



**SAFEWARE QUASAR LTD**

Delivering chemical regulatory compliance

# Safeware Guidance on CLP Notification

## Scope of the Briefing

This document covers the obligation to notify chemical substances, on their own, or in mixtures. It does not cover substances in Articles, as required by REACH Article 7. This briefing note contains some guidance but it is recommended that potential notifiers should consult the ECHA guidance “**Practical guide 7: How to Notify Substances to the Classification & Labelling Inventory**” which is available at:

[http://echa.europa.eu/doc/publications/practical\\_guides/pg\\_7\\_clp\\_notif\\_en.pdf](http://echa.europa.eu/doc/publications/practical_guides/pg_7_clp_notif_en.pdf)

**CLP Notification applies to those performing the following activities:**

- ◆ Manufacturing substances (including isolated intermediates) subject to registration in accordance with the REACH Regulation.
- ◆ Importing substances (e.g. dye stuffs) subject to registration in accordance with the REACH Regulation.
- ◆ Manufacturing or importing substances which are classified as hazardous, irrespective of the quantity involved.
- ◆ Importing mixtures containing hazardous substances, irrespective of the quantity involved.
- ◆ Importing articles containing substances which are subject to registration under REACH Article 7.

## What is notification under the CLP Regulation?

Articles 39 to 42 of the CLP Regulation deal with notification to the Classification and Labelling Inventory.

Notification under the CLP Regulation means that manufacturers and importers submit certain classification and labelling information for substances they are placing on the market to the Classification & Labelling Inventory.

Notification under the CLP Regulation applies to all hazardous substances of all tonnages and also to all non-hazardous substances subject to registration under REACH whenever they are placed on the market in the EU.

## Which substances do I have to notify to the Inventory?

The obligation to notify to the Classification & Labelling Inventory includes:

- (a) All Substances (Classified and Not Classified) subject to Registration in accordance with Regulation (EC) No 1907/2006.
- (b) Substances which meet the criteria for classification as hazardous and are placed on the market either on their own or in a mixture above the concentration limits specified in **Appendix 1** of this briefing, which results in the classification of the mixture as hazardous.



Note that you must notify a substance even if its classification and labelling is (completely) harmonised and it is listed in Part 3 of Annex VI to the CLP Regulation.

However, the obligation to notify does not apply to a number of **substances and mixtures in the finished state** and intended for the final user, or for uses for which there is specific legislation in place, e.g. radioactive materials, medicinal products, cosmetic products and food and feeding stuffs. For more details, please see Article 1: "Purpose and scope" of the CLP Regulation.

## Should I submit a notification for substances that are subject to registration?

You do not need to submit a separate notification for a substance that you have placed on the market if **YOU** have already registered **it under REACH and if the registration dossier contains the classification and labelling according to the CLP Regulation.**

This is because the registration dossier then contains already, the information that is required for substances to be notified to the Classification & Labelling Inventory.

If your substance is a phase-in substance to be registered in 2013 or 2018 only, but it is placed on the market earlier, you must submit a notification for this substance to the Classification & Labelling Inventory within one month of placing it on the market.

If you are placing it on the market on 1, 2 or 3 December 2010, you must submit a notification for this substance to the Classification & Labelling Inventory by 3 January 2011. If you place a phase-in substance on the market after 1 December 2010, a notification must be submitted within one month of placing it on the market.

Provided that the lead registrant has already submitted his registration, it is possible for the other SIEF members to agree to the classification & labelling provided by the lead registrant by ticking the box "I agree". The classification and labelling fields are then automatically filled in for the respective notification. However, this can only be done where the SIEF members have created their notification in REACH-IT. SIEF members may also decide to notify as a group of manufacturers and importers the agreed classification & labelling of a substance.



## Appendix 1

### Concentration limits for notification to the Inventory

#### Health and environmental hazards

The concentration limits referred to in CLP Article 39(b) are either the ones applicable under the Dangerous Preparations Directive 1999/45/EC (DPD) or under the CLP Regulation. If they are taken from DPD, these are either the specific concentration limits set under the Dangerous Substances Directive 67/548/EEC (DSD) or the generic concentration limits as referred to in Part B of Annex II to DPD for human health hazards and in Part B of Annex III to DPD for environmental hazards.

The applicable concentration limits under CLP and DPD are listed in the tables below.

#### CLP Health Hazards

Hazard Class (CLP)	Applicable % Concentration for Notification
Acute toxicity, cat. 1-3	0.1
Acute toxicity, cat. 4	1.0
Skin corrosion, cat. 1A, 1B or 1C (additive)	1.0
Skin corrosion, cat. 1A, 1B or 1C (non-additive)	1.0
Skin irritation, cat. 2 (additive)	1.0
Skin irritation, cat. 2 (non-additive)	3.0
Serious eye damage, cat. 1 (additive)	1.0
Serious eye damage, cat. 1 (non-additive)	3.0
Eye irritation, cat. 2 (additive)	1.0
Eye irritation, cat. 2 (non-additive)	3.0
Respiratory sensitisation, cat. 1	1.0
Skin sensitisation, cat. 1	1.0
Germ cell mutagenicity, cat. 1A or 1B	0.1
Germ cell mutagenicity, cat. 2	1.0
Carcinogenicity, cat. 1A or 1B	0.1
Carcinogenicity, cat. 2	1.0
Reproductive toxicity, cat. 1A or 1B	0.3
Reproductive toxicity, cat. 2	3.0
Effects on or via lactation	0.3
STOT-SE, cat. 1	1.0
STOT-SE, cat. 2	10.0
STOT-RE, cat. 1	1.0
STOT-RE, cat. 2	10.0
Aspiration toxicity, cat. 1	Not applicable; mixture must be tested in order to confirm its classification based on the presence of a particular substances that is classified for that hazard.

The limits quoted apply unless a lower specific concentration limit (SCL) exists



## CLP Environmental Hazards

Hazard Class (CLP)	Applicable % Concentration for Notification
Aquatic Acute Cat	0.1
Aquatic Chronic Cat 1	0.1
Aquatic Chronic Cat 2 - 4	1.0
Hazardous to the ozone layer	0.1

The limits for Aquatic Acute Cat 1 and Aquatic Chronic Cat 1 apply unless an M factor indicates a lower limit.

## DPD/DSD Categories of Danger

Category of Danger of the Substance	Applicable % Concentration for Notification
Very Toxic	0.1
Toxic	0.1
Carcinogenic Cat 1 or 2	0.1
Mutagenic Cat 1 or 2	0.1
Toxic for Reproduction Cat 1 or 2	0.1
Harmful	1.0
Corrosive	1.0
Irritant	1.0
Sensitising	1.0
Carcinogenic Cat 3	1.0
Mutagenic Cat 3	1.0
Toxic for Reproduction Cat 3	1.0
Dangerous for the Environment (N)	0.1
Dangerous to the Ozone layer	0.1
Dangerous for the Environment (R52/53)	1.0

The limits quoted apply unless a lower specific concentration limit (SCL) exists.



Category of Danger of the Substance	Concentration to take into consideration for	
	Gaseous Preparations %vol/vol	Other Preparations %w/w
Very Toxic	≥ 0,02	≥ 0,1
Toxic	≥ 0,02	≥ 0,1
Carcinogenic Category 1 or 2	≥ 0,02	≥ 0,1
Mutagenic Category 1 or 2	≥ 0,02	≥ 0,1
Toxic for reproduction Category 1 or 2	≥ 0,02	≥ 0,1
Harmful	≥ 0,2	≥ 1
Corrosive	≥ 0,02	≥ 1
Irritant	≥ 0,2	≥ 1
Sensitising	≥ 0,2	≥ 1
Carcinogenic Category 3	≥ 0,2	≥ 1

## Physical Hazards

Notification to the Inventory must also be done for substances classified for a particular physical hazard and contained in a mixture whenever the mixture is placed on the market and needs to be classified for a physical hazard due to the presence of that substance. It should be noted that the physical hazard class to which the mixture belongs could be different from that of the substance(s) causing the hazard. Expert judgment should be sought in case of any doubt.

## Please contact us

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