

Bridging Principles and Mixture Classification under CLP and DetNet - Challenges and Opportunities



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UN GHS in the European Union

- UN GHS criteria introduced in EU via CLP Regulation n.1272/2008 on Classification, Labelling and Packaging
- Replacing previous systems (DPD orange pictograms *less labelling overall*).
- EU is the only jurisdiction having fully implemented GHS criteria for general consumer chemical products.
- Since 2015 CLP is implemented on hazardous mixtures, relevant findings can be shared on its use for general consumer labels.



Hazard C&L for general public

Meet legal requirements and allow the consumer to:

- ✓ Recognise the hazard
- ✓ Distinguish between products of different hazard
- ✓ Make sense of the label

Safe product use

Effective consumer information

Sound Science

Appropriate and Relevant C&L

Transparent process

Harmonized approach

Optimal use of data



How does CLP tiered approach work for mixture classification?

- In principle, CLP gives priority to the use of all available data, bridging principles, weight of evidence.

CLP calculation method only to be used if the above fails (*while DPD gave priority to either calculation or actual product animal test data as the first step*).

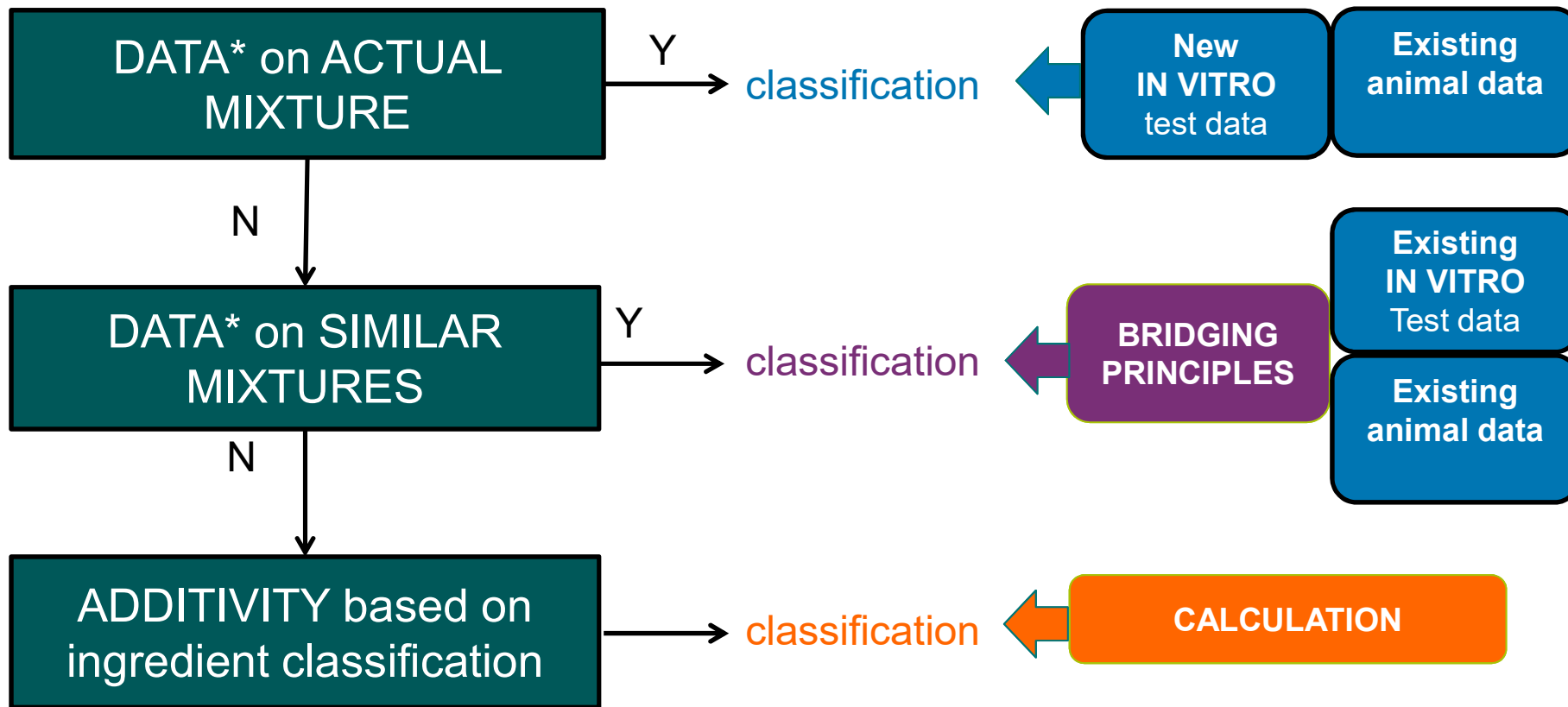
- In reality, complexity, uncertainty about interpretation (e.g. Bridging principles), and lack of non-animal tests, leads to frequent use of additivity method.



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GHS - Good use of data hierarchy



*No human testing for classification purposes, and no new animal testing.
Data generation = *in vitro* methods

Focus on Eye effects







2015: CLP introduced UN GHS criteria in EU, replacing former DPD

- Classification and labelling for eye hazards more severe than DPD when using additivity/calculation method (e.g. lower cut-off values/concentration limits).
- No validated in vitro test for Eye irritation (Cat. 2)
- Broader use of Corrosive Pictogram (eye).



Classification for serious eye damage/eye irritation by additivity (DPD vs GHS/CLP)



DPD until 2015	Eye Cat1 Ingredients %	GHS/CLP
≥ 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 to < 3 % WARNING , Eye Cat. 2 „Causes serious eye irritation“ 
	1 – 3	
	0 – 1	0 to < 1 %: no labelling

Hand wash detergents with corrosive picto?



- Main ingredients for detergents are surfactants: on average 10-20% (similar to shampoo/shower gel); often classified for severe eye damage Cat.1.
- GHS additivity: mixture with surfactants Eye Cat.1 > 3% will be classified as Eye Cat. 1 (Corrosive pictogram, Signal word 'Danger' word).
- Several mild products such as hand dish wash detergents can therefore be classified for Serious eye damage Cat. 1 if only additivity is used.



Typical C&L under DPD (until 2015)



A snapshot on Home Care Products (detergents, maintenance etc.):

Drain cleaners



Until GHS was implemented in EU via CLP 2015, the “corrosive pictogram” was only required for truly ‘corrosive for skin’ products (e.g. strong acid/alkaline mixtures such as Drain cleaners, Oven cleaners etc.).

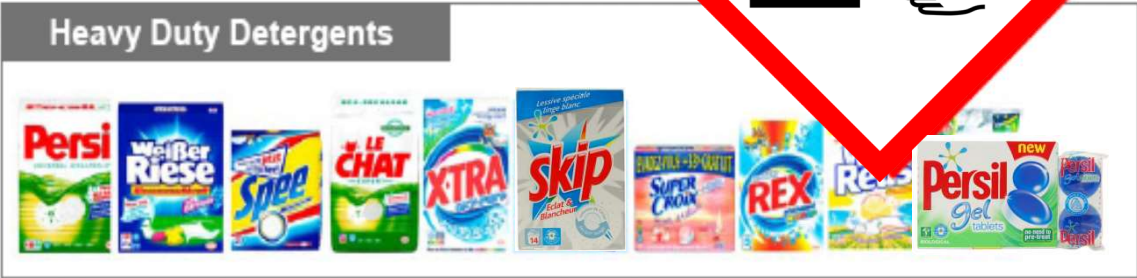
Toilet cleaners



UN GHS classification for eye (additivity)



Drain cleaners










Toilet cleaners



New cut-off values using additivity resulted in a very broad use of corrosive pictogram (eye effect) also with mild and daily used products.

Accidental Exposures – Severity of Effects



Products	Severity of effects	UN GHS / EU CLP classification
	Index*	Label pictogram (additivity approach)
Drain Cleaners	19	
Oven Cleaners	7	
Automatic Dishwashing Detergent	< 1	
Bathroom Cleansers	< 1	
Manual Dishwashing Detergent	< 1	
Heavy Duty Detergents	< 1	
All Purpose Cleaners	< 1	

Medical advice problematic for Poison centres (more difficult to distinguish truly corrosive)

*Data: Dr. Desel, Poison Control Centre, Göttingen 1996 - 2005
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Very different hazard profile same pictogram?



CLP/GHS calculation overclassifies

Recent scientific papers (Corvaro et al. 2017) found that among 85 preparations that would be classified as Category 1 for eye hazard according to the GHS calculation method, only 27% were actually classified for serious eye damage based on the standard in vivo test data.

“In the case of eye irritation, the calculation method tends to overestimate classification (i.e. yielding a more severe GHS category) in 41.4% of cases”.



Poison Centres experience on eye effects

2016 MAGAM DEAT+ DISC: eye exposures caused by cleaning products in DK, IT, DE, AT, IT, SK, CZ (171 Million pop. data collection 2013-15 by Poison Centres)
[-http://dx.doi.org/10.3109/15563650.2016.1165952](http://dx.doi.org/10.3109/15563650.2016.1165952)

1126 exposures: 90.5% No or minor symptoms, 9.2% moderate and 0.2% severe (residual symptoms after 20 days).

Most of eye exposures with detergents resulted in no effects or fully reversible symptoms; serious eye damage occurs rarely (<0.2%).



Implications for the CONSUMER

Many mild products (not previously classified) are now severely classified and labelled (Eye category 1):

- C&L does not fit with consumers' knowledge and experience (everyday used products with no special precautions...)
- Devaluation of warning labels: really hazardous products are no longer differentiated
- Confusion about what is dangerous & how to use, could lead to unsafe practices
- Poison centres difficulties to identify right medical advice

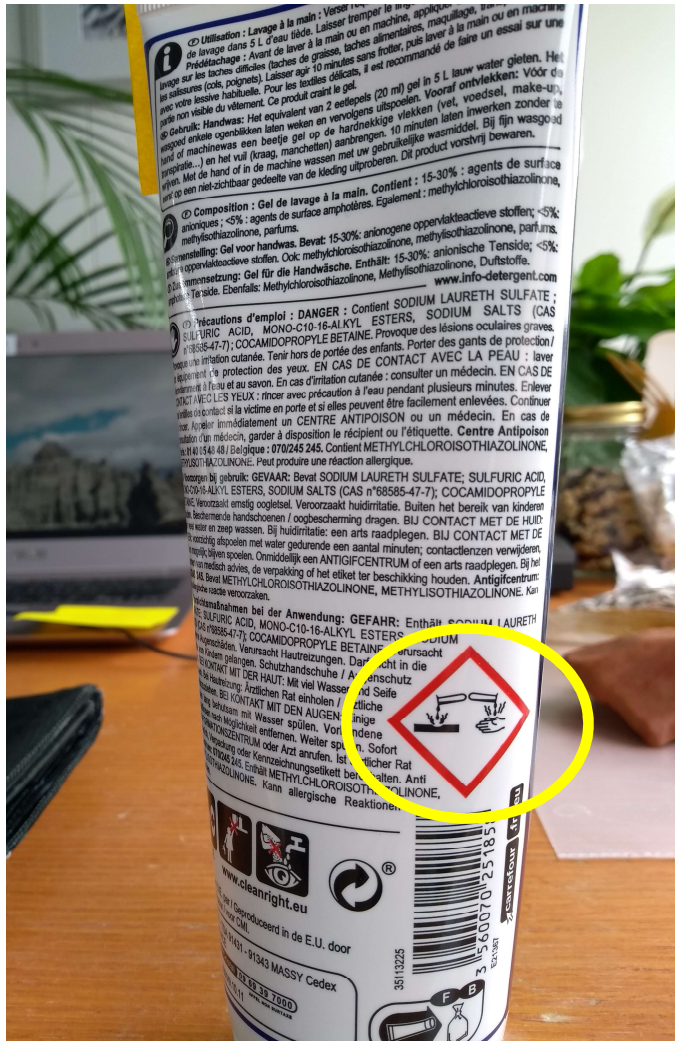


➔ ***Relevant classification and labelling is essential for safe use by consumers***

Hand wash detergent with corrosive picto



Are we providing a meaningful hazard communication to the general public?



Potential solutions

Potential over classification provided by additivity (eye effects) can be addressed with a correct use of the CLP tiered approach for mixture classification. Using existing data on the mixture or on similar mixtures via bridging principles and expert judgement can provide a more appropriate and precise classification.

- **DetNet** - A network to share to share data and expertise for hazard classification
- **Implementation of Bridging principles** – Working groups at EU COM and UN GHS level
- **In vitro test** - Development of In vitro test (e.g. OECD TG 438 revised based on AISE proposal).



DetNet legal basis: Par.1.1.0 Annex 1 CLP

- ✓ «Suppliers in an industry sector may cooperate through formation of a network to share data and expertise when classifying substances and mixtures (...).
- ✓ suppliers in an industry sector shall document fully the basis on which classification decisions are made and shall make available to the competent authorities and, on request, to the relevant enforcement authorities the documentation, together with the data and information on which classifications are based. (...)
- ✓ each supplier shall remain fully responsible for the classification, labelling and packaging of substances and mixtures he places on the market.»



DetNet: Detergent Industry Network for CLP Classification

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DetNet is a unique collective industry approach to classify and label detergent products (for skin and eye effects).

Industry experts can access a database of test data on detergent and cleaning products.

The classifier determines if it is possible to derive the classification of an untested mixture by comparison to skin and eye data and classification of a tested reference mixture (substantially similar).



DetNet's goals

Use of DetNet allows CLP practitioners to:

- minimise animal testing.
- optimise the use of existing data.
- develop representative and proportional classification schemes using robust data and scientific expertise.
- support and aid SME's by facilitating access to historic data and external expertise.
- Increase consistency of industry communication on classification and labelling



Key figures on DetNet

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- 237 reference formulations/tested mixtures
- 211 Member companies
- 355 registered experts (DetNet users)
- **31 DetNet Authority accounts**
- 1370 mixtures potentially classified using DetNet

DetNet transparency

2016 DetNet Workshop (public workshop with Commission, ECHA, Member States, Industry)

2017 DetNet access to enforcement authorities was open for training purposes: 32 users from 20 national/regional enforcement authorities across 6 countries obtained access to the platform.

DetNet remains open to all EU CLP competent authorities and login credentials are available upon request via detnet@aise.eu.



DetNet development

- ✓ Expansion of the original database (historical in vivo data + In vitro data).
- ✓ A further 13 reference formulations for extreme pH products will soon become available (end of 2018).
- ✓ Availability of an extensive collection of guidance, reference and support documentation for all expert users.
- ✓ Delivery of training webinars, available to all expert users.



Access to information by Enforcement Authorities

In the event of enforcement inspections, DetNet users may be requested to provide detailed documentation justifying the C&L of the inspected product. DetNet users can share the Classification Record and associated Tested Mixture study summaries.

The DetNet user can share Detailed information (i.e. full compositional details and/or full study reports), following a 'Procedure for access to detailed information on Tested Mixtures by Enforcement Authorities'.



Challenges and opportunities

Challenges:

- Building and maintaining trust in DetNet amongst authorities.
- Consistent interpretation of expert arguments.
- Maintaining relevance in the face of regulatory developments.

Opportunities:

- Data derived classification schemes for detergents and cleaning products.
- Representative and robust hazard information for end users.
- A constructive contribution to the safe use of hazardous chemicals.



Concluding remarks

DetNet can and has generated > 1,300 product classifications through the use of existing in vivo and in vitro data and the application of expert judgement.

This is achieved in compliance with the existing regulatory framework and provides a science based solution to the wider challenges identified.

Industry recognises that DetNet faces challenges but it also offer opportunities.

Let's work together for a sound hazard classification for a safe use of products.



Contacts

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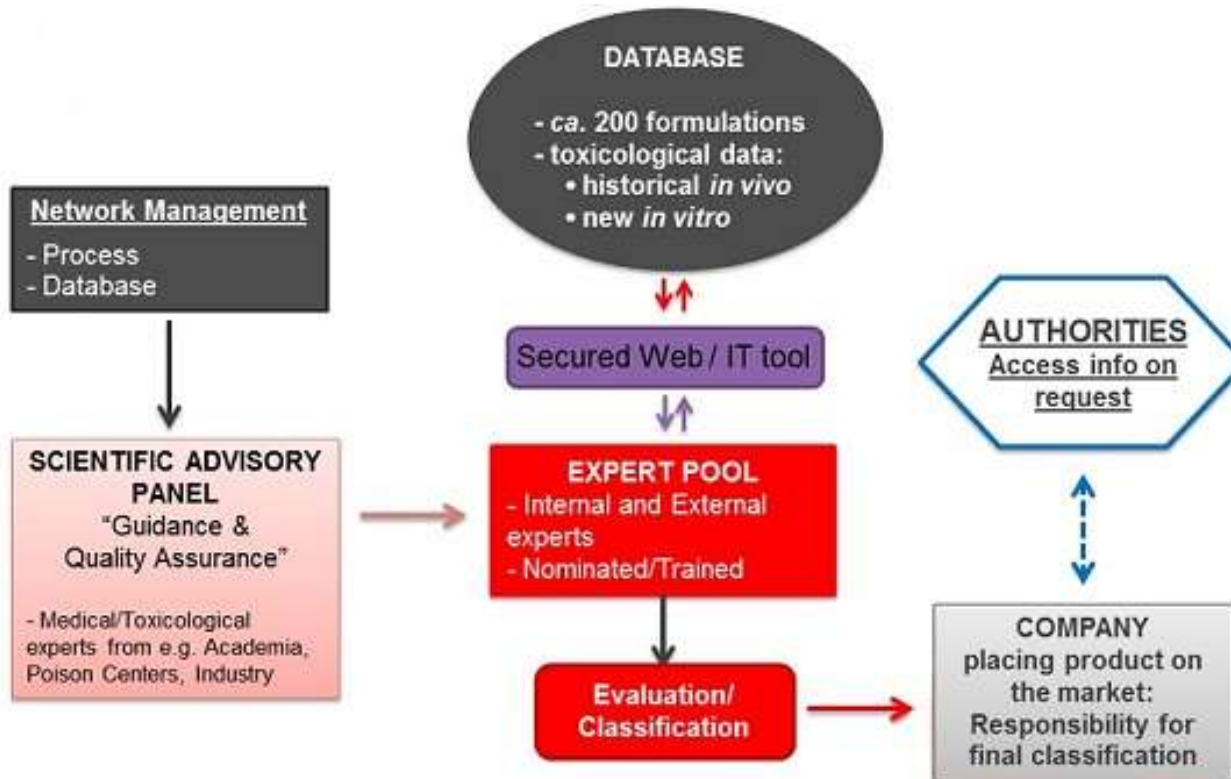
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More Information Available At:

<https://www.det-net.eu>



DetNet Structure

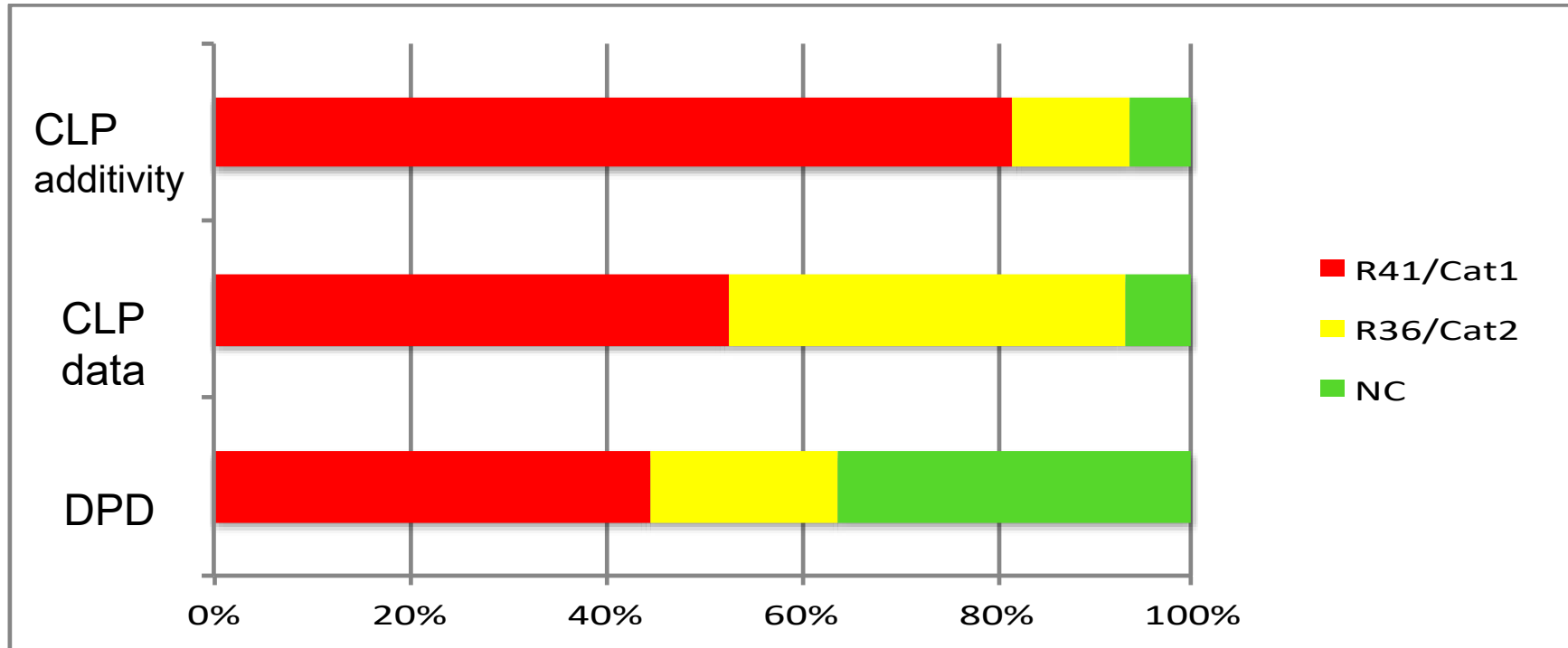


Structure is designed to ensure that DetNet is CLP compliant, scientifically robust and accessible to all participants in the detergents industry (both large and SME).

14 Nov 2018

Poison Control Centers Study 2013-15

Retrospective Classification Eye effects



- DPD and CLP retrospective C&L, sub set 185 cases
- DPD 44% Cat.1, 20% Cat.2, 36% NC
- CLP data (BPs, Exp.Jud) 52% Cat.1, 40% Cat.2, 7% NC
- CLP additivity 82% Cat.1, 12% Cat.2 , 6% NC.



Consumer Relevance of C&L

Consumer research by A.I.S.E., EU Eurobarometer, ECHA

- EU Eurobarometer 2011: only 26 to 50% always read safety instructions before using for the first time a hazardous product (see http://ec.europa.eu/commfrontoffice/publicopinion/archives/ebs/ebs_360_en.pdf)
- CLP Pictogram “Corrosive” is understood as corrosive / harsh chemicals by 54% but <1% recognize this as related to serious eye damage! (see <https://www.unece.org/fileadmin/DAM/trans/doc/2017/dgac10c4/UN-SCEGHS-34-INF05e.pdf>)
- CLP Pictograms comprehension is insufficient to understand Eye Hazard and to differentiate between eye damage and eye irritation.



