



CLP Regulation

AISE-CEPE Workshop on preservatives in paints and detergents

**Workshop on innovation and industry
challenges
Brussels 15 May 2019**

GROW / D.2 (chemicals industry)

Outline

- **Introduction to the CLP Regulation**
- History of CLP & the Globally Harmonised System (GHS)
- Scope & definitions
- Hazard classification
- Labelling & packaging
- Adaptations to technical progress
- Interface with downstream legislation
- Labelling of skin sensitisers

Introduction to CLP

- Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging (CLP) of dangerous substances and mixtures entered into force on 20 January 2009.
- Co-responsibility of DG GROW & ENV
- Purposes:
 - Ensuring a high level of protection of human health and the environment
 - Ensuring the free movement of chemical substances and mixtures
- Obligations for manufacturers, importers and downstream users

Introduction to CLP

- Introducing United Nations' criteria for Classification and Labelling of chemicals: the Globally Harmonised System (GHS)
- Replacing the Dangerous Substances (67/548/EEC) and Dangerous Preparations Directives (1999/45/EC) (orange pictograms)



Introduction to CLP

Horizontal legislation applying to all dangerous substances and mixtures. *Some examples: detergents, cement, paints, glues, dishwasher tablet, fertilisers, essential oils etc.*

PAINTCO SATIN WHITE

Product code 123456

Krasvaste zijdeglanslack - Couche de finition satinée résistante à l'abrasion - Scratch-resistant satin finish



NL: X Straat, 9999 YZ Stad, Tel. 0111-222333
www.paintco.nl
BE: Rue Y, B-9999 Ville, Tel. 045-678910
www.paintco.be
GB: Z Street, Town XY99 9YZ, Tel. 012-345678
www.paintco.co.uk

Waarschuwing. Ontvlambare vloeistof en damp.
Buiten het bereik van kinderen houden. Verwijderd houden van warmte/vonken/open vuur/hete oppervlakken. - Niet roken.
Inhoud/verpakking afvoeren naar een inzameelpunt bij de gemeente. Bij het inwinnen van medisch advies, de verpakking of het etiket ter beschikking houden.

Attention. Liquide et vapeurs inflammables.
Tenir hors de portée des enfants. Tenir à l'écart de la chaleur/des étincelles/des flammes nues/des surfaces chaudes. - Ne pas fumer. Éliminer le contenu/récipient au point de collecte municipale. En cas de consultation d'un médecin, garder à disposition le récipient ou l'étiquette.

Warning. Flammable liquid and vapour.
Keep out of reach of children. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Dispose of contents/container at the municipal collection point. If medical advice is needed, have product container or label at hand.

EU grenswaarde voor dit product (cat A/d): 300 g/l.
Dit product bevat maximaal 300 g/l VOS.
Valeur limite en UE pour ce produit (cat A/d): 300 g/l.
Ce produit contient au maximum 300 g/l COV.
EU limit for this product is (cat A/d): 300 g/l.
This product contains max 300 g/l VOC.



EWC: 080111



1L

[Trade Name]
Cleaning Product

INSTRUCTIONS FOR USE

Apply to surfaces using a damp sponge or cloth, then simply wipe over and gently rinse away

[Trade Name] contains amongst other ingredients

5-15% Anionic Surfactants
Less than 5% Non-ionic Surfactants
Contains: Perfumes (LIMONENE, HEXYL CINNAMAL),
2-BROMO-2-NITROPROPANE-1,3-DIOL



**Cleaning Product
Warning
Causes Serious
Eye Irritation**

Keep out of reach of children.
Read label before use

WEAR EYE/FACE PROTECTION.
Wash hands thoroughly after handling.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If medical advice is needed: Have product container or label at hand.

[Company Name]: 123 Via duct Road,
Anytown, Somewhere CZ99 0DD, UK
Phone: +44(0) 4081234567

For further information visit
[www.\[companyname\].com](http://www.[companyname].com)

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GHS

Globally harmonised system of classification of chemicals by types of hazard and hazard communication elements

Building blocks approach:

- Countries can choose which of the building blocks will be applied in different parts of their system
- Countries can choose not to use a certain GHS class or category or to combine categories
- However, where a system covers something that is in the GHS, the coverage should be consistent

History of GHS

- 1967: EEC **Dangerous Substances Directive**
- 1983: U.S. OSHA's **Hazard Communication Standard**
- 1989: **ILO Resolution** concerning the harmonization of systems of classification and labelling for the use of hazardous chemicals at work
- 1992: **Earth summit (UNCED)**: A globally harmonized hazard classification and compatible labelling system, including material safety data sheets and easily understandable symbols, should be available, if feasible, by the year 2000.
- 2002: Agreement on **first edition of GHS**
- 2003: **First edition of GHS** adopted by UN ECOSOC

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Scope & definitions

Scope:

Substances and mixtures

Substance:

a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition

Mixture:

a mixture or solution composed of two or more substances

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Hazard classification

- Obligation to classify hazards (intrinsic properties):
 - before placing on the market, or
 - if REACH requires classification; e.g. on-site isolated intermediate
- Art. 9(5): *"When evaluating the available information for the purposes of classification, the manufacturers importers and downstream shall consider the forms or physical states in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used."*
- Types of hazard classes (Annex I):
 - Physical hazards
 - Health hazards
 - Environmental hazards

Hazard classification

Physical hazards

- Explosives
- Flammable gases
- Flammable aerosols
- Oxidising gases
- Gases under pressure
- Flammable liquids/solids
- Self-reactive
- Pyrophoric liquids/solids
- Self-heating
- Emitting flammable gases in contact with water
- Oxidising liquids/solids
- Organic peroxides
- Corrosive to metals

Health hazards

- Acute toxicity
- Skin corrosion/irritation
- Serious eye damage/irritation
- Resp./skin sensitisation
- Germ cell mutagenicity
- Carcinogenicity
- Reproductive toxicity
- Specific target organ toxicity
- Aspiration hazard

Environmental hazards

- Hazardous to the aquatic environment
- Hazardous to the ozone layer

Each with different categories

Hazard classification

Two options:

- Self-classification
- Harmonised classification (CLH)

Self-classification:

- Identify and examine available information from different sources
- Evaluate the information
- Apply Annex I criteria, including expert judgment / weight of evidence
- Review in the light of new information

Hazard classification

Classification of a mixture

1. Use available test data for the mixture
2. Data on similar tested mixtures
→ use bridging principles
3. Use hazard data on individual ingredients
(additivity for some hazard classes)

*E.g. for serious eye damage /
eye irritation*

Table 3.3.3

Generic concentration limits of ingredients of a mixture classified as Skin corrosive Category 1 and/or eye Category 1 or 2 for effects on the eye that trigger classification of the mixture for effects on the eye (Category 1 or 2)

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

Harmonised classification (CLH)

CLH possible for:

- Specific hazard classes (respiratory sensitisation cat. 1, CMR)
- Active substances in plant protection products and biocides
- Other substances on a case-by-case basis, if justified

Procedure:

1. Competent authority, or the manufacturer, importer or downstream user of a substance submits CLH proposal to ECHA
2. Opinion by Committee for Risk Assessment of the Agency (RAC) adopts an opinion within 18 months, forwarded to COM
3. Decision by COM regarding inclusion in Annex VI

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Labelling

- pictograms, e.g.





- signal words, e.g.
danger/warning

- hazard statements, e.g.
H320 – causes eye irritation
H332 – harmful if inhaled

- precautionary statements, e.g.
P210 – keep away from heat
P262 – do not get on skin
- supplemental statements, e.g.

EUH statements (EUH201 – 'Contains lead. Should not be used on surfaces liable to be chewed or sucked by children')

1000000025	K12345678 808	25 ml	Exp. date: 31.12.11
pro analysi ACS	Lot		
n-Hexan för analys n-heksaani			Fara. Kan vara dödligt vid förtäring om det kommer ner i luftvägarna. Misstänks kunna skada fertiliteten. Vid FÖRTÄRING: Kontakta genast GIFT-INFORMATIONSCENTRAL eller läkare. Framkalla inte kräkning.
Index-No: 601-037-00-0 Company S.A., City, 80766 EU, www.company.com Tel. +41(0)1234 56-7890			Vaara. Voi olla tappavaa nieltynä ja joutuessaan hengitysteihin. Epäillään heikentävän hedelmällisyyttä. JOS KEMIKAALIA ON NIELTY: Ota välittömästi yhteys MYRKYTYSTI-ETOKESKUKSEEN tai lääkäriin. Ei saa oksennuttaa.

Labelling

The nine new
pictogrammes:



Packaging

Article 35:

Packaging containing a hazardous substance or mixture:

- Designed and constructed so that its contents cannot escape
- Strong and solid throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling
- Not attract or arouse the active curiosity of children, or mislead consumers, or have a similar presentation or design used for foodstuff or animal feeding stuff or medicinal or cosmetic products

Child-resistant fastenings and tactile warnings for certain hazard classes and/or specific substances

Outline

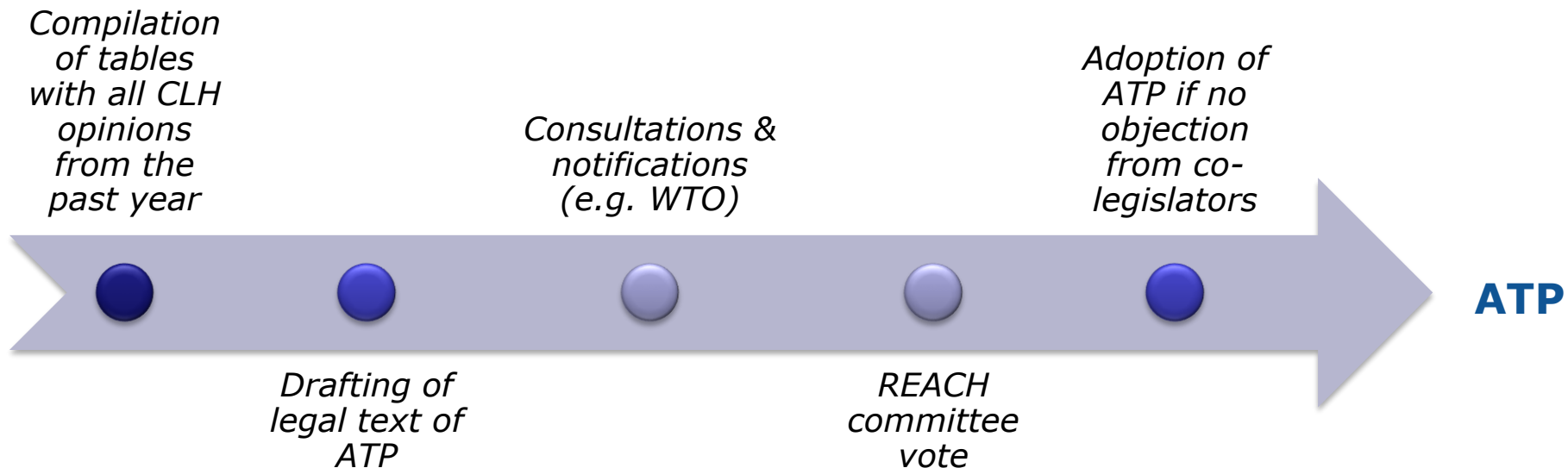
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Adaptations to Technical Progress (ATP) to the CLP Regulation

- Adaptations to Technical Progress allow for the revision of the Annexes (and certain articles)
- Main reasons:
 - Revisions of the Globally Harmonised System (GHS)
 - New harmonised classification & labelling for substances

Adaptations to Technical Progress (ATP): Committees

- Responsible regulatory committee: **REACH Committee**
- Expert group: **CARACAL** (Competent Authorities for REACH and CLP)
 - Subgroup on ATPs to CLP



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Downstream consequences

The position of CLP in the risk management process

Step 1: hazard assessment through CLP

Step 2: risk assessment (optional), taking into account exposure

Step 3: risk management measures through downstream legislation

e.g.

- bans or restrictions on use/manufacturing/placing on the market
- authorisations (with conditions)
- other measures, such as use of personal protective equipment, safety measures related to production site or transport, etc.

Hazard- or risk-based approach possible

Downstream consequences

Examples

- **Cosmetics** Regulation No 1223/2009
 - Substances classified as CMR Category 2 prohibited for use in cosmetic products, except if evaluated by the SCCS and found safe for use
 - Substances classified as CMR Cat 1A/1B prohibited for use in cosmetic products (except...)
- **Plant Protection Products** Regulation No 1107/2009
 - Annex II: Criteria for the approval of an active substance
3.6.2-3.6.4: no approval possible if CMR classification
(for C/R unless exposure of humans is negligible)

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Labelling of skin sensitisers

Hazard category: 1, 1A, 1B

Pictogram:



Signal word: Warning

Hazard statement: H317 May cause an allergic skin reaction

Labelling of skin sensitisers

Precautionary statements prevention:

- *P261 - Avoid breathing dust/fume/gas/mist/ vapours/spray.*
- *P272 - Contaminated work clothing should not be allowed out of the workplace.*
- *P280 Wear protective gloves/protective clothing/eye protection/face protection.*

Labelling of skin sensitisers

Precautionary statements response:

- *P302 – P352 - IF ON SKIN: Wash with plenty of water/...
...Manufacturer/supplier may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate.*
- *P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention.*
- *P321 Specific treatment (see ... on this label) ... Reference to supplemental first aid instruction.*
- *P362+P364 Take off contaminated clothing and wash it before reuse.*

Labelling of skin sensitisers

Precautionary statement disposal:

- *P501- Dispose of contents/container to in accordance with local/regional/ national/international regulations (to be specified).*

Summary

- The CLP Regulation sets common rules for classification, labelling and packaging of substances and mixtures
- Self-classification or legally binding harmonised classification
- Hazard communication through pictograms and H/P statements
- ATPs to implement GHS revision or new Annex VI substances
- Widespread downstream consequences of CLH
- Labelling requirements for skin sensitisers



Thank you for your attention

On behalf of the GROW D.2 CLP team:

Johanna Bernsel

Deputy Head of Unit

Visit our website:

https://ec.europa.eu/growth/sectors/chemicals/classification-labelling_en

Try the ECHA CLP quiz:

<https://echa.europa.eu/regulations/clp/clp-quiz>