

Existing Systems of Product Labelling

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Overview

- Labelling
- Where Labelling is implemented
- CE and other Examples
- "Nano"- Labelling
- The Product Identification Problem
- EU Art. 45 CLP Database of Products
- Discussion

What does Labelling mean?

Labelling is any written, electronic, or graphic communications on the packaging or on a separate label

Labelling is used for

- Information transmission
- Marketing
- Security
- Convenience
- Portion Size
- Warnings
- Controlling
- Categorisation
- Tradetransfer/-logistic



Hazard Labelling: Global Harmonisation of Symbols (GHS)

The Globally Harmonized System of Classification and Labeling of **Chemicals** or **GHS** is an internationally agreed upon system, created by the United Nations

Essential Informations for GHS-Labels:

- Pictograms
- Signal words
- Hazard statements
- Precautionary statements and pictograms
- Product identifier!
- Supplier information

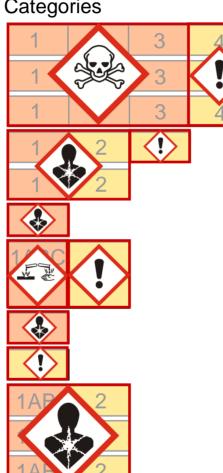
CLP-Regulation: Hazard Classes, Categories and Classification

CLP Regulation (EC) No 1272/2008

Health hazard classes

Acute toxicity Oral Acute toxicity Dermal Acute toxicity Inhalation STOT* - single exp STOT* - repeated exp Aspiration hazard Skin corrosion/irritation Eye damage/irritation Respiratory sensitisation Skin sensitisation Carcinogenicity Mutagenicity Reproductive toxicity Effect during lactation

Categories



^{*} Specific Target Organ Toxicity

Directive 1999/45/EC

Classification

T+ R28 / T R25 / Xn R22

T+ R27 / T R24 / Xn R21

T+ R26 / T R23 / Xn R20

T+ R39 / T R39 / Xn R68 / R37 / R67

T R48 / Xn R48

Xn R65

C R35 / C R34 / Xi R38

Xi R41 / Xi R36

Xn R42

Xi R43

cat.1/2 (T R45/R49) / cat.3 (Xn R40)

cat.1/2 (T R46) / cat. 3 (Xn R68)

cat.1/2 (T R60/R61) / cat.3 (Xn R62/R63)

R64



Examples for "Nano"- Labelling?

EU - Cosmetics Regulation:

From 2012 onwards the Use of Nanoparticles in Cosmetics

• Food:

From Autum 2014 a "Nanoindication" on Packages



Art. 45 CLP- Regulation:

From 2014 (?) onwards the Indication of Nano-formulated Substances (Yes/No)

Scope: All Products with Hazard Labels for Consumers and Non-Consumer Use?









Labelling and Clear Product Identification (Product Identifier)

The Tradename is a Problem for Consumers and Risk Management



BfR-Examples: Tradename, Products, Versions and Variations

BfR GIFAS-Database (2010)

Tradename	Products	Versions	BfR-Variations in Formula (Minimum)
Calgonit	100	116	216
Sidol	90	208	298
Loctide	95	115	210
P3	813	1562	2.375





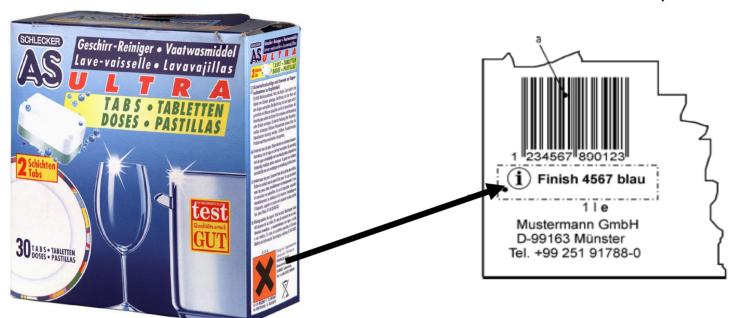




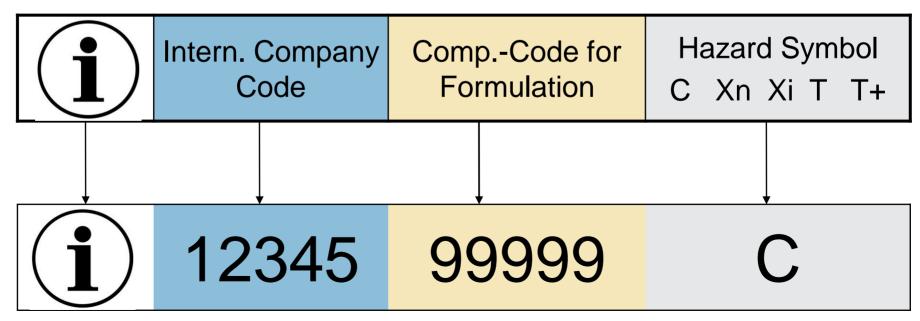


The CLP Art. 45 UPI (Product Identifier in a Productidentification Area)

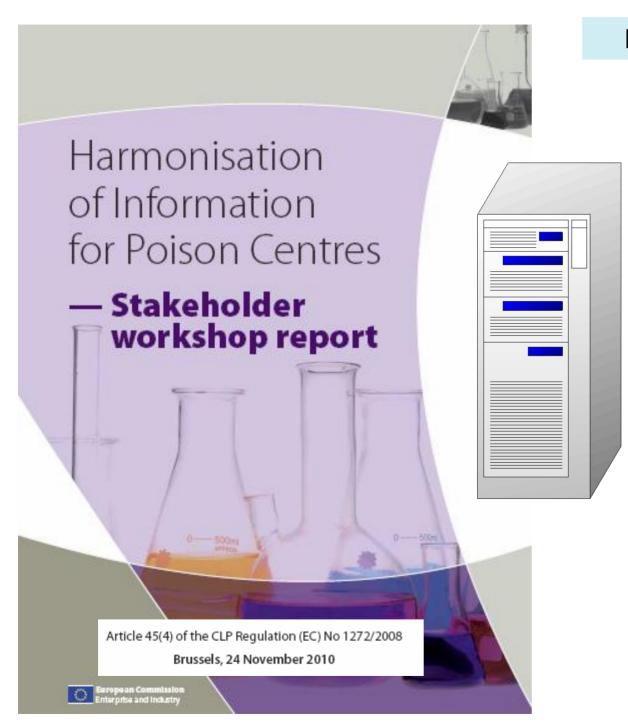
EU Standard CEN (EN 15178) since Nov 2007



BfR Recommendations based on the former UBA-Number



EU Art. 45 CLP-Database of Products (2014)



BfR Poison Information Database

1. Identification-No.		
2. Trade Name (!) /UPI		
3. Manufacturer/Distributor		
4. Adress		
5. Product-Classification		
6. Physic. chem. Properties		
7. R/S - H -Phrases		
8. Ingredients/Substances/Nano (Y/N)		
9 Name (Manufacturer)		
10 Name (Preferred Term)		
11 Share		
12 Rank of Toxicity		
13. Tox. Additional Information		
14 LD-Values		
15 Warnings		
16 First Aid Measures		
Optional		
18 Barcode (EAN-Code) etc.		

Art. 45 CLP-Database of Products (Proposal 20th January 2012)

COMPANY INFORMATION

- Company placing the mixture on the market Name, address, company identifier
- Company submitting the mixture information Name, address, telephone, e-mail, fax, company identifier
- Contact Point(s) in case of emergency

IDENTIFICATION OF THE MIXTURE

- Mixture identifiers

Mention the complete trade name(s) (in all relevant languages of the country of marketing) Other mixture identifiers present on the label (type should be specified) Under special conditions grouping of mixture variants is allowed.

- Product identification element A unique product identification element is highly recommended

COMPOSITION

- Substances in the mixture

Mention all substances (whatever their toxicity) present in the mixture. Names 'perfumes', 'fragrances', 'colouring agents', 'essential oil of ...' and 'extract of ...' can be used. CAS- and EC (EINECS/ELINCS) number (if available), 'functional group name', hazard classification, H-statements, nanoformulated ves/no

CLP-Database of Products

-Substance concentrations

Actual concentrations for substances classified as

- acute toxicity (oral, dermal, inhalation), category 1,2 and 3
- STOT single/repeated, category 1 and 2
- skin corrosion, category 1A, 1B and 1C
- serious eye damage, category 1

Specified concentration bands for other substances: 0-0,1%, 0,1-1%, 1-3%, 3-10%, 10-20%, 20-30%, 30-50%, 50-75%, >75%

Exact concentration for all substances is preferred but voluntary

- Reformulation rules

- substitution, addition or deletion of one or more substances
- change to other concentration bands
- change of exact concentration above specified limit (when review of classification is necessary)

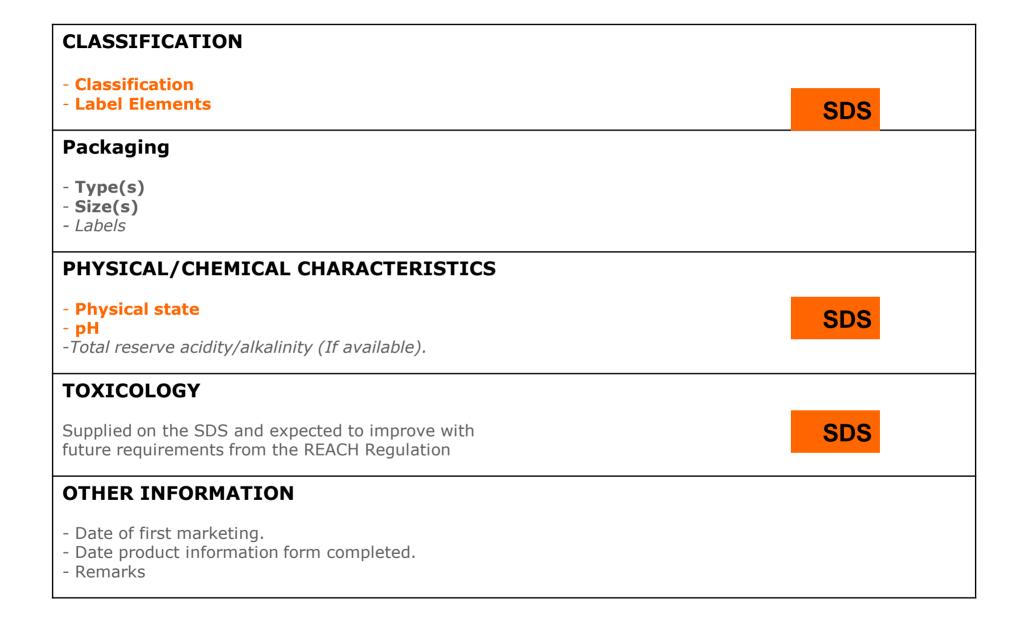
CATEGORISATION

- Product Category

Describe the intended use of the mixture.

-Consumer / Professional use

CLP-Database of Products



BfR Assessment and Monitoring

"Toxicovigilance" "Poison"Committee (47 Years)

