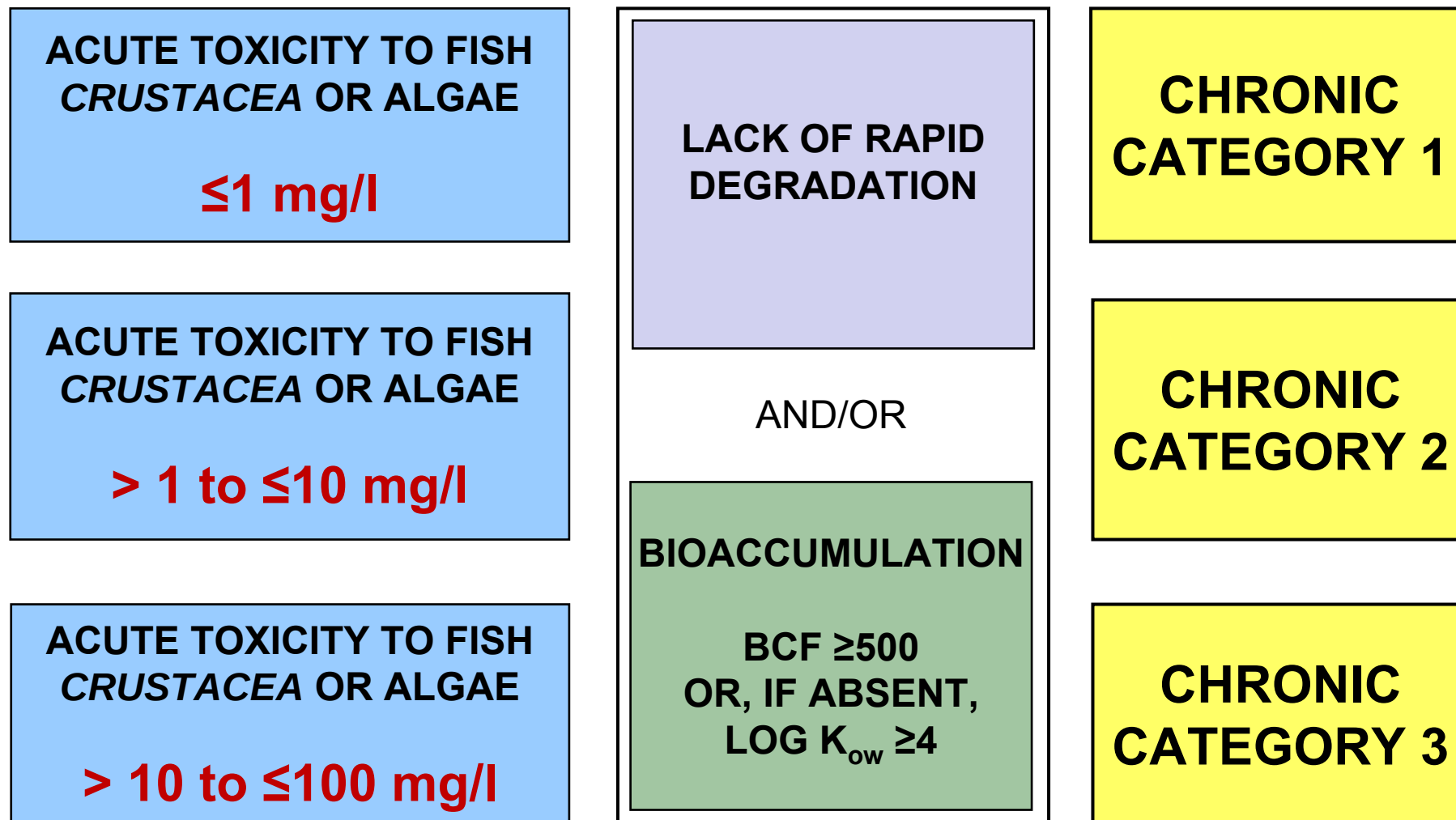


**Acute toxicity to Fish, Crustacea or Algae/Aquatic plant
and either**

Lack of degradability or $BCF \geq 500$ (or, if absent, $\text{LOG } K_{ow} \geq 4$)

Categories 1 – 3

are distinguished by the level of acute toxicity

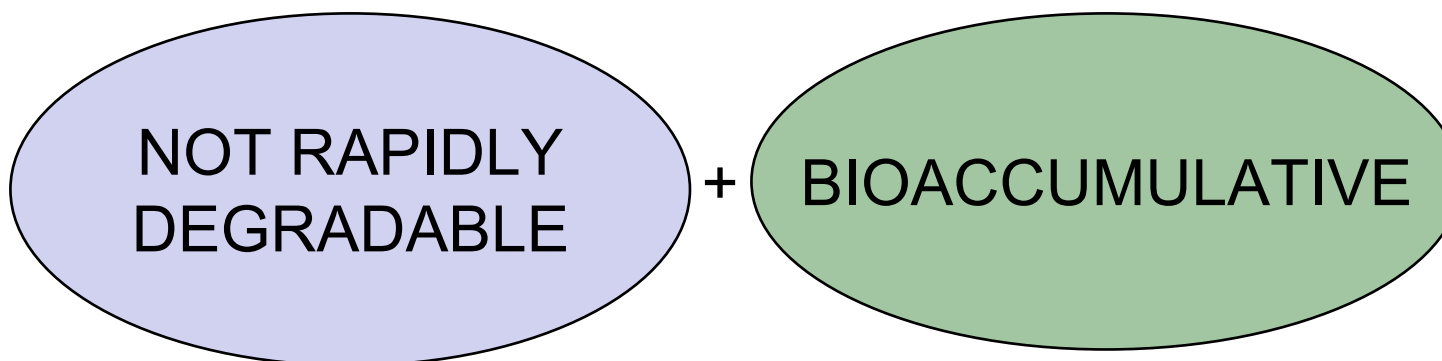


Labelling elements for Long-term aquatic hazard - Categories 1 to 3

Chronic	<u>Category 1</u>	<u>Category 2</u>	<u>Category 3</u>
Pictogram			No Pictogram
Signal word	Warning	No words	No words
Hazard Statement	<u>Very toxic</u> to aquatic life with long-lasting effects	<u>Toxic</u> to aquatic life with long-lasting effects	<u>Harmful</u> to aquatic life with long-lasting effects

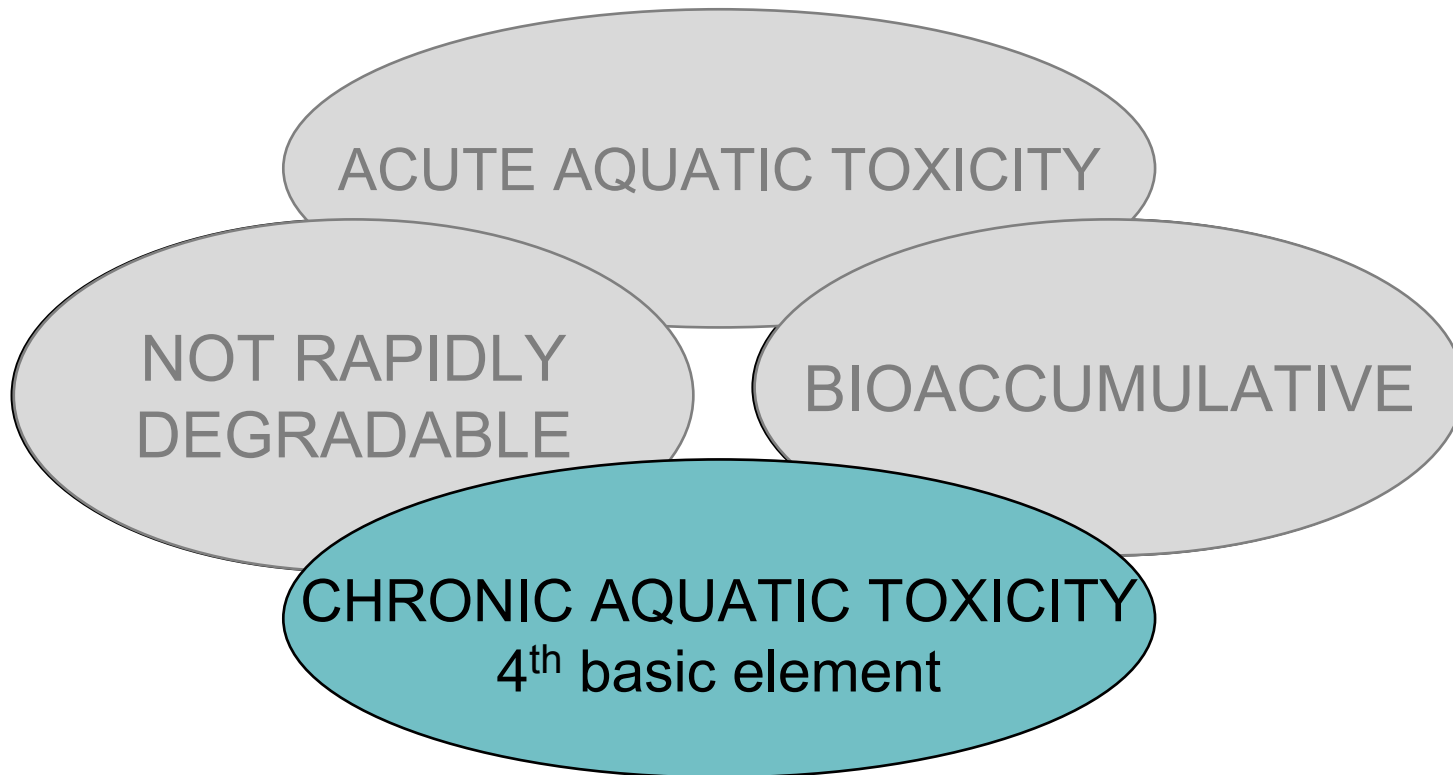
Chronic category 4

- 'Safety Net' Classification when standard criteria are not met, but there is a concern
- For example, poorly soluble substances that are:



'Escape Clause' – This classification can be removed by proven lack of Long-term toxicity at 1 mg/l (or at the level of water solubility)

Hazardous to the aquatic environment
“Escape Clause” – Chronic 2, 3 and 4



Can be removed by
relevant Long-term toxicity >1 mg/l
or
> the level of water solubility (Chronic 4)

Multiplying factors (M)

- Need to consider if substance classified as **Acute 1 or Chronic 1**, i.e. those with acute toxicity $L(E)C_{50} \leq 1$ mg/l
- Established by **substance supplier** based on lowest valid toxicity data point
- Used to derive by **the summation method** the classification of a mixture

$L(E)C_{50}$ value (mg/l)

M-factor

Ingr. conc. x 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
$0.0001 < L(E)C_{50} \leq 0.001$	1000

$$\rightarrow C_i \times 1$$

$$\rightarrow C_i \times 10$$

$$\rightarrow C_i \times 100$$

$$\rightarrow C_i \times 1000$$

And so on in factor of 10 intervals

For Classification of mixtures

- Same classification levels (categories) as for substances
- Same Signal Word, Pictogram and Hazard Statement applicability as substances
- In principle 3 or 4 classification methods:
 - **Test data** on the mixture itself
 - Strictly defined '**Bridging principles**' on similar tested mixtures
 - The '**Summation method**' - summation of components concentrations based on their classification
 - '**Additivity formula**' - summation of components concentrations based on their acute toxicity

Test data on the mixture itself

- Must be valid according to standard guidelines
- New testing not encouraged and only provided all other means been exhausted

Acute Toxicity test data

- Can be used to define Acute Hazard
- Must have fish, crustacea, aquatic plant

Chronic Toxicity test data

- Only used to declassify
Chronic categories 2, 3 and 4 (escape clause)
- Must have fish, crustacea, aquatic plant

Additivity formula:

Therefore, there is normally no need to use the additivity formula

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

- To calculate an acute toxicity value for the mixture or part of a mixture to substitute for acute toxicity in defining the acute hazard category.
- Only used if Summation Method not possible through lack of substance ingredient classifications.
- The substance acute classification and M-factor is, however, easily derived by comparison with the substance criteria.

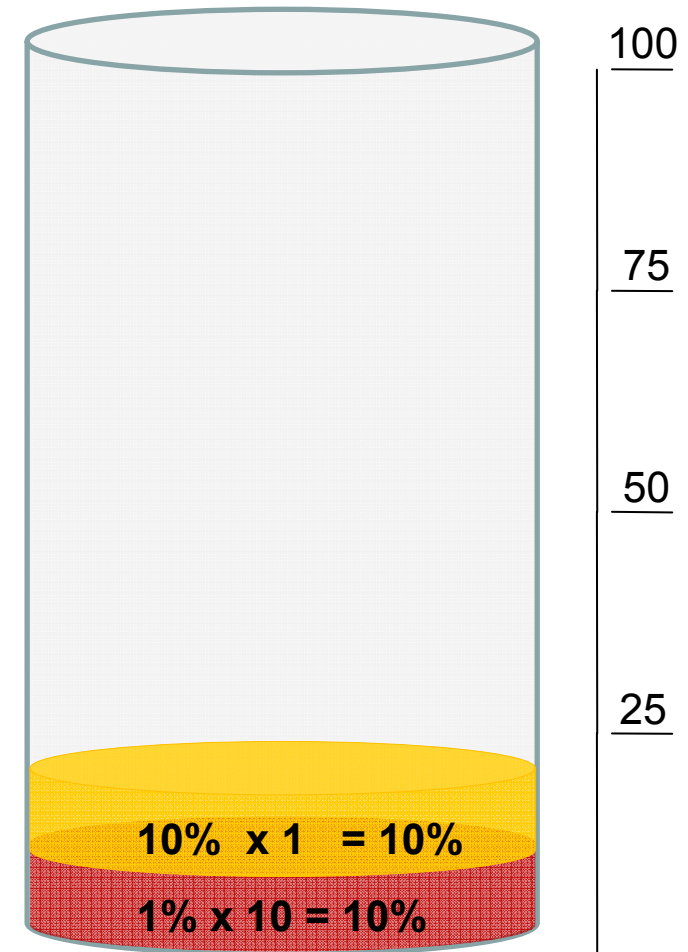
**GHS in general requires that the
“Summation method” be used**

Summation method, example on Long term effects step 1:

Mixture classified as Category Chronic 1 if

$$\sum(\text{Chronic Category 1} \times M) \geq 25\%$$

	Ingr. A	Ingr. B	Ingr. C
	<u>1%</u>	<u>10%</u>	<u>10%</u>
Chronic 3			
Chronic 2			●
Chronic 1, M1		●	
Chronic 1, M10	●		
Chronic 1, M100			

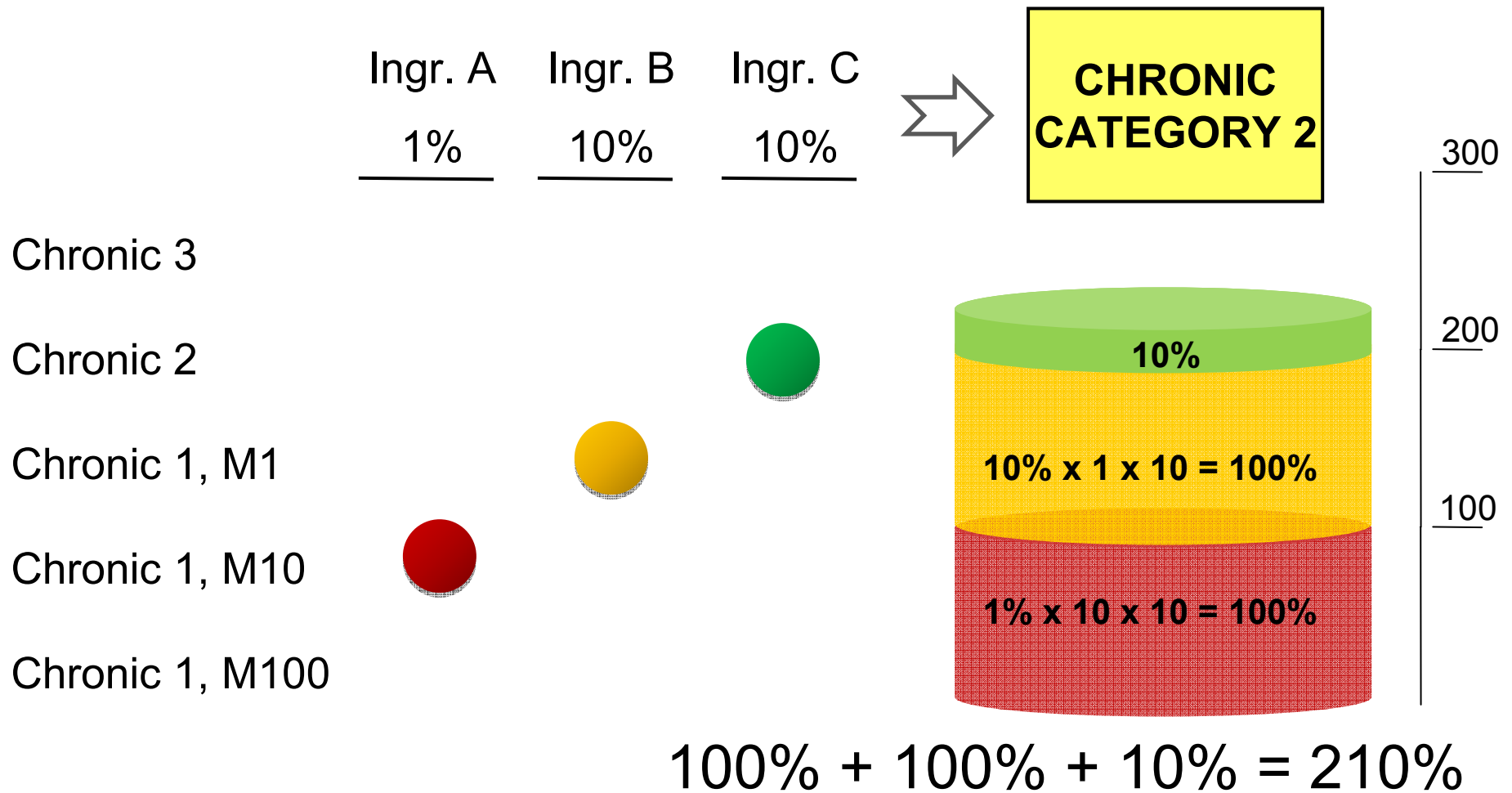


$$10\% + 10\% = 20\%$$

Summation method, example on Long term effects step 2:

Mixture classified as Category Chronic 2 if

$$\sum(\text{Chronic Category 1} \times M \times 10) + \sum(\text{Chronic Category 2}) \geq 25\%$$



Hazardous to the Ozone Layer

(Additional EU hazard class)

Substances

- That may present a danger to the structure and/or functioning of the stratospheric ozone layer;
- Includes substances in Annex I to Council Regulation (EC) No 2037/2000

Mixtures

- Concentration limit of 0.1%

In summary – Substances

(Changes from current scheme)

- Clearer distinction between short and long term hazard
- Bioaccumulation criterion changed from $\log K_{ow} \geq 3$ to $\log K_{ow} \geq 4$; BCF ≥ 100 changed to ≥ 500
- Extension of the use of long-term NOEC >1 mg/l escape to cover Chronic category 2, 3 and 4
- Need to derive M-factors if Acute 1 or Chronic 1
- New Signal Word, Pictogram and Hazard Statement applicability
- Extended use of QSARs

In summary – Mixtures

(Changes from current scheme)

- Clearer distinction between short and long term hazard
- Test data limited to Acute category
- Bridging principles can be applied
- Need to use M-factors if Acute 1 or Chronic 1 substance in mixture
- New Signal Word, Symbol and Hazard Statement applicability

ECHA guidance

- Explaining the system
- Interpretation of data and application of the criteria
- Based on Annex 9 of GHS
- Additional guidance for mixtures
- Several examples on classification of substances and mixtures
- Includes a classification strategy for metals and metal compounds