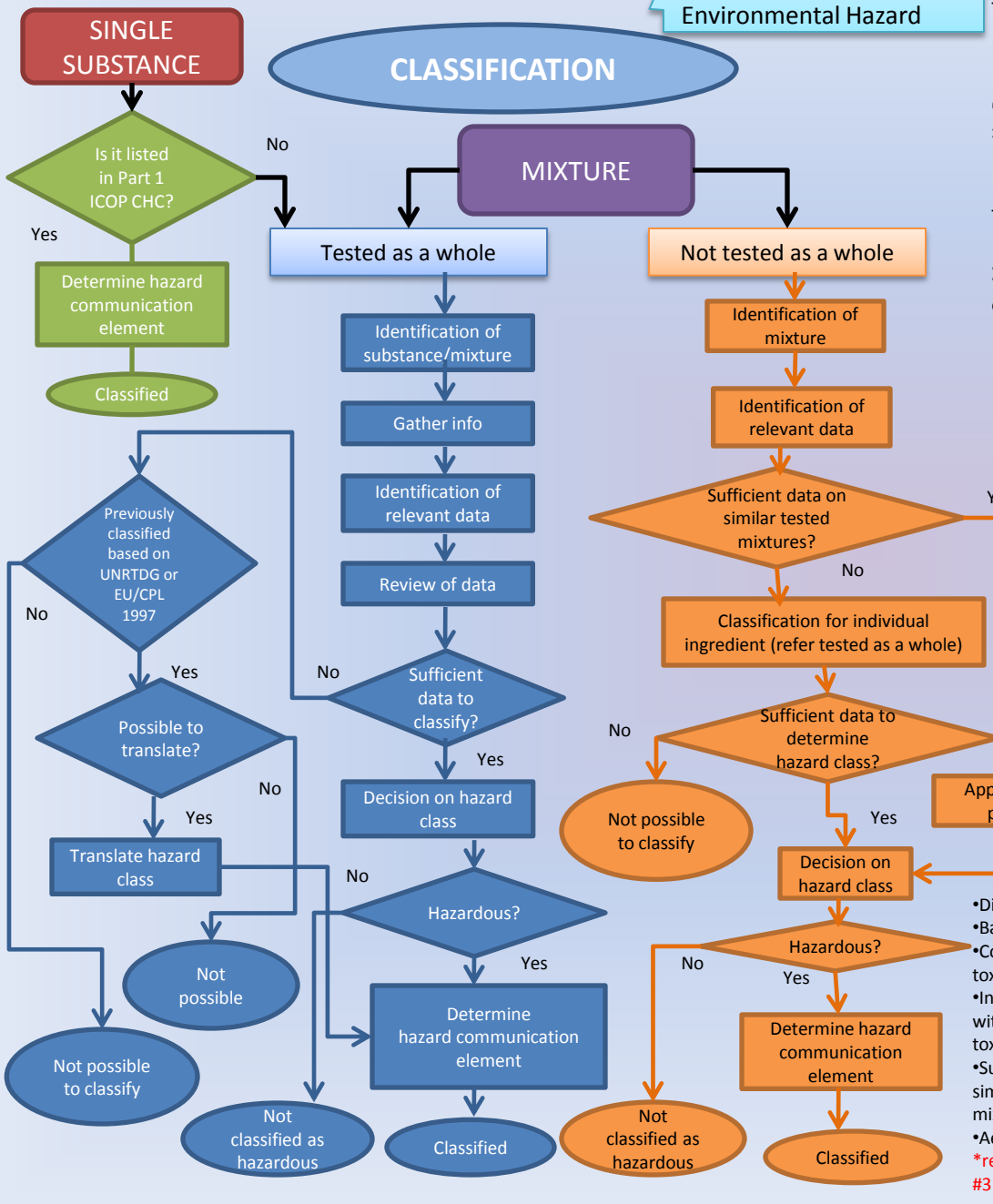
1 *CLASS REGULATIONS: CLASSIFICATION OF CHEMICALS ACCORDING TO ICOP

Classify chemicals:
Physical Hazard
Health Hazard
Environmental Hazard



- Dilution
- Batching
- Conc. of highly toxic mixtures
- Interpolation within one toxic category
- Substantially similar mixtures
- Aerosols

refer RQTM #3

X : Does not apply
O : May apply
△ : May apply but no testing method is prescribed

Class	Gas	Liquid	Solid	Relevant Chemical Structure
1. Explosives	X	O	O	Molecules contain atom groups associated with explosive properties
2. Flammable gases	O	X	X	
3. Flammable aerosols	O	O	O	
4. Oxidizing gases	O	X	X	
5. Gases under pressure	O	X	X	
6. Flammable liquids	X	O	X	
7. Flammable solids	X	X	O	(Powdered, granular or pasty substances are to be evaluated)
8. Self-reactive substances & mixtures	X	O	O	Molecules contain atom groups associated with explosive or self-reactive properties.
9. Pyrophoric liquids	X	O	X	
10. Pyrophoric solids	X	X	O	
11. Self-heating substances & mixtures	X	△	O	
12. Substances & mixtures which, in contact with water, emit flammable gases	X	O	O	Contain metals or metalloids (Si, Ge, As, Sb, Bi, etc.)
13.Oxidizing liquids	X	O	X	Molecules contain oxygen, fluorine or chlorine that is chemically bonded to an element other than carbon or hydrogen
14. Oxidizing solids	X	X	O	
15. Organic peroxides	X	O	O	Organic peroxide with an -O-O- bond. However, excludes substances containing little available oxygen
16. Corrosive to metals	△	O	△	

Hazard Class	Dilution	Batching	Concentration of toxic mixture	Interpolation	Similar mixture	Aerosol
1. Acute toxicity (oral/ dermal/ inhalation)	√	√	√	√	√	√
2. Skin corrosion/ irritation	√	√	√	√	√	√
3. Serious eye damage/ eye irritation	√	√	√	√	√	√
4. Respiratory/ skin sensitization	√	√	-	-	√	√
5. Germ cell mutagenicity	√	√	-	-	√	-
6. Carcinogenicity	√	√	-	-	√	-
7. Reproductive toxicity	√	√	-	-	√	-
8. Specific target organ toxicity - single & repeated exposure	√	√	√	√	√	√
9. Aspiration hazard	√	√	√	√	√	-
10. Hazardous to the aquatic environment – acute & chronic hazard	√	√	√	√	√	-

2 CLASSIFICATION FOR MIXTURE

Physical

Mixture tested as a whole, then apply for 16 criteria for single substance

Health

Bridging Principle

1 Acute toxicity

Additivity formula

Step 1
Use LD50 (mg/kg) data for each ingredient for oral & dermal and
Use LC50 mg/l (vapor, mist, dust) or ppm (gas) for inhalation
Step 2
Use additivity formula to determine ATEmix

Data available for all ingredients

$$\frac{100}{ATEmix} = \sum_{n} \frac{Ci}{ATE_i}$$

where:
C_i= concentration of ingredient i n ingredients and i is running from 1 to n
ATE_i=Acute Toxicity Estimate of ingredient i

Data are not available for one or more ingredients of the mixture

$$\frac{100 - \left(\sum C_{unknown} \text{ if } > 10\%\right)}{ATE_{mix}} = \sum_{n} \frac{Ci}{ATE_i}$$

- 11 Aspiration hazard
- 10 Specific Target Organ Toxicity (repeated exposure)
- 9 Specific Target Organ Toxicity (single exposure)
- 8 Reproductive toxicity

Step 1
Get information for composition and hazard category for each hazardous ingredient
Step 2
Use cut-off value for hazard category with Cat. 1 , then Cat. 2 and next…
Step 3
Compare to criteria for each hazard class
Step 4
Classify hazard category

- 2 Skin Corrosion /irritant
- 3 Serious eye damage /irritant
- 4 Respiratory sensitizer
- 5 Skin sensitizer
- 6 Germ cell mutagenicity
- 7 Carcinogenicity

Environmental

1 Hazardous to the aquatic environment-acute hazard

Additivity formula

Step 1
Use LC50 for fish (mg/l) , EC50 for crustacea, ErC50 for algae data for each ingredient
Step 2
Use additivity formula to determine L(E)C50m

Data available for all ingredients

$$\frac{\sum Ci}{L(E)C50_m} = \sum_{n} \frac{Ci}{L(E)C50_i}$$

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

Summation Method

Step 1
Get information for composition and hazard category for each hazardous ingredient
Step 2
Determine M factor
Step 3
Use the sum of concentration with Acute. 1 ,

Sum of components classified as:	Mixture is classified as:
Acute 1 × M[a] > 25%	Acute 1

Bridging Principle

2 Hazardous to the aquatic environment-chronic hazard

Additivity formula

Step 1
Use LC50 for fish (mg/l) , EC50 for crustacea, ErC50 for algae data for each ingredient
Step 2
Use additivity formula to determine $EqNOEC_m$

Data available for all ingredients

$$\frac{\sum C_i + \sum C_j}{EqNOEC_m} = \sum_{n} \frac{C_i}{NOEC_i} + \sum_{n} \frac{C_j}{0.1 \times NOEC_j}$$

Where
C_i =conc. of ingredient i (wt%) covering rapidly degradable ingredients;
C_j =conc. of ingredient j covering non-rapidly degradable ingredients;
$NOEC_i$=NOEC for ingredient i covering rapidly degradable ingredients, mg/l
$NOEC_j$=NOEC for ingredient j covering non-rapidly degradable ingredients
n = number of ingredients, and I and j are running from 1 to n
$EqNOEC_m$ = Equivalent NOEC of the part of the mixture with test data

Summation Method

Step 1
Get information for composition and hazard category for each hazardous ingredient
Step 2
Determine M factor
Step 3
Use the sum of concentration with Chronic 1 ,

Sum of components classified as:	Mixture is classified as:
Chronic 1 × M[a] >25%	Chronic 1
(M × 10 × Chronic 1)+Chronic 2 >25%	Chronic 2
(M × 100 × Chronic 1)+(10 × Chronic 2)+Chronic 3 >25%	Chronic 3
Chronic 1 + Chronic 2 + Chronic 3 + Chronic 4 > 25%	Chronic 4

Bridging Principle

3 Hazardous to ozone layer

Step 1
Get information for composition for hazard category
Step 2
Compare to criteria

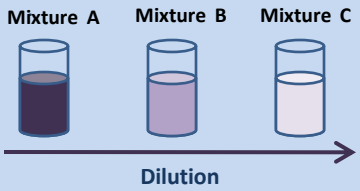
Bridging Principle

- Extrapolating data to determine the hazards of untested mixture as a whole
- Allows broader use of available data to complete a hazard classification.

1 Dilution

If a tested mixture is diluted with a diluent that has an equivalent or lower toxicity classification than the least toxic original ingredient, and which is not expected to affect the toxicity of other ingredients, then the new diluted mixture may be classified as equivalent to the original tested mixture

Example :

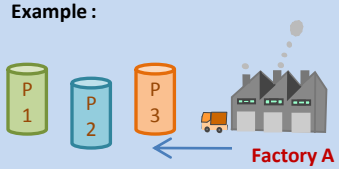


If Mixture A diluted with non hazardous solutions to produce B, then B should be classified same category with Mixture A. Also same with Mixture C when produced from dilution of B

2 Batching

The toxicity of a tested production batch of a mixture can be assumed to be substantially equivalent to that of another untested batch of the same commercial product when produced by or under the control of the same manufacturer, unless there is reason to believe there is significant variation such that the toxicity of the untested batch has changed. If the latter occurs, new classification is necessary.

Example :

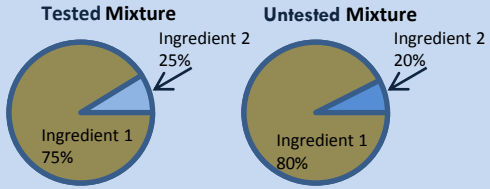


P1,P2, and P3 are the same commercial products produced by Factory A. As a first batch P1 had already tested classified. So that P2 for second batch and P3 for third batch should be classified in the same category with P1.

3 Concentration of Highly Toxic Mixtures

If a tested mixture is classified in the highest class and/or subcategory is concentrated, a More concentrated untested mixture should be classified in the highest class and/or subcategory without testing.

Example :

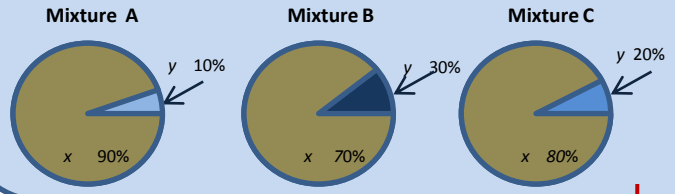


Ingredient 1 is category 1 and ingredient 2 is category 2. If the whole tested mixture is category 1, then untested mixture is classified as category 1 (based on 80% ingredient 1 of untested mixture > 75% ingredient 1 of tested mixture)

4 Interpolation Within One Toxic Category

For three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are in the same class and/or subclass and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same toxicity class as A and B.

Example :



If Mixture A and B are in category 2, then mixture C is classified as category 2

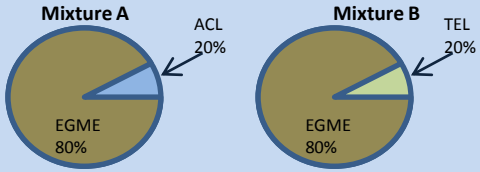
5 Substantially Similar Mixtures

Given the following:
Two mixtures: (i) A + B & (ii) C + B
(a)The concentration of ingredient B is essentially the same in both mixtures.
(b) The concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii)

(c)Data for A and C are available and Substantially equivalent, i.e. they are in

The same hazard class and are not expected to affect the toxicity of B.If mixture (i) or (ii) is already classified based on test data, then the other mixture can be assigned the same hazard category.

Example :



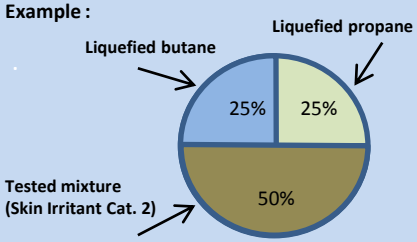
LD50 ACL=11 mg/kg
LD50 TEL=12.3 mg/kg
LD50 EGME=207 mg/kg

LD50 values of ACL and TEL are about the same value, mixture B is said to be similar to mixture A, hence the same hazard category

6 Aerosols

An aerosol form of a mixture may be classified in the same hazard category as the tested, non-aerosolized form of the mixture provided the added propellant does not affect the toxicity of the mixture on spraying

Example :



Tested mixture (Skin Irritant Category 2) is aerosolized using a 50/50 mixture of propane/butane as the propellant. **Then aerosolized untested mixture can be classified as Skin Irritant Category 2 without additional testing**