

GHS in SDS

Understanding CLP (GHS)

Classification and Calculations

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Schedule

- Expectations and Goals/objectives
- Back to Basics
- Terms and Definitions
- Non-additive Hazards
- Additive Hazards
- Discussion/Calculation

Goals and Objectives

- Understand the description of the Health Hazard classifications and be able to complete, without software, (Health Hazards) calculations included in the GHS EU/ CLP
- To be able to explain the different types of calculations included in the GHS and how to use them
- To understand impact of classification (changes) to 'ranking instruments'

Why? Because it is used a lot!

Hazard band	DGUV IFA Spaltenmodell	HSE COSHH	BAUA EMKG (inhalation)*	Solvay OEB
 E/5	300, 310, 330 (Tox) 340, 350, 350i (CM) EU032 (Tox gas release)	340, 341, 350(i) (CM) 334 (S) EU070 (Tox)	340, 350, 350i (CM) 360 _f (R)	372 (Tox) 340, 350 (CM) 334 (ICS)
D/4	301, 311, 331, 370, 372 (Tox) 341, 351, 360 _{xy} (CMR) EUH029, EUH031 (Tox gas release) 317, 334, 318, EUH070 (ICS)	300, 310, 330, 372 (Tox) 351, 360 _{xy} , 361, 362 (CR)	300, 330, 372 (Tox) 360 _o (R) EUH032 (Tox gas release)	300, 310, 330; 370, 373 (Tox) 314 (+ cat A), EUH071 (ICS), 341, 351, 360 _{xy} (CMR)
C/3	302, 312, 332(Tox) 314 (pH ≥ 11,5, pH ≤ 2), 371, EUH071 361 _{f/d} , 373, 362 non-toxic gases which may cause asphyxiation	301, 311, 331, 314, 370, 373 (Tox) 317, 318, 335, EUH071 (IC)	301, 331, 314, 370, 371, 373 (Tox) 334 (S) 341, 351, 361f/d (CMR) EUH031 (Tox gas release)	301, 311, 331; 371 (Tox) 304, EUH070 (lung, eye damage) 314 cat B and C, 317, 318, 335 (ICS) 361, 362 (R & Lact)
B/2	315, 319, 335, ** (I) 304, EUH066, 336 (solvents) ***	302, 312, 332, 371 (Tox)	302, 332 (Tox) 318 (C)	302, 312, 332, 336 (Tox) 315, 319, EUH066 (I)
A/1	substances which experience shows to be harmless (e.g. water, sugar, paraffin etc.)	303, 313, 333(GHS Tox4) 315, 316, (GHS) 319, 320 (I) 304, 305 (Aspiration) 336, EUH066 (solvents) and all H-numbers not otherwise listed	319, 335 (I) 336 (solvent) 304 (Aspiration) Non health hazard H-statement codes	303, 313, 333 (GHS Tox 4) 305 (ICS) 316 (GHS-> noCLP), 320 (GHS eye irr 2b->CLP 319)

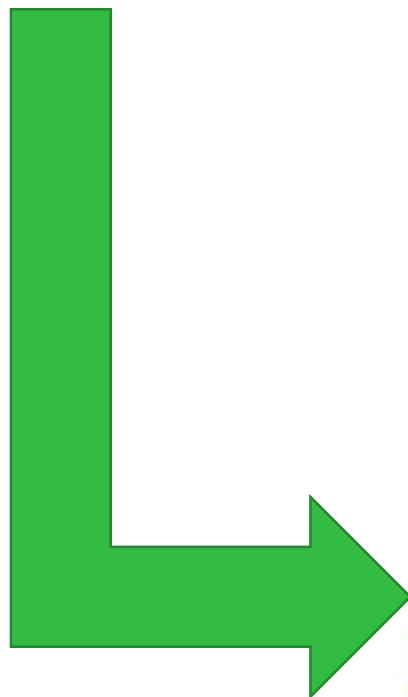
Copied from T. Scheffers, NVVA Symposium 2016

B Back

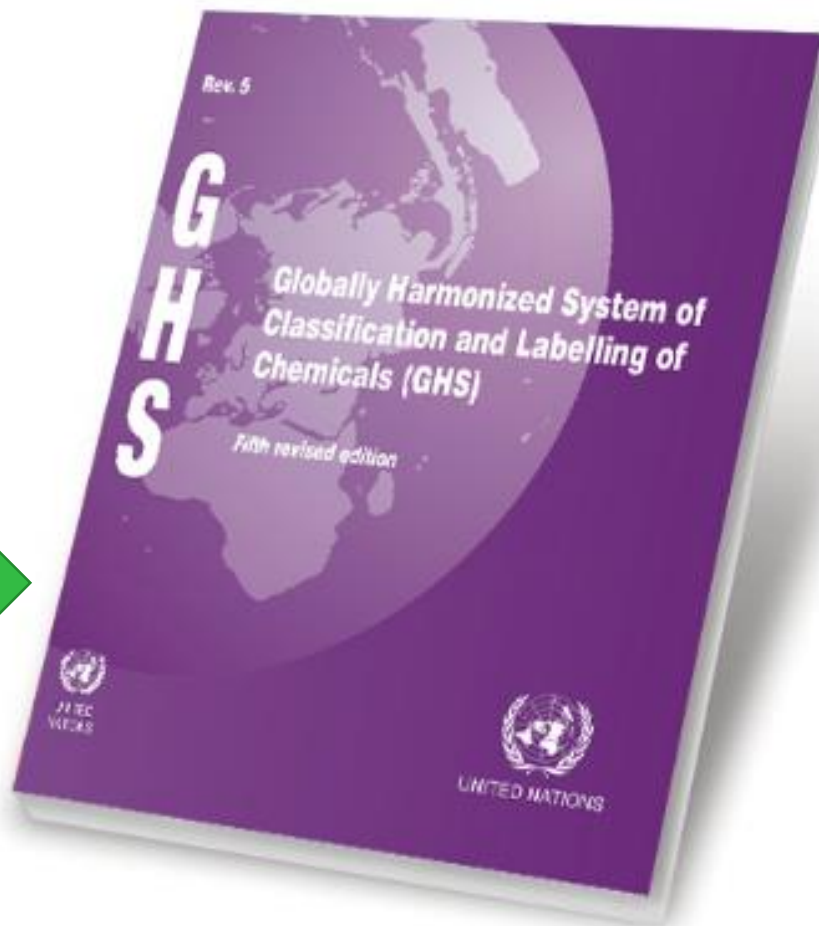
2 To

B Basics

GHS = Global Harmonized System of
Classification and Labelling of
Chemicals



Legal 'backbone'
for regulation in Europe



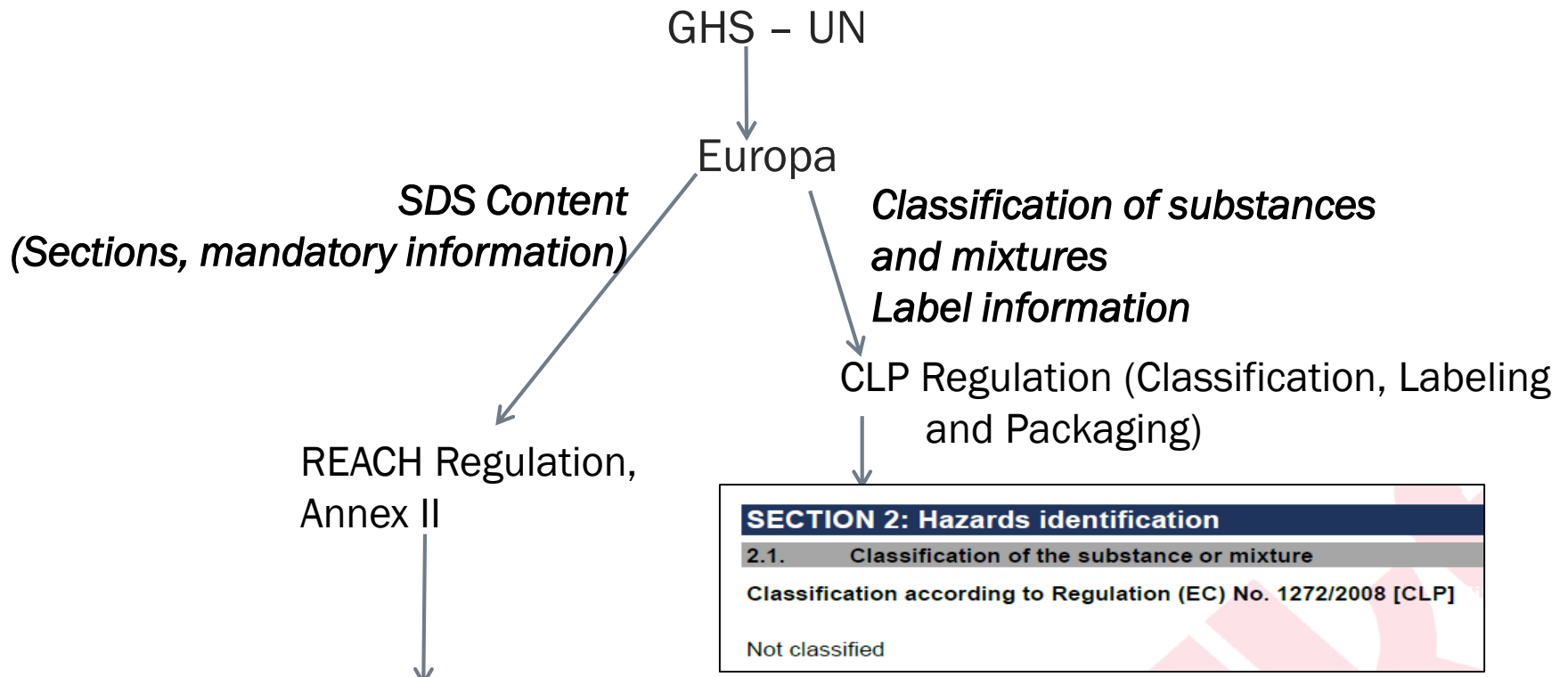
GHS


Publication/Revisions; every 2 years new revision



(*): Moving to Rev 5. End of transition period is Feb 2018

GHS implementation in Europe




	Safety Data Sheet	Page 1/5
According to 1907/2006/EC, amended by Regulation (EU) N° 2015/830		
Printing date 23.02.2016	Version number 1000	Revision: 23.02.2016
SECTION 1: Identification of the substance/mixture and of the company/undertaking		
· 1.1 Product identifier · Trade name: <u>Vulk Rubber</u>		

Example: Change with ATP 7

1H-imidazole, (Cas 35554-44-0) becomes Carc.Cat 2

“Worst case” H statement **H318** becomes **H341**

Hazard band	DGUV IFA Spaltenmodell	HSE COSHH	BAUA EMKG (inhalation)*	Solvay OEB
 E/5	300, 310, 330 (Tox) 340, 350, 350i (CM) EU032 (Tox gas release)	340, 341, 350(i) (CM) 334 (S) EU070 (Tox)	340, 350, 350i (CM) 360 _r (R)	372 (Tox) 340, 350 (CM) 334 (ICS)
D/4	301, 311, 331, 370, 372 (Tox) 341, 351, 360 _{ny} (CMR) EUH029, EUH031 (Tox gas release) 317, 334, 318, EUH070 (ICS)	300, 310, 330, 372 (Tox) 351, 360 _{ny} , 361, 362 (CR)	300, 330, 372 (Tox) 360 _r (R) EUH032 (Tox gas release)	300, 310, 330; 370, 373 (Tox) 314 (+ cat A), EUH071 (ICS), 341, 351, 360 _{ny} (CMR)
C/3	302, 312, 332 (Tox) 314 (pH ≥ 11,5, pH ≤ 2), 371, EUH071 361 _{t/d} , 373, 362 non-toxic gases which may cause asphyxiation	301, 311, 331, 314, 370, 373 (Tox) 317, 318, 335, EUH071 (IC)	301, 331, 314, 370, 371, 373 (Tox) 334 (S) 341, 351, 361f/d (CMR) EUH031 (Tox gas release)	301, 311, 331, 371 (Tox) 304, EUH070 (lung, eye damage) 314 cat B and C, 317, 318, 335 (ICS) 361, 362 (R & Lact)
B/2	315, 319, 335, ** (I) 304, EUH066, 336 (solvents) ***	302, 312, 332, 371 (Tox)	302, 332 (Tox) 318 (C)	302, 312, 332, 336 (Tox) 315, 319, EUH066 (I)
A/1	substances which experience shows to be harmless (e.g. water, sugar, paraffin etc.)	303, 313, 333 (GHS Tox4) 315, 316, (GHS) 319, 320 (I) 304, 305 (Aspiration) 336, EUH066 (solvents) and all H-numbers not otherwise listed	319, 335 (I) 336 (solvent) 304 (Aspiration) Non health hazard H-statement codes	303, 313, 333 (GHS Tox 4) 305 (ICS) 316 (GHS-> noCLP), 320 (GHS eye irr 2b->CLP 319)

Discussion

When to change the “ranking” of such a substance (and its mixtures?)

1. When new classification is published
2. When transition period starts
3. When supplier delivers the new classification (if ever....)

Content of Safety Data Sheet

1. Identification of the substance/mixture and of the company/undertaking
2. **Hazard identification**
3. **Composition/information on ingredients**
4. First aid measures
5. Fire-fighting measures
6. Accidental release measures
7. Handling and storage
8. Exposure controls/personal protection
9. **Physical and chemical properties**
10. Stability and reactivity
11. **Toxicological information**
12. **Ecological information**
13. Disposal considerations
14. **Transport information**
15. Regulatory information
16. Other information

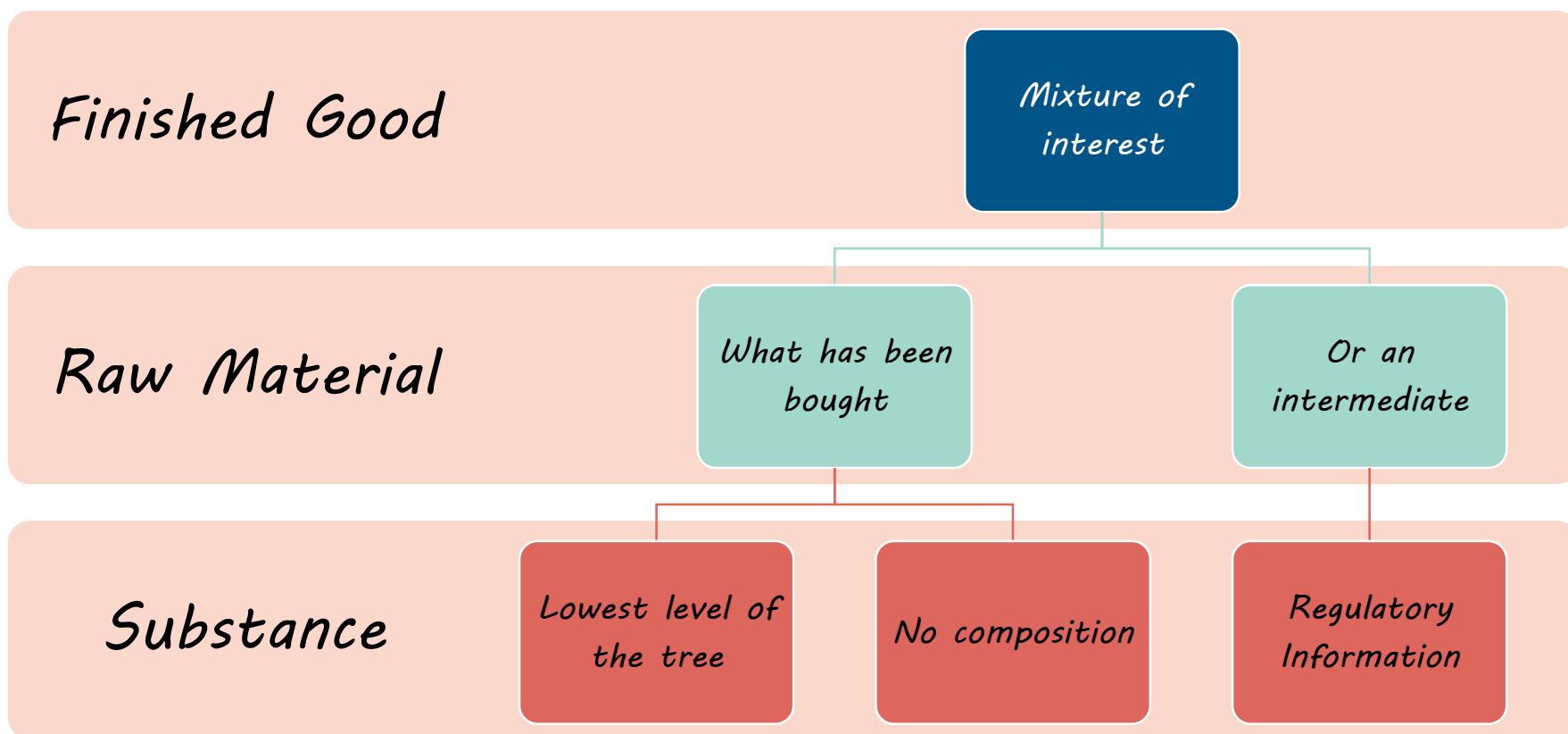
RED: Directly influence CLP/GHS rules

GREEN: Possible information for classification

Terms & Definitions



What products are we looking at?



What kind of analysis are we looking at?

Product Analysis Logic

*Finished
Good Level*

*Raw
Material*

*Raw
Material*

This level is generally ignored

*This level is
used for
Mixture
Analysis*

*All information
will be
considered*

*physical hazards
at this level will
generally be
ignored.*

Mixture Logic

This analysis is done using information at the substance level

Types of calculation for Mixture Logic (1)

Additive Calculation

In an additive calculation, multiple components can contribute toward the mixture classification

ADDITIVE HAZARDS

- Acute Toxicity
- Skin Corrosion/Irritation
- Serious Eye Damage/Eye Irritation
- Specific Target Organ Toxicity (Single Exposure) – Category 3
- Aspiration Hazard



Non-additive Calculation

Types of calculation for mixture logic (2)

Additive Calculation

Non-additive Calculation

In a non-additive calculation, substances are looked at individually to determine whether the overall mixture is classified.

If ingredient(s) are below Cut-off/Concentration Value, mixture is not classified.

Non-Additive Hazards

- Respiratory and Skin Sensitization
- Reproductive Toxicity
- Carcinogen
- Germ Cell Mutagenicity
- Specific Target Organ Toxicity (Single and Repeat Exposure)



Additive/Non-additive in a picture

Additive example...



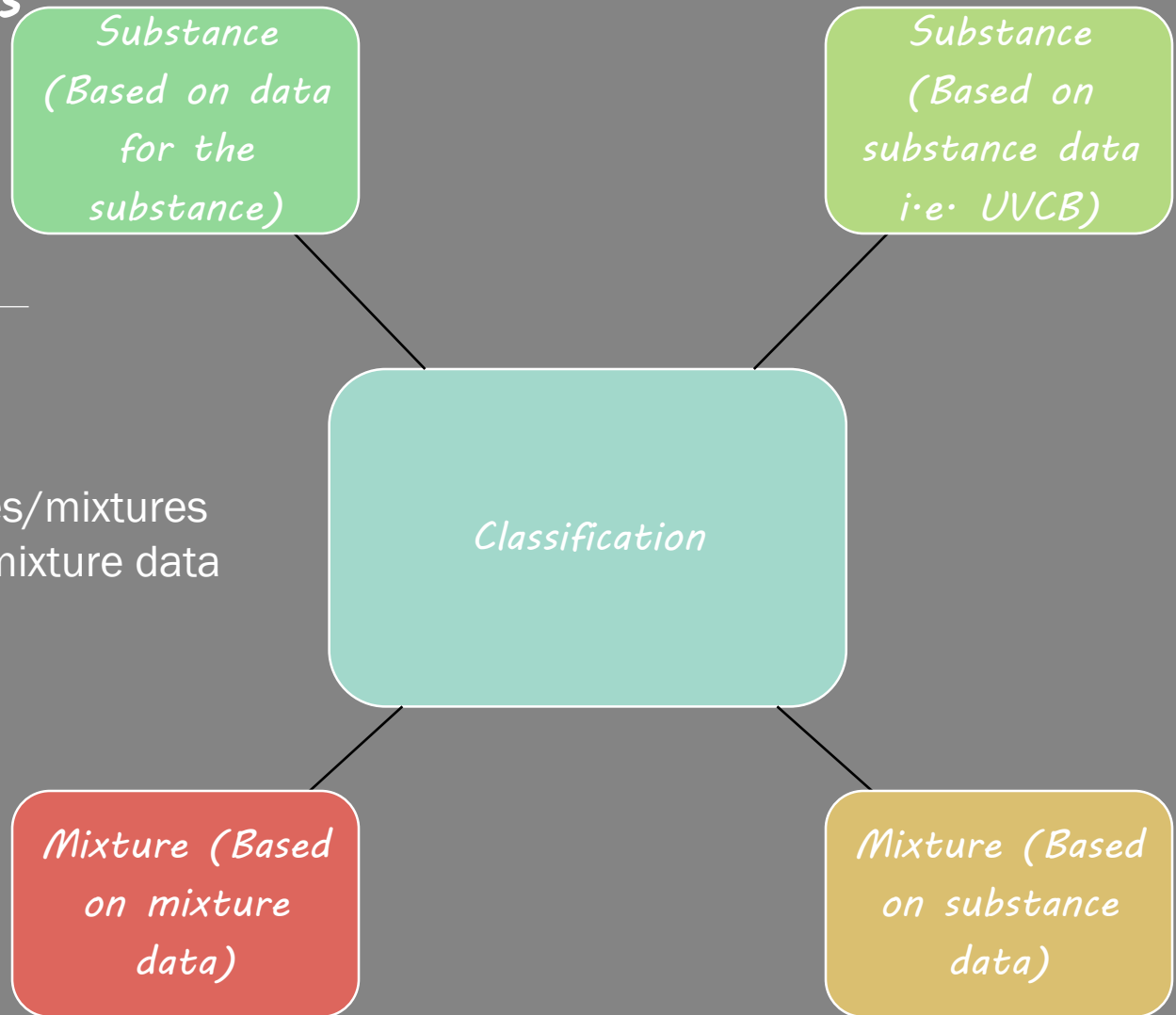
Non-additive example



If a mixture contains two ingredients classified as carcinogen category 1a which are present below the cut-off value/concentration limit, then the overall mixture will not be classified as carcinogen category 1a.

Classification steps for all Hazard Classifications

Classification for substances/mixtures based on substance data/mixture data will follow the same 'rules'



Non-additive hazards

Non-Additive Example:

Generic concentration limits of ingredients of a mixture classified as carcinogen that trigger classification of the mixture			
Ingredient classified as:	Generic concentration limits triggering classification of a mixture as:		
	Category 1 carcinogen		Category 2 carcinogen
	Category 1A	Category 1B	
Category 1A carcinogen	$\geq 0,1 \%$	—	—
Category 1B carcinogen	—	$\geq 0,1 \%$	—
Category 2 carcinogen	—	—	$\geq 1,0 \%$ [Note 1]

If a mixture contains a Category 1A ingredient at a concentration greater than or equal to 0.1%, then the overall mixture is classified as Category 1A.

Carcinogenicity & Germ Cell Mutagenicity

Do it yourself:

What is classification of the two mixtures below (use handout!).
1)

Substance	%	Classification
A	0.85	Carcinogen Cat 1b
B	0.09	Carcinogen Cat 2
C	99.06	Not classified

2)

A	0.65	Mutagen Cat 1a
B	0.09	Mutagen Cat 1b
C	99.26	Not classified

What is the overall classification of mixture 1 and 2?



What is the definition of a carcinogen?

3.6.	Carcinogenicity
3.6.1.	<i>Definition</i>
3.6.1.1.	Carcinogen means a substance or a mixture of substances which induce cancer or increase its incidence. Substances which have

Hazard categories for carcinogens

Categories	Criteria				
CATEGORY 1:	<p>Known or presumed human carcinogens</p> <p>A substance is classified in Category 1 for carcinogenicity on the basis of epidemiological and/or animal data. A substance may be further</p> <table> <tr> <td>Category 1A:</td><td>Category 1A, known to have carcinogenic potential for humans, classification is largely based on human evidence, or</td></tr> <tr> <td>Category 1B:</td><td>Category 1B, presumed to have carcinogenic potential for humans, classification is largely based on animal evidence.</td></tr> </table>	Category 1A:	Category 1A, known to have carcinogenic potential for humans, classification is largely based on human evidence, or	Category 1B:	Category 1B, presumed to have carcinogenic potential for humans, classification is largely based on animal evidence.
Category 1A:	Category 1A, known to have carcinogenic potential for humans, classification is largely based on human evidence, or				
Category 1B:	Category 1B, presumed to have carcinogenic potential for humans, classification is largely based on animal evidence.				
CATEGORY 2:	Suspected human carcinogens				

What is the definition of a Germ Cell Mutagen?

3.5. Germ cell mutagenicity

3.5.1. Definitions and general considerations

3.5.1.1. A mutation means a permanent change in the amount or structure of the genetic material in a cell. The term 'mutation' applies both to locations). The term 'mutagenic' and 'mutagen' will be used for agents giving rise to an increased occurrence of mutations in populations of cells and/or organisms.

Hazard categories for germ cell mutagens


Categories	Criteria
CATEGORY 1:	Substances known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cells of humans. <div><div>Category 1A: The classification in Category 1A is based on positive evidence from human epidemiological studies.</div><div>Category 1B: Substances to be regarded as if they induce heritable mutations in the germ cells of humans.</div></div>
CATEGORY 2:	Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans

Cut-off values for mixture logic (carcinogen and mutagen)

Ingredient classified as:	Concentration limits triggering classification of a mixture as:		
	Category 1		Category 2
	Category 1A	Category 1B	
Category 1A	$\geq 0,1 \%$	—	—
Category 1B	—	$\geq 0,1 \%$	—
Category 2	—	—	$\geq 1,0 \%$

chromium (VI) trioxide	215-607-8	1333-82-0	Ox. Sol. 1 Carc. 1A Muta. 1B	H271 H350 H340
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Outcome Mixture 1

Generic concentration limits of ingredients of a mixture classified as carcinogen that trigger classification of the mixture			
Ingredient classified as:	Generic concentration limits triggering classification of a mixture as:		
	Category 1 carcinogen		Category 2 carcinogen
	Category 1A	Category 1B	
Category 1A carcinogen	$\geq 0,1 \%$	—	—
Category 1B carcinogen	—	 $\geq 0,1 \%$	—
Category 2 carcinogen	—	—	$\geq 1,0 \%$ [Note 1]

Substance	%	Classification
A	0.85	Carcinogen Cat 1b
B	0.09	Carcinogen Cat 2
C	99.06	Not classified

Carcinogen Category 1b



Outcome mixture 2

A	0.65	Mutagen Cat 1a
B	0.09	Mutagen Cat 1b
C	99.26	Not classified

Ingredient classified as:	Cut-off/concentration limits triggering classification of a mixture as:		
	Category 1 mutagen		Category 2 mutagen
	Category 1A	Category 1B	
Category 1A mutagen	≥ 0.1% ●	--	--
Category 1B mutagen	--	≥ 0.1% ●	
Category 2 mutagen	--	--	≥ 1.0%

Mutagen Category 1a



Discussion

Would you include National CMR lists in the hazard ranking?

SAFETY DATA SHEET

ethanol


SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition : Mono-constituent substance

[Classification according to Regulation \(EC\) No. 1272/2008 \[CLP/GHS\]](#)

Flam. Liq. 2, H225



Product/ingredient name	List name	Name on list	Classification	Notes
ethanol	Netherlands Carcinogenic Chemicals	ethanol; ethylalcohol	Carc.	-
	Netherlands Reprotoxic Chemicals	ethanol; ethylalcohol	Repro. fertility category 1A, Dev. breast feeding (X), Dev. development category 1A	

Other examples: Xylene (NL: Reprotox), Carbon Black (BE: Carc)

Discussion....

GHS US includes IARC and NTP data for Carcinogen Classification.
CLP doesn't.

SAFETY DATA SHEET
titanium dioxide

Product definition	: Mono-constituent substance
Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]	
Aquatic Chronic 2, H411	
EU CLP Is Product Classified	

OSHA/HCS status	: This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).
Classification of the substance or mixture	: CARCINOGENICITY - Category 2

Leave CMR data from
other sources out?

The following table may be used to perform hazard classifications for carcinogenicity under the HCS (§1910.1200). It relates the approximated GHS hazard categories for carcinogenicity to the classifications provided by IARC and NTP, as described in Parts B and C of this Appendix.

Approximate Equivalences Among Carcinogen Classification Schemes		
IARC	GHS	NTP RoC
Group 1	Category 1A	Known
Group 2A	Category 1B	Reasonably Anticipated (See Note 1)
Group 2B	Category 2	

Respiratory and Skin Sensitizer

What is the definition of a Resp./Skin Sensitizer?

3.4.	Respiratory or skin sensitisation
3.4.1.	<i>Definitions and general considerations</i>
3.4.1.1.	Respiratory sensitizer means a substance that will lead to hypersensitivity of the airways following inhalation of the substance.
3.4.1.2.	Skin sensitizer means a substance that will lead to an allergic response following skin contact.

CATEGORY 1:	sensitizer
	A substance is classified (a) if there is evidence in humans that the substance can lead to specific respiratory hypersensitivity and/or (b) if there are positive results from an appropriate animal test ² .
Sub-category 1A:	Substances showing a high frequency of occurrence in humans; or a probability of occurrence of a high sensitization rate in humans based on animal or other tests ² . Severity of reaction may also be considered.
Sub-category 1B:	Substances showing a low to moderate frequency of occurrence in humans; or a probability of occurrence of a low to moderate sensitization rate in humans based on animal or other tests ² . Severity of reaction may also be considered.

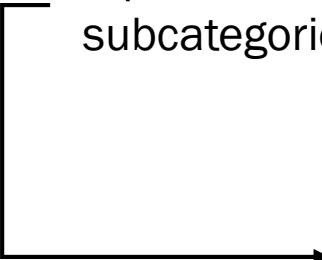
Cut-off values for respiratory/skin sensitizers

Generic concentration limits of components of a mixture classified as either respiratory sensitisers or skin sensitisers that trigger classification of the mixture			
Component classified as:	Generic concentration limits triggering classification of a mixture as:		
	Respiratory sensitiser Category 1		Skin sensitiser Category 1
	Solid/liquid	Gas	All physical states
Respiratory sensitiser Category 1	$\geq 1,0 \%$	$\geq 0,2 \%$	
Respiratory sensitiser Sub-category 1A	$\geq 0,1 \%$	$\geq 0,1 \%$	
Respiratory sensitiser Sub-category 1B	$\geq 1,0 \%$	$\geq 0,2 \%$	
Skin sensitiser Category 1			$\geq 1,0 \%$
Skin sensitiser Sub-category 1A			$\geq 0,1 \%$
Skin sensitiser Sub-category 1B			$\geq 1,0 \%$

Additional information (1)

Cut-off values for respiratory/skin sensitizers

If a mixture contains a Category 1a ingredient at a concentration greater than or equal to 0.1%, then the overall mixture is classified as Category 1 (no subcategories).



Component classified as:	Generic concentration limits triggering classification of a mixture as:		
	Respiratory sensitiser Category 1		Skin sensitiser Category 1
	Solid/liquid	Gas	All physical states

Additional information (2)

Cut-off values for respiratory/skin sensitizers

Elicitation of a (sensitizing) ingredient must be done at 1/10 of cut-off;

→ Cat 1/1B at 0.1%

→ Cat 1A at 0.01%

Not many Cat 1A substances → in annex 3

aclonifen (ISO); 2-chloro-6-nitro-3-phenoxy- aniline	277-704-1	74070-46-5	Carc. 2	H351
			Skin Sens. 1A	H317

Even if not classified: the user is warned for possible allergic reactions

Example:

Hazard statements (CLP)	: H304 - May be fatal if swallowed and enters airways H319 - Causes serious eye irritation H372 - Causes damage to organs (central nervous system) through prolonged or repeated exposure H412 - Harmful to aquatic life with long lasting effects
EUH phrases	: EUH208 - Contains Reaction mass of 2-tert-butyl-4,6-dimethylphenol and 4-tert-butyl-2,5-dimethylphenol. May produce an allergic reaction EUH066 - Repeated exposure may cause skin dryness or cracking

Reproductive Toxicity

Question:

SAFETY DATA SHEET

Bromodeoxyuridine (BrdU)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product use : Research.

Area of application : Industrial applications.

Product/ingredient name	Identifiers	%	Regulation (EC) No. 1272/2008 [CLP]
broxuridine	EC: 200-415-9 CAS: 59-14-3	<3	Muta. 1B, H340 Repr. 2, H361fd (Fertility and Unborn child)

Is this product classified? (Use Handout)

What is the definition or Reproductive Toxicity?

In this classification system, reproductive toxicity is subdivided under two main headings:

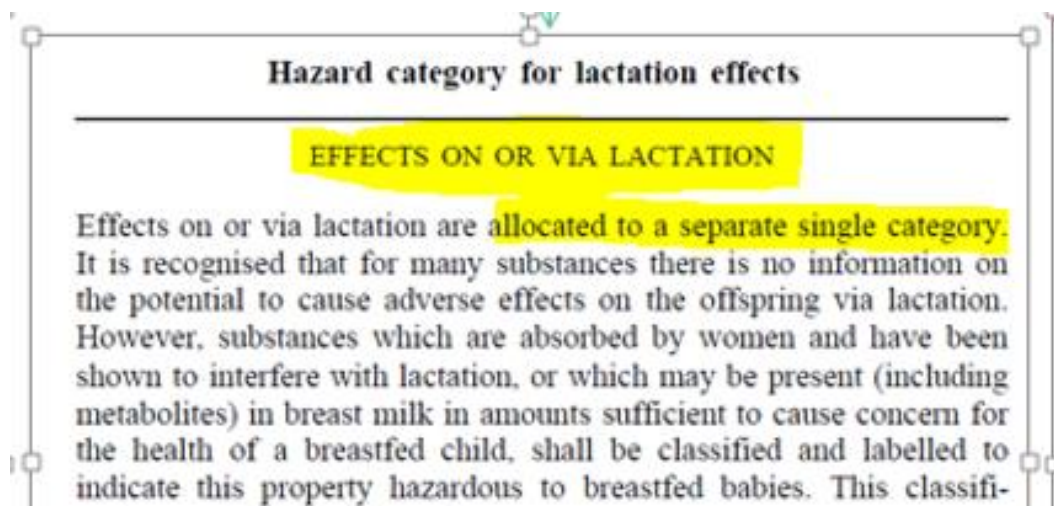
- (a) Adverse effects on sexual function and fertility;
- (b) Adverse effects on development of the offspring.

Some reproductive toxic effects cannot be clearly assigned to either impairment of sexual function and fertility or to developmental toxicity. Nonetheless, chemicals with these effects would be classified as reproductive toxicants with a general hazard statement.

Hazard categories for reproductive toxicants

Categories	Criteria				
CATEGORY 1	<p>Known or presumed human reproductive toxicant</p> <table> <tr> <td>Category 1A</td><td> <p>Known human reproductive toxicant</p> <p>The classification of a substance in Category 1A is largely based on evidence from humans.</p> </td></tr> <tr> <td>Category 1B</td><td> <p>Presumed human reproductive toxicant</p> <p>The classification of a substance in Category 1B is largely based on data from animal studies.</p> </td></tr> </table>	Category 1A	<p>Known human reproductive toxicant</p> <p>The classification of a substance in Category 1A is largely based on evidence from humans.</p>	Category 1B	<p>Presumed human reproductive toxicant</p> <p>The classification of a substance in Category 1B is largely based on data from animal studies.</p>
Category 1A	<p>Known human reproductive toxicant</p> <p>The classification of a substance in Category 1A is largely based on evidence from humans.</p>				
Category 1B	<p>Presumed human reproductive toxicant</p> <p>The classification of a substance in Category 1B is largely based on data from animal studies.</p>				
CATEGORY 2	Suspected human reproductive toxicant				

Special category within in the Reprotoxicity



Product/ingredient name	Identifiers	%	<u>Classification</u>		Type
			67/548/EEC	Regulation (EC) No. 1272/2008 [CLP]	
rosin	EC: 232-475-7 CAS: 8050-09-7 Index: 650-015-00-7	≥75 - ≤90	R42/43	Skin Sens. 1, H317 Aquatic Chronic 4, H413	[1]
tetrahydro-2-furylmethanol	EC: 202-625-6 CAS: 97-99-4 Index: 603-061-00-7	≤10	Repr. Cat. 2; R61 Repr. Cat. 3; R62 Xi; R36	Acute Tox. 4, H302 Eye Irrit. 2, H319 Repr. 1B, H360Df (Unborn child and Fertility)	[1]
1,2,5,6,9,10-hexabromocyclododecane	EC: 221-695-9 CAS: 3194-55-6 Index: 602-109-00-4	≤3	Repr. Cat. 3; R63 R64	Acute Tox. 2, H300 Acute Tox. 1, H310 Lact., H362	[1] [3]

Cut-off values for Reproductive Toxicity

Generic concentration limits of ingredients of a mixture classified as reproduction toxicants or for effects on or via lactation that trigger classification of the mixture

Ingredient classified as:	Generic concentration limits triggering classification of a mixture as:			
	Category 1 reproductive toxicant		Category 2 reproductive toxicant	Additional category for effects on or via lactation
	Category 1A	Category 1B		
Category 1A reproductive toxicant	$\geq 0,3 \%$ [Note 1]			
Category 1B reproductive toxicant		$\geq 0,3 \%$ [Note 1]		
Category 2 reproductive toxicant			$\geq 3,0 \%$ [Note 1]	
Additional category for effects on or via lactation				$\geq 0,3 \%$ [Note 1]

Note:

The concentration limits in Table 3.7.2 apply to solids and liquids (w/w units) as well as gases (v/v units).

Answer

SAFETY DATA SHEET

Bromodeoxyuridine (BrdU)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product use : Research.

Area of application : Industrial applications.

Signal word : Danger

Hazard statements : H340 - May cause genetic defects.

Product/ingredient name	Identifiers	%	Regulation (EC) No. 1272/2008 [CLP]
broxuridine	EC: 200-415-9 CAS: 59-14-3	<3	Muta. 1B, H340 Repr. 2, H361fd (Fertility and Unborn child)

*Specific Target
Organ Toxicity
(Single/Repeated Exposure)*

What is the definition of Specific Target Organ Toxicity (Single or Repeated Exposure)?

3.8.1.1 The purpose of this chapter is to provide a means of classifying substances and mixtures that produce specific, non lethal target organ toxicity arising from a single exposure. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed and not specifically addressed in chapters 3.1 to 3.7 and 3.10 are included (see also para. 3.8.1.6).

3.9.1.1 The purpose of this chapter is to provide a means of classifying substances and mixtures that produce specific target organ toxicity arising from a repeated exposure. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed are included.

the present chapter. Other specific toxic effects, listed below are assessed separately in the GHS and consequently are not included here:

- (a) acute toxicity (Chapter 3.1);
- (b) skin corrosion/irritation (Chapter 3.2);
- (c) serious eye damage/eye irritation (Chapter 3.3);
- (d) respiratory or skin sensitization (Chapter 3.4);
- (e) germ cell mutagenicity (Chapter 3.5);
- (f) carcinogenicity (Chapter 3.6);
- (g) reproductive toxicity (Chapter 3.7); and
- (h) aspiration toxicity (Chapter 3.10).

Categories of Specific Target Organ Toxicity (for non-additive calculation)

<u>CATEGORY 1:</u>	<p>Substances that have produced significant toxicity in humans, or that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to produce significant toxicity in humans following single exposure</p> <p>Placing a substance in Category 1 is done on the basis of:</p> <ul style="list-style-type: none">(a) reliable and good quality evidence from human cases or epidemiological studies; or(b) observations from appropriate studies in experimental animals in which significant and/or severe toxic effects of relevance to human health were produced at generally low exposure concentrations. Guidance dose/concentration values are provided below (see 3.8.2.1.9) to be used as part of weight-of-evidence evaluation.
<u>CATEGORY 2:</u>	<p>Substances that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to be harmful to human health following single exposure</p> <p>Placing a substance in Category 2 is done on the basis of observations from appropriate studies in experimental animals in which significant toxic effects, of relevance to human health, were produced at generally moderate exposure concentrations. Guidance dose/concentration values are provided below (see 3.8.2.1.9) in order to help in classification.</p> <p>In exceptional cases, human evidence can also be used to place a substance in Category 2 (see 3.8.2.1.9).</p>

Cut-off values for STOT (SE and RE)

Generic concentration limits of ingredients of a mixture classified as a specific target organ toxicant that trigger classification of the mixture as Category 1 or 2

Ingredient classified as:	Generic concentration limits triggering classification of the mixture as:	
	Category 1	Category 2
Category 1 Specific Target Organ Toxicant	Concentration $\geq 10 \%$	$1,0 \% \leq \text{concentration} < 10 \%$
Category 2 Specific Target Organ Toxicant		Concentration $\geq 10 \%$ [(Note 1)]

Do it yourself:

What is classification of this liquid mixture?

<i>Substance</i>	<i>%</i>	<i>Classification</i>
<i>A</i>	<i>4.5</i>	<i>Specific Target Organ (Single Exposure) Cat 1 Respiratory Sensitizer Cat 1b</i>
<i>B</i>	<i>5.6</i>	<i>Carcinogen Cat 1a</i>
<i>C</i>	<i>89.9</i>	<i>Not classified</i>



Answer

Substance	%	Classification
A	4.5	Specific Target Organ (Single Exposure) Cat 1 Respiratory Sensitizer Cat 1b
B	5.6	Carcinogen Cat 1a
C	89.9	Not classified

Generic concentration limits of ingredients of a mixture classified as a specific target organ toxicant that trigger classification of the mixture as Category 1 or 2

Ingredient classified as:	Generic concentration limits triggering classification of the mixture as:	
	Category 1	Category 2
Category 1 Specific Target Organ Toxicant	Concentration $\geq 10\%$	$1.0\% \leq \text{concentration} < 10\%$
Category 2 Specific Target Organ Toxicant		Concentration $\geq 10\%$ [(Note 1)]

Specific Target Organ (SE) Cat 2



Answer (cont)

Substance	%	Classification
A	4.5	Specific Target Organ (Single Exposure) Cat 1 Respiratory Sensitizer Cat 1b
B	5.6	Carcinogen Cat 1a
C	89.9	Not classified

Ingredient classified as:	Cut-off values/concentration limits triggering classification of a mixture as:		
	Respiratory sensitizer Category 1		Skin sensitizer Category 1
	Solid/Liquid	Gas	All physical states
Respiratory sensitizer Category 1	≥ 0.1% (see note)	≥ 0.1% (see note)	--
Respiratory sensitizer Sub-category 1A	≥ 1.0%	≥ 0.2%	
Respiratory sensitizer Sub-category 1B	≥ 0.1%	≥ 0.1%	
Respiratory sensitizer Sub-category 1B	≥ 1.0% ●	≥ 0.2%	--
Skin sensitizer Category 1	--	--	
Skin sensitizer Sub-category 1A	--	--	
Skin sensitizer Sub-category 1B	--	--	≥ 0.1% (see note)
			≥ 1.0%
			≥ 0.1%
			≥ 1.0%



Respiratory Sensitizer Cat 1

Answer (cont)

Substance	%	Classification
A	4.5	Specific Target Organ (Single Exposure) Cat 1 Respiratory Sensitizer Cat 1b
B	5.6	Carcinogen Cat 1a
C	89.9	Not classified

Ingredient classified as:	Cut-off/concentration limits trigger	
	Category 1 carcinogen	
	Category 1A	Category 1B
Category 1A carcinogen	≥ 0.1 % ●	--
Category 1B carcinogen	--	≥ 0.1 %
Category 2 carcinogen	--	--

Carcinogen Cat 1a

Overall Classification:
 Carcinogen Cat 1a
 Resp. Sensitizer Cat 1
 STOT (SE) Cat 2



Discussion: How to “rank” this product?

SAFETY DATA SHEET

Paracem Deco Matt

Product description : Paint.

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]
STOT RE 2, H373 (inhalation)

Product/ingredient name	Identifiers	%	<u>Classification</u> Regulation (EC) No. 1272/2008 [CLP]	Type
cristalline, cristobalite silica	EC: 238-455-4	≥5 - <10	STOT RE 1, H372 (inhalation)	[1] [2]
calcium silicate	CAS: 14464-46-1 EC: 233-250-6	≥3 - <5	Eye Irrit. 2, H319 STOT SE 3, H335	[1]
quartz, respirable fraction	CAS: 10101-39-0 EC: 238-878-4	≥1 - <3	STOT RE 1, H372 (respiratory tract) (inhalation)	[1] [2]
	CAS: 14808-60-7		See Section 16 for the full text of the H statements declared above.	

For you to know as well...

Specific Concentration Limit This is a limit for a specific substance, which will cause classification of a mixture

Specifieke concentratiegrenzen:

Naam	Productidentificatie	Specifieke concentratiegrenzen
Waterstofperoxide, waterige oplossing	(CAS-nr) 7722-84-1 (EG nr) 231-765- (EU-Identificatienu (REACH-nr) 01-2	(5 =<C < 8) Eye Irrit. 2, H319
		Specifieke concentratiegrenzen
		(5 =<C < 8) Eye Irrit. 2, H319
		(8 =<C < 50) Eye Dam. 1, H318
		(C >= 35) STOT SE 3, H335
		(35 =<C < 50) Skin Irrit. 2, H315
		(50 =<C < 70) Skin Corr. 1B, H314
		(50 =<C < 70) Ox. Liq. 2, H272
		(C >= 70) Skin Corr. 1A, H314
		(C >= 70) Ox. Liq. 1, H271

Additive hazards

Remember?

Additive Calculation

In an additive calculation, multiple components can contribute toward the mixture classification

ADDITIVE HAZARDS

- Acute Toxicity
- Skin Corrosion/Irritation
- Serious Eye Damage/Eye Irritation
- Specific Target Organ Toxicity (Single Exposure) – Category 3
- Aspiration Hazard



Non-additive Calculation

Additive Calculation: important to know

Relevant Ingredient
Threshold

This is the limit at which a substance is included in
an additive calculation

The “relevant ingredients” of a mixture are those which are present in concentrations $\geq 1\%$ (w/w for solids, liquids, dusts, mists and vapours and v/v for gases), unless there is a reason to suspect that an ingredient present at a concentration $< 1\%$ is still relevant for classifying the mixture for acute toxicity. This point is particularly relevant when



RIT for Acute Tox Cat 1/2/3 = 0.1%

Examples:

- ~~0.1% Asp. Haz. Cat 1~~ + 5% Asp. Haz. Cat 1 = 5% Asp. Haz. Cat 1
- 0.1% Acute Tox. Cat. 1 + 3% Acute Tox. Cat 1 = 3.1%
- 3% Skin Corr. Cat 1 + 0.9 Skin Corr. Cat. 1 = 3% Skin Corr. Cat 1
- ~~0.5% Eye Irr. Cat 2~~ + 2% Eye Irr. Cat 2 = 2% Eye Irr. Cat 2

Specific Target Organ Toxicity (Single Exposure)

Categories of Specific Target Organ Toxicity (for additive calculation)

CATEGORY 3: Transient target organ effects

There are target organ effects for which a substance/mixture may not meet the criteria to be classified in Categories 1 or 2 indicated above. These are effects which adversely alter human function for a short duration after exposure and from which humans may recover in a reasonable period without leaving significant alteration of structure or function. This category only includes narcotic effects and respiratory tract irritation. Substances/mixtures may be classified specifically for these effects as discussed in 3.8.2.2.

Cut-off/concentration value

3.8.3.4.5 Care should be exercised when extrapolating the toxicity of a mixture that contains Category 3 ingredient(s). A cut-off value/concentration limit of 20% has been suggested; however, it should be recognized that this cut-off value concentration limit may be higher or less depending on the Category 3 ingredient(s) and that some effects such as respiratory tract irritation may not occur below a certain concentration while other effects such as narcotic effects may occur below this 20% value. Expert judgment should be exercised. Respiratory tract irritation and narcotic effects are to be evaluated separately in accordance with the criteria given in 3.8.2.2. When conducting classifications for these hazards, the contribution of each ingredient should be considered additive, unless there is evidence that the effects are not additive.

Do it yourself:

What is classification of this liquid mixture?

<i>Substance</i>	<i>%</i>	<i>Classification</i>
<i>A</i>	<i>1.5</i>	<i>Specific Target Organ (Single Exposure) Cat 3</i>
<i>B</i>	<i>18.5</i>	<i>Respiratory Sensitizer Cat 1b</i> <i>Specific Target Organ (Single Exposure) Cat 3</i>
<i>C</i>	<i>86.0</i>	<i>Not classified</i>



Answer

Substance	%	Classification
A	1.5	Specific Target Organ (SE) Cat 3
B	18.5	Respiratory Sensitizer Cat 1b Specific Target Organ (Single Exposure) Cat 3
C	86.0	Not classified

Ingredient classified as:	Cut-off values/concentration limits triggering classification of a mixture as:		
	Respiratory sensitizer Category 1		Skin sensitizer Category 1
	Solid/Liquid	Gas	All physical states
Respiratory sensitizer Category 1	$\geq 0.1\%$ (see note) $\geq 1.0\%$	$\geq 0.1\%$ (see note) $\geq 0.2\%$	--
Respiratory sensitizer Sub-category 1A	$\geq 0.1\%$	$\geq 0.1\%$	
Respiratory sensitizer Sub-category 1B	$\geq 1.0\%$ ●	$\geq 0.2\%$	

Respiratory Sensitizer Cat 1

Answer (cont.)

Substance	%	Classification
A	1.5	Specific Target Organ (SE) Cat 3
B	18.5	Respiratory Sensitizer Cat 1b Specific Target Organ (Single Exposure) Cat 3
C	86.0	Not classified

3.8.3.4.5 Care should be exercised when extrapolating the toxicity of a mixture that contains Category 3 ingredient(s). A cut-off value/concentration limit of 20% has been suggested; however, it should be recognized that this cut-off value concentration limit may be higher or less depending on the Category 3

→ 20% of Substance STOT SE Cat 3 (1.5 + 18.5)

STOT - SE: Classified

Overall Classification:
Respiratory Sensitizer Cat 1
STOT SE Cat 3



Skin + Eye Corrosion/Irritation

What is the definition of Skin Corrosion (irritation) and Eye Damage (irritation)?

3.2.1.1 *Skin corrosion* is the production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, following the application of a test substance for up to 4 hours¹. Corrosive reactions are typified by ulcers, bleeding, bloody scabs, and, by the end of observation at 14 days, by discolouration due to blanching of the skin, complete areas of alopecia, and scars. Histopathology should be considered to evaluate questionable lesions.

Skin irritation is the production of reversible damage to the skin following the application of a test substance for up to 4 hours¹.

3.3.1.1 *Serious eye damage* is the production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application¹.

Eye irritation is the production of changes in the eye following the application of test substance to the anterior surface of the eye, which are fully reversible within 21 days of application¹.

Categories of Skin Corrosion/Irritation

(a) **Category 1 (skin corrosion)**

This category may be further divided into up to three sub-categories (1A, 1B and 1C) which can be used by those authorities requiring more than one designation for corrosivity (see Table 3.2.1)

(b) **Category 2 (skin irritation)** (see Table 3.2.2)

Table 3.2.1

Skin Corrosive category and subcategories

		Corrosive in > 1 of 3 animals	
	Corrosive subcategories	Exposure	Observation
Category 1: Corrosive	1A	≤ 3 minutes	≤ 1 hour
	1B	> 3 minutes - ≤ 1 hour	≤ 14 days
	1C	> 1 hour - ≤ 4 hours	≤ 14 days

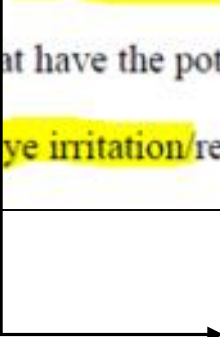
Categories of Serious Eye Damage/Irritation

Substances are allocated to one of the categories within this hazard class, Category 1 (serious eye damage) or Category 2 (eye irritation), as follows:

(a) **Category 1 (serious eye damage)**/irreversible effects on the eye):

substances that have the potential to seriously damage the eyes (see Table 3.3.1).

(b) **Category 2 (eye irritation)**/reversible effects on the eye):



Category	Criteria
Irreversible effects on the eye (Category 1)	<p>If, when applied to the eye of an animal, a substance produces:</p> <ul style="list-style-type: none">— at least in one animal effects on the cornea, iris or conjunctiva that are not expected to reverse or have not fully reversed within an observation period of normally 21 days; and/or— at least in 2 of 3 tested animals, a positive response of:<ul style="list-style-type: none">— corneal opacity ≥ 3 and/or— iritis $> 1,5$ <p>calculated as the mean scores following grading at 24, 48 and 72 hours after installation of the test material.</p>

Concentration limits for Skin and Eye Corrosion/Irritation

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Skin Corrosive	Skin Irritant
	Category 1 (see note below)	Category 2
Skin Corrosive Categories 1A, 1B, 1C	$\geq 5\%$	$\geq 1\%$ but $< 5\%$
Skin irritant Category 2		$\geq 10\%$
(10 × Skin Corrosive Category 1A, 1B, 1C) + Skin irritant Category 2		$\geq 10\%$

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	$\geq 3\%$	$\geq 1\%$ but $< 3\%$
Eye Effects Category 2		$\geq 10\%$
(10 × Eye Effects Category 1) + Eye effects Category 2		$\geq 10\%$
Skin Corrosive Category 1A, 1B, 1C + Eye effects Category 1	$\geq 3\%$	$\geq 1\%$ but $< 3\%$
10 × (Skin Corrosive Category 1A, 1B, 1C + Eye Effects Category 1) + Eye Effects Category 2		$\geq 10\%$

Skin Corrosion also influences Eye Damage!

Additional information (Skin)

Note

The sum of all ingredients of a mixture classified as Skin Corrosive Category 1A, 1B or 1C respectively, shall each be $\geq 5\%$ respectively 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 $\geq 5\%$, the mixture shall be classified as Skin Corrosive Category 1B. Similarly, if the sum of Skin Corrosive Category 1A+1B ingredients is $< 5\%$ but the sum of Category 1A+1B+1C ingredients is $\geq 5\%$ the mixture shall be classified as Skin Corrosive Category 1C.

A mixture may be classified in sub-categories of skin corrosion category 1 under certain conditions.

→ 3% Cat 1A + 3% Cat 1B = Cat 1B

2% Cat 1A + 5% Cat 1B + 7% Cat 1C = Cat 1B

Additional information (Skin and Eye)

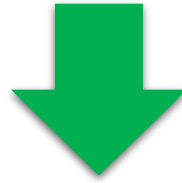
For strong acids and bases, pH should be used to determine the classification instead of cut-off/concentration limit since it is a better indicator of corrosion for these type of mixtures.

Concentration of ingredients of a mixture when the **additivity approach does not apply**, that would trigger classification of the mixture as hazardous

Ingredient	Concentration	Mixture classified as:
Acid with $\text{pH} \leq 2$	$\geq 1\%$	Category 1
Base with $\text{pH} \geq 11.5$	$\geq 1\%$	Category 1

Additional information (Eye)

- ^a *Where a chemical is classified as skin Category 1, labelling for serious eye damage/eye irritation may be omitted as this information is already included in the hazard statement for skin Category 1 (Causes severe skin burns and eye damage) (see Chapter 1.4, para. 1.4.10.5.3.3).*



- (d) If the statement H314 “Causes severe skin burns and eye damage” is assigned, the statement H318 “Causes serious eye damage” may be omitted.

Example SDS

Trade name: VB 225™ H

Application of the substance / the mixture: A Moisture vapor emissions reduction system



H302+H332 Harmful if swallowed or if inhaled.
 H314 Causes severe skin burns and eye damage.
 H317 May cause an allergic skin reaction.
 H411 Toxic to aquatic life with long lasting effects.

Ingredients according Regulation (EU) 830/2015:		
CAS: 68082-29-1 NLP: 500-191-5	Fatty acids, C18-unsatd., dimers, oligomeric reaction products with tall-oil fatty acids and triethylenetetramine ⚠ Eye Dam. 1, H318; ⚠ Aquatic Chronic 2, H411; ⚠ Skin Irrit. 2, H315	25-50%
CAS: 100-51-6 EINECS: 202-859-9 Index number: 603-057-00-5 Reg.nr.: 01-2119492630-38-XXXX	Benzyl alcohol ⚠ Acute Tox. 4, H302; Acute Tox. 4, H332; Eye Irrit. 2, H319	10-25%
CAS: 90-72-2 EINECS: 202-013-9 Index number: 603-069-00-0	2,4,6-tris(dimethylaminomethyl)phenol ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319	2.5-10%
CAS: 109-55-7 EINECS: 203-680-9 Index number: 612-061-00-6 Reg.nr.: 01-2119486842-27-0000	3-aminopropyldimethylamine ⚠ Flam. Liq. 3, H226; ⚠ Acute Tox. 3, H311; Acute Tox. 3, H331; ⚠ Skin Corr. 1B, H314; ⚠ Acute Tox. 4, H302; Skin Sens. 1, H317	2.5-10%

Do it yourself

Untested liquid mixture consists of three substances with the following classifications and concentrations.

1)

Substance	%	Classification
A	3.5	Skin corrosion/irritation Cat 1a
B	5.5	Skin corrosion/irritation Cat 2
C	91.0	Not classified

2)

A	4.5	Skin corrosion/irritation Cat 1b
B	8.5	Skin corrosion/irritation Cat 1c
C	87.0	Not classified

What is the overall classification of the untested mixtures?

Answer 1)

Substance	%	Classification
A	3.5	Skin corrosion/irritation Cat 1a
B	8.5	Skin corrosion/irritation Cat 2
C	91.0	Not classified

Table 3.2.3

Generic concentration limits of ingredients classified for skin corrosive/irritant hazard (Category 1 or 2) that trigger classification of the mixture as corrosive/irritant to skin

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Skin Corrosive	Skin Irritant
	Category 1 (see note below)	Category 2
Skin Corrosive Categories 1A, 1B, 1C	$\geq 5\%$	$\geq 1\%$ but $< 5\%$ ●
Skin irritant Category 2		$\geq 10\%$
(10 × Skin Corrosive Category 1A, 1B, 1C) + Skin irritant Category 2		● $\geq 10\%$

Since substance A was classified as Category 1a, a classification of Serious eye damage Category 1 is assumed.

Skin irritation Cat 2
Serious Eye damage Cat 1



Answer 2)

Substance 2	%	Classification
A	4.5	Skin corrosion/irritation Cat 1b
B	8.5	Skin corrosion/irritation Cat 1c
C	87.0	Not classified

NOTE: Where the sub-categories of skin Category 1 (corrosive) are used, the sum of all ingredients of a mixture classified as sub-category 1A, 1B or 1C respectively, should each be $\geq 5\%$ in order to classify the mixture as either skin sub-category 1A, 1B or 1C. Where the sum of 1A ingredients is $< 5\%$ but the sum of 1A+1B ingredients is $\geq 5\%$, the mixture should be classified as sub-category 1B. Similarly, where the sum of 1A + 1B ingredients is $< 5\%$ but the sum of 1A + 1B + 1C ingredients is $\geq 5\%$ the mixture should be classified as sub-category 1C. Where at least one relevant ingredient in a mixture is classified as Category 1 without sub-categorisation, the mixture should be classified as Category 1 without sub-categorisation if the sum of all ingredients corrosive to skin is $\geq 5\%$.

Skin corrosion Cat 1c
Serious eye damage Cat 1

Aspiration hazard

What is the definition of Aspiration Hazard?

3.10.1.2 *Aspiration* means the entry of a liquid or solid chemical directly through the oral or nasal cavity, or indirectly from vomiting, into the trachea and lower respiratory system.

3.10.1.3 Aspiration toxicity includes severe acute effects such as chemical pneumonia, varying degrees of pulmonary injury or death following aspiration.

Hazard category for aspiration toxicity

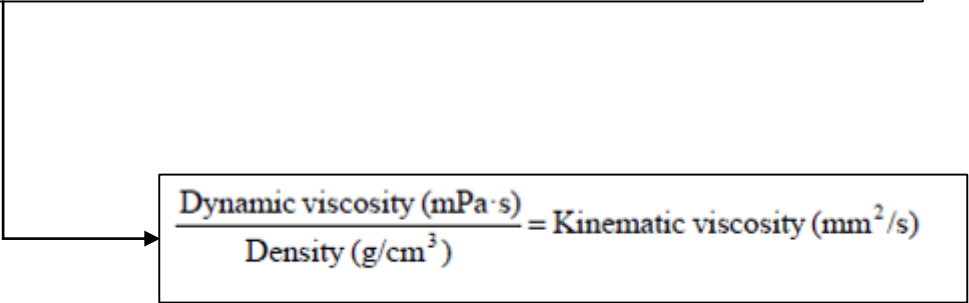
Category	Criteria
Category 1	<p>Substances known to cause human aspiration toxicity hazards or to be regarded as if they cause human aspiration toxicity hazard</p> <p>A substance is classified in Category 1:</p> <p>(a) based on reliable and good quality human evidence</p> <p>or</p> <p>(b) if it is a hydrocarbon and has a kinematic viscosity of 20,5 mm²/s or less, measured at 40 °C.</p>

Concentration limits for Aspiration Hazard

3.10.3.3.1. Category 1

3.10.3.3.1.1. A mixture which contains a total of 10 % or more of a substance or substances classified in Category 1, and has a kinematic viscosity of 20,5 mm² /s or less, measured at 40 °C, shall be classified in Category 1.

3.10.3.3.1.2. In the case of a mixture which separates into two or more distinct layers, one of which contains 10 % or more of a substance or substances classified in Category 1 and has a kinematic viscosity of 20,5 mm² /s or less, measured at 40 °C, then the entire mixture is classified in Category 1.


$$\frac{\text{Dynamic viscosity (mPa}\cdot\text{s)}}{\text{Density (g/cm}^3\text{)}} = \text{Kinematic viscosity (mm}^2\text{/s)}$$

Acute toxicity

Acute toxicity

The question is, how do we translate this...

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Formaldehyde, solution	LC50 Inhalation Gas.	Rat	250 ppm	4 hours
	LD50 Dermal	Rabbit	270 mg/kg	-
	LD50 Oral	Rat	100 mg/kg	-

Classification of the substance or mixture

: FLAMMABLE LIQUIDS - Category 4
ACUTE TOXICITY (oral) - Category 3
ACUTE TOXICITY (dermal) - Category 3
ACUTE TOXICITY (inhalation) - Category 2
SKIN CORROSION/IRRITATION - Category 2
SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2A
AQUATIC HAZARD (ACUTE) - Category 1
AQUATIC HAZARD (LONG-TERM) - Category 1

We have the data

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Formaldehyde, solution	LC50 Inhalation Gas.	Rat	250 ppm	4 hours
	LD50 Dermal	Rabbit	270 mg/kg	-
	LD50 Oral	Rat	100 mg/kg	-

now we need the key....

Exposure route	Category 1	Category 2	Category 3	Category 4
Oral (mg/kg bodyweight) <i>See notes (a) and (b)</i>	5	50	300	2000
Dermal (mg/kg bodyweight) <i>See notes (a) and (b)</i>	50	200	1000	2000
Gases (ppmV) <i>See notes (a), (b) and (c)</i>	100	500	2500	20000
Vapours (mg/l) <i>See notes (a), (b), (c), (d) and (e)</i>	0.5	2.0	10	20
Dusts and Mists (mg/l) <i>See notes (a), (b), (c) and (f)</i>	0.05	0.5	1.0	5

Note: Gases concentration are expressed in parts per million per volume (ppmV).

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Formaldehyde, solution	LC50 Inhalation Gas. LD50 Dermal LD50 Oral	Rat Rabbit Rat	250 ppm 270 mg/kg 100 mg/kg	4 hours - -

Exposure route	Category 1	Category 2	Category 3	Category 4
Gases (ppmV ⁽¹⁾)				
see: Note (a) Note (b) Note (c)	ATE ≤ 100	100 < ATE ≤ 500	500 < ATE ≤ 2 500	2 500 < ATE ≤ 20 000
Vapours (mg/l)				
see: Note (a) Note (b) Note (c) Note (d)	ATE ≤ 0,5	0,5 < ATE ≤ 2,0	2,0 < ATE ≤ 10,0	10,0 < ATE ≤ 20,0
Dusts and mists (mg/l)				
see: Note (a) Note (b) Note (c)	ATE ≤ 0,05	0,05 < ATE ≤ 0,5	0,5 < ATE ≤ 1,0	1,0 < ATE ≤ 5,0

⁽¹⁾ Gas concentrations are expressed in parts per million per volume (ppmV).

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Formaldehyde, solution	LC50 Inhalation Gas. LD50 Dermal LD50 Oral	Rat Rabbit Rat	250 ppm 270 mg/kg 100 mg/kg	4 hours - -

Exposure route	Category 1	Category 2	Category 3	Category 4
Oral (mg/kg bodyweight) See: Note (a) Note (b)	$ATE \leq 5$	$5 < ATE \leq 50$	$50 < ATE \leq 300$	$300 < ATE \leq 2\,000$
Dermal (mg/kg bodyweight) See: Note (a) Note (b)	$ATE \leq 50$	$50 < ATE \leq 200$	$200 < ATE \leq 1\,000$	$1\,000 < ATE \leq 2\,000$

Do it yourself:

Bezene

Oral LD50 of 930 mg/kg (rat)

Oral LD50 of 4700 mg/kg (mouse)

Methanol

Oral LD50 of 5600 mg/kg (rat)

Acrylonitril

Dermal LD50 of 148 mg/kg (rat)

Dermal LD50 of 63 mg/kg (rabbit)



Answer:

Bezene

Oral LD50 of 930 mg/kg (rat)

Category 4

(Not classified on basis of CLP)

Methanol

Oral LD50 of 5600 mg/kg (rat)

*Not classified on basis of test
(Cat 3 on basis of CLP)*

Acrylonitrile

Dermal LD50 of 63 mg/kg (rabbit)

Category 2

(Cat 3 on basis of CLP)



Additional Information

Inhalation Tests

- (c) *Inhalation cut-off values in the table are based on 4 hour testing exposures. Conversion of existing inhalation toxicity data which has been generated according to 1 hour exposures should be by dividing by a factor of 2 for gases and vapours and 4 for dusts and mists;*

$$4_hour_Dust / Mist = \frac{1 - hour_test}{4}$$

$$4_hour_Gases / Vapors = \frac{1 - hour_test}{2}$$

Result	Species	Dose	Exposure
LC50 Inhalation Dusts and mists	Rat	15 mg/l	1 hours

$$\frac{15}{4} = 3.75$$

Discussion: How would you rank these substances?

Substance X: LD50 oral (rat) : 4.5 mg/kg



Substance Y: LD50 oral (rat): 45 mg/kg

Substance Z; LD50 oral (rat): 450 mg/kg

Like: $X > Y > Z$ or differently?

Discussion: Ranking Cat 1 and Cat 2

Substance X: LD50 oral (rat) : 4.5 mg/kg → (Cat 1) H Statement 300
 Substance Y: LD50 oral (rat): 45 mg/kg → (Cat 2) H Statement 300
 Substance Z; LD50 oral (rat): 450 mg/kg →(Cat 4) H Statement 302

Classification	Category 1	Category 2
GHS Pictograms		
Signal Word	Danger	Danger
Hazard Statement: — Oral	H300: Fatal if swallowed	H300: Fatal if swallowed
— Dermal	H310: Fatal in contact with skin	H310: Fatal in contact with skin
— Inhalation (see Note 1)	H330: Fatal if inhaled	H330: Fatal if inhaled

Classifying a mixture when there is $\leq 10\%$ of ingredients within unknown toxicity

The ATE of the mixture is determined by calculation from the ATE values for all relevant ingredients according to the following formula below for oral, dermal or inhalation toxicity:

$$\frac{100}{ATE_{mix}} = \sum_n \frac{C_i}{ATE_i}$$

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 ;

C_i is easy, this is just the concentration of the component in the mixture.

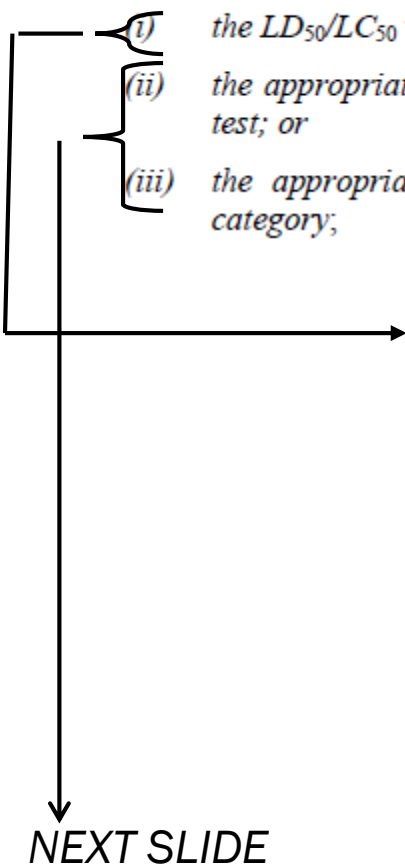
ATE_i is the ATE of the ingredient (use handout to find)

This is the calculation that will be used when there is data available on all ingredients.

Classifying a mixture when there is $\leq 10\%$ of ingredients within unknown toxicity (cont.)

(b) The acute toxicity estimate (ATE) for a substance in a mixture is derived using:

- (i) the LD_{50}/LC_{50} where available; otherwise,
- (ii) the appropriate conversion value from Table 3.1.2 that relates to the results of a range test; or
- (iii) the appropriate conversion value from Table 3.1.2 that relates to a classification category;



Exposure route	Category 1	Category 2	Category 3	Category 4
Oral (mg/kg bodyweight) <i>See notes (a) and (b)</i>	5	50	300	2000
Dermal (mg/kg bodyweight) <i>See notes (a) and (b)</i>	50	200	1000	2000
Gases (ppmV) <i>See notes (a), (b) and (c)</i>	100	500	2500	20000
Vapours (mg/l) <i>See notes (a), (b), (c), (d) and (e)</i>	0.5	2.0	10	20
Dusts and Mists (mg/l) <i>See notes (a), (b), (c) and (f)</i>	0.05	0.5	1.0	5

Note: Gases concentration are expressed in parts per million per volume (ppmV).

NEXT SLIDE

Classifying a mixture when there is $\leq 10\%$ of ingredients within unknown toxicity (cont.)

Exposure routes	Classification Category or experimentally obtained acute toxicity range estimate	Converted acute toxicity point estimate (see Note 1)
Oral (mg/kg body-weight)	$0 < \text{Category 1} \leq 5$ $5 < \text{Category 2} \leq 50$ $50 < \text{Category 3} \leq 300$ $300 < \text{Category 4} \leq 2\,000$	0,5 5 100 500
Dermal (mg/kg body-weight)	$0 < \text{Category 1} \leq 50$ $50 < \text{Category 2} \leq 200$ $200 < \text{Category 3} \leq 1\,000$ $1\,000 < \text{Category 4} \leq 2\,000$	5 50 300 1\,100
Gases (ppmV)	$0 < \text{Category 1} \leq 100$ $100 < \text{Category 2} \leq 500$ $500 < \text{Category 3} \leq 2\,500$ $2\,500 < \text{Category 4} \leq 20\,000$	10 100 700 4\,500
Vapours (mg/l)	$0 < \text{Category 1} \leq 0,5$ $0,5 < \text{Category 2} \leq 2,0$ $2,0 < \text{Category 3} \leq 10,0$ $10,0 < \text{Category 4} \leq 20,0$	0,05 0,5 3 11
Dust/mist (mg/l)	$0 < \text{Category 1} \leq 0,05$ $0,05 < \text{Category 2} \leq 0,5$ $0,5 < \text{Category 3} \leq 1,0$ $1,0 < \text{Category 4} \leq 5,0$	0,005 0,05 0,5 1,5

This table will give you an acute toxicity point estimate for components which only have range values or a hazard category.

Do it yourself (together)

Substance 1 - 45%, Oral LD50 4mg/kg

Substance 2 - 25%, Oral LD50 55,g/kg

Substance 3 - 29.2%, Acute Tox. Cat 2 (ATE value 5)

Substance 4 - 0.8%, Oral LD50 350mg/kg



Answer

Substance 1 - 45%, Oral LD50 4mg/kg

Substance 2 - 25%, Oral LD50 55,g/kg

Substance 3 - 29.2%, Acute Tox. Cat 2 (ATE value 5)

~~Substance 4 - 0.8%, Oral LD50 350mg/kg~~

Which Ingredients would be considered 'relevant'?

- Ingredient 1, the substance is considered 'classified' and is in the composition above 0.1%
- Ingredient 2, the substance is considered 'classified' and is in the composition above 0.1%
- Ingredient 3, the substance is considered 'classified' and is in the composition above 0.1%

Ingredient 4 is not considered 'relevant' because it is in the composition at <1%



Answer (cont)

Substance 1 - 45%, Oral LD50 4mg/kg

Substance 2 - 25%, Oral LD50 55,g/kg

Substance 3 - 29.2%, Acute Tox. Cat 2 (ATE value 5)

~~Substance 4 - 0.8%, Oral LD50 350mg/kg~~

$$\frac{100}{ATE_{mix}} = \frac{C_i}{ATE_i}$$

$$\frac{100}{ATE_{mi}} = \frac{45}{4} + \frac{25}{55} + \frac{29.2}{5}$$

x

$$\frac{100}{ATE_{mix}} = 11.25 + 0.455 + 5.84$$

$$\frac{100}{ATE_{mix}} = 17.54$$

$$ATE_{mix} = \frac{100}{17.54}$$

$$ATE_{mix} = 5.7$$



Acute Toxicity (Oral) - Category 2

Under what circumstances would you need to complete the Acute Toxicity Mixture Calculation multiple times?



Do it yourself (do we?)

<i>Substance</i>	<i>Conc.</i>	<i>Oral (mg/kg)</i>	<i>Dermal (mg/kg)</i>	<i>Inhalation</i>
<i>Substance 1</i>	<i>75%</i>	<i>LD50 55</i>	<i>LD50 1500</i>	<i>None</i>
<i>Substance 2</i>	<i>24.8%</i>	<i>LD50 10</i>	<i>LD50 2500</i>	<i>None</i>
<i>Substance 3</i>	<i>0.2%</i>	<i>LD50 400</i>	<i>LD50 1100</i>	<i>None</i>



Answer

Substance	Conc.	Oral (mg/kg)	Dermal (mg/kg)	Inhalation
Substance 1	75%	LD50 55	LD50 1500	None
Substance 2	24.8%	LD50 10	LD50 2500	None
Substance 3	0.2%	LD50 400	LD50 1100	None

Which Ingredients would be considered 'relevant'?

Ingredient 1, the substance is considered 'classified' and is in the composition above 1%

Ingredient 2, the substance is considered 'classified' and is in the composition above 1%

Ingredient 3 is not considered 'relevant' because it is in the composition at <1%



Answer (cont)

Substance	Conc.	Oral (mg/kg)	Dermal (mg/kg)	Inhalation
Substance 1	75%	LD50 55	LD50 1500	None
Substance 2	24.8%	LD50 10	LD50 2500	None
Substance 3	0.2%	LD50 400	LD50 1100	None

Oral

$$\frac{100}{ATE_{mix}} = \frac{C_i}{ATE_i}$$

$$\frac{100}{ATE_{mix}} = \frac{75}{55} + \frac{24.8}{10}$$

$$\frac{100}{ATE_{mix}} = 1.36 + 2.48$$

$$\frac{100}{ATE_{mix}} = 3.84$$

$$ATE_{mix} = \frac{100}{3.84}$$

$$ATE_{mix} = 26.04$$



Answer (cont.)

Substance	Conc.	Oral (mg/kg)	Dermal (mg/kg)	Inhalation
Substance 1	75%	LD50 55	LD50 1500	None
Substance 2	24.8%	LD50 10	LD50 2500	None
Substance 3	0.2%	LD50 400	LD50 1100	None

$$ATE_{mix} = 26.04$$

Acute Toxicity (Oral) -
Category 2

Exposure route	Category 1	Category 2	Category 3	Category 4
Oral (mg/kg bodyweight) <i>See notes (a) and (b)</i>	5	50	300	2000
Dermal (mg/kg bodyweight) <i>See notes (a) and (b)</i>	50	200	1000	2000
Gases (ppmV) <i>See notes (a), (b) and (c)</i>	100	500	2500	20000
Vapours (mg/l) <i>See notes (a), (b), (c), (d) and (e)</i>	0.5	2.0	10	20
Dusts and Mists (mg/l) <i>See notes (a), (b), (c) and (f)</i>	0.05	0.5	1.0	5

Note: Gases concentration are expressed in parts per million per volume (ppmV).

Answer (cont.)

Substance	Conc.	Oral (mg/kg)	Dermal (mg/kg)	Inhalation
Substance 1	75%	LD50 55	LD50 1500	None
Substance 2	24.8%	LD50 10	LD50 2500	None
Substance 3	0.2%	LD50 400	LD50 1100	None

Dermal

$$\frac{100}{ATE_{mix}} = \frac{C_i}{ATE_i}$$

$$\frac{100}{ATE_{mix}} = \frac{75}{1500} + \frac{24.8}{2500}$$

$$\frac{100}{ATE_{mix}} = 0.05 + 0.01$$

$$\frac{100}{ATE_{mix}} = 0.06$$

$$ATE_{mix} = \frac{100}{0.06}$$

$$ATE_{mix} = 1666.67 \text{ mg/kg}$$



Answer (cont.)

Substance	Conc.	Oral (mg/kg)	Dermal (mg/kg)	Inhalation
Substance 1	75%	LD50 55	LD50 1500	None
Substance 2	24.8%	LD50 10	LD50 2500	None
Substance 3	0.2%	LD50 400	LD50 1100	None

$$ATE_{mix} = 1666.67 \text{ mg/kg}$$

Acute Toxicity
(Dermal) -
Category 4

Exposure route	Category 1	Category 2	Category 3	Category 4
Oral (mg/kg bodyweight) <i>See notes (a) and (b)</i>	5	50	300	2000
Dermal (mg/kg bodyweight) <i>See notes (a) and (b)</i>	50	200	1000	2000
Gases (ppmV) <i>See notes (a), (b) and (c)</i>	100	500	2500	20000
Vapours (mg/l) <i>See notes (a), (b), (c), (d) and (e)</i>	0.5	2.0	10	20
Dusts and Mists (mg/l) <i>See notes (a), (b), (c) and (f)</i>	0.05	0.5	1.0	5

Note: Gases concentration are expressed in parts per million per volume (ppmV).

Answer (cont.)

Substance	Conc.	Oral (mg/kg)	Dermal (mg/kg)	Inhalation
Substance 1	75%	LD50 55	LD50 1500	None
Substance 2	24.8%	LD50 10	LD50 2500	None
Substance 3	0.2%	LD50 400	LD50 1100	None

Overall Classification

Acute Toxicity (Oral) - Category 2

Acute Toxicity (Dermal) - Category 4



Do it yourself (or is this for later?)

<i>Substance</i>	<i>Conc.</i>	<i>Inhalation (mg/l)</i>
<i>Substance 1</i>	<i>85%</i>	<i>LCC50 Vapor 9, 1 hr test</i>
<i>Substance 2</i>	<i>0.05%</i>	<i>LCC50 Vapor 9, 1 hr test</i>
<i>Substance 3</i>	<i>14.5%</i>	<i>NLCC50 Vapor 12, 4 hr test</i>



Answer

Substance	Conc-	Inhalation (mg/l)
Substance 1	85%	LCC50 Vapor 9, 1 <u>hr</u> test
Substance 2	0.05%	LCC50 Vapor 9, 1 <u>hr</u> test
Substance 3	14.5%	NLCC50 Vapor 12, 4 <u>hr</u> test

Which Ingredients would be considered 'relevant'?

Ingredient 1, the substance is considered 'classified' and is in the composition above 1%

Ingredient 3, the substance is considered 'classified' and is in the composition above 1%

Ingredient 2 is not considered 'relevant' because it is in the composition at <0.1%



Answer (cont)

Substance	Conc.	Inhalation (mg/l)
Substance 1	85%	LCC50 Vapor 9, 1 <u>hr</u> test
Substance 2	0.05%	LCC50 Vapor 9, 1 <u>hr</u> test
Substance 3	14.5%	NLCC50 Vapor 12, 4 <u>hr</u> test

Inhalation

1 hour test conversion

$$4 \text{ Hour Gases/Vapors} = \frac{1 \text{ Hour Test}}{2}$$

$$\frac{9}{2} = 4.5$$



Answer (cont)

Substance	Conc.	Inhalation (mg/l)
Substance 1	85%	LCC50 Vapor 9, 1 <u>hr</u> test
Substance 2	0.05%	LCC50 Vapor 9, 1 <u>hr</u> test
Substance 3	14.5%	NLCC50 Vapor 12, 4 <u>hr</u> test

Inhalation

$$\frac{100}{ATE_{mix}} = \frac{C_i}{ATE_i}$$

$$\frac{100}{ATE_{mix}} = \frac{85}{4.5} + \frac{14.5}{12}$$

$$\frac{100}{ATE_{mix}} = 18.89 + 1.21$$

$$\frac{100}{ATE_{mix}} = 20.1$$

$$ATE_{mix} = \frac{100}{20.1}$$

$$ATE_{mix} = 4.98 \text{ mg/l}$$



Answer (cont)

Substance	Conc.	Inhalation (mg/l)
Substance 1	85%	LCC50 Vapor 9, 1 <u>hr</u> test
Substance 2	0.05%	LCC50 Vapor 9, 1 <u>hr</u> test
Substance 3	14.5%	NLCC50 Vapor 12, 4 <u>hr</u> test

$$ATE_{mix} = 4.98 \text{ mg/l}$$

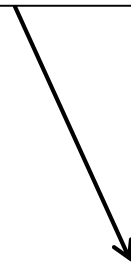
Acute Toxicity
(inhalation) -
Category 3

Exposure route	Category 1	Category 2	Category 3	Category 4
Oral (mg/kg bodyweight) <i>See notes (a) and (b)</i>	5	50	300	2000
Dermal (mg/kg bodyweight) <i>See notes (a) and (b)</i>	50	200	1000	2000
Gases (ppmV) <i>See notes (a), (b) and (c)</i>	100	500	2500	20000
Vapours (mg/l) <i>See notes (a), (b), (c), (d) and (e)</i>	0.5	2.0	10	20
Dusts and Mists (mg/l) <i>See notes (a), (b), (c) and (f)</i>	0.05	0.5	1.0	5

Note: Gases concentration are expressed in parts per million per volume (ppmV).

Additional not on classification

- (c) If the converted acute toxicity point estimates for all ingredients of a mixture are within the same category, then the mixture should be classified in that category;



Mathematically, when you are looking at the borders of the classification ranges for the ATE, it is possible to have all components classified as Category 2, but have the calculated classification turn out to be a category 1.

This note states that if all the components are classified with the same category for a certain route of entry, then the material should be classified in that category.

Example

Mixture contains:

70% Substance A Oral Category 2 (ATE value 5)

30% Substance B Oral Category 2 (ATE value 5)

Exposure route	Category 1	Category 2	Category 3	Category 4
Oral (mg/kg bodyweight) <i>See notes (a) and (b)</i>	5	50	300	2000

$$\frac{100}{ATE_{mix}} = \frac{C_i}{ATE_i}$$

$$ATE_{mix} = \frac{100}{\frac{70}{5} + \frac{30}{5}} = 5 = \text{Category 1}$$



But: the note indicates that this should be classified as a category 2.

Additional note on classification

3.1.3.6.2.3 If the total concentration of the relevant ingredient(s) with unknown acute toxicity is $\leq 10\%$ then the formula presented in 3.1.3.6.1 should be used. If the total concentration of the relevant ingredient(s) with unknown toxicity is $> 10\%$, the formula presented in 3.1.3.6.1 should be corrected to adjust for the percentage of the unknown ingredient(s) as follows:

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

The only new part is the total concentration of the unknown components.

Classification is more 'severe' (punishment for not knowing the toxicity of an ingredient)

Example

Mixture contains:

40% Substance A Oral Category 3 (ATE value 100)

30% Substance B Oral Category 2 (ATE value 5)

30% Substance C Unknown toxicity

$$\frac{100 - 30}{ATE_{mix}} = \frac{C_i}{ATE_i}$$

$$ATE_{mix} = \frac{70}{\frac{40}{100} + \frac{30}{5}} = 10.9 = \text{Category 2}$$



If not "unknown" ATE would be: 15.6 (same cat.)

Supplemental Hazard Information (EUHXX)

- No “official” classification categories
- Usually added at the mixture level (except EUH070)

EUH029: Contact with water liberates toxic gas.

EUH031: Contact with acids liberates toxic gas.

EUH032: Contact with acids liberates very toxic gas.

EUH066: Repeated exposure may cause skin dryness or cracking.

EUH070: Toxic by eye contact.

EUH071: Corrosive to the respiratory tract.

Discussion

Classification vs Hazards not Classified?

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

H225	FLAMMABLE LIQUIDS - Category 2
H302	ACUTE TOXICITY (oral) - Category 4
H312	ACUTE TOXICITY (dermal) - Category 4
H332	ACUTE TOXICITY (inhalation) - Category 4
H319	SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2
H400	ACUTE AQUATIC HAZARD - Category 1
H410	LONG-TERM AQUATIC HAZARD - Category 1

diethylstilbestrol	EC: 200-278-5 CAS: 56-53-1	<0.1	Eye Irrit. 2, H319 Carc. 1A, H350 STOT RE 2, H373 (cardiovascular system and liver) Aquatic Chronic 1, H410 (M=10)
methyltestosterone	EC: 200-366-3 CAS: 58-18-4	<0.1	Carc. 1B, H350 Aquatic Chronic 1, H410 (M=1000)
Estra-4,9,11-trien-3-one, 17-hydroxy-, (17 β)-ethinylestradiol	CAS: 10161-33-8 EC: 200-342-2 CAS: 57-63-6	≤ 0.1 <0.1	Aquatic Chronic 1, H410 (M=10000) Acute Tox. 4, H302 Carc. 1B, H350 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1000000)
Estradiol	EC: 200-023-8	<0.1	Carc. 1B, H350



Exercises

From existing SDS's

Product 1

1.2.1. Relevant geïdentificeerd gebruik

Hoofdgebruikscategorie : Professioneel gebruik

Gebruik van de stof of het mengsel : Reinig

Naam	Productidentificatie	%	Indeling conform Verordening (EG) Nr. 1272/2008 [CLP]
Propaan-2-ol, isopropylalcohol, isopropanol	(CAS-nr) 67-63-0 (EG nr) 200-661-7 (EU-Identificatienummer) 603-	40 - 90	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
Nafta (aardolie), waterstofbehandelde zware, Gehydrogeneerde nafta met laag kookpunt, Een complexe verzameling koolwaterstoffen, verkregen door behandeling van een aardoliefractie met waterstof in aanwezigheid van een katalysator. Bestaat uit koolwaterstoffen, overwegend C6 tot en met C13, met een kooktraject van ongeveer 65°C tot 230°C. (Noot P)	(CAS-nr) 64742-48-9 (EG nr) 265-150-3 (EU-Identificatienummer) 649-	10 - 20	Asp. Tox. 1, H304 Flam. Liq. 3, H226

Viscositeit, kinematisch	: Geen gegevens beschikbaar
Viscositeit, dynamisch	: Geen gegevens beschikbaar

Answer

- Eye Irritation: Additive classification (>10%): Classified
- STOT RE 3: Additive classification (>20%) : Classified
- Aspiration Hazard: More than 10% Asp.Haz Cat 1, BUT
No kinematic viscosity known → Not classified

Overall classification: Eye Irr. Cat 2
 STOT RE Cat 3 (narcotic)

Answer

- Eye Irritation: Additive classification

- Cat 1: 2,5% (less than 3%): Not Classified
- Cat 2: Cat 1 ingredient is >1 and < 3%: Classified

- Acute Toxicity:

$$\frac{2,5}{500} = \frac{100}{ATE_{mix}} \rightarrow ATE_{mix} = 20000 \rightarrow \underline{\text{Not classified}}$$

Supplier:

2.1 Indeling van de stof of het mengsel

Classificatie volgens richtlijn 67/548/EEG of richtlijn 1999/45/EG

Geen

Classificatie conform Verordening (EG) Nr. 1272/2008 [CLP]

Geen

Answer

Gevaarlijke bestanddelen

2-(2-BUTOXYETHOXY)ETHANOL ; EG-nr. : 203-961-6; CAS-nr. : 112-34-5

Gewichtsaandeel : 1 - 2,5 %

Inschaling 67/548/EG : Xi ; R36

Inschaling 1272/2008 [CLP] : Eye Irrit. 2 ; H319

ALCOHOLETHOXYLAAT ; CAS-nr. : 68439-45-2

Gewichtsaandeel : 1 - 2,5 %

Inschaling 67/548/EG : Xi ; R41 Xn ; R22

Inschaling 1272/2008 [CLP] : Eye Dam. 1 ; H318 Acute Tox. 4 ; H302

Product 3

Product/ingredient name	Identifiers	%	Regulation (EC) No. 1272/2008 [CLP]
copper (I) oxide	EC: 215-270-7 CAS: 1317-39-1 Index: 029-002-00-X	≥25 - ≤27	Acute Tox. 4, H302 - Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=10)
xylene	REACH #: 01-2119488216-32 EC: 215-535-7 CAS: 1330-20-7 Index: 601-022-00-9	≥10 - ≤25	Flam. Liq. 3, H226 C Acute Tox. 4, H312 Acute Tox. 4, H332 Skin Irrit. 2, H315
zinc oxide	REACH #: 01-2119463881-32 EC: 215-222-5 CAS: 1314-13-2 Index: 030-013-00-7	≥10 - ≤25	Aquatic Acute 1, H400 (M=10) - Aquatic Chronic 1, H410 (M=10)
zinc ethylene-1,2-bis-dithiocarbamate (zineb)	EC: 235-180-1 CAS: 12122-67-7 Index: 006-078-00-2	≥5 - ≤10	Skin Sens. 1, H317 - Repr. 2, H361d (Unborn child) Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1)
ethylbenzene	REACH #: 01-2119489370-35 EC: 202-849-4 CAS: 100-41-4 Index: 601-023-00-4	≥1 - ≤3	Flam. Liq. 2, H225 - Acute Tox. 4, H332 STOT RE 2, H373 (hearing organs)
C10 aromatics hydrocarbons, <1% naphthalene	REACH #: 01-2119463583-34 EC: 918-811-1 CAS: 64742-94-5	≥1 - ≤3	Asp. Tox. 1, H304 - STOT SE 3, H336 Asp. Tox. 1, H304 Aquatic Chronic 2, H411
4-methylpentan-2-one	REACH #: 01-2119473980-30 EC: 203-550-1 CAS: 108-10-1 Index: 606-004-00-4	≥1 - ≤3	EUH066 - Flam. Liq. 2, H225 Acute Tox. 4, H332 Eye Irrit. 2, H319 STOT SE 3, H335
copper (metallic)	EC: 231-159-6 CAS: 7440-50-8	<1	EUH066 - Flam. Sol. 2, H228 Acute Tox. 4, H302 Acute Tox. 4, H332 Aquatic Acute 1, H400 (M=10000)
2-methylthio-4-tert.-butylamino-6 -cyclo-propylamino-s-triazine	EC: 248-872-3 CAS: 28159-98-0	<1	Skin Sens. 1, H317 - Aquatic Acute 1, H400 (M=10000) Aquatic Chronic 1, H410 (M=1000)
terbutryn	EC: 212-950-5 CAS: 886-50-0	≤0.1	Aquatic Acute 1, H400 (M=100) - Aquatic Chronic 1, H410 (M=100) See Section 16 for the full text of the H statements declared above.

Viscosity :

Testing not relevant due to nature of the product.

Product 3

%	Regulation (EC) No. 1272/2008 [CLP]	
≥25 - ≤27	Acute Tox. 4, H302 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=10)	-
≥10 - ≤25	Flam. Liq. 3, H226 Acute Tox. 4, H312 Acute Tox. 4, H332 Skin Irrit. 2, H315	c
≥10 - ≤25	Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=10)	-
≥5 - ≤10	Skin Sens. 1, H317 Repr. 2, H361d (Unborn child) Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1)	-
≥1 - ≤3	Flam. Liq. 2, H225 Acute Tox. 4, H332 STOT RE 2, H373 (hearing organs)	-
≥1 - ≤3	Asp. Tox. 1, H304 STOT SE 3, H336 Asp. Tox. 1, H304 Aquatic Chronic 2, H411 EUH066	-
≥1 - ≤3	Flam. Liq. 2, H225 Acute Tox. 4, H332 Eye Irrit. 2, H319 STOT SE 3, H335 EUH066	-
<1	Flam. Sol. 2, H228 Acute Tox. 4, H302 Acute Tox. 4, H332	-
<1	Aquatic Acute 1, H400 (M=10000) Skin Sens. 1, H317	-

Asp.Haz: No viscosity → Not classified

Repr. Cat 2: > 1% → Classified

Skin Sens Cat 1: > 1% → Classified

Stot RE Cat 2: < 10% → Not classified

Skin Irr. Cat 2: (total) > 10% → Classified

Eye Irr. Cat 2: (total) < 3% → Not classified

STOT SE Cat 3: (total) < 20% → Not classified

Acute Tox (oral): ATE = 1785 → Classified Cat 4 (oral)

Acute Tox (dermal): ATE = 5000 → Not classified

Acute Tox (inhalation, vapours): ATE = 34 → Not classified

Product 3

- Supplier Info

2.1 Classification of the substance or mixture

Product definition : Mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Flam. Liq. 3, H226	FLAMMABLE LIQUIDS - Category 3
Skin Irrit. 2, H315	SKIN CORROSION/IRRITATION - Category 2
Skin Sens. 1, H317	SKIN SENSITIZATION - Category 1
Repr. 2, H361d (Unborn child)	TOXIC TO REPRODUCTION (Unborn child) - Category 2
Aquatic Acute 1, H400	AQUATIC HAZARD (ACUTE) - Category 1
Aquatic Chronic 1, H410	AQUATIC HAZARD (LONG-TERM) - Category 1

Hazard statements :

- H226 - Flammable liquid and vapor.
- H315 - Causes skin irritation.
- H317 - May cause an allergic skin reaction.
- H361d - Suspected of damaging the unborn child.
- H410 - Very toxic to aquatic life with long lasting effects.