

What are endocrine disruptors?

Chemicals that may interfere with hormone function –endocrine systems– in humans and other animals. The interference may cause a variety of effects, many of which are seen only after extended periods of exposure.

Where do we typically find endocrine disruptors?

- BPA:** Plastic packaging
- PBDEs:** Electronics & textiles
- Alkyl phenols:** Detergents products
- Phthalates:** Air fresheners, toys & cosmetics

Bisphenol A (BPA), a known endocrine disruptor, is used to manufacture polycarbonate plastics. BPAs can cause diabetes, reproductive problems and cancers specific to females or males. BPAs are banned in food packaging for children under three. Polybrominated diphenyl ethers (PBDEs) are endocrine disruptors used as flame retardants in various products. PBDEs may cause liver tumors and neurodevelopmental and thyroid dysfunctions. Other known endocrine disruptors include phthalates and alkyl phenols.

How are endocrine disruptors currently regulated in the EU?

- Endocrine disruptors can be regulated under existing REACH and BPR legislation.
- An endocrine disruptor expert group was established by Competent Authorities for REACH and CLP (CARACAL).
- Under REACH, substances can be considered as Substances of Very High Concern (SVHC) based on their endocrine disrupting properties that may affect human health or the environment.
- The EU also has an endocrine disruptor assessment list.

How are endocrine disruptors currently displayed on EU SDSs?

For mixtures, information shall be provided for each such substance that is present in the mixture at a concentration $\geq 0.1\%$ by weight.

Section 2.3: Other Hazards

For a mixture, information shall be provided for each such substance that is present in the mixture at a concentration $\geq 0.1\%$ by weight.

Section 3: Composition/information on ingredients

Substance must be listed if above 0.1% and if identified as having endocrine disrupting properties in accordance with the criteria set out in Delegated Regulation (EU) 2017/2100 or Regulation (EU) 2018/605.

- Section 11.2:** Information on other hazards
- Section 12.6:** Endocrine disrupting properties

How will endocrine disruptors be regulated in the future?

CLP Hazard classification proposal for endocrine disruptors

A chemical is defined as an endocrine disruptor if it meets the following criteria:

- Shows an adverse effect in an intact organism or its progeny;
- Shows endocrine activity;
- Has an endocrine disrupting mode of action, i.e., there is a biologically plausible link between endocrine activity and an adverse effect.



CLP Proposed Health Hazard Categories for Endocrine Disruptor

Category 1

Known or presumed endocrine disruptors for human health.

A substance is classified in Category 1 for endocrine disrupting properties for human health if it is known or presumed to meet the criteria defined in 3.11.1.2.

The classification in Category 1 is based on evidence from human and/or animal studies. Such data shall provide clear evidence of endocrine activity, an adverse effect, and that the adverse effect is a consequence of the endocrine activity.

However, when there is information that raises doubt about the relevance of the endocrine disrupting mode of action for humans, classification in Category 2 may be more appropriate.

Category 2

Suspected endocrine disruptors for human health

A substance is classified in Category 2 for endocrine disrupting properties for human health when there is some evidence of an adverse effect, which is a consequence of the endocrine activity, and where the evidence is not sufficiently convincing to place the substance in Category 1

Where there is evidence demonstrating that the adverse effects identified are not relevant to humans, the substance should not be considered an endocrine disruptor for human health.



CLP Proposed Environment Hazard Categories for Endocrine Disruptor

Category 1

Known or presumed endocrine disruptors for the environment.

A substance is classified in Category 1 for endocrine disrupting properties for the environment if it is known or presumed to meet the criteria defined in 4.2.1.2.

Category 1 classification is based on evidence from human and/or animal studies. Such data shall provide clear evidence of an adverse effect that is relevant for the (sub-)population level and which is a consequence of endocrine activity.

If there is doubt about the relevance of the effect for the (sub-)population level, classification in Category 2 may be more appropriate.

Category 2

Suspected endocrine disruptors for the environment

A substance is classified in Category 2 for endocrine disrupting properties for the environment when there is some evidence of an adverse effect that is relevant for the (sub-)population level and which is a consequence of the endocrine activity, and where the evidence is not sufficiently convincing to place the substance in Category 1.

Generic concentration limits triggering classification of a mixture

Ingredient classification:	Category 1 HH/ENV	Category 1 HH/ENV
Category 1	$\geq 0.1\%$	
Category 2		$\geq 1\%$

Proposed Label Elements for Endocrine Disruptors

Health Hazard Label Elements

Classification	Category 1	Category 2
Hazard pictograms		
Signal Word	Danger	Warning
Hazard statement	EUHXXX: May cause endocrine-related adverse effects on human health	EUHXXX: Suspected of causing endocrine-related adverse effects on human health

Environmental Hazard Label Elements

Classification	Category 1	Category 2
Hazard pictograms		
Signal Word	Danger	Warning
Hazard statement	EUHXXX: May cause endocrine-related adverse effects on the environment	EUHXXX: Suspected of causing endocrine-related adverse effects on the environment

Where to find information on endocrine disruptors?

Regulatory sources on endocrine disruptors in the ChemADVISOR™ Regulatory Database

- Endocrine Disruptor Priority List: May 2007 study released by the European Commission (Directorate-General for the Environment)
- European Commission Endocrine Disruptor Candidate List
- EU SVHC Candidate List
- EU Community Rolling Action Plan (CoRAP) List
- ECHA Endocrine Disrupter Assessment List: Substances under endocrine disruptor assessment in REACH or BPR
- Endocrine Disruptor List published by the national authorities of Belgium, Denmark, France, the Netherlands and Sweden
- French Agency for Food, Environmental and Occupational Health & Safety (ANSES) endocrine disruptors assessment program list

Other endocrine disruptor resources:

United States Environmental Protection Agency (EPA) Endocrine Disruptor Screening Program (EDSP)

- Final list of chemicals for tier 1 screening
- Final second list of chemicals for tier 1 screening

Japan – Extended Tasks on Endocrine Disruption (EXTEND) – Selected substances subject to reliability assessment

United Nations Environment Programme (UNEP) – Endocrine Disrupting Chemicals – Table 5

UNEP – Potential Endocrine Disrupting Chemicals – Table 6

Reference

4th Meeting of Competent Authorities Sub-Group on Endocrine Disruptors

