

REACH REGULATION 1907/2006/EC

GENERAL INFORMATION

The European Regulation 1907/2006 coming into force on 1st of June 2008 rules the assessment of chemical substances, which were premarket before 1983. These substances are called phase-in-substances. In the opinion of the European authorities producers should hold responsibility for safe handling and chemical assessment because of their knowledge about associated risks for both the human health and the environment. With REACH the producers of chemical substance are obliged to make sure the safe handling of their products.

For this purpose all manufacturers had to pre-register their phase-in-substances within 1st of December 2008 to keep on selling their products.

Now, further steps depend on the annual production quantity, which determines the information that must be contained in the registration dossier e. g. exposure scenarios and risk management measures. This registration dossier will be evaluated by the European Chemical Agency (ECHA) and for single cases an authorization may result. At that time, mostly manufacturers of chemical substances have special obligations under REACH.

OUR OBLIGATION UNDER REACH

Our Masterbatches consist of two or more substances and are defined as mixtures or preparations. Those are not subject to registration, and as a formulator, our role under REACH is a Downstream User. Since the pre-registration period has ended on 1st of December we are allowed to use only substances that have been pre-registered. On our current knowledge we act on the assumption that all of our masterbatches are compliant to the new REACH regulation.

SUBSTANCES OF VERY HIGH CONCERN (SVHC)

Regarding the Substances of Very High Concern SVHC, the Title VI of the REACH Regulation presents:

- Article 57 states criteria to consider a substance as a SVHC
- Article 59 describes the process to identify and to add a Substance of Very High Concern to the Candidate List
- In Article 58 the process to include the substances identified by the Candidate List in Annex XIV „List of substances to Authorisation“ the Agency will make the first priority list to be included in Annex XIV by 1st June 2009.

Analyzing the information available from our suppliers and considering that REACH Annex II obliges the chemical manufacturer to indicate on the Material Safety Data Sheet (MSDS) the presence of substances showing a health or environment hazard within the meaning of the Directive 67/548/EEC and of substances that are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), if their individual concentration is greater than 0.1% w/w.

Therefore, we kindly ask you to check our MSDS to identify, if any SVHC are in the formulation. In case our MSDS is issued in accordance with the REACH Regulation, you will find the information in chapter 3. If the MSDS is issued before 1st June 2006, it is still valid and the data is stated in Chapter 2.

Every time our suppliers give us new information, you can derive this relevant information to evaluate the SVHC status of your finished article taking into account the list on the ECHA homepage and the data in chapter 3 of our MSDS.

If you don't have a MSDS for your product you may apply for it.



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In the near future there will be some changes regarding the Material Safety Data Sheet. Since the new Regulation EG 1272/2008 entered into force on 20th of January 2009, a new system of classification, labelling and packaging of substances and mixtures are adopted. This regulation is sometimes mentioned as EU-GHS or CLP regulation and repeals the guidelines 67/548/EEC for substances and 1999/45/EG for preparations. There is a transition period until 01st of December for substances, after this period the classification, labeling and packaging should be in accordance with the new regulation. For mixtures the transition period ends on 1st of June 2015.

It is not necessary to make a declaration on both classification systems in the MSDS.

Recipients of our product must take responsibility for observing existing laws and regulations. The information submitted in this publication is based on our current knowledge and experience. In view of the many factors that may affect during processing and application this data should not be viewed as a sure guarantee, either for profession description or for detailed application.

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