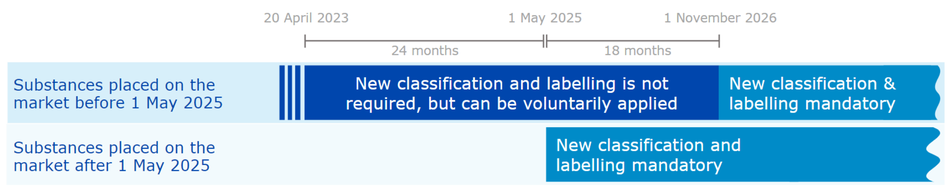
# New Hazard Classes under the CLP regulation

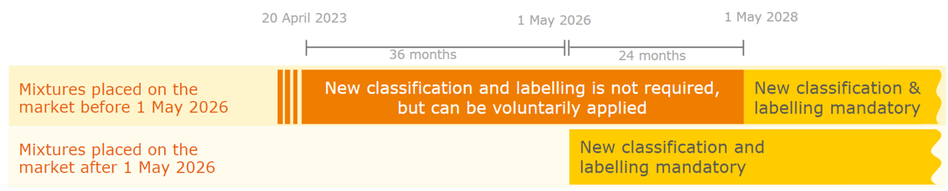
The European Commission has updated the Classification, Labelling and Packaging Regulation with the new hazard classes. The new rules are in force as of 20 April 2023. It applies to all chemical substances and mixtures placed on the EU market under REACH. It also applies to active substances in biocidal products and plant protection products, which are normally prioritised for harmonised classification in the EU.

This EU legislation is binding to manufacturers, importers, downstream users and distributors placing substances on the European Union market. Member States will also refer to the new hazard classes and criteria when making proposals for harmonised classification and labelling.

The new hazard classes will be included in the IT tool IUCLID during spring 2024. From then on, companies will be able to include information related to the new hazard classes in their classification and labelling notifications, REACH registrations and dossiers for product and process orientated research and development (PPORD), as well as in their submissions under the Biocidal Products Regulation and poison centre notifications.

After the transition periods, it will be mandatory for companies to indicate if the substance is classified in any of the new hazard classes.




## The new hazard classes are:

### PBT (persistent, bioaccumulative, toxic), vPvB (very persistent, very bioaccumulative)

| Hazard class and category code | Hazard statement code | Hazard statement |
|---|---|---|
| PBT | EUH440 | Accumulates in the environment and living organisms including in humans |
| vPvB | EUH441 | Strongly accumulates in the environment and living organisms including in humans |

#### Criteria

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| **P** | A substance shall be considered to fulfil the persistence criterion (P) where any of the following conditions is met:<br>(a) the degradation half-life in marine water is higher than 60 days;<br>(b) the degradation half-life in fresh or estuarine water is higher than 40 days;<br>(c) the degradation half-life in marine sediment is higher than 180 days;<br>(d) the degradation half-life in fresh or estuarine water sediment is higher than 120 days;<br>(e) the degradation half-life in soil is higher than 120 days. |
| **vP** | A substance shall be considered to fulfil the 'very persistent' criterion (vP) where any of the following situations is met:<br>(a) the degradation half-life in marine, fresh or estuarine water is higher than 60 days;<br>(b) the degradation half-life in marine, fresh or estuarine water sediment is higher than 180 days;<br>(c) the degradation half-life in soil is higher than 180 days. |

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| **B** | A substance shall be considered to fulfil the bioaccumulation criterion (B) where the bioconcentration factor in aquatic species is higher than 2000. |
| **vB** | A substance shall be considered to fulfil the "very bioaccumulative" criterion (vB) where the bioconcentration factor in aquatic species is higher than 5 000. |

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| **T** | A substance shall be considered to fulfil the toxicity criterion (T) in any of the following situations:<br>(a) the long-term no-observed effect concentration (NOEC) or ECx (e.g EC10) for marine or freshwater organisms is less than 0,01 mg/l;<br>(b) the substance meets the criteria for classification as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B, or 2);<br>(c) there is other evidence of chronic toxicity, as identified by the substance meeting the criteria for classification as specific target organ toxicity after repeated exposure (STOT RE category 1 or 2);<br>(d) the substance meets the criteria for classification as endocrine disruptor (category 1) for human health or the environment |

### PMT (persistent, mobile, toxic), vPvM (very persistent, very mobile)

| Hazard class and category code | Hazard statement code | Hazard statement |
|---|---|---|
| PMT | EUH450 | Can cause long-lasting and diffuse contamination of water resources |
| vPvM | EUH451 | Can cause very long-lasting and diffuse contamination of water resources |

#### Criteria

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| **M** | A substance shall be considered to fulfil the mobility criterion (M) when the log $K_{OC}$ is less than 3. For an ionisable substance, the mobility criterion shall be considered fulfilled when the lowest log $K_{OC}$ value for pH between 4 and 9 is less than 3. |
| **vM** | A substance shall be considered to fulfil the 'very mobile' criterion (vM) when the log $K_{OC}$ is less than 2. For an ionisable substance, the mobility criterion shall be considered fulfilled when the lowest log $K_{OC}$ value for pH between 4 and 9 is less than 2. |

For P and T criteria see above

### ED HH in Category 1 and Category 2 (Endocrine disruption for human health)

| Hazard class and category code | Hazard statement code | Hazard statement |
|---|---|---|
| ED HH 1 | EUH380 | May cause endocrine disruption in humans |
| ED HH 2 | EUH381 | Suspected of causing endocrine disruption in humans |

#### Criteria

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| **Category 1** | **Known or presumed endocrine disruptors for human health**<br>The classification in Category 1 shall be largely based on evidence from at least one of the following:<br>a) human data;<br>b) animal data; c) non-animal data providing an equivalent predictive capacity as data in points a or b.<br><br>Such data shall provide evidence that the substance meets all the following criteria: (a) endocrine activity;<br>(b) an adverse effect in an intact organism or its offspring or future generations;<br>(c) a biologically plausible link between the endocrine activity and the adverse effect.<br><br>However, where there is information that raises serious doubt about the relevance of the adverse effects to humans, classification in Category 2 may be more appropriate. |
| **Category 2** | **Suspected endocrine disruptors for human health**<br>A substance shall be classified in Category 2 where all the following criteria are fulfilled:<br>(a) there is evidence of: i. an endocrine activity; and ii. an adverse effect in an intact organism or its offspring or future generations;<br>(b) the evidence referred to in point (a) is not sufficiently convincing to classify the substance in Category 1;<br>(c) there is evidence of a biologically plausible link between the endocrine activity and the adverse effect. |

### ED ENV in Category 1 and Category 2 (Endocrine disruption for the environment)

| Hazard class and category code | Hazard statement code | Hazard statement |
|---|---|---|
| ED ENV 1 | EUH430 | May cause endocrine disruption in the environment |
| ED ENV 2 | EUH431 | Suspected of causing endocrine disruption in the environment |

#### Criteria

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| **Category 1** | **Known or presumed endocrine disruptors for the environment**<br>The classification in Category 1 shall be largely based on evidence from at least one of the following:<br>a) animal data;<br>b) non-animal data providing an equivalent predictive capacity as data in point a.<br><br>Such data shall provide evidence that the substance meets all the following criteria:<br>(a) endocrine activity;<br>(b) an adverse effect in an intact organism or its offspring or future generations;<br>(c) a biologically plausible link between the endocrine activity and the adverse effect.<br><br>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. |
| **Category 2** | **Suspected endocrine disruptors for the environment**<br>A substance shall be classified in Category 2 where all the following criteria are met:<br>(a) there is evidence of an endocrine activity; and an adverse effect in an intact organism or its offspring or future generations;<br>(b) the evidence referred to in point (a) is not sufficiently convincing to classify the substance in Category 1;<br>(c) there is evidence of a biologically plausible link between the endocrine activity and the adverse effect. |


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