

EU New Hazard Classes 2023 for:

Endocrine Disruptors for Human Health (ED HH)

Substance Classification

Substance alters a function of the endocrine system, resulting in a change in morphology, physiology, growth, development, reproduction or lifespan of an organism/system/population causing impairment.

There should be a biologically plausible link (correlation) between the endocrine activity and the adverse effect in the organism, its offspring or future generations.

A substance must meet all three criteria for classification with evidence for the endocrine disruption, the adverse effect and the plausible link.

Adverse effects that are solely the result of other direct toxicity (already classified) shall not be considered for this hazard class.

Category	Criteria
Category 1	Known or Presumed Human or animal evidence of (a) Endocrine activity and (b) An adverse effect and (c) A biologically plausible link between (a) and (b)
Category 2	Suspected Human or animal evidence of (a) Endocrine activity and adverse effect and (b) Biologically plausible link and (c) Does not meet the criteria for Category 1

Example: Dibutyl Phthalate (CAS# 84-74-2) → ENDOCRINE DISRUPTOR FOR HUMAN HEALTH

Endocrine Activity → Decreased testosterone

Adverse Effect → Reduced sperm quality, Leydig Cell tumours, Repro Tract Malformation

Plausible Link → Cascade reaction: decreased foetal testosterone leading to decreased androgen receptor activity interferes with androgen development

Classification	Category 1	Category 2
Pictogram	-	-
Signal Word	Danger	Warning
Hazard Statement	EUH380 - May cause endocrine disruption in humans	EUH381 - Suspected of causing endocrine disruption in humans
Precautionary Statement Prevention	P201 - Obtain special instructions before use P202 - Do not handle until all safety precautions have been read and understood. P263 - Avoid contact during pregnancy and while nursing P280 - Avoid contact during pregnancy and while nursing	P201 - Obtain special instructions before use P202 - Do not handle until all safety precautions have been read and understood. P263 - Avoid contact during pregnancy and while nursing P280 - Avoid contact during pregnancy and while nursing
P - Statement Response	P308+P313 - IF exposed or concerned: Get medical advice/ attention	P308+P313 - IF exposed or concerned: Get medical advice/ attention
P - Statement Storage	P405 - Store locked up	P405 - Store locked up
P - Statement Disposal	P501 - Dispose of contents/container to ...	P501 - Dispose of contents/container to ...

*Precedence applies, EUH381 should not appear where EUH380 applies

Mixture Classification

		Concentration Limits Triggering the classification of a Mixture as:	
Component	Product CLP Class	ED HH 1	ED HH 2
ED HH 1		C ≥ 0.1 %	-
ED HH 2		-	C ≥ 1 %

*EUH210 applies for non-hazardous mixtures containing => 0.1% of ED HH 2 Substance

Permitted bridging principles

● Dilution ● Batching ● Substantially similar mixtures ● Review of classification