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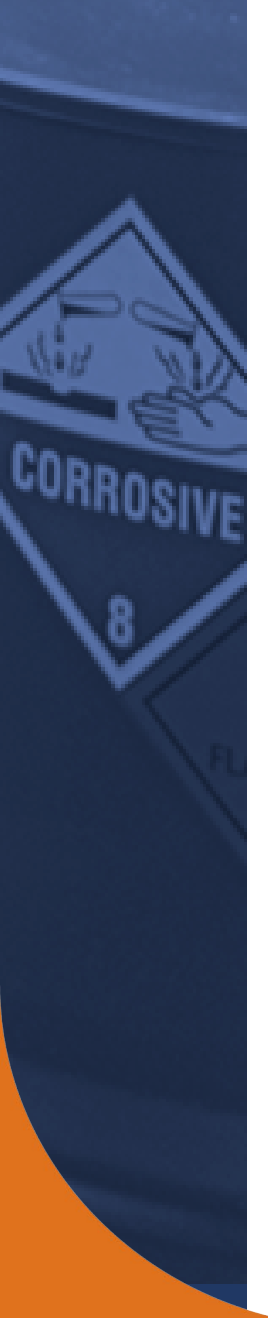
New CLP hazard classes for endocrine disrupting properties for the environment

Mike Broderick

6th March 2025



Overview

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- Overview of the new ED Env Classification criteria under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation).

- Highlight some specific areas of the ECHA guidance on application of CLP criteria for ED ENV classification.

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ED ENV Classification Criteria

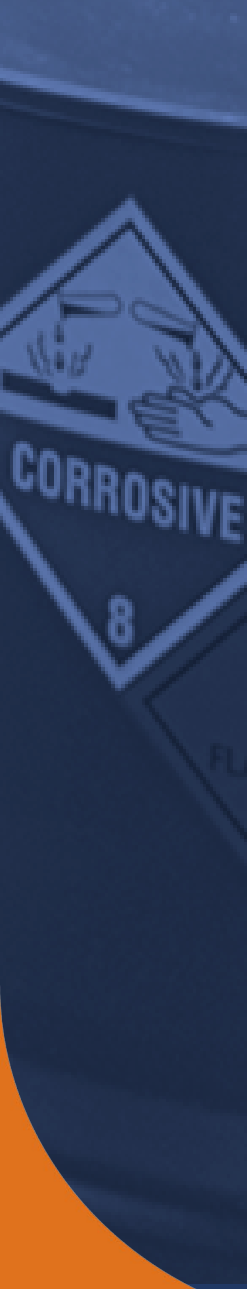

Table 4.2.1.
Hazard categories for endocrine disruptors for the environment

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Categories	Criteria
CATEGORY 1	**Known or presumed endocrine disruptors for the environment** The classification in Category 1 shall be largely based on evidence from at least one of the following: a) animal data; b) non-animal data providing an equivalent predictive capacity as data in point a. Such data shall provide evidence that the substance meets all the following criteria: a) endocrine **activity**; b) an **adverse effect** in an intact organism or its offspring or future generations; c) a **biologically plausible link** between the endocrine activity and the adverse effect. However, where there is information that raises serious doubt about the relevance of the adverse effects identified at population or subpopulation level, classification in Category 2 may be more appropriate.

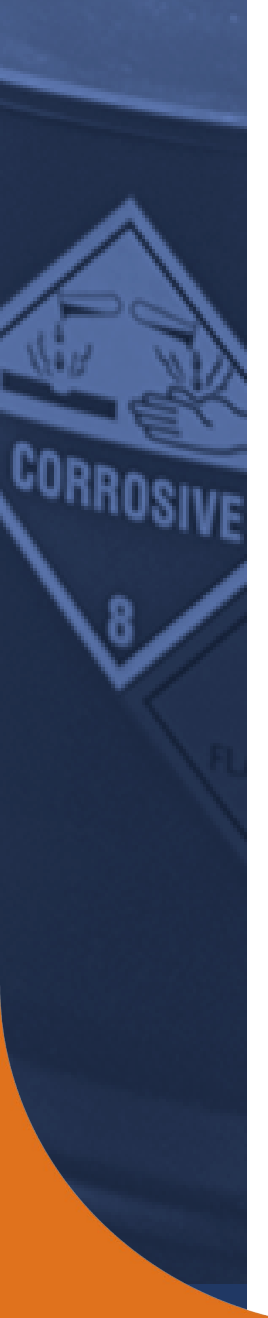

Table 4.2.1.
Hazard categories for endocrine disruptors for the environment

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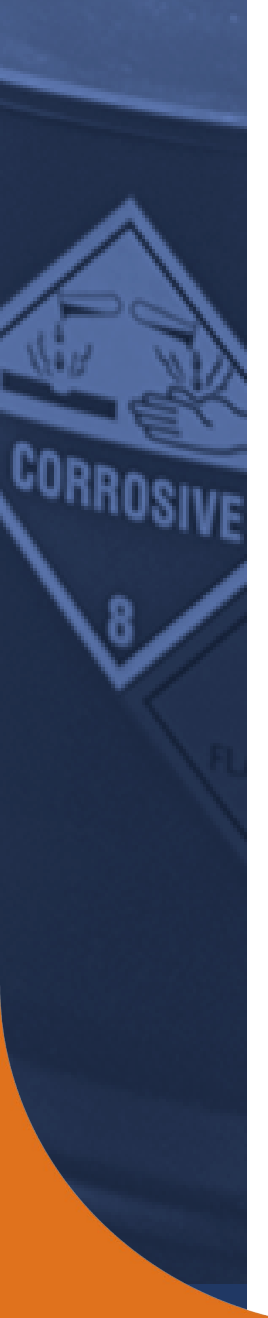
Categories	Criteria
CATEGORY 2	**Suspected endocrine disruptors for the environment** A substance shall be classified in Category 2 where all the following criteria are met: a) there is evidence of: i. an endocrine **activity**; and ii. an **adverse effect** in an intact organism or its offspring or future generations; b) the evidence referred to in point (a) is not sufficiently convincing to classify the substance in Category 1; c) there is evidence of a plausible biological link between the endocrine activity and the adverse effect.



Basis of classification

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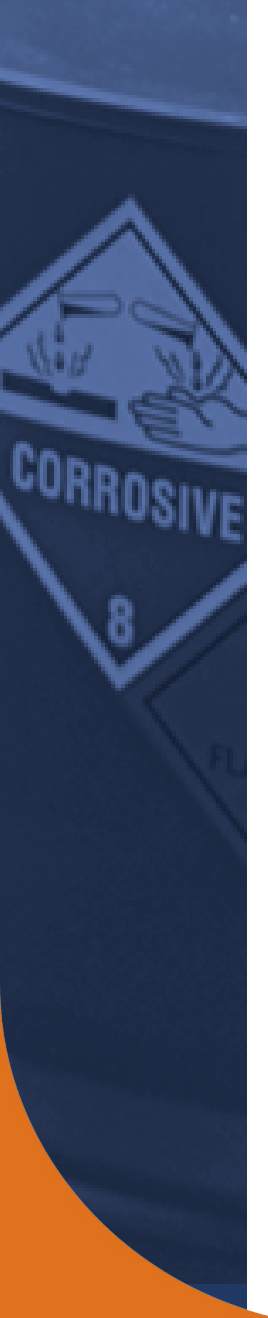
- Classification shall be made on the basis of the appropriate criteria outlined above, a weight of evidence determination (WoE) of each of the criteria and an overall weight of evidence determination.

- Adverse effects that are solely non-specific consequences of other toxic effects shall not be considered for the identification of a substance as endocrine disruptor for the environment.



Classification criteria for mixtures

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- A mixture shall be classified as an ED ENV where at least one component has been classified as a Cat 1 or Cat 2 ED ENV and is present at or above the appropriate generic concentration limit.

- When more than one classified component is present it is important to assess the potential for additivity.

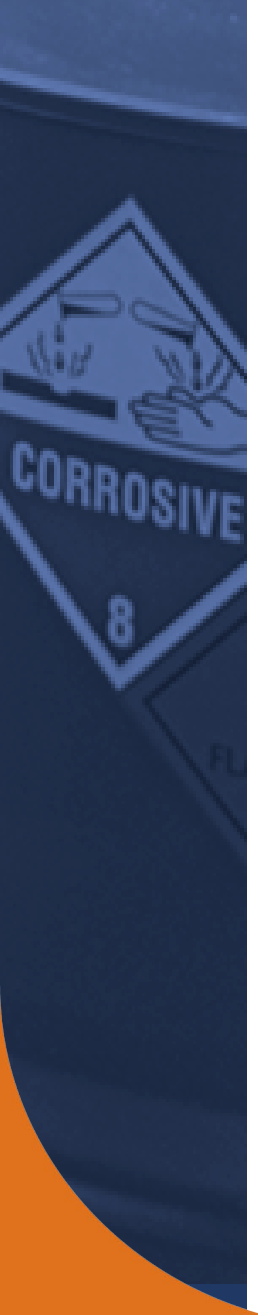

Table 4.2.2.
Generic concentration limits of components of a mixture classified as endocrine disruptor for the environment that trigger classification of the mixture

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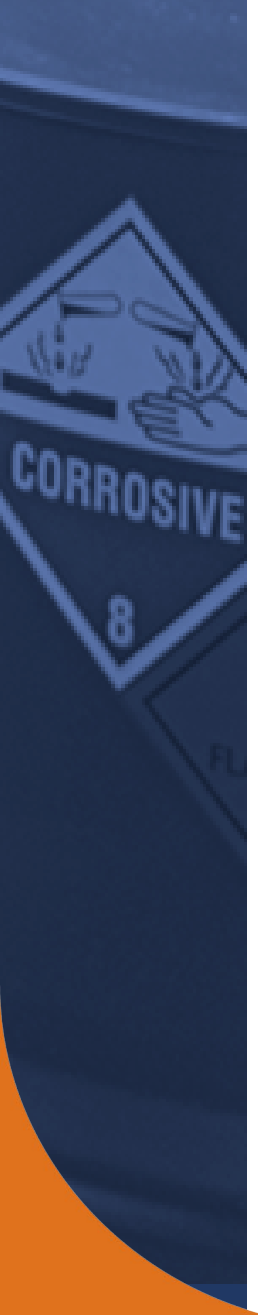
Component classified as:	Generic concentration limits triggering classification of a mixture as:	
	Category 1 Endocrine disruptor for the environment	Category 2 Endocrine disruptor for the environment
Category 1 endocrine disruptor for the environment	≥ 0,1 %	
Category 2 endocrine disruptor for the environment		≥ 1 % [Note 1]

Note: The concentration limits in this Table apply to solids and liquids (w/w units) as well as gases (v/v units).



Hazard Communication

Label elements of ED ENV

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	Category 1	Category 2
Signal Word	**Danger**	**Warning**
Hazard Statement	**EUH430**: May cause endocrine disruption in the environment	**EUH431**: Suspected of causing endocrine disruption in the environment
Pictogram	Currently no pictograms, may be introduced in GHS	Currently no pictograms, may be introduced in GHS
Precautionary Statements (Prevention, response, storage and disposal)	Outlined in Table 4.3.1. in CLP Annex I: 4.3.4.	Outlined in Table 4.3.1. in CLP Annex I: 4.3.4.

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Guidance on the Application of the CLP Criteria

Part 4 – Endocrine Disruption for the Environment.

New Guidance Contents Part 4: Env Hazards

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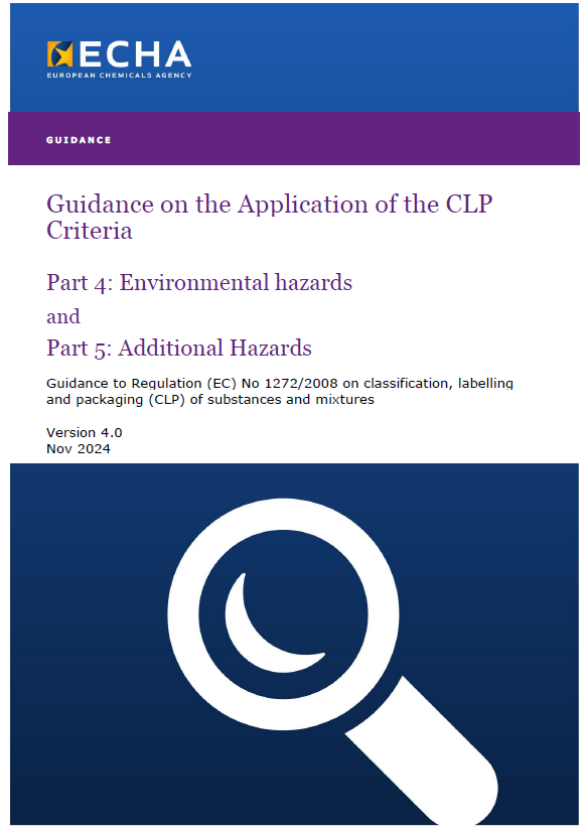
- 4.2. Endocrine disruption for environment
- 4.2.1. **Definitions** and general considerations for endocrine disruption
- 4.2.2. **Classification of substances** for endocrine disruption for environment
- 4.2.3. **Classification of mixtures** for endocrine disruption for environment



4.2.1. Definitions and general considerations for endocrine disruption

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CLP, Annex I, section *4.2.1.1.* *For the purposes of section 4.2., the following definitions shall apply:*

(a) 'endocrine disruptor' means a substance or a mixture that alters one or more functions of the endocrine system and consequently causes adverse effects in an intact organism, its progeny, populations or subpopulations;

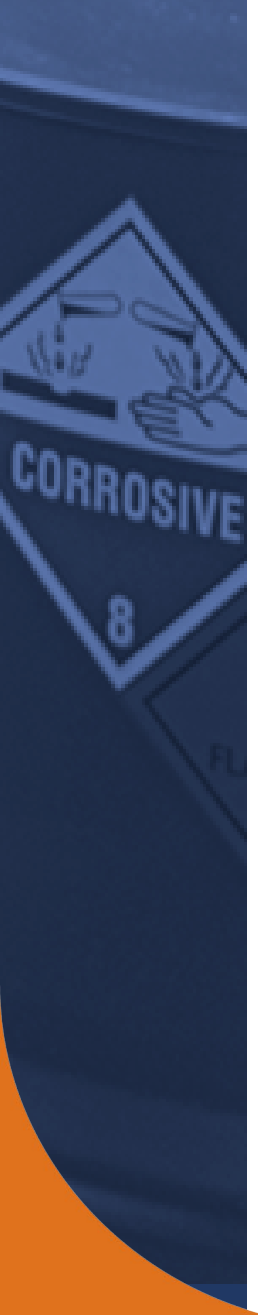
(b) 'endocrine disruption' means the alteration of one or more functions of the endocrine system caused by an endocrine disruptor;

(c) 'endocrine activity' means an interaction with the endocrine system that may result in a response of that system, of target organs or target tissues and that confers on a substance or mixture the potential to alter one or more functions of the endocrine system;

(d) 'adverse effect' means a change in morphology, physiology, growth, development, reproduction or lifespan of an organism, system, population or subpopulation that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;

(e) 'biologically plausible link' means the correlation between an endocrine activity and an adverse effect, based on biological processes, where the correlation is consistent with existing scientific knowledge.

Taxa covered



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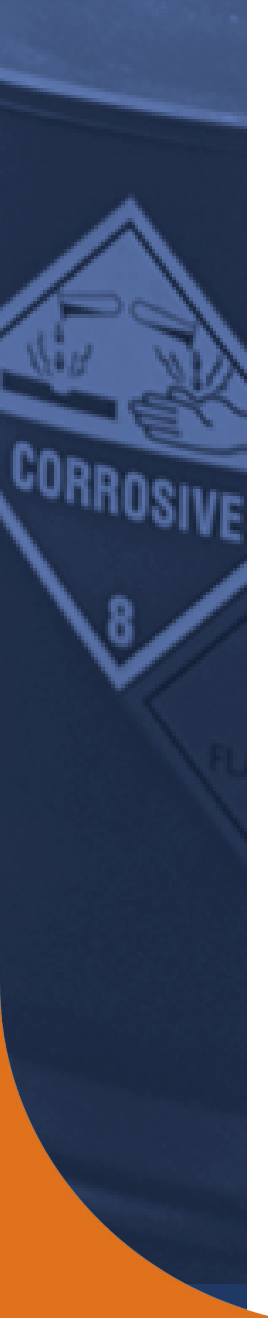
- Focus on vertebrates (mainly fish and amphibians)

- For other vertebrate taxa (besides mammals), e.g. birds and reptiles, currently no standard methods which investigate endocrine specific endpoints are available.

- Nevertheless, the general principles outlined in ECHA's guidance for evaluation of the data are also applicable to those organisms, if data is available.



Identification of hazard information

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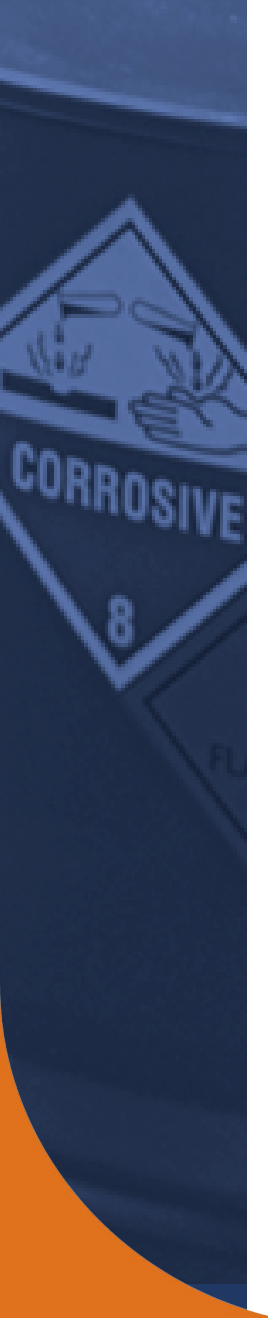
Gather all available information:

- Studies and data from registration dossiers (REACH, BPR, PPPR)

- Literature search or a systematic literature review designed to avoid bias

Evaluation of hazard information



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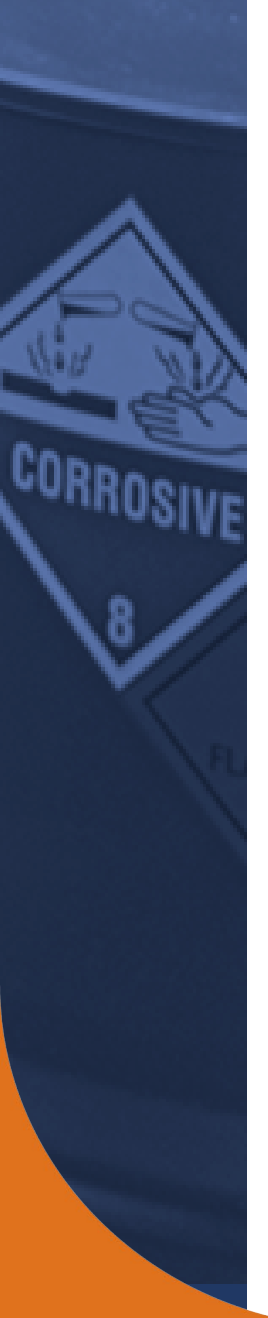
- All parameters related to effects on reproduction (*e.g.* fertility, fecundity, etc.) in the case of EAS modalities, on development/growth (hindlimb length, developmental stage, time to metamorphosis) for the T modality, and behavioural effects that are considered to be population relevant, must be considered in the assessment of adversity.

- **NOTE** - OECD GD 150 provides guidance on how to interpret parameters normally investigated in ecotoxicity studies, i.e., EATS-mediated and Sensitive too but not diagnostic of EATS.



Population relevance

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- The criteria stipulate that substances and mixtures fulfilling the criteria must be considered as ED ENV unless there is *evidence conclusively demonstrating* that the adverse effects identified are not relevant at the population level.

- Refer to section 4.2.2.3.2. of the Guidance on the Application of the CLP Criteria for further details on assessing population relevant effects.

4.2.3. Classification of mixtures for endocrine disruption for environment

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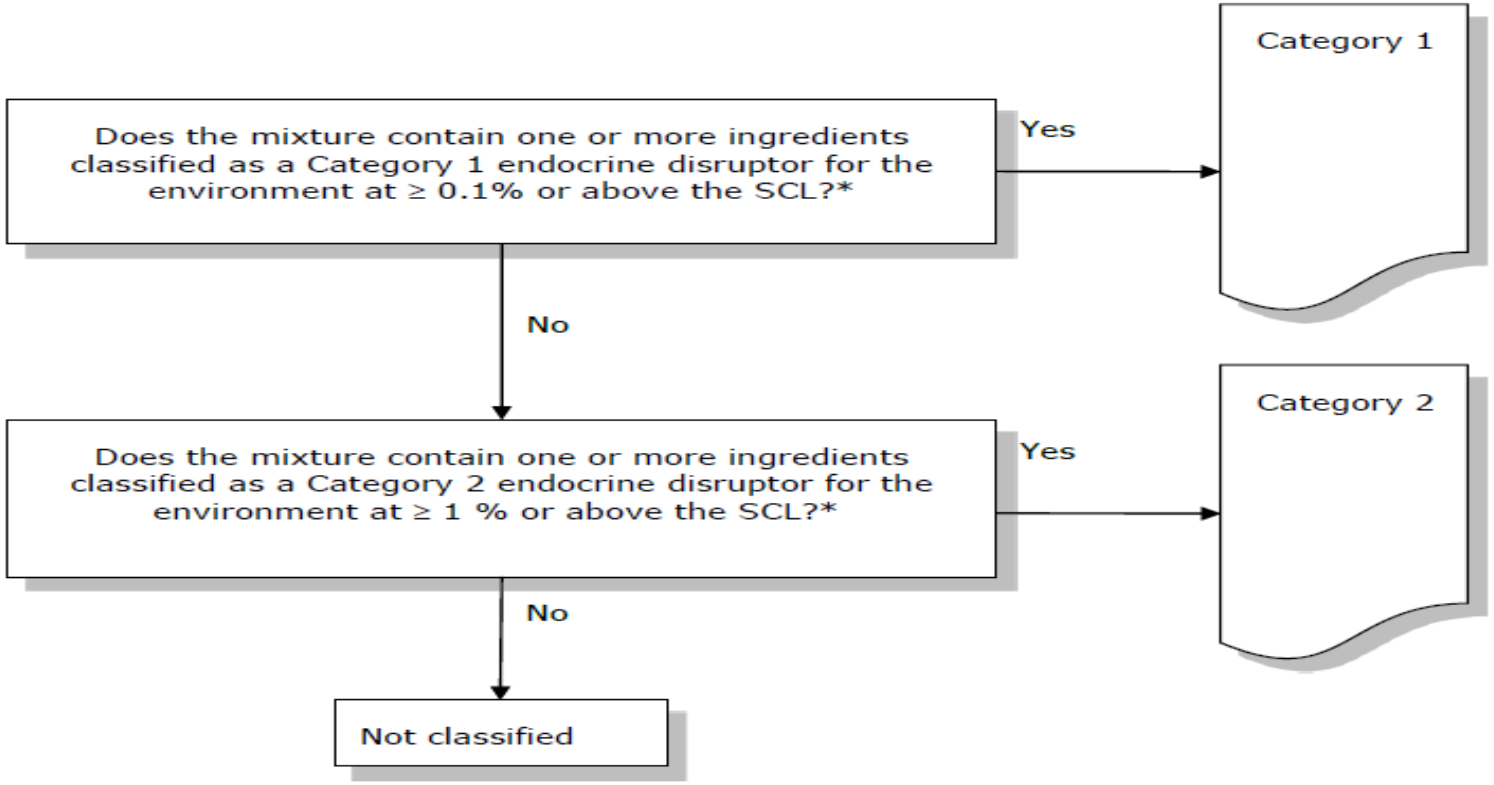
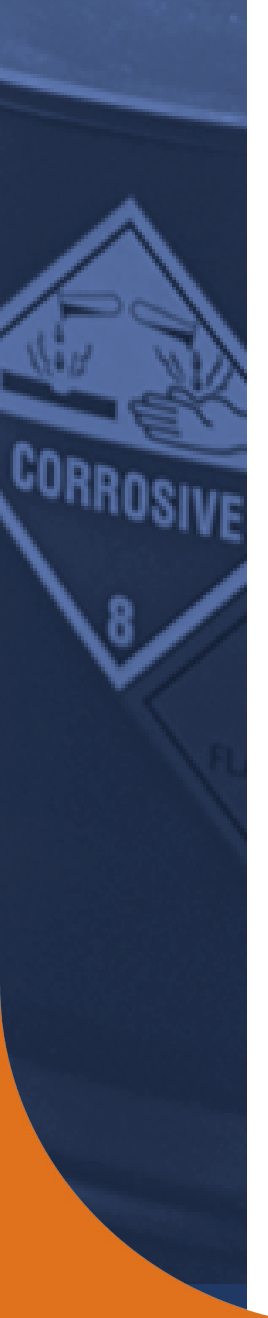
Figure 4.2.3 Decision logic for classification of mixtures based on individual ingredients of the mixture



*Applicability of additivity approach should also be considered.



Specific concentration limits (SCLs)

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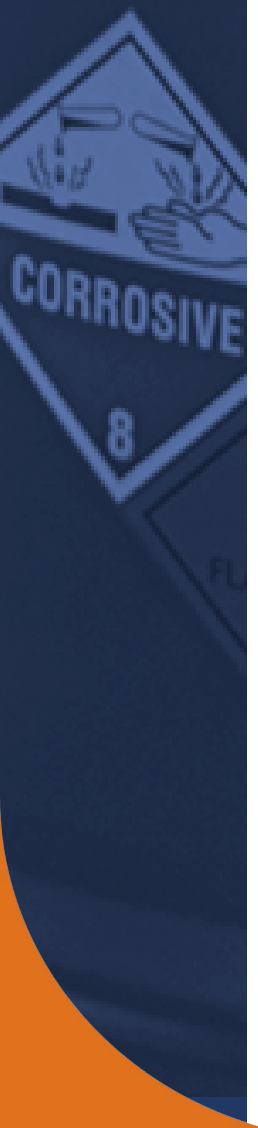
- To align protection levels for ED HH and ED ENV, SCLs for ED effects for most potent chemicals need to be derived
- SCLs for ED properties are set based on potency of adverse effect
- Setting SCL for ED ENV will depend on source of data used to classify a substance for this hazard class.

Table 4.2.2 SCL derivation based on non-mammalian data



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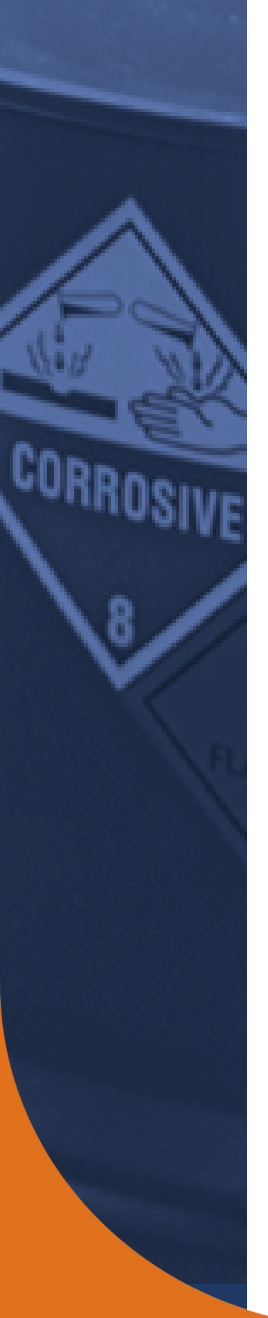
Potency	Effect leading to adverse effect(s) (Non-mammalian study) [mg/L][a, b]	SCL (Cat1)	SCL (Cat2)
Very high potency (see bullet point a.i. above)	EC_{10} or NOEC ≤ 0.00001	GCL/100 = 0.001%	GCL/10 = 0.01%
High potency (see bullet point a.ii. above)	0.00001 < EC_{10} or NOEC ≤ 0.001	GCL/10 = 0.01%	GCL/10 = 0.1%
Medium potency (see bullet point a.iii. above)	0.001 < EC_{10} or NOEC ≤ 0.1	no SCL derived, GCL =0.1%	no SCL derived, GCL =1%
Low potency (see bullet point b. above)	EC_{10} or NOEC > 0.1 mg/L	no SCL derived, GCL =0.1%	no SCL derived, GCL =1%

[a] *When the adverse effect used for ED ENV classification would come from the non-aquatic non-mammalian toxicity study where the results are expressed in mg/kg (e.g. bird reproduction studies), the SCLs should be calculated based on the same principles as described in section 3.11.2.6, particularly following a method similar to 3.7.2 above.*

[b] *If a NOEC value is not available, the LOEC may be used to calculate the SCL, however, when calculating the SCL it should be taken into account that the NOEC value would be lower than the LOEC.*



In Conclusion

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- Substances are classified as EDs for the environment in Cat 1 or 2 when there is sufficient evidence that **the three elements** as indicated in CLP, Annex I: Table 4.2.1 are met: endocrine activity, adverse effect and biologically plausible link.
- With regards to mixtures - SCLs for most potent chemicals need to be derived as per Table 4.2.2 in the ECHA GD on Application of CLP Criteria.

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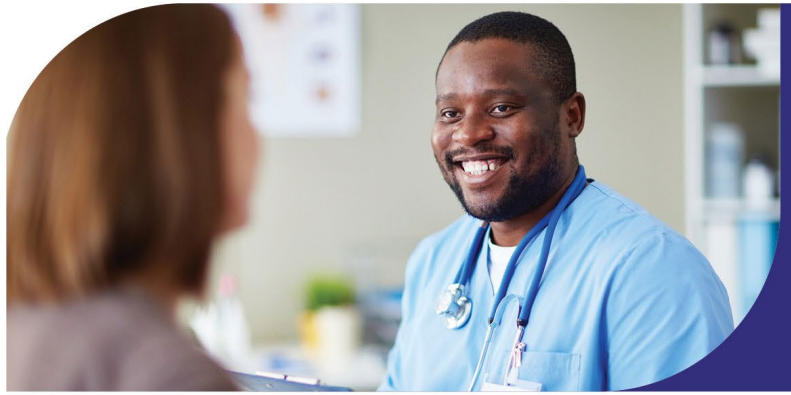
Thank you



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