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VCI POSITION PAPER ON THE CLASSIFICATION OF PARTICLE EFFECTS UNDER CLP

Avoid classification of substances based on particle effects!

The harmonised classification and labelling (CLH) of particulate, powdery substances under Regulation (EC) No. 1272/2008 (CLP) is increasingly leading to problematic assessments: In recent years, substance classifications have in some cases been made on the basis of long known, unspecific dust effects. The result is serious legal consequences for important areas of application and occupational safety. It is feared that this will initiate a cascade of new classification proposals for particulate substances, which would have serious consequences in the EU. VCI is therefore advocating the development of a clear solution of the described problems herein in order to avoid negative consequences for products that can be used safely.

Particulate substances are widely used in many everyday products:

- In food as food additives,
- In cosmetics and personal care,
- In industrial applications as carriers,
- In tires or polymers, e.g. as additives,
- In pharmaceuticals and medical products,
- In paints and plastics as pigments or auxiliaries,
- In building materials and construction chemicals.

Automatic legal consequences of CLH classifications such as bans in consumer products, restrictions on use in sector regulations, in occupational health and safety as well as reputational image, shown by the example of titanium dioxide (legal review of the classification)

Classification challenges under CLP

Particle/dust effects are not intrinsic properties of substances

The CLP Regulation carries out a hazard assessment based on substance-specific intrinsic properties. In CLH substance dossiers of particulate substances, the hazard classes ‘acute toxicity’, ‘carcinogenicity’ or ‘specific organ toxicity with repeated exposure (STOT RE)’ have recently been discussed more often, mostly with reference to inhalation. The evaluation of the test data often leads to a classification, although it can be shown that similar effects occur with many particulate substances and are based on particle effects.[1] However, particle and dust effects are not intrinsic properties, but are initially associated exclusively with a specific test system and should therefore not be classified under CLP.

Required particle concentrations in animal studies are not scientifically appropriate

The current CLP guideline values for classification into the hazard classes STOT RE 2 and STOT RE 1 of 200 and 20 mg/m^3 respectively for inhalative exposure (CLP Annex I, section 3.9.2.9) are too high for particulate substances. It must be questioned whether systemic and localised particulate effects should be measured on the same scale. High concentrations lead to overloading of the lung's internal cleaning mechanisms and ultimately to inflammatory reactions in the lungs in the case of poorly soluble particles, regardless of their chemical composition. Recently, such effects have been used as a basis for classification.

[1] Klaus Weber *et al.*, *Toxicology Letters*, 399, 49 (2024), https://doi.org/10.1016/j.toxlet.2023.12.011.

Guideline requirements for inhalation studies with aerosols not suitable for CLP
The specifications for OECD inhalation studies with aerosols in rats require the use of alveolar particle sizes (penetrating into the pulmonary alveoli). Particles with no or very low intrinsic toxicity and low solubility are usually not present as respirable particles in air and in solution, but as aggregates and agglomerates and must therefore be artificially reduced in size for studies at great technical expense.[2] The CLP legal text, on the other hand, requires tests to be carried out on substances in the form in which they are marketed and used (Article 8(6)). Technically complex animal testing, which can only clarify the hazard to humans (CLP protection goal) to a limited extent, must be questioned regarding ethical acceptability. Due to this clear discrepancy, the classification of substances based on rat studies with artificially generated particles under CLP should be avoided.

VCI recommendations and demands

For consideration in the harmonised classification of particulate substances:

- **Assess only the relevant particle fraction in the CLH procedure**: If a harmonised classification of a substance is considered necessary for regulatory purposes, only the **relevant particle fraction** of a marketed substance, which triggers adverse health effects, should be assessed and lead to a specific classification – usually the alveolar fraction. The classification of the marketed substance as a whole or its derived products is thus determined on a product-specific basis (e.g. by technical quantification of the particle fraction)
- Revision of the classification guidance values for STOT RE in the Annex of CLP
- According to the CLP legal text, substances should be tested in OECD Test Guidelines in the form in which they are placed on the market and marketed in products

In addition: Development of an **alternative approach** for the regulation of particle effects to avoid inappropriate substance classifications under CLP**:**

- Clear concepts for dealing with particle effects by regulatory bodies are needed
- Cooperation and expert discussions with affected industries to find solutions
- European harmonisation towards a generic dust limit value in occupational health and safety may be a suitable alternative approach

Exposure and limit value-based regulation is the appropriate instrument for regulating general dust effects in the workplace (e.g. general dust limit value according to German TRGS 900). A general European dust limit value is therefore also conceivable as an alternative regulatory approach that can avoid future inhalation studies and simplify the regulation of particulate substances. This places the risk-based approach in the foreground and avoids automatic legal consequences resulting from classification and labelling under CLP in downstream sectors and application.

[2] (1) Franz Lohse *et al.*, *Toxicology Letters*, 399, 73-79 (2024), https://doi.org/10.1016/j.toxlet.2024.02.006; (2)Wolfgang Dekant *et al.*, *Toxicology Letters*, 399, 2-11 (2024), https://doi.org/10.1016/j.toxlet.2023.02.002.

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