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Encapsulation principle masterbatches
Short version

The encapsulation principle

When a hazardous substance is encapsulated in a solid matrix (e.g. plastic), it is encased and immobilised, and its surface area is greatly reduced. Consequently, the individual hazard characteristics of the contained substance are no longer apparent.

Exception in the CLP Regulation

In granulated masterbatch products, colourants and/or additives are embedded in the plastic at high concentrations. As intermediate products in the plastics supply chain, these masterbatches are added to the final plastic product in much smaller quantities. Pure colourants or additives can sometimes be classified as hazardous substances under the CLP Regulation, which would result in the respective masterbatch being given the same classification due to the high concentrations used. However, the CLP Regulation provides an exemption from labelling for mixtures placed on the market (i.e. masterbatches) if proof of their harmlessness to human health and the aquatic environment is provided.

If a masterbatch is classified as a hazardous mixture in accordance with the CLP Regulation due to the raw materials it contains, it is possible in certain cases to dispense with labelling in accordance with CLP Regulation, Article 23 and Annex I Section 1.3.

> ***Annex I***
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> ***1.3.4*** *Metals in massive form, alloys, mixtures containing polymers, mixtures containing elastomers*
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> ***1.3.4.1*** *Metals in massive form, alloys, mixtures containing polymers and mixtures containing elastomers do not require a label according to this Annex, if they do not present a hazard to human health by inhalation, ingestion or contact with skin or to the aquatic environment in the form in which they are placed on the market, although classified as hazardous in accordance with the criteria of this Annex.*
>
> ***1.3.4.2*** *Instead, the supplier shall provide the information to downstream users or distributors by means of the SDS.*

This labelling exemption can therefore be applied if the supplied mixture does not pose a risk to human health or the aquatic environment.
This generally applies to granular masterbatches that do not contain any migrating components.

Results of the study demonstrate a reduced release of hazardous substances from masterbatches

A study[1] carried out by Masterbatch Verband on selected hazardous substances shows that the plastic matrix attenuates the release of a contained hazardous substance, so that - compared to the calculation method of the CLP Regulation - a smaller proportion of the hazardous substance is available externally. The study examined the granulated form, which cannot be inhaled and does not lead to excessive skin contact. Ingestion of the granules is also negligible, even taking into account foreseeable misuse.

[1] *Non-public study, experimental evidence of reduced release of hazardous substances from masterbatches (Technical Commission of the Masterbatch Association (TKM) 28 May 2018)*

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This means that the exposure assessment is limited to brief skin contact with individual granules and release into water, e.g. following a transport accident.

Various granulated masterbatches were tested using an elution process in water at 20°C for eight hours each.

The masterbatches examined contained the following functional additives/colourants (addition quantity under worst-case conditions, highest possible loading):

- Inorganic pigment in LD-polyethylene (LD-PE)
- Antistatic agent in polypropylene (PP) and acrylonitrile butadiene styrene copolymer (ABS)
- Colourant in polycarbonate (PC)
- Organic pigment in polyamide (PA6)
- UV absorbers in polypropylene (PP) and acrylonitrile butadiene styrene copolymer (ABS)
- UV stabiliser in polyamide (PA6)

The mass released into the water was determined gravimetrically and compared to the theoretical release according to the CLP Regulation (maximum value). This results in an attenuation factor FMB, which reflects this reduced release.

Based on the chosen experimental approach and the available measurement results, the calculation can be applied to characterise a granulated masterbatch for the investigated polymers LD-PE, PP, PC and ABS.

Granulated masterbatches based on PA6 cannot be corrected based on the available results. Individual case studies are required that take into account the release of the pure matrix.

In conjunction with the mentioned water-insoluble polymers, it is therefore possible to dispense with the labelling of a hazardous substance masterbatch if, given the same or similar chemical structure and water solubility of the hazardous substance, the labelling threshold specified in Regulation (EU) No. 1272/2008 is not undercut, taking into account the attenuation factor.

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Masterbatch Verband – German Masterbatch Association
The association represents the interests of German manufacturers of colour and additive masterbatches. It is a sector group of Verband der Mineralfarbenindustrie e. V. (VdMi).

The VdMi is listed in the Lobbying Register for the Representation of Special Interests vis-à vis the German Bundestag and the Federal Government (Lobbyregister des Deutschen Bundestags, number R000760) as well as in the Transparency Register of the EU Commission (number 388728111714-79).