Classification of Mixtures
- Health Hazards -

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Implementing GHS

Health hazards

Decrease in severity

Hazard Class	Hazard Category				
Acute Toxicity					
Oral	1	2	3	4	
Dermal	1	2	3	4	
Inhalation	1	2	3	4	
Skin Corrosion/Irritation	Corrosive			Irritant	
	1A	1B	1C	2	
Serious Eye Damage/Irritation	1			2	
Sensitization					
Respiratory	1A	1B			
Skin	1A	1B			
Germ Cell Mutagenicity	1A	1B	2		
Carcinogenicity	1A	1B	2		
Reproductive Toxicity	1A	1B	2	Lactation	
STOT - Single Exposure	1	2	3		
STOT - Repeated Exposure	1	2			
Aspiration hazard	1				

Classification of mixtures

- Test data available for the complete mixture
  - Mandatory for physical hazards

- Test data not available for the complete mixture
  - Bridging principles
  - Classification based on the ingredients
    - Classification of ingredient substances
    - Concentration of ingredient substances
      - Calculation method
      - Concentration limits

Generic cut-off values

Acute Toxicity:

- Category 1-3 0,1 %
- Category 4 1 %

Skin corrosion/Irritation	1 %
Serious damage to eyes/eye irritation	1 %

Additivity formula for classification of a mixture based on the acute toxicity of the ingredients

1) Data available for all ingredients

$$\frac{100}{ATE_{mixture}} = \sum_{n} \frac{Ci}{ATEi}$$

C_i	= concentration of ingredient ”i” (% w/w or % v/v)
i	= the individual ingredient from 1 to *n*
n	= the number of ingredients
ATE_i	= Acute Toxicity Estimate of ingredient *”i”*

Classification of a mixture: acute oral toxicity

	%	ATE	Classification
Substance A	1	225 mg/kg	
Substance B	3	100 mg/kg	
Substance C	10		acute tox, cat 3
Water	86		

Conversion from range value/category to point estimate

Exposure Route		Category or experimental estimate	Converted point estimate
Oral (mg/kg bw)		0 < category 1 ≤ 5 5 < category 2 ≤ 50 50 < category 3 ≤ 300 300 < category 4 ≤ 2000	0.5 5 100 500
Dermal (mg/kg/bw)		0 < category 1 ≤ 50 50 < category 2 ≤ 200 200 < category 3 ≤ 1000 1000 < category 4 ≤ 2000	5 50 300 1100
Inhalation	Gases (ppmV)	0 < category 1 ≤ 100 100 < category 2 ≤ 500 500 < category 3 ≤ 2500 2500 < category 4 ≤ 2000	10 100 700 4500
	Vapours (mg/l)	0 < category 1 ≤ 0,5 0,5 < category 2 ≤ 2,0 2,0 < category 3 ≤ 10 10 < category 4 ≤ 20	0,05 0,5 3 11
	Dust/mists (mg/l)	0 < category 1 ≤ 0,05 0,05 < category 2 ≤ 0,5 0,5 < category 3 ≤ 1,0 1,0 < category 4 ≤ 5	0,005 0,05 0,5 1,5

Classification of a mixture: acute oral toxicity

	%	ATE	Classification
Substance A	1	225 mg/kg	
Substance B	3	100 mg/kg	
Substance C	10		acute tox, cat 3
Water	86		

Point estimate: 100

$$\frac{100}{ATE_{mixture}} = \sum_{n} \frac{Ci}{ATEi}$$

$$\frac{100}{ATE_{mixture}} = \frac{1}{225} + \frac{3}{100} + \frac{10}{100} \rightarrow ATE_{mixture} = 743$$

classification: acute tox, cat 4

Additivity formula for classification of a mixture based on the acute toxicity of the ingredients

2) Data not available for all ingredients

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

C_i	= concentration of ingredient ”i” (% w/w eller % v/v)
i	= the individual ingredient from 1 to *n*
n	= the number of ingredients
ATE_i	= Acute Toxicity Estimate for ingredient *”i”*

Classification of a mixture: acute oral toxicity

	%	ATE	Classification
Substance A	4	LD_{50}: 125 mg/kg	Oral Category 3
Substance B	92	No data available	Not possible
Substance C	3	$LD_{50:}$ 1500 mg/kg	Oral Category 4
Substance D	0,9	No data available	Not possible
Substance E	0,1	LD_{50}: 10 mg/kg	Oral Category 2

Classification of a mixture: acute oral toxicity

	%	ATE	Classification
Substance A	4	LD_{50}: 125 mg/kg	Oral Category 3
Substance B	92	No data available	Not possible
Substance C	3	$LD_{50:}$ 1500 mg/kg	Oral Category 4
Substance D	0,9	No data available	Not possible
Substance E	0,1	LD_{50}: 10 mg/kg	Oral Category 2

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

$$\frac{100-(92)}{ATE_{mixture}}=\frac{4}{125}+\frac{3}{1500}=0{,}032+0{,}002=0{,}034$$

$ATE_{mixture}$ = 235 mg/kg ➔ Category 3,

and *"92% of the mixture consists of an ingredient of unknown toxicity."*

Classification of a mixture: skin corrosion/irritation

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Skin Corrosive Category 1*	Skin Irritant Category 2
Skin Corrosive Categories 1A, 1B, 1C	≥ 5%	≥ 1% but < 5%
Skin irritant Category 2		≥ 10%
(10 x Skin Corrosive Category 1A, 1B, 1C) + Skin Category 2		≥ 10%

- The sum of all ingredients of a mixture classified as Skin Corrosive Category 1A, 1B or 1C, respectively, should each be ≥ 5% in order to classify the mixture as either Skin Corrosive Category 1A, 1B or 1C.
- If the sum of the Skin Corrosive Category 1A ingredients is < 5% but the sum of Category 1A+1B ingredients is ≥ 5%, the mixture should be classified as Skin Corrosive Category 1B.
- If the sum of the Skin Corrosive Category 1A+1B ingredients is < 5% but the sum of of Category 1A+1B+1C ingredients is ≥ 5% the mixture should be classified as Skin Corrosive Category 1C.

Classification of a mixture when the additivity approach does not apply

Ingredient	Concentration	Mixture classified as: Skin
Acid with pH ≤ 2	≥ 1%	Category 1
Base with pH ≥ 11,5%	≥ 1%	Category 1
Other corrosive (Categories 1A, 1B, 1C) ingredients for which additivity does not apply	≥ 1%	Category 1
Other irritant (Category 2) ingredients for which additivity does not apply, including acids and bases.	≥ 3%	Category 2

Classification of a mixture: serious eye damage/eye irritation

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Irreversible Eye Effects	Reversible Eye Effects
	Category 1	Category 2
Eye Effects Category 1 or Skin Corrosive Category 1A, 1B, 1C	≥ 3%	≥ 1% but < 3%
Eye Effects Category 2		≥ 10%
(10 x Eye Effects Category 1) + Eye effects Category 2		≥ 10%
Skin Corrosive Category 1A, 1B, 1C + Eye Effects Category 1	≥ 3%	≥ 1% but < 3%
10 x (Skin Corrosive Category 1A, 1B, 1C + Eye Effects category 1) + Eye Effects Category 2		≥ 10%

Classification of a mixture when the additivity approach does not apply

Ingredient	Concentration	Mixture classified as: Eye
Acid with pH ≤ 2	≥ 1%	Category 1
Base with pH ≥ 11.5%	≥ 1%	Category 1
Other corrosive (Category 1) ingredients for which additivity does not apply	≥ 1%	Category 1
Other irritant (Category 2) ingredients for which additivity does not apply, including acids and bases	≥ 3%	Category 2

Serious eye damage/eye irritation

	Wt %	Classification
Substance A	91	--
Substance B	5	Eye Cat. 2
Substance C	3	--
Substance D	0,9	Eye Cat. 1
Substance E	0,1	--

Category 1?

(a) ∑%Eye Category 1 = 0,9 *which is not* ≥ *3%*
(b) ∑%Skin Category 1 = 0,0 *which is not* ≥ *3%*
(c) ∑%Skin Category 1 + ∑%Eye Cat 1 = 0,9 *which is not* ≥ *3%*

➔ The mixture is *not* classified in Category 1 for serious eye damage/eye irritation

Serious eye damage/eye irritation

	Wt %	Classification
Substance A	91	--
Substance B	5	Eye Cat. 2
Substance C	3	--
Substance D	0,9	Eye Cat. 1
Substance E	0,1	--

Category 2?

(d) ∑%Eye Category 1= 0,9 *which is not ≥ 1% but < 3%*
(e) ∑% Skin Category 1 = 0 *which is not ≥ 1% but < 3%*
(f) ∑%Eye Category 2 = 5 *which is not ≥ 10%*
(g)(10× ∑%Eye Category 1) + ∑%Eye Category 2 = (10 × 0,9) + 5 = 14% *which is ≥ 10%*

➔ The mixture is classified in Category 2 for serious eye damage/eye irritation

Aspiration toxicity

Category 1
A mixture which contains a total of ≥10% of a substance or substances classified in Category 1, and has a kinematic viscosity of ≤20,5 mm^2/s measured at vid 40°C
A mixture which separates into two or more distinct layers, one of which contains ≥10% of a substance classified in Category 1 and has a kinematic viscosity of ≤20,5 mm^2/s measured at 40°C

Classification of a mixture: respiratory sensitisation

Component classified as:	Concentration triggering classification of a mixture as:	
	Respiratory Sensitiser Category 1	
	Solid/Liquid	Gas
Respiratory sensitiser Category 1	≥ 1,0%	≥ 0,2%
Respiratory sensitiser Sub-category 1A	≥ 0,1%	≥ 0,1%
Respiratory sensitiser Sub-category 1B	≥ 1,0%	≥ 0,2%

Classification of a mixture: skin sensitisation

Component classified as:	Concentration triggering classification of a mixture as:
	Skin sensitiser Category 1
Skin sensitiser Category 1	≥ 1,0%
Skin sensitiser Sub-category 1A	≥ 0,1%
Skin sensitiser Sub-category 1B	≥ 1,0%

Classification of a mixture: Germ cell mutagenicity

Ingredient classified as:	Concentration limits triggering classification of a mixture as:		
	Category 1A mutagen	Category 1B mutagen	Category 2 mutagen
Category 1A mutagen	≥ 0,1%	-	-
Category 1B mutagen	-	≥ 0,1%	-
Category 2 mutagen	-	-	≥ 1,0%

Classification of a mixture: Carcinogenicity

Ingredient classified as:	Concentration limits triggering classification of a mixture as:		
	Category 1 carcinogen		Category 2 carcinogen
	Category 1A	Category 1B	
Category 1A carcinogen	≥ 0,1%	-	-
Category 1B carcinogen	-	≥ 0,1%	
Category 2 carcinogen	-	-	≥ 1,0%*

**If a Category 2 carcinogen is present in the mixture as an ingredient at a concentration at or above 0,1% a SDS shall be available for the mixture upon request.*

Classification of a mixture: reproduction toxicity

Ingredient classified as:	**Concentration limits triggering classification of a mixture as:**			
	Category 1 reproductive toxicant		Category 2 reproductive toxicant	Effects on or via lactation
	Category 1A	Category 1B		
Category 1A reproductive toxicant	≥ 0,3%*	-	-	-
Category 1B reproductive toxicant	-	≥ 0,3%*	-	
Category 2 reproductive toxicant	-	-	≥ 3,0%*	-
Effects on or via lactation	-	-	-	≥ 0,3%*

**If a Category 1 or Category 2 reproductive toxicant or a substance classified for effect on or via lactation is present in the mixture as an ingredient at a concentration at or above 0,1% a SDS shall be available for the mixture upon request.*

Classification of a mixture: STOT SE

Ingredient classified as:	Generic concentration limits triggering classification of the mixture as:	
	Category 1	Category 2
Category 1 STOT	≥ 10%	1,0 ≤ C < 10%
Category 2 STOT	-	≥ 10%*

**If a Category 2 specific target organ toxicant is present in the mixture as an ingredient at a concentration at or above 1,0% a SDS shall be available for the mixture upon request.*

Classification of a mixture: STOT RE

Ingredient classified as:	Generic concentration limits triggering classification of the mixture as:	
	Category 1	Category 2
Category 1 STOT	≥ 10%	1,0 ≤ C < 10%
Category 2 STOT	-	≥ 10%*

**If a Category 2 specific target organ toxicant is present in the mixture as an ingredient at a concentration at or above 1,0% a SDS shall be available for the mixture upon request.*

Mixture 1

Ingredient	Wt %	Classification
Substance A	0,5	Acute tox. Cat.3 (oral) Skin Cat. 1 Carcinogenicity Cat. 2
Substance B	9	Eye Cat. 1
Substance C	7	Skin Cat. 2 Acute Cat. 4 (oral)
Water	83,5	Not classified

Conversion from range value/category to point estimate

Exposure Route	Category or experimental estimate	Converted point estimate
Oral (mg/kg bw)	0 < category 1 ≤ 5 5 < category 2 ≤ 50 50 < category 3 ≤ 300 300 < category 4 ≤ 2000	0.5 5 100 500

Mixture 1

Ingredient	Wt %	Classification
Substance A	0,5	Acute tox. Cat.3 (oral) Skin Cat. 1 Carcinogenicity Cat. 2
Substance B	9	Eye Cat. 1
Substance C	7	Skin Cat. 2 Acute Cat. 4 (oral)
Water	83,5	Not classified

Acute toxicity

$$\frac{100}{ATE_{mixture}} = \sum_{n} \frac{Ci}{ATEi}$$

Exposure Route	Category or experimental estimate	Converted point estimate
Oral (mg/kg bw)	0 < category 1 ≤ 5 5 < category 2 ≤ 50 50 < category 3 ≤ 300 300 < category 4 ≤ 2000	0.5 5 100 500

$$\frac{100}{ATE_{mixture}} = \frac{0,5}{100} + \frac{7}{500} = 0,005 + 0,014 = 0,019$$

$ATE_{mixture}$ = 5 263 mg/kg ➔ **Not classified**

Mixture 1

Ingredient	Wt %	Classification
Substance A	0,5	Acute tox. Cat.3 (oral) Skin Cat. 1 Carcinogenicity Cat. 2
Substance B	9	Eye Cat. 1
Substance C	7	Skin Cat. 2 Acute Cat. 4 (oral)
Water	83,5	Not classified

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Skin Corrosive Category 1*	Skin Irritant Category 2
Skin Corrosive Categories 1A, 1B, 1C	≥ 5%	≥ 1% but < 5%

Skin corrosion/Irritation

The additivity formula is used:

$$(10\times \sum\%\text{Skin Category 1}) + \sum\%\text{Skin Category 2} = (10 \times 0{,}5) + 7 = 12\%$$

which is $\geq 10\%$

➔Mixture is classified as **Skin irritant Cat.2**

Mixture 1

Ingredient	Wt %	Classification
Substance A	0,5	Acute tox. Cat.3 (oral) Skin Cat. 1 Carcinogenicity Cat. 2
Substance B	9	Eye Cat. 1
Substance C	7	Skin Cat. 2 Acute Cat. 4 (oral)
Water	83,5	Not classified

Serious Eye damage/Eye irritation

Table 3.3.3 is used
Substance B is present in ≥3%

➔Mixture is classified as **Eye damage Cat.1**

Mixture 1

Ingredient	Wt %	Classification
Substance A	0,5	Acute tox. Cat.3 (oral) Skin Cat. 1 Carcinogenicity Cat. 2
Substance B	9	Eye Cat. 1
Substance C	7	Skin Cat. 2 Acute Cat. 4 (oral)
Water	83,5	Not classified

Carcinogenicity

Table 3.6.1 is used
Substance A is not present at ≥1%

➔ Mixture is **not classified** as carcinogenic

Label elements

Classification	Eye damage Cat.1 Skin irritation Cat.2
Pictogram	
Signal word	Danger
Hazard statements	H315 (Causes skin irritation) H318 (Causes serious eye damage)

Note: Exclamation mark (Skin irritation cat 2) omitted as precedence rule apply

Mixture 2

Ingredient	Wt %	Classification
Substance A	8	Skin irrit. 2
Substance B	10	Carc. 2
Substance C	3	Skin corr. 1B
Substance D	0,4	Carc. 1B
Substance E	78	Not classified

Mixture 2

Ingredient	Wt %	Classification
Substance A	8	Skin irrit. 2
Substance B	10	Carc. 2
Substance C	3	Skin corr. 1B
Substance D	0,4	Carc. 1B
Substance E	78	Not classified

Step 1: Check the classification of the mixture as ***skin corrosive***.

Substance C is classified as Skin corrosive Cat. 1B and is present in the solution in 3 %.

Using table 3.2.3 we find:
The generic concentration value for skin corrosive ingredients in Cat. 1 is: ≥ 5%.
The skin corrosive substance is present in 3 %, therefore the mixture is **not corrosive.**

Mixture 2

Ingredient	Wt %	Classification
Substance A	8	Skin irrit. 2
Substance B	10	Carc. 2
Substance C	3	Skin corr. 1B
Substance D	0,4	Carc. 1B
Substance E	78	Not classified

Step 2: Check the classification of the mixture for ***skin irritation***.

Substance A is classified as skin irritant Cat. 2 and is present in the solution in 8 %.

Using table 3.2.3 we find:
This is below the classification limit (≥ 10 %). Thus, Substance A does not *by itself* give rise to classification.

Mixture 2

Ingredient	Wt %	Classification
Substance A	8	Skin irrit. 2
Substance B	10	Carc. 2
Substance C	3	Skin corr. 1B
Substance D	0,4	Carc. 1B
Substance E	78	Not classified

Step 3: Substance C (Skin Corr. 1B) *may contribute* to classification of the mixture as skin irritant.

The concentration of substance C is 3 % and this concentration of a skin corrosive ingredient (≥ 1 % but < 5 %) is sufficient to classify the mixture as skin irritant. In this case, there is no need to consider substance A and to use the formula in Table 3.2.3.

The mixture should be classified as: **Skin irritant, Cat. 2.**

Mixture 2

Ingredient	Wt %	Classification
Substance A	8	Skin irrit. 2
Substance B	10	Carc. 2
Substance C	3	Skin corr. 1B
Substance D	0,4	Carc. 1B
Substance E	78	Not classified

Step 4: A mixture containing substances corrosive or irritant to skin may also be classified for ***serious eye damage or eye irritation***.

Substance C is classified as Skin corrosive Cat. 1B. Using table 3.3.3 we find that the concentration of substance C is at the limit value (≥3%).

The mixture should be classified as: **Serious Eye Damage, Cat. 1.**

Mixture 2

Ingredient	Wt %	Classification
Substance A	8	Skin irrit. 2
Substance B	10	Carc. 2
Substance C	3	Skin corr. 1B
Substance D	0,4	Carc. 1B
Substance E	78	Not classified

Step 5: Check the classification of the mixture for ***carcinogenicity.***

Substance C is present at 0,4%. The relevant concentration limit is 0,1% (Carc. 1B) according to Table 3.6.2.

The mixture should be classified as **Carc. 1B.**

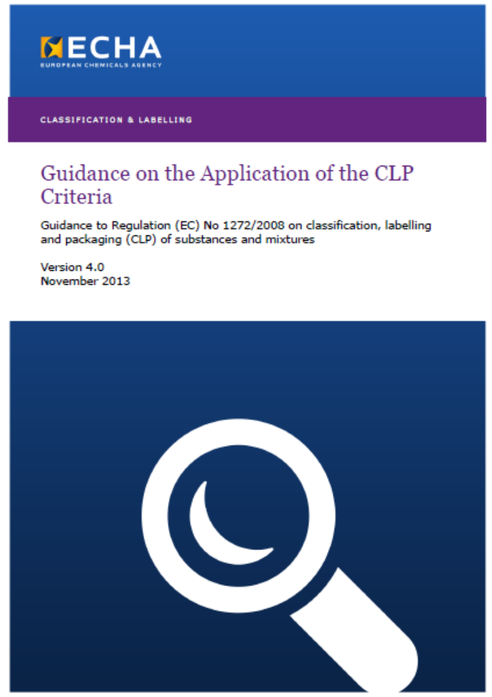
Label elements

Classification	Eye damage Cat.1 Skin irritation Cat.2 Carc. 1B
Pictogram	
Signal word	Danger
Hazard statements	H315 (Causes skin irritation) H318 (Causes serious eye damage) H350 (May cause cancer)

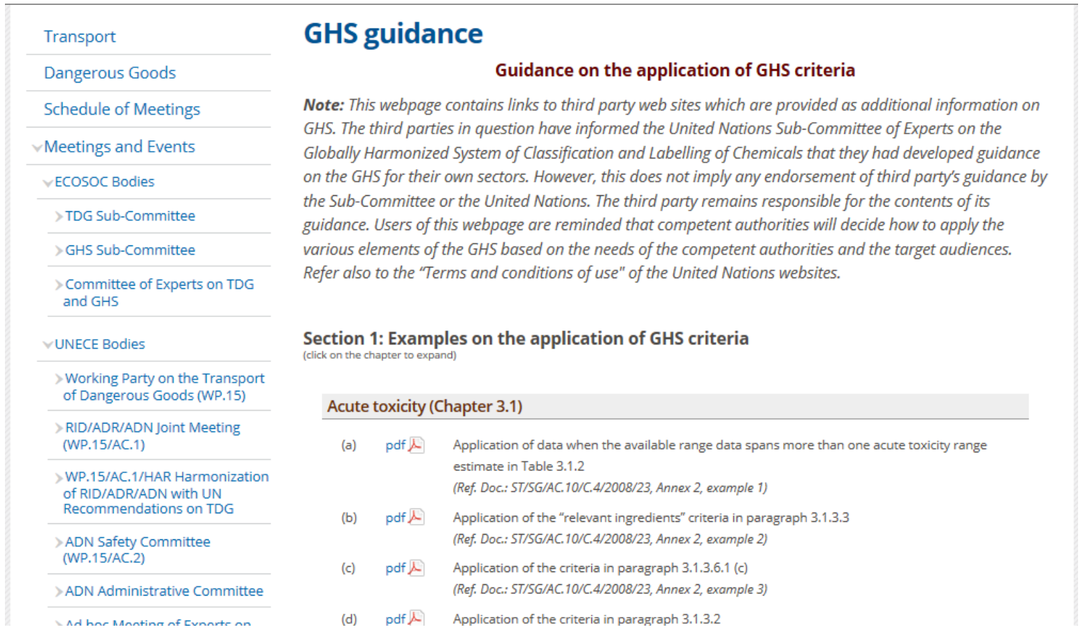
Note: Exclamation mark (Skin irritation cat 2) omitted as precedence rule apply

References and guidance

- ECHA: Guidance on the Application of the CLP criteria
  - http://echa.europa.eu/documents/10162/13562/clp_en.pdf



- UNECE: Examples on the application of the GHS criteria
  - http://www.unece.org/trans/danger/publi/ghs/guidance.html



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Swedish Chemicals Agency

Thank you very much for your kind attention

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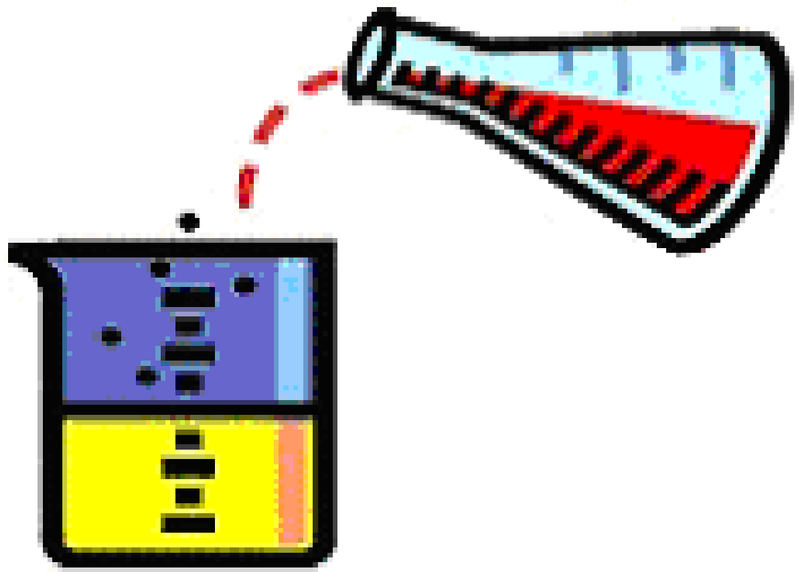
Bridging principles

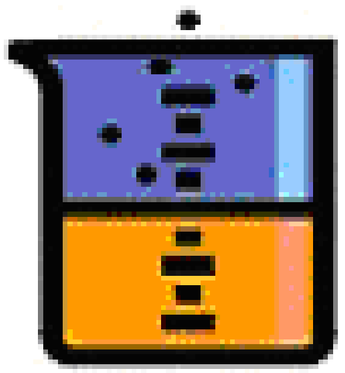
1. Dilution
2. Batching
3. Concentration of highly hazardous mixtures
4. Interpolation within one toxicity category
5. Substantially similar mixtures
6. Review of classification where the composition of a mixture has changed
7. Aerosols

1. Dilution



Mixture A
(tested; Acute tox. Cat.2)

Diluent B
(Classification known)



Mixture C
(A+B)

If diluent B has an equivalent or lower acute toxicity classification than the least acutely toxic ingredient in mixture A and is not expected to affect the hazard classification of other ingredients, then mixture C may also be classified as Acute tox. Cat.2.

Note: this approach may over-classify mixture C, thus the supplier may choose to apply the additivity formula instead.

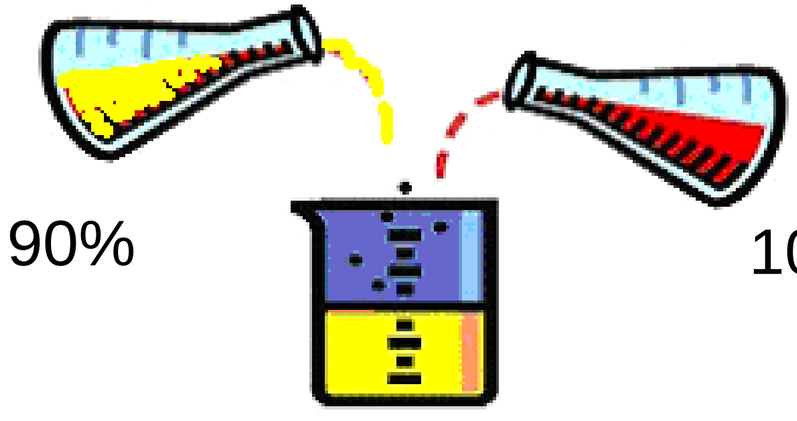
2. Batching

Where a batch of a mixture is produced under a controlled process, then it can be assumed that the hazards of each new batch are equivalent to those of previous batches.
This method must not be used where there is reason to believe that the composition may vary significantly, affecting the hazard classification.

3. Concentration of highly hazardous ingredients

Where a tested mixture is already classified in the highest hazard category or sub-category, an untested mixture which contains a higher concentration of those ingredient substances that are in that category or sub-category should also be classified in the highest hazard category or sub-category.

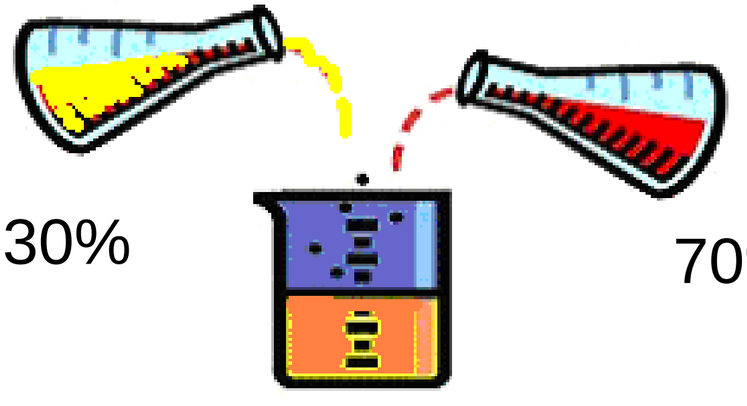
4. Interpolation



90%

10%

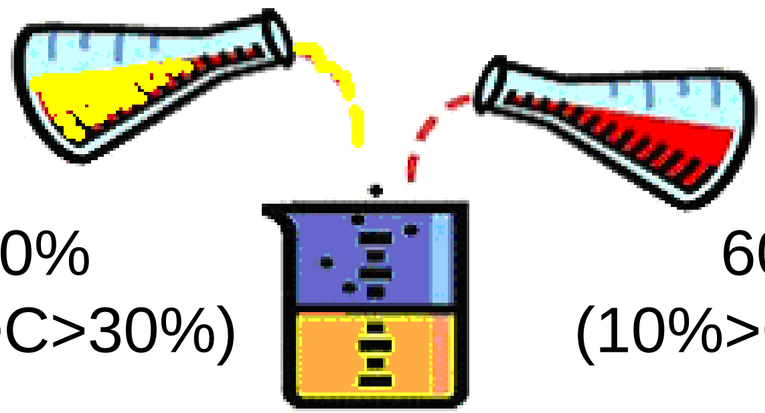
Mixture A
(Aquatic Acute 1)



30%

70%

Mixture B
(Aquatic Acute 1)

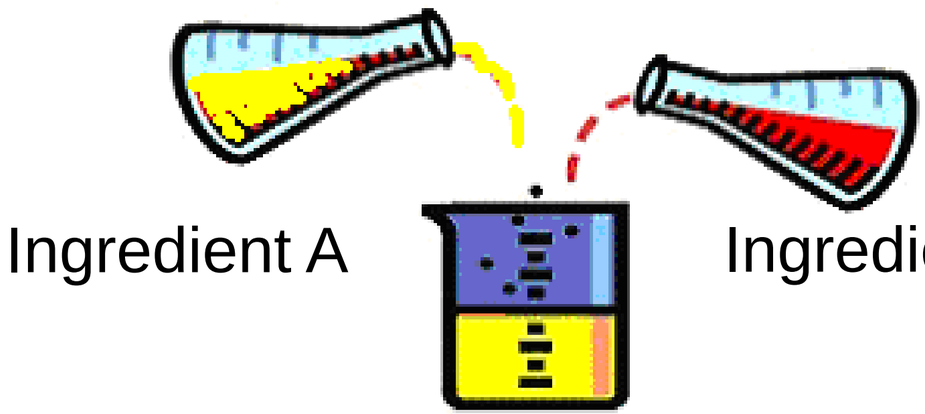


40%
(90%>C>30%)

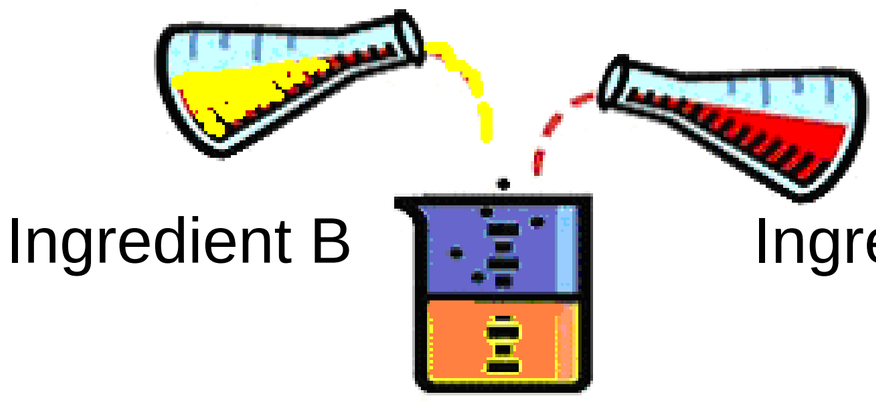
60%
(10%>C>70%)

Mixture C
(Interpolated as
Aquatic Acute 1)

5. Substantially similar mixtures



Mixture P
(tested)
(Skin Irrit. 2)



Mixture Q
(not tested)

If the Ingredient C has the same hazard category and the same potency as Ingredient A, then Mixture Q can be classified as Skin Irrit. 2 like Mixture P.

6. Review of classification where the composition of a mixture has changed

Initial concentration range of the constituent	Permitted variation in initial concentration range of the constituent
≤ 2,5 %	± 30 %
2,5 < C ≤ 10 %	± 20 %
10 < C ≤ 25 %	± 10 %
25 < C ≤ 100 %	± 5 %

6. Example

Ingredients	Mixture P	Mixture Q
Substance A	2%	2,5%
Substance B	12%	12,5%

Mixture P is classified as hazardous based on the initial concentration of two hazardous constituents, substance A (2%) and substance B (12%).

Mixture Q is similarly classified as hazardous by applying the bridging principle as the concentrations of the ingredient substances A and B is within the permitted variations

- for substance A ± 30% of the initial concentration (i.e. 1,4-2,6%)
- for substance B ± 10 % (10,8-13,2%).

7. Aerosols

A mixture in aerosol form is considered to have the same classification as the non-aerosolised form of a mixture, provided that the propellant used does not affect these hazards upon spraying and data demonstrating that the aerosolised form is not more hazardous than the non-aerosolised form is available.

Skin corrosion/Irritation
Evaluation of test data (OECD TG 404)

Animal no.	Degree of erythema after					Degree of oedema after					Mean 24/48/72h ≥2.3?	
	1h	24h	48h	72h	7d	1h	24h	48h	72h	7d	Erythema	Oedema
1	3	3	3	2	0	1	2	2	2	0		
		Mean score = 2,7					Mean score = 2,0				Yes	No
2	3	3	3	3	0	1	2	2	1	0		
		Mean score = 3					Mean score = 1,7				Yes	No
3	1	1	1	0	0	1	1	1	1	0		
		Mean score = 0,66					Mean score = 1,0				No	No

2/3 ”positive responders” (exceeding mean score 2,3 for erythema)
➔ Skin Irritant Category 2

Concentration limits for specific labeling requirements and SDS: respiratory sensitisation

Ingredient classified as:	Concentration limit for elicitation	
	Respiratory Sensitiser Category 1	
	Solid/Liquid	Gas
Respiratory sensitiser Category 1	≥ 0,1	≥ 0,1%
Respiratory sensitiser Sub-category 1A	≥ 0,01%	≥ 0,01%
Respiratory sensitiser Sub-category 1B	≥ 0,1%	≥ 0,1%

Concentration limits for specific labeling requiremets and SDS: skin sensitisation

Ingredient classified as:	Concentration limit for elicitation
	Skin sensitiser Category 1
Skin sensitiser Category 1	≥ 0,1%
Skin sensitiser Sub-category 1A	≥ 0,01%
Skin sensitiser Sub-category 1B	≥ 0,1%

Application of SCLs when applying the additivity approach

Specific concentration limits (SCL) take precedence over GCLs (CLP Art. 10.6).

Ingredient	Wt %	Classification	SCL
Substance A	3,8	Skin Cat 2	Not assigned
Substance B	4,5	Not classified	
Substance C	5,4	Skin Cat 1B	C ≥ 10%; Skin Cat 1B 5% ≤ C < 10%: Skin Cat 2
Substance D	2	Skin Cat 1B	Not assigned
Water	84,3	Not classified	

The mixture is classified for skin corrosion/irritation if the
Sum of (ConcA / clA) + (ConcB / clB) + ….+ (ConcZ / clZ) is ≥ 1

ConcA = the concentration of substance A in the mixture;
clA = the concentration limit (either specific or generic) for substance A;
ConcB = the concentration of substance B in the mixture;
clB = the concentration limit (either specific or generic) for substance B; etc.

Application of SCLs when applying the additivity approach

Ingredient	Wt %	Classification	SCL
Substance A	3,8	Skin Cat 2	Not assigned
Substance B	4,5	Not classified	
Substance C	5,4	Skin Cat 1B	C ≥ 10%; Skin Cat 1B 5% ≤ C < 10%: Skin Cat 2
Substance D	2	Skin Cat 1B	Not assigned
Water	84,3	Not classified	

Step 1:

Check the classification of the mixture as *Skin corrosive (Cat. 1)*:

- Substance B and water can be disregarded as they are not classified for skin corrosion/irritation.
- No SCLs are assigned to substance D or A, thus GCLs (Annex 1, Table 3.2.3) apply for these ingredients.
- SCLs are assigned to substance C.

(% substance D/GCL) + (% substance C/SCL) = (2/5) + (5,4/10) = 0,94 which is < 1

The mixture is not classified as Skin Corr. Cat 1

Application of SCLs when applying the additivity approach

Ingredient	Wt %	Classification	SCL
Substance A	3,8	Skin Cat 2	Not assigned
Substance B	4,5	Not classified	
Substance C	5,4	Skin Cat 1B	C ≥ 10%; Skin Cat 1B 5% ≤ C < 10%: Skin Cat 2
Substance D	2	Skin Cat 1B	Not assigned
Water	84,3	Not classified	

Step 2:
Check the classification of the mixture as *Skin irritant (Cat. 2)*:

(% substance D/GCL) + (% substance C/SCL) + (% substance A/GCL) = (2/1) + (5,4/5) + (3,8/10) = 3,46 which is > 1

The mixture should be classified as Skin Irrit. Cat. 2

Label elements

Classification	Skin irritation Cat.2
Pictogram	
Signal word	Warning
Hazard statements	H315 (Causes skin irritation)