

New CLP Hazard Classes for PBT/vPvB and PMT/vPvM properties

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Overview



Outline the new environmental hazard categories

CLP classification criteria

Labelling elements under CLP

ECHA guidance on application of CLP criteria for classification

HSA

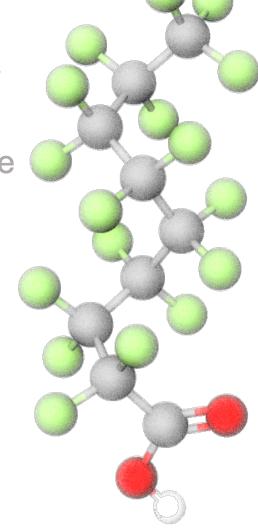
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• PBT – persistent, bioaccumulative and toxic

vPvB – very persistent, very bioaccumulative

PMT – persistent, mobile and toxic

vPvM – very persistent, very mobile





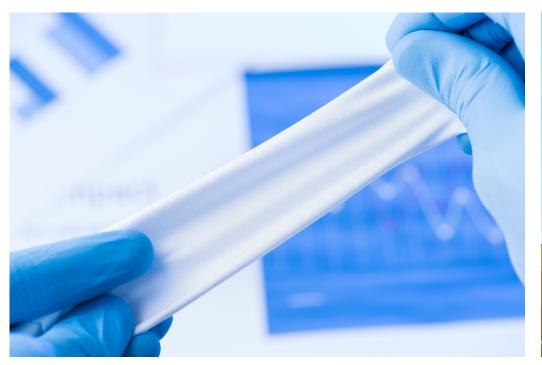
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CLP descriptor for PBT/vPvB and PMT/vPvM properties





P – Persistence
 resistance of chemicals to transformation and degradation processes

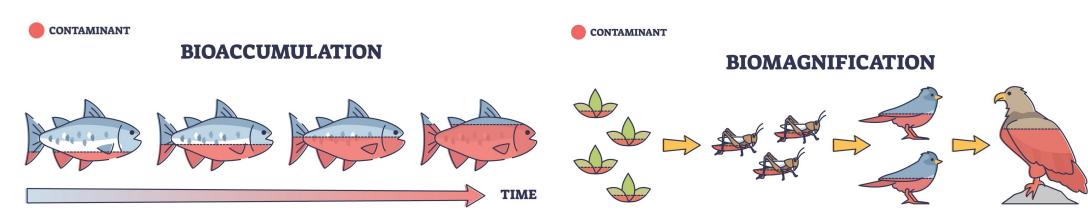








- B Bioaccumulation
 - net uptake, transformation and elimination of a substance in an organism through exposure
 - the accumulation of a substance in living organisms by direct adsorption or through the food chain







T – Toxicity

property of a substance to cause adverse effect to organisms, including humans, through exposure to the substance









M – Mobility

potential of a substance once released to the environment to move under natural forces and reach waterbodies, including drinking water and groundwater, or a distance from the site of release







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CLP criteria for PBT/vPvB and PMT/vPvM properties



CLP criteria for new hazard classes (CLP Annex I) – Persistence



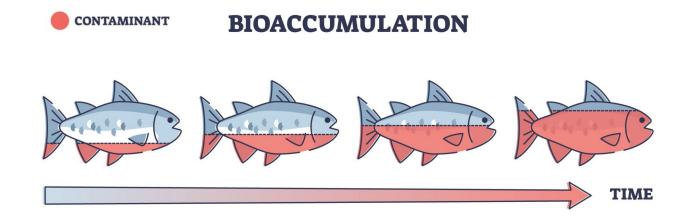
Environmental Compartment	Degradation half-life		
	Persistent	Very Persistent	
Marine Water	>60 days	>60 days	
Fresh or estuarine water	>40 days	>60 days	
Marine sediment	>180 days	>180 days	
Fresh or estuarine water sediment	>120 days	>180 days	
Soil	>120 days	>180 days	



CLP criteria for new hazard classes (CLP Annex I) – Bioaccumulation



- Bioaccumulative: Bioconcentration factor >2000
- Very Bioaccumulative: Bioconcentration factor >5000





CLP criteria for new hazard classes (CLP Annex I) – Toxicity



- Ecotoxicity
 - no observed effect concentration or EC10 for marine and freshwater organisms <0.01 mg/L
- Mammalian toxicity

Hazard class	CLP Category
Carcinogenicity	Cat. 1A or 1B
Germ cell mutagenicity	Cat. 1A or 1B
Toxic for reproduction	Cat. 1A, 1B or 2
STOT RE	Cat. 1 or 2
Endocrine disruption HH & ENV	Cat. 1



CLP criteria for new hazard classes (CLP Annex I) – Mobility



 K_{OC}: Organic carbon to water partition coefficient - reflects the substance ability to be adsorbed on organic fraction of soil, sludge or sediment





CLP criteria for new hazard classes (CLP Annex I) – Mobility



- Mobile : $\log K_{OC} < 3$

- Very : $\log K_{OC} < 2$ Mobile

For ionisable substance mobile criteria will be met is lowest log $K_{\rm oc}$ value at pH between 4 and 9 is below 3





Basis of Classification

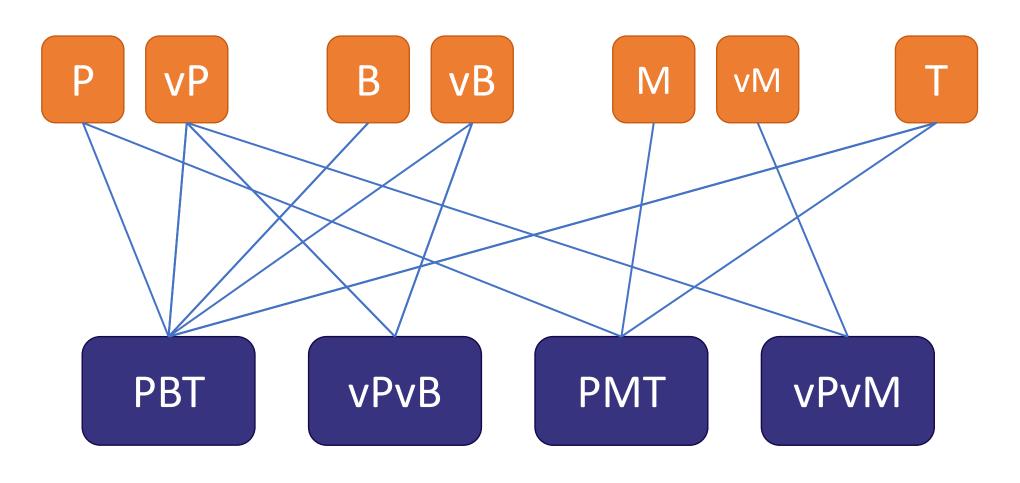


 Classification will be made on the basis of the appropriate criteria, a weight of evidence assessment of each criteria and a weight of evidence determination for classification using expert judgement

PBT/vPvB and PMT/vPvM hazard classes may apply to all organic and organo-metallic substances and mixtures







Classification criteria for mixtures



• A mixture shall be classified respectively as a PBT/vPvB or PMT/vPvM when at least one component contained in the mixture has been classified respectively as a PBT/vPvB or PMT/vPvM and is present at or above 0.1 % (weight/weight).

 Mixtures are considered to include any relevant constituent, additive, impurity and PBT/vPvB or PMT/vPvM assessment can be applied to individual components or the whole mixture





Hazard Communication



Label elements of PBT & vPvB

Classification	PBT	vPvB
Signal Word	Danger	Danger
Hazard Statement	EUH440 : Accumulates in the environment and living organisms including in humans	EUH441 : Strongly accumulates in the environment and living organisms including in humans
Pictogram	Currently no pictogram, may be introduced in GHS	Currently no pictogram, may be introduced in GHS
Precautionary Statement (Prevention, response, storage and disposal	Outlined in Table 4.3.1 in CLP Annex I	Outlined in Table 4.3.1 in CLP Annex I



Hazard Communication



Label elements of PMT & vPvM

Classification	PMT	vPvM
Signal Word	Danger	Danger
Hazard Statement	EUH450: Can cause long- lasting and diffuse contamination of water resources	EUH451 : Can cause very long-lasting and diffuse contamination of water resources
Pictogram	Currently no pictogram, may be introduced in GHS	Currently no pictogram, may be introduced in GHS
Precautionary Statement (Prevention, response, storage and disposal	Outlined in Table 4.4.1 in CLP Annex I	Outlined in Table 4.4.1 in CLP Annex I



Guidance on the application of the CLP criteria part 4: Environmental Hazards





Guidance on the application of the CLP criteria part 4: Environmental Hazards, version 4.0

- Section 4.3 Persistent, Bioaccumulative and Toxic or very Persistent, very Bioaccumulative (PBT/vPvB) and Persistent, Mobile and Toxic or very Persistent, very Mobile (PMT/vPvM) properties
- 4.3.1 **Definitions** and general considerations for PBT/vPvB and PMT/vPvM properties
- 4.3.2 CLP criteria for PBT/vPvB and PMT/vPvM substances
- 4.3.3 Identification and assessment of hazard information for PBT/vPvB and PMT/vPvM substances
- 4.3.6 Classification criteria for PBT/vPvB and PMT/vPvM mixtures



Guidance on the Application of the CLP Criteria

Part 4: Environmental hazards

Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures

Version 4.0 Nov 2024











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Go raibh maith agaibh Thank you



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