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Eurocolour information on nano specific information in safety data sheets

The safety data sheet (SDS) as implemented in REACH Annex II is the most typical way to pass information along the supply chain. Even though it is limited to and thus only mandatory for hazardous substances, it is nowadays common market practice to provide a SDS, whether legislation requires one or not.

From January 2023 at the latest, REACH Annex II demands a new format for the SDS including nano specific information. With this information letter, Eurocolour would like to break down what the new requirements are, for which nanomaterials they will be mandatory and how companies may handle this amendment for voluntary SDSes.

As there is so far no common, harmonized definition of a nanomaterial across all product specific regulatory sectors, communication within the supply chain is a key factor to provide relevant information to customers and further downstream users.

REACH Article 31 and Annex II – the basis of a SDS

Safety data sheets (SDS) were included in the UN GHS and implemented in the EU via the REACH Regulation[1] to ensure users of hazardous substances or mixtures have sufficient information for safe use, meaning protection of employee's health and of the environment.

REACH Article 31(1) defines for which substances and mixtures a SDS is mandatory:

a) Substances and mixtures fulfilling the classification criteria according to the CLP Regulation[2]
b) Substances fulfilling the PBT or vPvB criteria[3] according to REACH Annex XIII.
c) Substances listed in REACH Annex XIV (authorization list)

Additionally, a SDS for mixtures is mandatory in the cases described in REACH Article 31(3):

a) The concentration of a substance hazardous for human health or the environment exceeds 1 %wt. (0.2 %vol. for gases)
b) The concentration of a substance falling under specific hazard classes[4] exceeds 0.1 %wt.
c) Mixture includes a substance for which there are community workplace exposure limits[5]

Requirements for the compilation of a SDS are laid down in REACH Annex II.

Nowadays, SDSes are often also provided for non-hazardous substances and mixtures, giving additional, non-mandatory information and/or advice for safe handling, storage, and so on. Even though this information could also be provided in a technical data sheet for example, the

[1] Regulation (EC) No. 1907/2006, available e. g. on EUR-Lex.
[2] Regulation (EC) No. 1272/2008, available e. g. on EUR-Lex.
[3] PBT = persistent, bioaccumulative, and toxic; vPvB = very persistent, very bioaccumulative.
[4] Carcinogen (cat. 2), toxic for reproduction (cat. 1A, 1B, or 2), skin sensitizer (cat. 1), respiratory sensitizer (cat. 1), substances affecting lactation, PBT, vPvB, or substances listed in REACH Annex XIV.
[5] National occupational exposure limits (OEL) for which there is no (binding or indicative) OEL on EU level do not trigger this condition.

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comfort of sticking to one, harmonized system facilitates information processing and communication in a standardized fashion. However, the requirements laid down in REACH Annex II only strictly apply to substances and mixtures requiring a SDS according to REACH Article 31. Since many companies align voluntary SDS or SDS-like documents with these requirements of Article 31 to facilitate processing for their customers in the supply chain, it is important to differentiate between cases where legal requirements apply and cases where additional information are given on a voluntary basis.

Irrespective of these facts, the information requirements according to REACH Article 32 for substances that do not require a SDS must also be observed. These include e. g. the registration number, information on authorizations or restrictions, and necessary information for appropriate risk management measures including exposure scenarios.

Nanoforms under REACH

Since January 2020, nanomaterials need to be registered separately under the REACH Regulation. The term *nanoform* was introduced which is in line with the current recommendation for a nanomaterial definition[6].

To register a nanoform under REACH, specific information requirements must be fulfilled. This way, a full assessment of possible hazards, exposure, and risk can be performed for these nanomaterials. So far, 149 substances[7] have been registered with at least one nanoform. A minimum of 97 of these substance dossiers were updated by Eurocolour members as lead registrants. As a result, pigments and fillers affected by the definition currently represent the majority of registered nanoforms.

With the revised REACH Annex II, nano specific information will become mandatory in SDSes from 1st January 2023 onwards. This covers all information necessary to identify the nanoform according to REACH Annex VI, Note 2, sub-section 2.4.2 – 2.4.5: number-based particle size, surface treatment and/or functionalization, morphological features including particle form, crystallinity and surface area.

However, Annex II in general is only binding if the legal text requires a SDS (see REACH Article 31) for the substance or mixtures. Therefore, the requirements of REACH Annex II do not apply for pigments and fillers not classified as hazardous, irrespective of whether nanoforms are present or not.

Special regulatory requirements for nanomaterials

Even though it has yet to be demonstrated that commercial nanomaterials on the market exhibit any additional/new hazardous properties in comparison to the bulk form of the same material, several regulations require special treatment of nanomaterials. Additional information requirements, separate notification and authorization obligations and labelling requirements may apply. For an overview of nano specific requirements in some of the most relevant regulations, please see also the *Comparative compilation of relevant nano definitions in different regulations and their corresponding consequences*[8] from Verband der Mineralfarbenindustrie (VdMi), the German's association for manufacturers of pigments and fillers and member of Eurocolour.

[6] Revised recommendation published on 10th June 2022 and available e. g. on EUR-Lex.
[7] Status: 8th April 2022. Figures given by ECHA at the 15. Internationaler Behördendialog on 12th May 2022 in Luzern.
[8] Available for download on the VdMi homepage.

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As there is so far no common, harmonized definition of a nanomaterial across all product specific regulatory sectors, the same product may be treated as a nanomaterial under one regulation but does not fulfill the nano criteria of another regulation. As a result, manufacturers simply cannot give a general answer, whether a product is a nanomaterial. Statements can only be given with reference to the respective application and its nanomaterial definition. This limits the suitability of the SDS as an appropriate communication tool on the nanomaterial status of the product.

Possible means to provide nano specific information in cases where a SDS is not required

Most pigments and fillers do not legally require a SDS as they do not fall under one of the hazard classes included in REACH Article 31 and there are no EU-based OELs. National (exposure) limits or values like e. g. the standard assessment value for nanomaterials implemented in the German TRGS 527[9] are not considered an EU-based OEL. Therefore, the requirements of REACH Annex II do not apply for most pigments and fillers.

In general, there are several options to communicate nano specific information to users in cases where a SDS is not legally required. Some of them are listed below. This listing is only illustrative and should not be considered as being comprehensive. There may also be other communication possibilities.

- Companies may stick to the requirements laid down in REACH Annex II.[10] These SDS will include all information as described above. Such a SDS may be marked with phrases like “SDS according to REACH Annex II”.
- Companies may separate general information given in a SDS from application specific information whether or not a nanomaterial is present according to the nano definition relevant for the respective application. In this way, confusion based on the differences in nano definitions can be avoided. Such a SDS may follow the same structure as laid down in REACH Annex II but may also be named “technical information”, “product data sheet”, or likewise.
- Companies may provide information in other document forms (different structure, different sections/headings, and so on) than a typical SDS.
- Companies may also provide no information at all if there is no legal requirement.

Information for customers and downstream users

Based on a survey among the Eurocolour members, the manufacturers of nanomaterials plan to use different means to provide their customers with information on their products including nanoforms.

Even though the changes in REACH Annex II have no influence on obligations laid down in product specific regulations for nanomaterials, we recommend contacting your supplier directly in case of any questions regarding possible consequences of updated information. Additionally, do not hesitate to contact Eurocolour for general information on nanomaterials/-forms within the pigments and fillers industry.

[9] See also TRGS 527, section 3.3.4 (download only available in German).
[10] See for example the initiative *Responsible Care* by the German Chemical Industry Association (VCI).

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About Eurocolour:

Eurocolour e. V. is the umbrella association for manufacturers of pigments, dyes, fillers, frits, ceramic and glass colours, and ceramic glazes in Europe.