Masterbatch
(Farbkonzentrate)
Für alle thermoplastischen Kunststoffe

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PRODUCT SAFETY OF MASTERBATCHES

Our products are tailor-made for the application of our customers and therefore they have to comply with different legal requirements, both national and international.

Below you will find an overview of the intended uses of our masterbatches and of legal requirements corresponding with each application, for which both the pigments/dyes and the carriers have to be considered.

Since all subsequent regulations refer to the final article, our declarations do not absolve the manufacturers and distributors from their obligations to implementing their own migration testing.

A Food Contact Materials and Drinking Water

For plastics intended to come into contact with food the European Regulation (EU) No. 10/2011, called "Plastics Implementation Measure" with all its amendments is applying. There is a Whitelist included in Annex I of the PIM named Unionlist containing all substances to be approved for food contact including monomers and additives.

Color-Service is using the Unionlist to check the compliance of the materials to the food: drinking water.

Pigment/dyes are excluded from the Unionlist and national legislative is applicable. However, the supplier is maintained to confirm that it is in accordance with Regulation (EC) no. 1935/2004. As per Article 3 of this Regulation human health is not endangered or in accordance with Regulation (EU) 10/2011 (Article 19) the supplier is obliged to risk analysis and must eventual communicate the hazard potential in the supply chain.

Germany

In Germany, for articles coming in to contact with food the „Lebens- und Futtermittelgesetzbuch", stipulates in §30 and §31 that the human health should not be derogated. For this reason, there are several purity requirements for colorants, polymers and additives and particularly their constituents must not migrate from the plastic material into food. The Bundesinstitut für Risikobewertung (BfR) is registering all purity requirements.

Europe

The European Community has settled purity requirements for pigments in the European Resolution AP (89) I which is consistent with the register of BfR.

USA

In the US, the Food and Drug Administration (FDA) is regulating the demands for food contact materials in the Codes of Federal Regulation (CFR). Especially PART 178 of the 21. CFR is applying for colorants (dyes, pigments) also including their intended use and conditions of use.

B Toys

The requirements for the safe handling of toys are determined in the European Directive 2009/48/EC and the European Standard EN 71 part 3 is implementing them in terms of the restrictions of 19 heavy metals. Quite a number of organic substances, hazardous to the health of children, are regulated in part 9.

C Packaging

European directive 94/62/EC rules the handling of waste; packages are also regulated hereunder. For these an overall amount of 100 ppm of the toxic heavy metals cadmium, lead, mercury and hexavalent chromium should be considered. These limitations are adopted from the CONEG regulation (Coalition of Northeastern Governors).

D Automotive industry

In the past the recycling of raw materials became more and more important. For this reason the European Community issued the directive 2000/53/EG, better known as ELV „End of life vehicles“. Here, the toxic heavy metals cadmium, lead, mercury and hexavalent chromium are banned unless otherwise stipulated for technical reasons.

E Electro and Electronic Industry

Also in the industry for EE-Equipment the above mentioned toxic heavy metals are prohibited. Furthermore, the use of polybrominated biphenyls (PBB) and polybrominated diphenyl ether (PBDE) acting as flame retardants is banned. Our color concentrates fulfil the requirements of the RL 2002/95/EC (RoHS = Restriction of Hazardous Substances) replaced by RL 2011/65/EU (effective since 03.01.2013).

F Medical Products

The product liability for medical products is focused on testing of the final article. Not all regulations do contain instructions of the quality of raw materials due to the fact that suppliers of raw materials are partly not able to issue a statement of physiological harmlessness respectively.

We have to divide medical articles into pharmaceutical packaging and medical devices.

Pharmaceutical packaging
The requirements of medical packaging are defined in the European Pharmacopoeia (EurPh), chapter 3 “Materials for production of containers”. Unless otherwise stipulated in the chapters 3.1.X, which are regulating the chemical constitution of plastics, pigments and additives must follow the approvals of the national authorities. According to the German BfR a substance is suitable if the food contact conditions are fulfilled.

For the use of pigments for medical packaging made of plastics we have to distinguish between primary and secondary packaging.

A. Secondary packaging

This kind of packaging does not get direct in contact with drugs and therefore it is not subject to specific regulations. For this reason suppliers of dyes recommend pigments that are physiological harmless, do not migrate, comply with BfR recommendation and do not contain lead or cadmium.

B. Primary packaging

For products with oral application pigments may be safely used in accordance with the corresponding chapters of the EurPh if they meet the demands as described for secondary packaging.

If the final article is set for parenteral use, in most cases any coloration is not permitted and also manufacturers of colorants do not give any recommendation for these purposes.

Medical devices
For the coloration of medical devices which come in contact with body fluids or viscera the manufacturers of colorants do not provide any statement of physiological harmlessness because in general there are no purity requirements existing for colorants for this kind of application.

Concerning the product safety of our masterbatches you will get our product information, which we will make available upon request. 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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