Basic guidance
to
Regulation
(EC) No 1272/2008
on
Classification,
Labelling and
Packaging
of substances and
mixtures

CLP / GHS: generic issues

Staf Laget – Umicore

EUROMETAUX

GHS & ENVIRONMENTAL CLASSIFICATION WORKSHOPS

Brussels, 5-6 March

Content

CLP and REACH: the registration

REACH	Substances registered before 1 December 2010 shall be registered with a classification according to DSD. However, the registration may also contain the classification according to CLP, as far as available
	Substances registered between 1 December 2010 and 1 June 2015 shall be registered with a classification according to both DSD and CLP
	Substances registered after 1 June 2015 shall be registered with a classification according to CLP alone

Registration timelines are determining the type of classifications in the registration dossier

Up to 1 June 2015 the DSD classification is required in registration dossiers

CLP and REACH: notification of C&L

Obligation to notify "certain information" to the Agency:

SCOPE:

- Substance is subject to registration and is placed on the market.

  (registered substance should not be notified anymore if CLP information is in registration)

- Substance is classified as hazardous under CLP and is placed on the market
- Substance is classified as hazardous under CLP and is present in a mixture above the concentration limits (DSD or CLP) which results in the classification of the mixture as hazardous (and the mixture is placed on the market)

The last two conditions apply to all substances without any tonnage threshold

Intermediates are substances and therefore the above mentioned conditions should be checked for the intermediates

CLP contains new end-points and some new criteria or threshold values: Substances not classified as hazardous in DSD can become hazardous in CLP

CLP and REACH: notification of C&L

Data requirements for notification:

- your identity, as specified in section 1 of Annex VI to the REACH Regulation;
- the identity of the substance, as specified in CLP Article 18;
- the classification of the substance (CLP classification!);
- where the substance has been classified in some but not all CLP hazard classes or differentiations, an indication of whether this is due to lack of data, inconclusive data, or data which are conclusive although insufficient for classification;
- where applicable, specific concentration limits, or M-factors related to the classification as hazardous for the aquatic environment, i.e. acute category 1 and chronic category 1, together with a justification for their use; and
- the labelling elements for the substance, including the supplemental hazard statements referred to in CLP Article 25(1).

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CLP as GHS for the EU

Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures

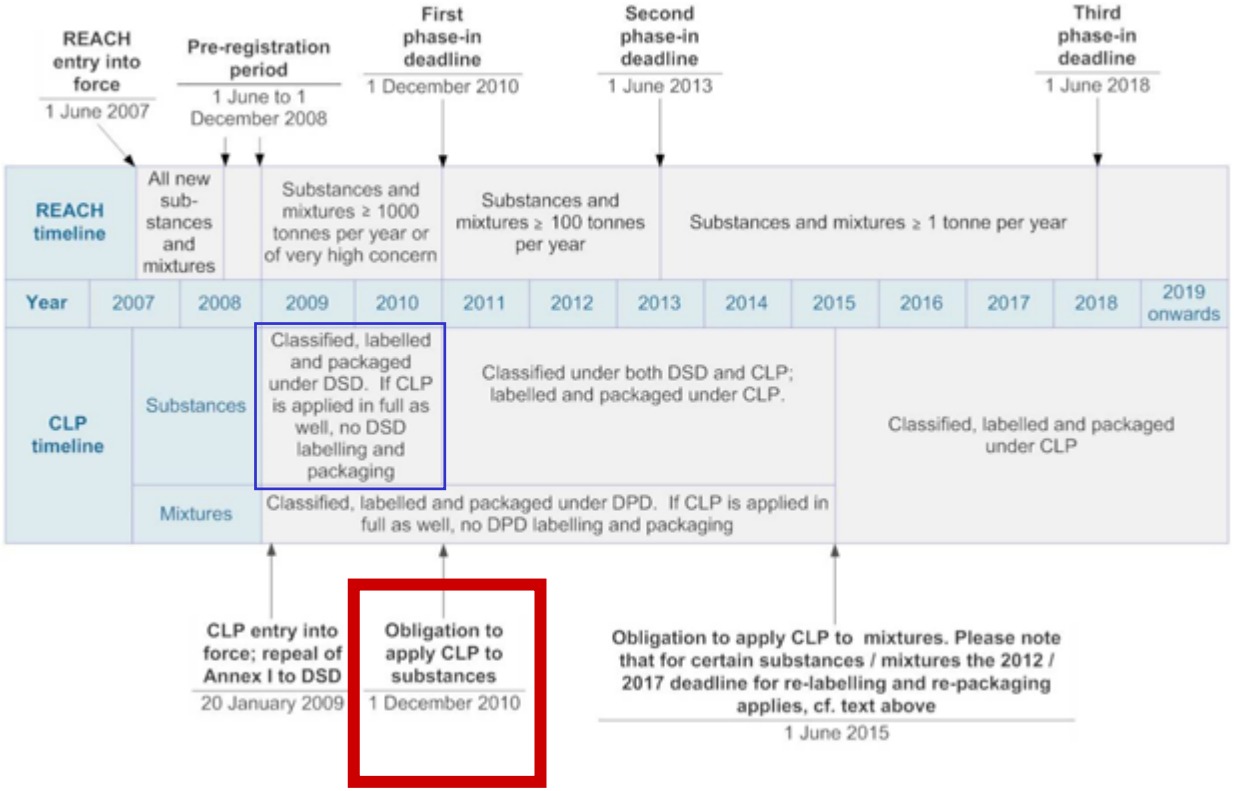
- CLP Regulation translates the Internationally agreed GHS into EU law by implementing basic concepts
- CLP takes on board basic features and procedures of the DSD and the DPD
- CLP will not be identical to the GHS implementation of countries outside the EU
- CLP gradually supersedes the DSD and DPD.
- DSD and DPD will finally be repealed on 1 June 2015

EU transition into GHS has long transition period
with a long overlap between current DSD/DPD and the CLP/GHS

CLP as GHS for the EU

CLP was published on 31 December 2008

CLP came into force on 20 January 2008



CLP as GHS for the EU: classification principles

Harmonized classification continues to exist

Harmonized classifications of the past are introduced in Annex VI of CLP

Obligation to follow the harmonized classifications if they exist

CLP contains harmonized classification in DSD format and GHS format

Future harmonized classifications:

- will apply for CMR and respiratory sensitisation
- other end-points only on case-by-case

Proposals for harmonized classification:

- by Member States or by industry (strict format and procedure)
- Industry cannot submit a proposal to deviate from existing harmonized classification (only by submitting a proposal to the CA in the MS where substance is place on the market)

CLP as GHS for the EU: classification end-points

Physical hazards
Explosives (Unstable explosives, Divisions 1.1, 1.2, 1.3, 1.4, 1.5, and 1,6) D
Flammable gases (Category 1 and 2) D
Flammable aerosols (Category 1 and 2) D
Oxidising gases (Category 1) D
Gases under pressure (Compressed gas, liquefied gas, refrigerated liquefied gas, dissolved gas)
Flammable Liquids (Category 1, 2 and 3) D
Flammable solids (Category 1 and 2) D
Self-reactive substances and mixtures (Type A, B, C, D, E, F, & G) (Types A and B) D
Pyrophoric liquids (Category 1) D
Pyrophoric solids (Category 1) D
Self-heating substances and mixtures (Category 1 and 2)
Substances and mixtures which in contact with water emit flammable gases (Category 1, 2 and 3) D
Oxidising liquids (Category 1, 2 and 3) (Cat 1 and 2) D
Oxidising solids (Category 1, 2 and 3) (Cat 1 and 2) D
Organic peroxides, (Type A, B, C, D, E, F & G) (Types A to F) D
Corrosive to metals (Category 1)

Health hazards
Acute toxicity, (Category 1, 2, 3 and 4) D
Skin corrosion/irritation, (Category 1A, 1B, 1C and 2) D
Serious eye damage/eye irritation, (Category 1 and 2) D
Respiratory or skin sensitisation (Category 1) D
Germ cell mutagenicity, (Category 1A, 1B and 2) D
Carcinogenicity, (Category 1A, 1B and 2) D
Reproductive toxicity (Category 1A, 1B and 2) D plus additional category for effects on or via lactation
Specific target organ toxicity (STOT) – single exposure ((Category 1, 2) D and Category 3 for narcotic effects and respiratory tract irritation, only)
Specific target organ toxicity (STOT) – repeated exposure (Category 1 and 2) D
Aspiration hazard (Category 1) D

Environmental hazards
Hazardous to the aquatic environment (Acute Category 1, Chronic Category 1, 2, 3, and 4) D
Hazardous to the ozone layer D

CLP as GHS for the EU: use of the harmonized classification

Harmonized classifications no longer include the generic concentration limits:

→ Don't copy the harmonized classification as such but check all end-points for concentration limits

Many harmonized classifications are considered to be minimum classifications, indicated by (*)

→ If real data are available, the classification related to the real data should be used

Some specific concentration limits require special attention, indicated by (*) in SCL column

→ Classification for acute tox may be of special concern

International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
			Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
cobalt dichloride	231-589-4	7646-79-9	Carc. 1B Acute Tox. 4 * Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350i H302 H334 H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H350i H302 H334 H317 H410		Carc. 1B; H350i: C ≥ 0,01 % *	1

The published harmonized classifications are obligatory
but it happens that more severe classifications have to be used
because of additional data

CLP as GHS for the EU: substances without harmonized classification

Self-classification is the basic principle

Data available:

- Apply the criteria in Annex I of CLP
- Weight of evidence / expert judgment can be used

No data available but DSD classification available (before 1 Dec 2010):

- Translation tables from DSD to CLP/GHS can be used
- Not all end-points are covered by the translation tables

CLP as GHS for the EU: mixtures

Available data from testing of mixtures should primarily be exploited

If no testing data available:

- Bridging principles (use data from similar tested mixtures / ingredients)
- Calculations with the specific GHS calculation rules
- Expert judgment
- Weight of evidence

Absence of data on mixtures: ingredients information is key to the classification

Calculation rules can differ very much from the DPD calculation rules

CLP as GHS for the EU: mixtures

Calculation rules can differ very much from the DPD calculation rules

Example of Acute Tox calculation rules under CLP / GHS (oral, dermal, inhalation):

Ingredients without Tox data influence the approach:

Less than 10% with unknown tox data:

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

More than 10% with unknown tox data:

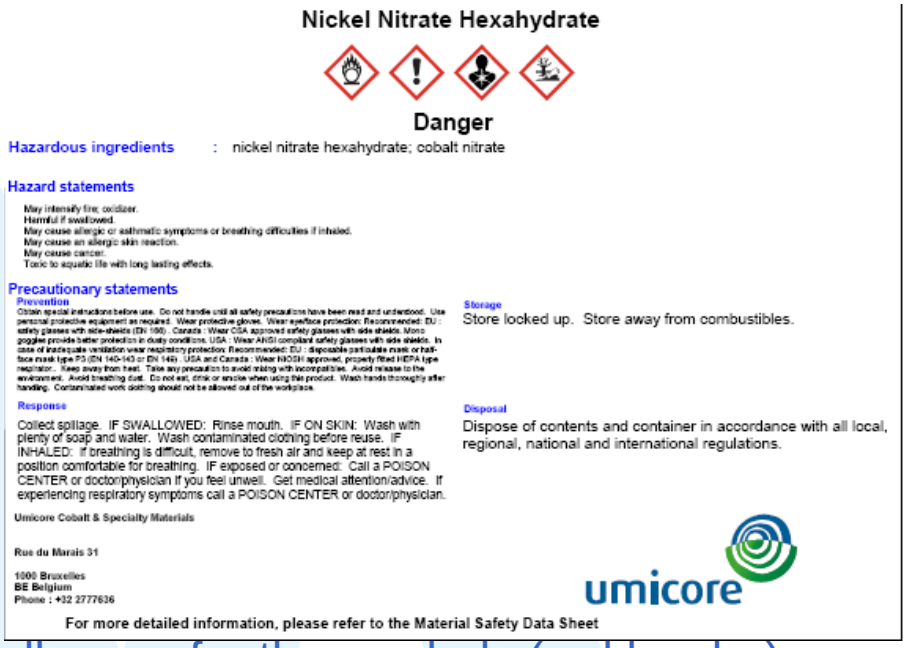
$$\frac{100 - \left(\sum C_{\text{unknown if}} > 10\ \%\right)}{ATE_{mix}} = \sum_{n} \frac{C_i}{ATE_i}$$

ATE of mixture has to be compared with classification criteria (Annex I)

ATE is the new concept:
Acute Toxicity Estimate

CLP as GHS for the EU: Labelling methodology

- New symbols
- New wording
- New colours
- New type of sentences
- New headers/sections



Nickel Nitrate Hexahydrate

Danger

Hazardous ingredients : nickel nitrate hexahydrate; cobalt nitrate

Hazard statements

May intensify fire; oxidizer.
Harmful if swallowed.
May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.
May cause cancer.
Toxic to aquatic life with long lasting effects.

Precautionary statements

Prevention

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Wear protective gloves. Wear eye/face protection: Recommended: EU : safety glasses with side-shields (EN 166). Canada : Wear CSA approved safety glasses with side shields. Mono goggles provide better protection in dusty conditions. USA : Wear ANSI compliant safety glasses with side shields. In case of inadequate ventilation wear respiratory protection: Recommended: EU : disposable particulate mask or half-face mask type P3 (EN 140-143 or EN 149). USA and Canada : Wear NIOSH approved, properly fitted HEPA type respirator. Keep away from heat. Take any precaution to avoid mixing with incompatibles. Avoid release to the environment. Avoid breathing dust. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace.

Storage

Store looked up. Store away from combustibles.

Response

Collect spillage. IF SWALLOWED: Rinse mouth. IF ON SKIN: Wash with plenty of soap and water. Wash contaminated clothing before reuse. IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. IF exposed or concerned: Call a POISON CENTER or doctor/physician if you feel unwell. Get medical attention/advice. If experiencing respiratory symptoms call a POISON CENTER or doctor/physician.

Disposal

Dispose of contents and container in accordance with all local, regional, national and international regulations.

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For more detailed information, please refer to the Material Safety Data Sheet

- Lay-out of your labels needs revision
- Printing black and white only creates challenges for the symbols (red border)

- If CLP (GHS) classification in MSDS: obligation to label following CLP (GHS)

Languages on the labels:
official language(s) of the MS where the substance is placed on the market
unless the MS concerned provides otherwise

CLP as GHS for the EU: Labelling methodology

Palladium (II) Nitrate Solution

Danger

Hazardous ingredients : nitric acid; palladium dinitrate

Hazard statements

Harmful if swallowed.
Causes severe skin burns and eye damage.

Precautionary statements

Prevention

Wear protective gloves. Wear eye/face protection. Wear protective clothing. Do not eat, drink or smoke when using this product. Wash thoroughly after handling.

Storage

Store locked up.

Response

Immediately call a POISON CENTER or doctor/physician. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. Wash contaminated clothing before reuse. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing.

Disposal

Dispose of contents and container in accordance with all local, regional, national and international regulations.

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For more detailed information, please refer to the Material Safety Data Sheet

Content

CLP as support to GHS in other regions

Self-classification is the basic principle

Data available:

- Apply the criteria of GHS / local implementation of GHS
- Weight of evidence / expert judgment can be used

No data available:

- EU guidance can be helpful to provide classification
- Translation tables from DSD to GHS can be used

Warning!
Some GHS implementations use hazard categories not used by the EU
Some GHS implementations publish list of classifications (e.g. Japan)

Content

CLP as DSD

DSD classification of substances:

- Allowed as classification until 30 November 2010
- Used as additional information in MSDS and Registration dossier until 2015

Status of the Harmonized Classifications under CLP:

- Annex VI contains the DSD Annex I classifications up to ATP 29

What about ATP 30 and ATP 31 to DSD?

ATP 30: entry into force 5 Oct 2008

- transposition into MS law before 1 June 2009

ATP 31: entry into force 5 Feb 2009

- transposition into MS law before 1 June 2009

Intention of the Commission to publish ATP 1 to CLP in H1 2009 to transfer ATP 30+31 into CLP

Deadline for entry into force of ATP 1 to CLP 1 Dec 2010?

CLP as DSD

transition between ATP 29 (annex VI of CLP) and ATP 1 to CLP

Substance with published harmonized classification in CLP (up to ATP29):

continue to implement the CLP classification

Substance without published harmonized classification in CLP (up to ATP29):

use ATP 30 and 31 as source of information

use other sources of information (e.g. supplier) to classify

Why?

If harmonized classification exists: no right to deviate
If no harmonized classification exists: self-classification based upon available information (ATP 30 and ATP 31 are available data!)

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CLP as DPD

DPD classification of mixtures:

Allowed as classification until 1 June 2015

Used as additional information in MSDS if CLP classification is applied

Impact of CLP Annex VI (and future ATP 1 to CLP) on mixtures classification

CLP Annex VI is not identical to DSD Annex I ATP 29:

- Some substances have different SCL (specific concentration limits) compared to Annex I
- Many substances have no SCL anymore if the SCL were equal to the generic concentration limits
- Many substances don't have the ecotox SCL anymore (equal to generic concentration limits)
- Some substances have * in the SCL column, pointing towards special concern

DPD rules have to be applied to the substances as published in Annex VI to CLP:

- if no ecotox SCL published: the real ecotox values should be used to calculate the

The absence of « agreed » ecotox reference values for metals and metal compounds will result in different ecotox classifications by the operators

Content

CLP to amend or correct Annex VI

Current harmonized classifications: all end-points

Future harmonized classifications:

- will apply for CMR and respiratory sensitisation
- other end-points only on case-by-case (and only based upon a strong justification why action at Community level is required)

Industry and Member States can apply for a harmonized classification by submitting a proposal to the ECHA (if new)

Member state can submit a proposal to the ECHA for a hazard already classified

If industry wants to submit such proposal (to correct existing hazard classification), the competent authority in a MS where substance is placed on the market should submit the proposal

Content

CLP archiving

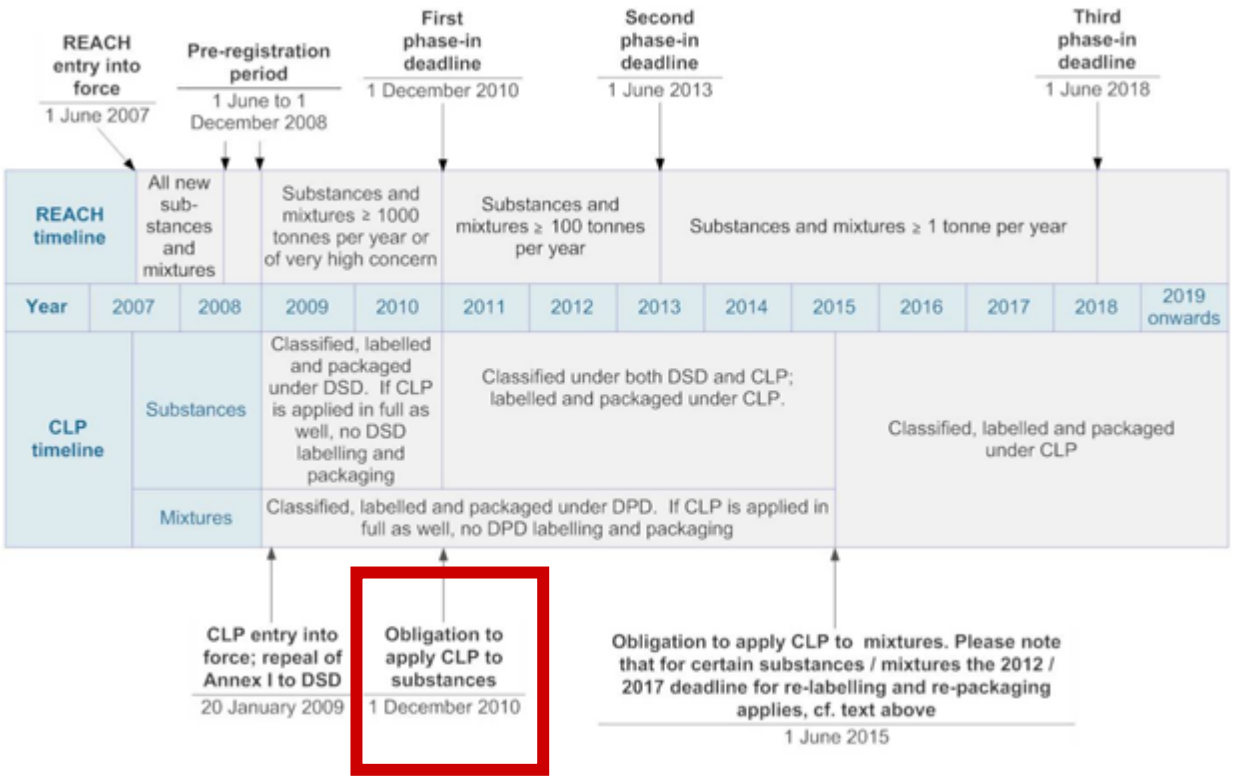
Obligations under CLP	
1	You should classify, label and package substances and mixtures according to CLP before placing them on the market You should also classify substances not placed on the market that are subject to registration or notification in line with Articles 6, 9, 17 or 18 of REACH *(CLP Article 4)*
2	You should classify in line with CLP Title II *(CLP Articles 5-14)*
3	You should label in line with CLP Title III *(CLP Articles 17-33)*
4	You should package in line with CLP Title IV *(CLP Article 35)*
5	You should notify the classification and labelling elements to the classification and labelling inventory established at the Agency in case you place substances on the market *(CLP Article 40)*
6	You should take all reasonable steps available to you to make yourself aware of new scientific or technical information that may affect the classification of the substances or mixtures you place on the market. When you become aware of such information which you consider to be adequate and reliable you should, without undue delay, carry out a new evaluation of the relevant classification *(CLP Article 15)*

Obligations under CLP	
7	You should update the label following any change to the classification and labelling of that substance or mixture, in certain cases without undue delay *(CLP Article 30)*
8	If you have new information which may lead to a change of the harmonised classification and labelling elements of a substance *(part 3 of Annex VI to CLP)* you should submit a proposal to the competent authority in one of the Member States in which the substance is placed on the market *(CLP Article 37(6))*
9	You should assemble and keep available all the information required for the purposes of classification and labelling under CLP for a period of at least 10 years after you have last supplied a substance or mixture. This information should be kept together with the information required in Article 36 of REACH *(CLP Article 49)*

Document classification data expert judgment, weight of evidence such that it can be retrieved up to 10 years after last supply

Content

CLP timelines in operational transactions



All substance with GHS classification and labels before 1.12.2010

If classified with CLP GHS, no DSD label allowed

CLP timelines in operational transactions

All substance with GHS classification and labels before 1.12.2010

If classified with CLP GHS, label has to be CLP GHS label

Assess the appropriate time to start transfer from DSD to CLP (GHS)

Avoid packagings with DSD labels leaving the plants after 30.11.2010

Take into account that time is required to produce the new labels and the new MSDS

Take into account the distribution channels of your products:

- Products on the market before 1.12.2010 and DSD labelled have until 1.12.2012 before they need to be relabelled in the distribution chain

CLP timelines in operational transactions

All mixtures with GHS classification and labels before 1 June 2015

If classified with CLP GHS, label has to be CLP GHS label

Do you need to wait for the mixtures CLP GHS classification?

If you have the information to classify under CLP: no need to wait

Assess the options to implement mixtures in parallel to substances and avoid too many labelling differences

Check the export requirements to other GHS regions or countries.

Implementation of mixtures CLP classification and labelling for the EU can be synchronised with the GHS implementations in the other countries

CLP implementation – generic issues

- EU offers a lot of flexibility and company specific implementation
- CLP contains a lot of details with impact on the correct classification
- New rules, new calculation rules, more room for deviation from the strict rules…
- Differences in interpretation and in implementation between competitors can result in « correct » but different classifications for the same substance or mixture.
- SIEF / Consortia are ideal fora to agree on common CLP classifications for substances in the scope of REACH
- Study the Guidance to the CLP page by page once the final version becomes available

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Your practical guidance document for CLP