Mixtures Classification for Health Hazards: **Skin Corrosion / Irritation Serious Eye Damage / Eye Irritation**

Cefic/Eurométaux/Fecc/DUCC Workshop

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Hierarchy of hazard information for mixtures CLP-Regulation (EC) No 1272/2008, Art. 9:

-- 1. Test data for the mixture

III. 2. Expert judgement / Weight of evidence approch

II. 3. Bridging principles

I. 4. Calculation method/ Concentration limits (Annex I, parts 3 and 4)

Order in the presentation

Calculation Method

CLP Regulation (EC) No 1272/2008
Annex I
Part 3.2: Skin Corrosion/Irritation
Part 3.3: Eye Damage / Irritation

GHS05
Danger

GHS07
Warning

Mixtures with pH ≤ 2 or ≥ 11,5

ECHA: „Guidance on the application of the CLP criteria“
http://echa.europa.eu/documents/10162/13562/clp_en.pdf (Nov. 2013)

3.2.3.2.1.1

- ***General rule:*** mixtures with a pH of ≤ 2 or ≥ 11.5 should be considered as corrosive.
- ***But:***
  1) Consideration of the buffering capacity of the mixture (acid or alkali reserve; method of YOUNG et al.)
     - If the result is “irritant” or “not irritant”, it shall be confirmed by an in vitro testing
     - Classification according to in vitro testing; **no in-vivo testing**
  2) If the only corrosive/irritant ingredient present in the mixture is an acid or base with an assigned SCL (either in CLP Annex VI or set by supplier), then the mixture should be classified according to the SCL.

Corrosive or irritant effects on skin, e. g. mixture contains R34/Skin Cat. 1B substance

Labelling of the preparation (DPD: 1999/45/EC)	Scale	Labelling of the mixture (GHS, CLP-Regulation)
Triggering content, symbol, ***hazard indication***, risk phrase	%	**Triggering content**, pictogram, **SIGNAL WORD**, Hazard statement
≥ 10 %, „*Corrosive*“, „Causes burns“ 	10 -100	≥ 5 % **DANGER,** (Cat.1); „Causes severe skin burns and eye damage.“ 
≥ 5 to < 10 %, „*Irritant*“ „Irritating to skin“ 	5 - 10	
0 to < 5 %: no labelling	1 - 5	≥ 1 % to < 5 % **WARNING, (**Cat. 2); „Causes skin irritation“ 
	0 - 1	0 to 1 %: no labelling

Corrosive or irritant effects on eyes
e. g. mixture contains R41/Eye Cat. 1 substance

Labelling of the preparation (DPD: 1999/45/EC)	Scale	Labelling of the mixture (GHS)
Triggering content, symbol, ***hazard indication***, risk phrase	%	**Triggering content**, pictogram, **SIGNAL WORD,** Hazard statement
≥ 10 %, „*Irritant*“ „Risk of serious damage to eyes.“ 	10 – 100	≥ 3 % **DANGER,** (Eye Cat. 1) „Causes serious eye damage“ 
≥ 5 to < 10 %, „*Irritant*“ „Irritating to eyes“ 	5 – 10	
0 to < 5 %: no labelling	3 – 5	
	1 – 3	≥ 1 to < 3 % **WARNING** (Eye Cat. 2) „Causes serious eye irritation“ 
	0 – 1	**0 to < 1 %: no labelling**

GHS: Impact on different detergent product categories

corrosive

non corrosive

Drain cleaners

Toilet cleaners

Heavy Duty Detergents

Liquid Detergents

Special Cleaners

Manual Dishwashing Detergents

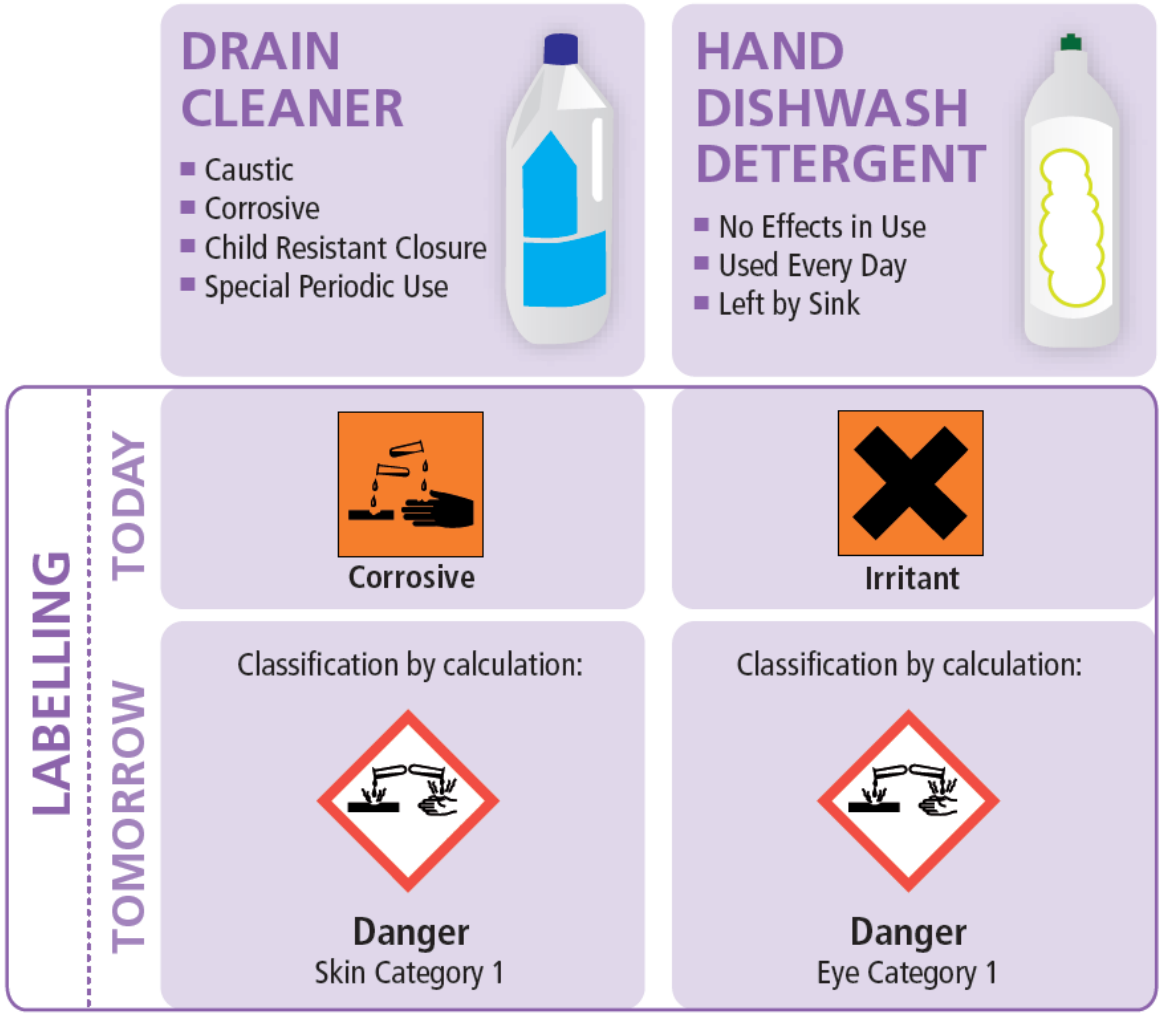
Automatic Dishwashing Detergents

Softeners

All Purpose Cleaners

Glass Cleaners

GHS-Concentration limits and labelling: Loss of differentiation



DPD (1999/45/EC)

CLP (EC)
No 1272/2008

Bridging priciples (Annex I, Part 1.1.3) for Health and Environmental Hazards

- Mixture itself is not tested
- Sufficient data available for similar tested mixtures and for hazardous ingredients

Bridging principles for skin/eye irritation, corrosion, damage:

- Dilution (1.1.3.1)
- Interpolation (1.1.3.4)
- Substantially similar mixtures (1.1.3.5)
- Permitted variations (1.1.3.6), only for mixtures classified as hazardous

Bridging Principle 1.1.3.1 Dilution Example

	Content [%] in	
Ingredient	***mixture 1, tested***	***mixture 2, <u>not</u> testet***
Substance A (Skin Cat. 2, H315)	12,0	11,4
Substance B (Skin Cat. 2, H315)	9,0	8,5
Substance C (Skin Cat. 1B, H314)	1,0	1,0
Substance D (not classified)	78,0	74,1
Substance X (not classified)	--	5,0

Mixture 2 may be classified for skin irritation as **Mixture 1**.

Bridging Priciple 1.1.3.4 Interpolation/ Example

	Mixture 1	Mixture 3	Mixture 2
Test result	Not irritating the skin	**Not tested**	Not irritating the skin
Substance A (Skin Cat. 2, H315)	10 %	12 %	13 %
Substance B (Skin Cat. 2, H315)	10 %	9 %	7 %
Substance C (not irritating the skin, not corrosive for skin)	15 %	12 %	11 %
Water	65 %	67 %	69 %

Mixture 3 may be classified for skin irritation as **mixtures 1 and 2**.

Bridging Principle 1.1.3.5
Substantially Similar Mixtures / Example

	Mixture 1	Mixture 2
Test result	Not irritating the skin	Not tested
Substance **A** (Skin Cat. 2, H315)	**10 %**	--
Substance B (not irritating the skin, not corrosive for skin)	7 %	8%
Substance **C** (Skin Cat. 2, H315)	--	**10 %**
Water	83 %	82 %

Mixture 2 may be classified for skin irritation as **mixture 1**.

Bridging Principle 1.1.3.6
Permitted Variations of Mixtures

Article 15: **Review of classification for mixtures**
Paragraph 2: change to a **hazardous mixture**, of
Letter a: one or more of the hazardous constituents in concentrations at or above the limits in Table 1.2 of Part 1 of Annex I:

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

Bridging Principle 1.1.3.6
Permitted Variations of Mixtures / Example

	Mixture 1	Mixture 2: *possible variations*
Test result	Skin Cat. 2	Not tested
Substance A Skin Cat. 2, H315	10 %	Range: ± 10 % i.e: ***9 % bis 11 %***
Substance B Skin Cat. 2, H315	9 %	Range: ± 20 % i.e.: ***7,2 % bis 10,8 %***
Substance C Not irritating, not corrosive	7 %	Not to be considered, as ingredients are not hazardous.
Water	74 %	

If content of substance A between 9 % and 11 %,
and of substance B between 7,2 % and 10,8 %,
then the Mixture 2 may be classified as Skin Cat. 2.

Weight of evidence approach
Expert judgement

Expert judgement ≠ **Application of bridging principles**

Weight of evidence approach REACh Annex XI, Nr. 1.2

- sufficient weight of evidence from several independent sources of information
- leading to the assumption/conclusion that a substance has or has not a particular dangerous property,
- while the information from each single source alone is regarded insufficient to support this notion.

Consequences:

- to omit further testing on vertebrate animals for that property,
- further testing not involving vertebrate animals may be omitted.
- adequate and reliable documentation shall be provided.

Expert Judgement, Weight of Evidence (CLP, Annex. I, No 1.1.1.1)

Where

- the criteria cannot be applied directly to available identified information,

  or

- for the mixture itself no or insufficient test data are available

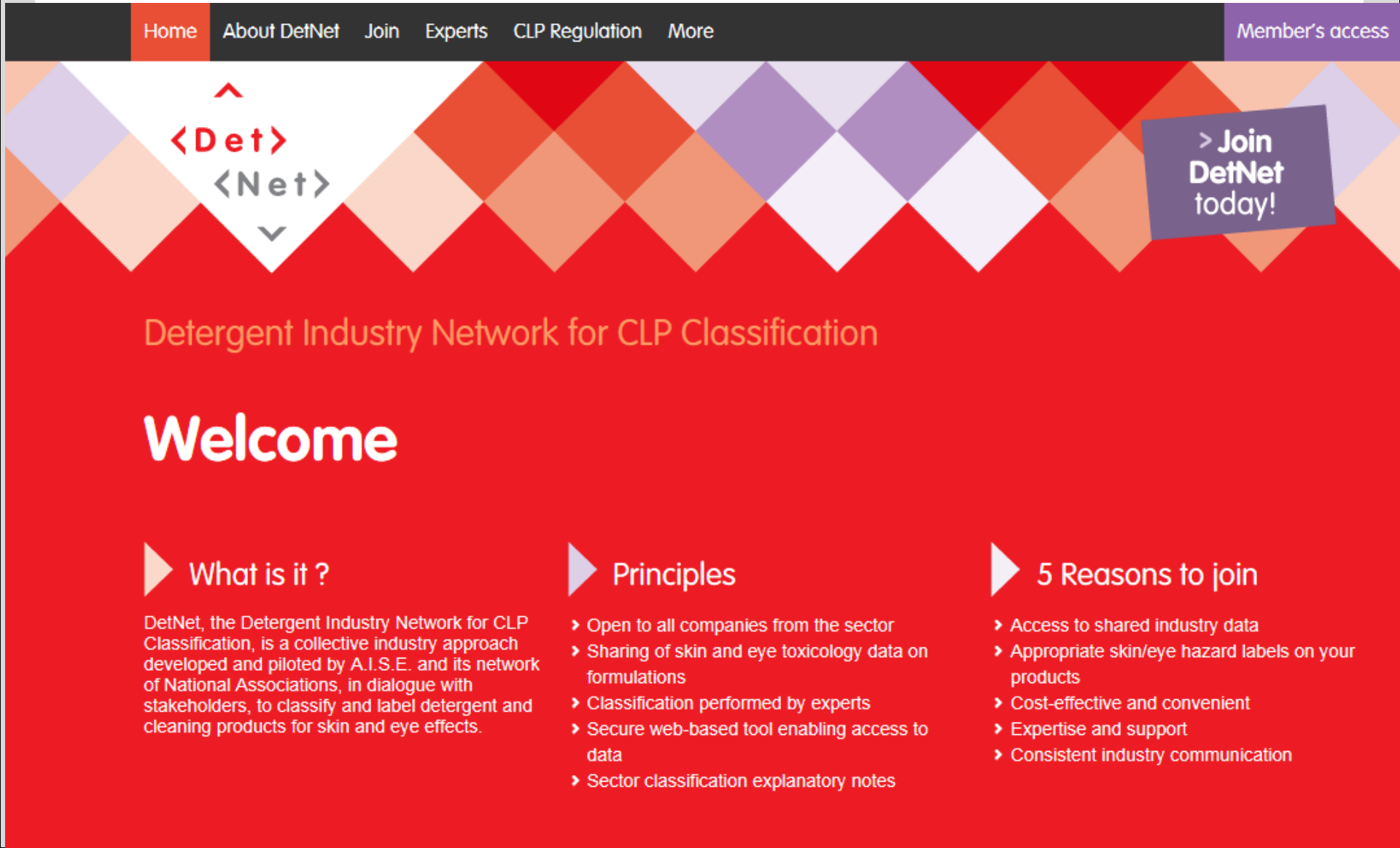
  then

- the weight of evidence determination using expert judgment shall be applied in accordance with Article 9(3) or 9(4) respectively.

Weight of evidence determination, CLP, Annex I, 1.1.1.3

- All available information bearing on the determination of hazard is considered together, e. g.
  - results of suitable in vitro tests,
  - relevant animal data,
  - ...
  - human experience such as occupational data and data from accident databases, epidemiological and clinical studies and well documented case reports and observations.
- The quality and consistency of the data shall be given appropriate weight.
- Both positive and negative results shall be assembled together in a single weight of evidence determination

www.det-net.eu
Available since 6 January 2014



Basis:
CLP Regulation (EC) No 1272/2008, Annex I

No 1.1.0. *Cooperation to meet the requirements in this Regulation*

- ***Suppliers in an industry sector may cooperate through formation of a network*** *… to share data and expertise when classifying substances and mixtures in accordance with Title II of this Regulation. …*
- *Where suppliers in an industry sector cooperate in this way,* ***each supplier shall remain fully responsible for the classification, labelling and packaging*** *of substances and mixtures he places on the market, and for meeting any other requirements of this Regulation.*

DetNet

DetNet: Detergents Industry Network

- Industry approach for classification on skin and eye effects
- For laundry detergents, hand dishwashing detergents, all purpose cleaners
- Offers about 200 tested formulations and test results
  - in vitro; „Low Volume Eye Test" (LVET), „Human Patch Test" (HPT)

- open to all companies of the sector
- Annual fee depends of turnover with laundry detergents, hand dishwashing detergents, all purpose cleaners
- Fixed fee per classification

Classification of Mixtures: How can DetNet fit in?

1. Collect available data for the mixture (e. g. pH-value) and for ist ingredients

2. Compare with tested mixtures classified as dangerous: Only ***permitted variations*** according to Annex I, Table 1.2?

yes → **Classification**

no

3. Bridging Principle ***Dilution*** applicable?

yes → **Classification**

no

3. Bridging principle „Dilution“ applicable?

no

4. Use of A.I.S.E. DetNet

4a. Are there two reference formulations with the same classification for **interpolation**?

yes → Classification

no

4b. Is there a **subtancially similar** reference formulation?

yes → Classification

no

4b. Is there a substancialy similar reference formulation?

no

4c. Is (are) there ***substantially similar*** reference formulation(s), which may be used with expert judgement?

yes → Classification

no

5. Run in-vitro-Testing

yes → Classification

no

Classification according to calculation method

Turnover* [Mio. €]	Annual Fees [€]	
	Mmbers of A.I.S.E. and ist National Associations	Non Members
< 1	250	1.250
1 - 5	500	2.500
5 - 25	750	3.750
25 - 100	1.000	5.000
100 - 1.000	1.500	7.500
1.000 - 2.500	2.500	
> 2.500	3.500	

* with „DetNet-Products“ in EU + CH, N, Island, Liechtenstein

+ Fee per classification: € 90,00

Thank you for your attention!

DetNet-Experts Possibilities