

How to bring your registration dossier in compliance with REACH – Tips and Hints (Part 3)

Classification in relation to aquatic toxicity

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REACH information requirements (I)

Art. 10(a)(iv)	A registration [...] shall include [...] (a) a technical dossier including: [...] (iv) the classification and labelling of the substance as specified in section 4 of Annex VI;
Annex VI Section 4.1	The hazard classification of the substance(s), resulting from the application of Title I and II of Regulation (EC) No 1272/2008 for all hazard classes and categories in that Regulation, In addition, for each entry, the reasons why no classification is given for a hazard class or differentiation of a hazard class should be provided (i.e. if data are lacking, inconclusive, or conclusive but not sufficient for classification).

- Classification to be reported in Section 2.1 of IUCLID.

REACH information requirements (II):

- Classification plays a key role in REACH; it triggers certain provisions such as:
 - the performance of an exposure assessment and risk characterisation as part of the chemical safety assessment (Art 14);
 - the obligation to provide a safety data sheet (Art 31).



CLP Regulation(I):

- The provisions of the second ATP (Adaptation to Technical and scientific Progress) amending the CLP Regulation must be applied to substances since 1 December 2012.
- Revision of the classification criteria for aquatic chronic toxicity – chronic toxicity data need to be considered.
- The acute and the long-term hazard classification categories are applied independently:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:083:0001:0053:en:PDF>

- Annex VI to the CLP Regulation includes lists of harmonised classification and labelling for certain substances or groups of substances which are legally binding within the European Union.

CLP Regulation (II):

- The basic elements used for classification for aquatic environmental hazards are:
 - **acute (short-term) aquatic toxicity**
 - **chronic (long-term) aquatic toxicity**
 - bioaccumulation
 - degradation

CLP Regulation (III)

Substances are considered rapidly degradable in the environment if one of the following criteria holds true:

- (a) Readily biodegradable in biodegradation screening test; or
- (b) Ratio of the five-day biochemical oxygen demand / chemical oxygen demand (BOD_5/COD) $\geq 0,5$; or
- (c) Other convincing scientific evidence that the substance can be degraded in the aquatic environment to a level $> 70\%$ within a 28-day period.

CLP Regulation (IV):

- Classification is based on available toxicity data for fish, crustacea, and algae/aquatic plant.
- The result showing the highest toxicity should normally be chosen.
- There are circumstances, however, when a weight of evidence approach is appropriate.

CLP Regulation (V):

- The core classification system for substances consists of one acute hazard classification category and three long-term hazard classification categories;
 - **Acute Category 1**
 - **Chronic Category 1**
 - Chronic Category 2
 - Chronic Category 3
- "Safety net" classification;
 - Chronic Category 4

CLP Criteria:



Category Acute 1	
96 hr LC ₅₀ (for fish)	≤ 1 mg/l and/or
48 hr EC ₅₀ (for crustacean)	≤ 1 mg/l and/or
72 or 96 hr ErC ₅₀ (for algae or other aquatic plants)	≤ 1 mg/l.
Category Chronic 1	
<i>Non-rapidly degradable substances for which there are adequate chronic toxicity data available</i>	
Chronic NOEC or EC _x (for fish)	≤ 0.1 mg/l and/or
Chronic NOEC or EC _x (for crustacea)	≤ 0.1 mg/l and/or
Chronic NOEC or EC _x (for algae or other aquatic plants)	≤ 0.1 mg/l.
<i>Rapidly degradable substances for which there are adequate chronic toxicity data available</i>	
Chronic NOEC or EC _x (for fish)	≤ 0.01 mg/l and/or
Chronic NOEC or EC _x (for crustacea)	≤ 0.01 mg/l and/or
Chronic NOEC or EC _x (for algae or other aquatic plants)	≤ 0.01 mg/l.

Multiplying factors (M-factors)

- The concept of M-factors has been established to give an increased weight to very toxic substances when classifying mixtures.
- M-factors should be established for substances classified as Acute Category 1 and/or Chronic Category 1.
- M-factors shall be set for acute and long-term hazards separately, when applicable.

Acute toxicity	M factor	Chronic toxicity	M factor	
L(E)C ₅₀ value		NOEC value	NRD ^a components	RD ^b components
0.1 < L(E)C ₅₀ ≤ 1	1	0.01 < NOEC ≤ 0,1	1	-
0.01 < L(E)C ₅₀ ≤ 0,1	10	0.001 < NOEC ≤ 0,01	10	1
0.001 < L(E)C ₅₀ ≤ 0,01	100	0.0001 < NOEC ≤ 0,001	100	10
0.0001 < L(E)C ₅₀ ≤ 0,001	1000	0.00001 < NOEC ≤ 0,0001	1 000	100
0.00001 < L(E)C ₅₀ ≤ 0.0001	10000	0.000001 < NOEC ≤ 0.00001	10 000	1000
(continue in factor 10 intervals)		(continue in factor 10 intervals)		

^a Non-rapidly degradable ^b Rapidly degradable

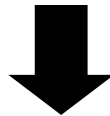
Example (I)

Aquatic acute toxicity data with LC50 below 1 mg/L.

Results and discussions

Effect concentrations

Duration	Endpoint	Effect conc.	Nominal/Measured	Conc. based on	Basis for effect
48 h	LC50	0.60 mg/L	meas. (arithm. mean)	test mat.	mortality
48 h	NOEC	0.080 mg/L	meas. (arithm. mean)	test mat.	mortality



Environmental hazards

Hazardous to the aquatic environment (acute/short-term)

Hazard category:

Hazard statement:

Reason for no classification:

Registrants need to ensure consistency between the endpoint section and the classification section and classify according to the CLP-criteria, or to provide a justification why the study indicating the need for classification has not been considered.

Example (II)

Aquatic chronic toxicity data with NOEC below 0.01 mg/L (10 µg/L).

Results and discussions

Effect concentrations

Duration	Endpoint	Effect conc.	Nominal/Measured	Conc. based on
28 d	NOEC	1.27 µg/L		
28 d	LOEC	2.86 µg/L		



Environmental hazards

Hazard category	Hazard statement	Reason for no classification
Hazardous to the aquatic environment (acute/short-term) Aquatic Acute 1	H400: Very toxic to aquatic life.	
Hazardous to the aquatic environment (long-term)		data lacking

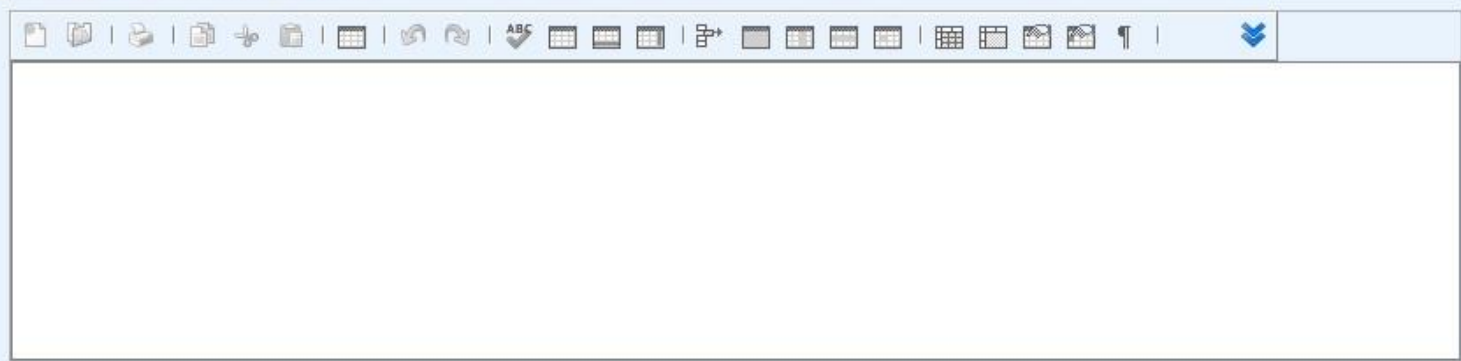
Registrants need to ensure consistency between the endpoint section and the classification section and classify according to the CLP-criteria, or to provide a justification why the study indicating the need for classification has not been considered.

Example (III)

- Conclusion on the environmental hazard assessment and on classification and labelling - in chemical safety report (CSR).
- Conclusion on classification in Section 6 of IUCLID.

Conclusion on classification

Environmental classification justification



Example (IV)

Environmental hazards

Hazard category	Hazard statement
Hazardous to the aquatic environment (acute/short-term)	
Hazardous to the aquatic environment (long-term) Aquatic Chronic 1	H410: Very toxic to aquatic life with long lasting effects.
M-Factor acute	
M-Factor chronic	

Environmental hazards

Hazard category	Hazard statement
Hazardous to the aquatic environment (acute/short-term) Aquatic Acute 1	H400: Very toxic to aquatic life.
Hazardous to the aquatic environment (long-term) Aquatic Chronic 1	H410: Very toxic to aquatic life with long
M-Factor acute 10	
M-Factor chronic 10	

- There may also be a need for acute classification when the substance is classified for chronic aquatic hazard.
- M-factor(s) need to be included when classifying substances as Acute Category 1 and/or Chronic Category 1.

Links

- Commission Regulation (EU) No 286/2011 of 10 March 2011 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging (CLP) of substances and mixtures;
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2008R1272:20110419:EN:PDF>
- Guidance on the application of the CLP criteria: Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packing (CLP) of substances and mixtures, Version 3.0, November 2012.
http://echa.europa.eu/classification/clp_guidance_en.asp

Thank you

