Mixture classification

Mixture classification and communicating safe use of mixtures. Advice for formulators and importers

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1. What is the CLP Regulation?

2. What is the difference between CLP and previous legislation?

3. Who needs to classify mixtures?

4. Five steps to mixture classification

What is the CLP Regulation?

- Implements the Globally Harmonised System of Classification and Labelling of Chemicals (UN GHS) in the EU

- Aims to:

  o ensure a high level of protection of human health and the environment

  o facilitate international trade in chemicals

- Replaces the Dangerous Substances Directive (DSD) and the Dangerous Preparations Directive (DPD)

- Ensures that hazard information is directly provided to the user via the label

A known hazard ➡ **safer use!**

Timelines in CLP

Until 1 June 2015

Substances	• must be **classified** in accordance with **both** DSD and CLP • must be labelled and packaged in accordance with CLP • C&L information in accordance with **both** systems must be included in the SDS
Mixtures	• **must** be classified in accordance with **DPD** • **may also** be classified in accordance with CLP; If so, also must label and package in accordance with CLP

Timelines in CLP

After 1 June 2015

Substances	• must be classified, labelled and packaged in accordance with **CLP** • **only** C&L information in accordance with CLP must be included in the SDS
Mixtures	• **must** be classified, labelled and packaged in accordance with **CLP** • re-labelling and re-packaging of mixtures classified, labelled and packaged in accordance with the DPD, already placed on the market before 1 June 2015, is not required before 1 June 2017

CLP vs previous legislation? (1/2)

A similar system (DSD/DPD) has already been in place in the EU.

- hazard based, not risk based
- similar classification criteria for many hazards, e.g. CMRs
- overall scope of classification is similar
- **same** main approaches to classify mixtures:
  - ○ normally based on ingredient substances using concentration limits
  - ○ the use of additivity for certain hazards

CLP vs previous legislation? (2/2)

New:

- Bridging principles where there are data on similar tested mixtures

- The form or physical state(s) in which the mixture can reasonably be expected to be used must also be considered (Article 9(5))

Not (really) **new**: apply a weight of evidence using expert judgement when the criteria cannot be directly applied (Article 9(3))

Mixture classification
- who should classify? (1)

If you place a mixture on the market:

- you need to be aware of the hazards of the imported or formulated mixture, and **classify** accordingly

- you need to communicate the hazards in your supply chain via the SDS and the **label**.

- you need to **package** in accordance with CLP
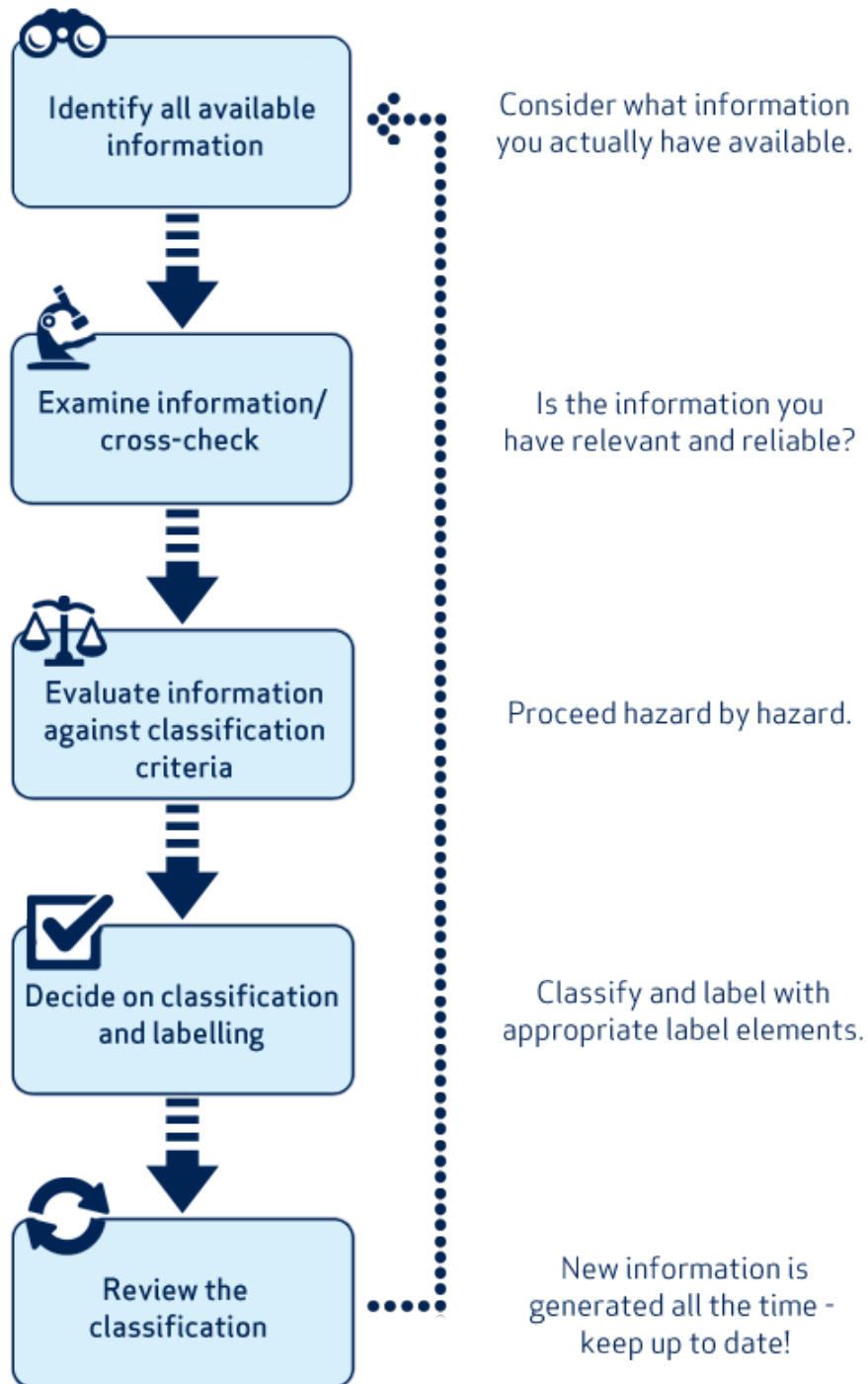
Mixture classification
- who should classify? (2)

If you **import**, **formulate** or **change the composition of a mixture**,

➡️ you must derive the classification of the mixture

If you **do NOT change the composition (and are not an importer)** of a mixture

➡️ you may take over the classification provided by another actor in the supply chain

![ECHA - European Chemicals Agency]

Five steps to mixture classification

Identify all available information → Consider what information you actually have available.

Examine information/cross-check → Is the information you have relevant and reliable?

Evaluate information against classification criteria → Proceed hazard by hazard.

Decide on classification and labelling → Classify and label with appropriate label elements.

Review the classification → New information is generated all the time - keep up to date!

1. **Identify all available information**

Identify information:

- **on the mixture itself**
- **on the individual substances** in the mixture

Your primary source of information should be your **suppliers**.

Where should you look for information? (1/2)

- in-house data

- up-to-date **SDS** or another format of safety information, provided by your supplier(s)

- Classification and Labelling Inventory of substances: (a) **harmonised classification and labelling** (CLH) (legally binding), (b) classifications as provided by manufacturers and importers

- RAC opinions (e.g. if there is no classification) on substances in a mixture or other information on ECHA's website

Where should you look for information? (2/2)

- ECHA's database on registered substances

- transport classification (may indicate some hazards for further consideration, but does not cover all hazards for supply and use)

- other sources, e.g. OECD **eCHEMPortal** and others listed in Chapter 10 of the *Introductory guidance on the CLP Regulation*

- open literature

Basic information needed

For **each substance** in the mixture you need to know (at least):

- the identity of the ingredient substance
- the concentration of the substance in the mixture
- its classification and any assigned specific concentration limit (SCL) or multiplying factor(s) (M-factor(s))
- details of any impurities and additives in the substance

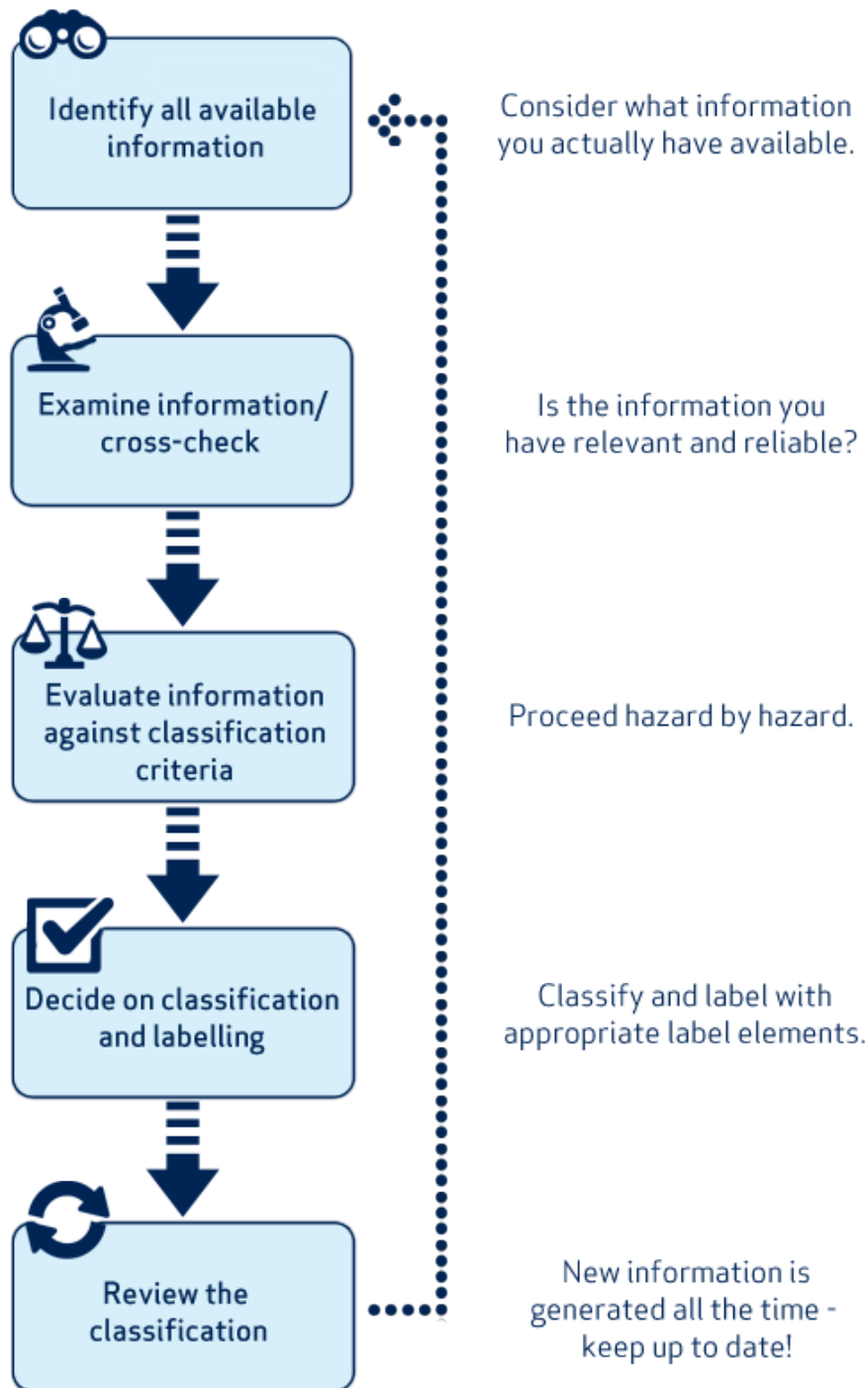If a component in the mixture is itself a mixture:

get information on the substances of that component mixture

Specific information

For example, test data on the mixture itself, or on the substance(s) in the mixture, e.g. in the form of

- study reports
- study summaries
- relevant parameters derived from test data (e.g. acute toxicity estimate values)

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## 2.	Examine available information

Ensure that the information is complete

- For every hazard, check that you have information either on each substance in the mixture or on the mixture itself.

    - In most cases, **basic information** is sufficient in order to classify your mixture

- Note that for the majority of physical hazards, test data on the mixture itself is needed.

- If there is **specific information**, such as test data on the mixture itself and/or on substances in the mixture you need to consider whether the data are **relevant, reliable and adequate.**

Is the information relevant, reliable and adequate?

What is relevant, reliable and adequate?

Relevant = data and tests are appropriate for identification of a particular hazard. Has the test been validated and accepted for mixtures? Any type of mixture?

Reliable = the inherent quality of a test report or publication relating to the description of the methodology, experimental procedure and results to give evidence of the clarity and plausibility of the findings

Adequate = the usefulness of data for hazard/risk assessment purposes – was the test validated for the purpose?

➡️ **To ensure high quality information,** allowing a well-justified decision on hazard classes

Is the information about classification of substance(s) you have received from your supplier...

- *....*incomplete or insufficient for classifying your mixture?

- ....inconsistent with...

  1.... the **legally binding** harmonised classification (Annex VI, CLP) for an ingredient substance?

  2.... the classification(s) notified in the C&L Inventory?

  3.... other available relevant information?

Classification discrepancies

1. If you receive different classifications from different suppliers for the same substance:
   - Verify substance identity and properties
   - Contact your suppliers

2. If the discrepancy is not explained or resolved by your suppliers:
   1. Take over the most relevant classification and document justification for this choice
   2. If your evaluation leads to a different classification decision to that of any of your suppliers, you must report this classification to ECHA.
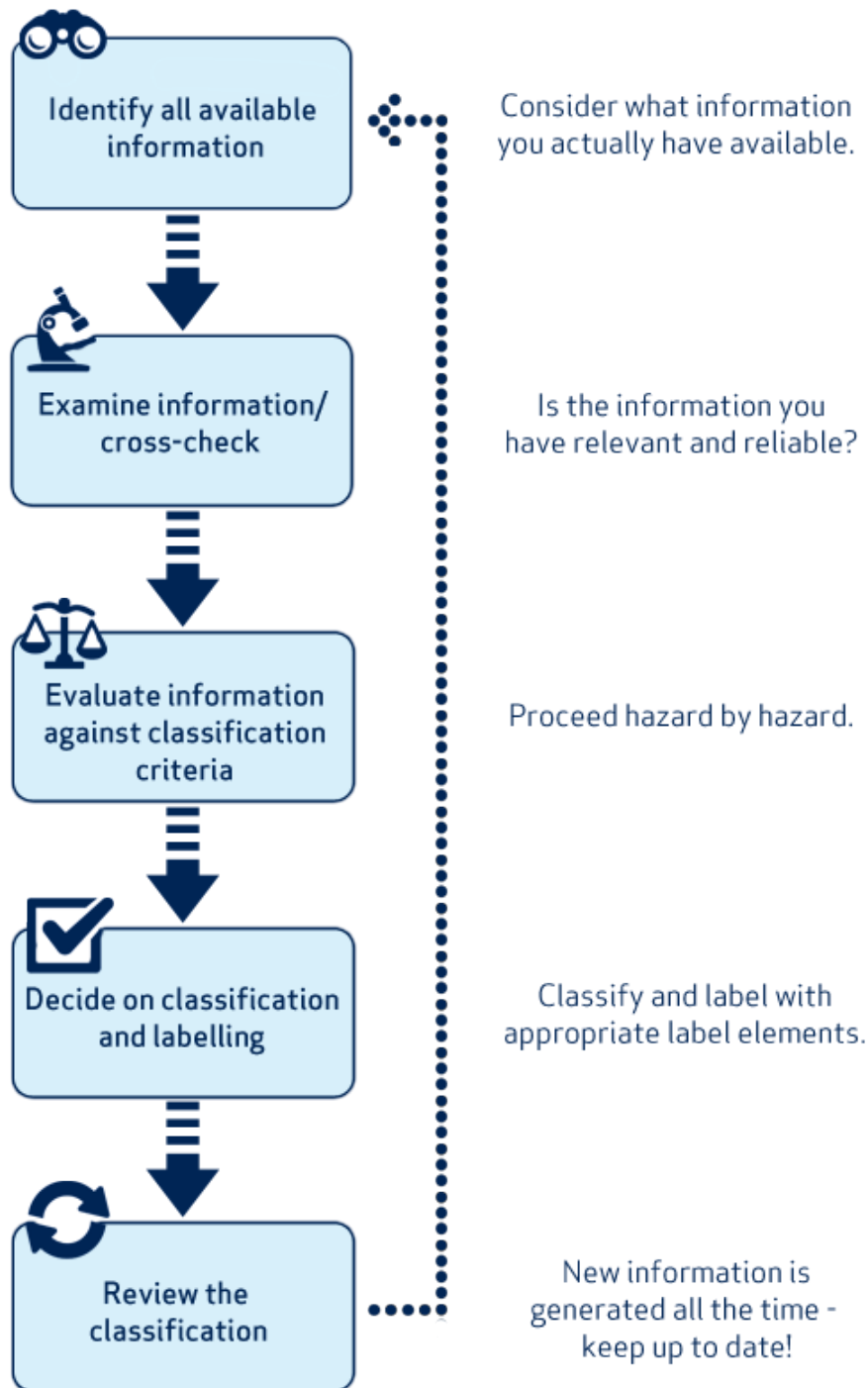
Legally binding harmonised classification of substances

Harmonised classifications of substances in **Annex VI** to CLP are legally binding.

All hazard classes or differentiations **not covered** in Annex VI, must be evaluated and accordingly 'self-classified' before placing a substance on the market.

Mixtures are always 'self-classified', taking into account both the harmonised classification and any additional classification 'self-classified' by the supplier.

Five steps to mixture classification

Identify all available information
····→ Consider what information you actually have available.

Examine information/ cross-check
Is the information you have relevant and reliable?

Evaluate information against classification criteria
Proceed hazard by hazard.

Decide on classification and labelling
Classify and label with appropriate label elements.

Review the classification
New information is generated all the time – keep up to date!

3.   Evaluate information against classification criteria

How to classify a mixture? (1/2)

Classifying a mixture for health or environmental hazards:

1. Based on relevant, reliable and adequate test data for the **mixture as a whole.**
2. Based on the use of **"bridging principles"** (where you have data on similar tested mixtures and individual ingredients).
3. Based on the hazardous properties of the **individual ingredient substances** of the mixture (concentration limits and cut offs - calculations).

Above approaches generally applied in this order

(For certain hazards the starting point must be the ingredients (i.e. (3) above))

How to classify a mixture? (2/2)

Classifying a mixture for physical hazards:

1. Based on testing mixture according to CLP provisions.

2. Check which hazard classes are applicable – molecular structure, physical state, known properties etc.

3. If available, use test data from testing for transport purposes.

Some hazards have to be evaluated based only on information on individual substances. Which ones?

- Carcinogenicity, mutagenicity, reproductive toxicity (as a rule of thumb).

- Bioaccumulation and biodegradation properties within the evaluation for 'hazardous to the aquatic environment'.

- Hazardous to the ozone layer.

Some hazards have to be evaluated based only on information on individual substances...

In practice, a mixture is also always classified as a respiratory or skin sensitiser when at least one component has been classified as such and it is present at or above the generic or specific concentration limit.

Classification based on individual ingredients

- Concentration limits and M-factors (tables in Annex I for hazard classes other than acute toxicity).

- Summation formulas may need to be used for certain hazards (acute toxicity, skin/eye irritation/damage and environmental hazards).

   Same basic principles as under DPD.

What about testing?

Physical hazards

Test data on the mixture itself needs to be generated where adequate and reliable information is not already available.

Health or environmental hazards

- Testing for the purpose of classification for health or environmental hazards is *not* required in CLP.

- Avoid unnecessary testing on animals, such data should normally not be generated for mixtures. Instead, all available information on the individual substances in the mixture should be used to decide on a classification.

Normally, testing is not needed.

Was your mixture already classified in accordance with DPD? (1/2)
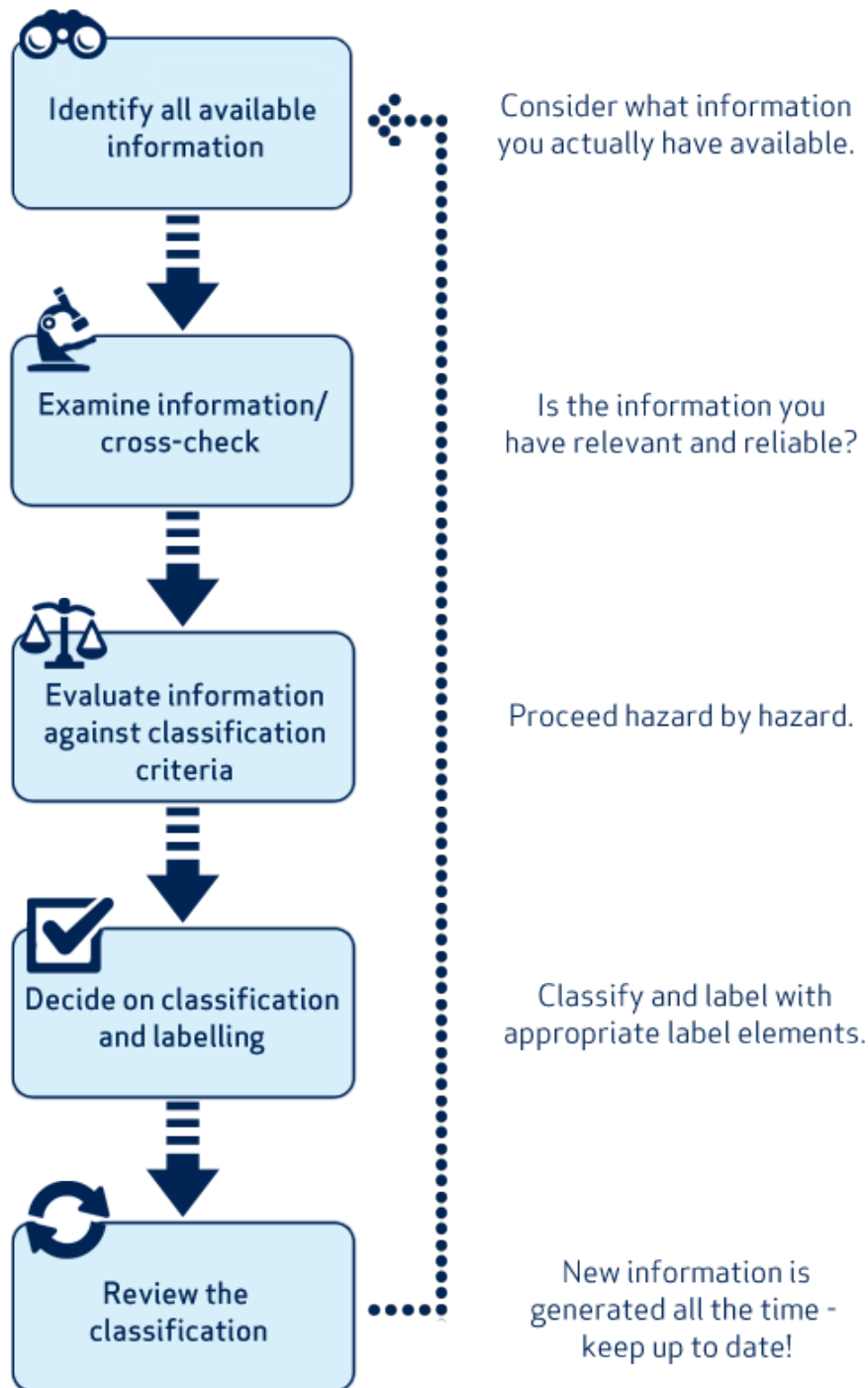
Re-evaluate the classification

But why?

- CLP and DPD classifications may differ for some hazard classes (e.g. acute toxicity, irritation, sensitisation and reproductive toxicity).

- New information can affect a classification and thus the DPD classification may no longer be accurate.

Was your mixture already classified in accordance with DPD? (2/2)

- When reclassifying, make sure that you consider all the relevant chapters in Annex I to CLP.

- If, despite all efforts, you do not have access to any data on the mixture or the substances in the mixture, the translation table 1.1 in Annex VII to CLP may be used, but only to help to **provide a direction** for a possible classification of the mixture.

- The possibilities and limitations of using Annex VII to CLP are explained in chapter 1.7 of the *Guidance on the application of CLP criteria*.

Five steps to mixture classification

Identify all available information

Consider what information you actually have available.

Examine information/ cross-check

Is the information you have relevant and reliable?

Evaluate information against classification criteria

Proceed hazard by hazard.

Decide on classification and labelling

Classify and label with appropriate label elements.

Review the classification

New information is generated all the time - keep up to date!

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4. Decide on classification and labelling

Decide on appropriate classification and labelling

Annex I to CLP:

- Hazard class, category or differentiation.
- Hazard statement(s).
- Pictograms, signal word.
- Precautionary statements.

ECHA
EUROPEAN CHEMICALS AGENCY

Product Identifier

PRODUCT ABC

Contains:
Substance D
Substance E

Main hazardous substances

Hazard pictograms

DANGER

May be fatal if swallowed and enters airways. Causes skin irritation. May cause drowsiness or dizziness. Very toxic to aquatic life with long lasting effects.

Avoid breathing dust/fume/gas/mist/vapours/spray. Wear protective gloves/protective clothing/eye protection/face protection. IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. IF ON SKIN: Wash with plenty of soap and water. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Avoid release to the environment.

Nominal quantity

25 L*

Supplier information

Company X
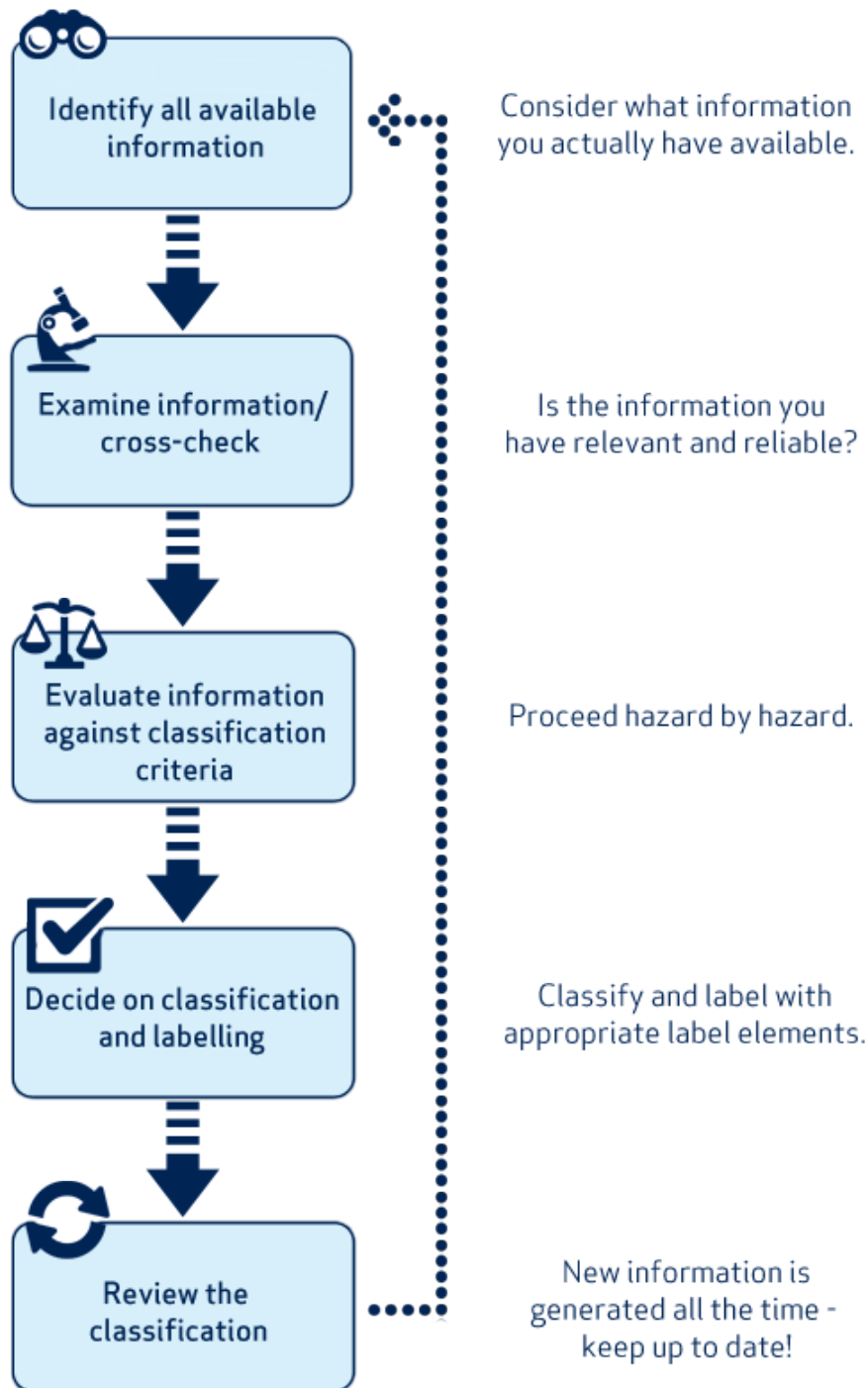XXXX Street
Helsinki
Post Code ABC
Phone: + 222335 1 358

Hazard & Precautionary statements

Space for supplemental information

*Minimum label size 74 x 105 mm
Minimum pictogram size 23 x 23 mm

echa.europa.eu

Five steps to mixture classification

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Decide on classification and labelling — Classify and label with appropriate label elements.

Review the classification — New information is generated all the time - keep up to date!

5. Review the classification

When do you need to review the classification of your mixture?

- Changes in legally binding harmonised classification (Annex VI).

- Changes in self-classification(s).

- Changes in the SDS from the supplier.

- Changes in the mixture, e.g.:

  - A change in the concentration of one or more of the hazardous constituents.

  - A change in the composition by removal, substitution or addition of one or more constituents.

- Changes in criteria for classification of substances (legislation/guidance).

Support?

Mixture classification web pages:

- provide support to those who must **classify mixtures according to the classification requirements of CLP.**

- are mainly based on the ECHA *Guidance on the application of the CLP criteria* and the *Guidance on labelling and packaging.*

- should be read together with Part 1 of the *Guidance on the application of the CLP criteria*, especially Chapter 1.6 which specifically addresses mixtures.

- give links to other useful sources of information to support mixtures classification

http://www.echa.europa.eu/support/mixture-classification
http://www.echa.europa.eu/guidance-documents/guidance-on-clp

Evaluate information against classification criteria

After gathering all the information and assessing its validity, it is time for you to compare the data to the criteria for classification and decide on the classification of the mixture. The criteria are given for each hazard class or differentiation in Parts 2 to 5 of **Annex I** to the CLP Regulation.

In the evaluation of the gathered data, it is recommended that you follow the logic of the step-wise approach in **Figure 1.6.1-a** in the Guidance on the application of CLP criteria. You will need to follow the decision sequence separately for each hazard class. In general, the following situations need to be considered:

> If for a certain hazard class data are available on the individual substances, the decision on the classification of the mixture can be based either on the concentration of the substances in the mixture, taking into account the SCLs and M-factors, or on calculations using specific formulae. The methods are specified separately for each hazard class in Annex I to CLP (see **Section 1.6.3.4** of the Guidance document).

> If test data on the mixture itself are available, they can mostly be directly compared to the classification criteria for substances in Annex I to CLP and the mixture classified accordingly (see **Section 1.6.3.1** of the Guidance on the application of CLP criteria).

> Even if you do not have data on the mixture itself, you may have it on similar tested mixtures. If the mixture and the similar tested mixtures fulfil the conditions explained in **Chapter 1.6.3.2** of the Guidance on the application of CLP criteria, **bridging principles** may be used to classify the mixture. The bridging principles mainly apply to either very simple mixtures or very straightforward compositional changes in an already classified mixture. The Guidance provides simple examples concerning bridging principles.

If you decide that the information on the mixture or the substances in the mixture is not sufficient for classification purposes, contact your suppliers.

The process of evaluating hazard information is outlined in Chapter 2 (Articles 9 to 12) of the CLP Regulation. We recommend using the specific sections in Annex I to CLP to structure your work.

- Back to mixture classification
- Where do I start?

Related links

> CLP Regulation (including annexes)
> Guidance on the application of CLP criteria
> Q&As on CLP

Other websites

> Irish CA page on CLP
> BAuA page on mixture classification
> Check-List for classification of mixtures (German)
> Example of a label for a mixture (German)
> Napo leaflet
> General material on CLP by OSHA

Decide on classification and labelling

If your evaluation of the mixture shows that the hazards associated with it meet the criteria for classification in one or more hazard classes, categories or differentiations, you will need to **decide** on the appropriate physical, health or environmental hazard class, category or differentiation.

After making this decision, you must check which labelling elements correspond to the hazard classifications. The tables in Parts 2 to 5 in Annex I to CLP relate the criteria of each hazard class and category/division with the appropriate classification and labelling elements. Remember to check if a statement, signal word or a pictogram overrules another one. The rules of precedence for these label elements are explained in **Chapters 3 to 6 of the Guidance on labelling and packaging.**

When you have decided on the classification, you will need to consider what hazard information to give on the label. The label needs to include the following information:

> supplier details

> product identifier

> nominal quantity

> hazardous components

> hazard pictograms

> the signal word

> hazard statements

> precautionary statements (usually not more than six unless they are necessary to reflect the nature and the severity of the hazards)

> supplemental information where relevant.

> Label example

The obligation to classify and assign the appropriate hazard statements is outlined in Article 13 of the CLP Regulation.

> **Hazard statements**

> **Precautionary statements**

> **Labelling**

Related links

> CLP Regulation (including annexes)

> ECHA-Term

> Guidance on labelling and packaging

> Guidance on the compilation of SDS

In conclusion

- List the individual substances in the mixtures.
- Identify and evaluate the hazards - and classify accordingly.
- Communicate those hazards to the users.

Imagine you are the user of your product:

Can you use the chemical safely based on the information you have been given?

Thank you

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