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Information Sheet:

Colorants and additives for pharmaceutical packaging / medical devices

Requirements regarding the quality of pharmaceutical packaging are specified in the “European Pharmacopoeia” (Ph. Eur., 11th edition 2023). Under 3.1 "Materials used for the manufacture of containers", 3.2 "Containers", 3.2.2 "Plastic containers and closures for pharmaceutical use", and 3.3 “Containers for human blood and blood components, and materials used in their manufacture; transfusion sets and materials used in their manufacture; syringes”, it is stated that if the relevant subsections of the European Pharmacopoeia contain no specific provisions any colorants and additives used must be approved by the appropriate national authorities.

With regard to the use of colorants and additives in plastics for pharmaceutical packaging and medical devices, there is no specific European or global regulation. It varies from jurisdiction and jurisdiction.

1. Pharmaceutical Packaging

Pharmaceutical packaging is part of the pharmaceutical drug registration. The requirements depend on the risk class of the end application.

In so-called “Secondary Packaging”, the packaging does not come into direct contact with packed pharmaceuticals or drugs. In this case, colorants or additives used for secondary packaging are not subject to any official legal requirements or recommendations.

In Europe, we recommend for this purpose masterbatches produced from raw materials (colorants, additives, polymers etc.), that meet following requirements:

- Compliance to European Plastic Waste Packaging Directive 94/62/EC, which limits the content of heavy metals up to 100 ppm (Cd, Pb, Hg, Cr (VI));
- Compliance to Regulation (EU) No 10/2011 (and its amendments) for utilised polymer carriers and the intentionally added additives;
- All colorants used should meet the requirements established in European Resolution AP (89) I in regard to the maximum permissible levels of heavy metals, primary aromatic amines, sulphonated aromatic amines and polychlorinated biphenyls.

Primary packaging, i.e. plastic containers for pharmaceutical purposes intended to hold medicinal products are or can be in direct contact with pharmaceuticals. The closure is part of the container. Such plastic containers can be made from materials with certain additives. Types and quantities of additives depend on the types of polymers used, production processes and intended purpose of the container. Relevant descriptions are provided in the Pharmacopoeia.

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To ensure compatibility of containers and packed goods (preparations), manufacturers of containers must perform several tests: Adsorption behavior of a preparation in respect of the plastic container, migration behavior of constituents of the plastic container, impairments to the stability of the preparation, toxicity risk etc.

For products administered by parenteral means (injection preparations, units of blood etc.) coloration is prohibited in almost all cases. Exemptions are ultramarine blue used in plasticized PVC containers for blood, plasma and aqueous solutions for intravenous infusion (3.1.1.1) as well as titanium dioxide as a light stabilizer in polyolefin (3.1.3), provided this is not ruled out by more specific requirements in another section.

2. Medical devices

Normally no Product Stewardship statements can be issued confirming the physiological safety of plastic colorants and additives for the purpose of production of medical devices.

The medical device is an instrument, apparatus, in-vitro agent etc. to diagnose, prevent or treat disease or others. The medical device application is highly regulated. It varies globally from jurisdiction.

The requirements depend on the risk class of the end application. The approval of the end application requires a considerable amount of data on plastic raw materials, converting steps and safety assessments.

There is no specific regulation for all plastic raw materials. In the EU, all medical devices have to be identified with the CE mark.

Nevertheless, some masterbatch producers offer an extra portfolio of color and additive masterbatches intended for medical device applications. These dedicated masterbatches are produced with selected raw materials under controlled conditions according to ISO 13485:2016-03 standards (Medical devices – Quality management systems – Requirements for regulatory purposes).

For further information, please contact your personal masterbatches sales contact.

Disclaimer

This information corresponds to the present state of knowledge and is intended as a general description of our products and their possible applications. We make no warranties, expressed or implied, as to the information’s accuracy, adequacy, sufficiency or freedom from defect and assume no liability in connection with any use of this information. Any user of this information is responsible for determining the suitability of our products for its particular application. Nothing included in this information waives any of our General Terms and Conditions of Sale.

Since we have no influence on subsequent processing, this information cannot be extended to finished material or article. Indeed, the compliance of the end material or article with pharmaceutical packaging or medical device regulations is in responsibility of the converter. He is committed to meet all relevant legal requirements and to test the migration limits according to conditions of use (temperature, time, simulants) of the article in its finished form

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(e.g. volume, geometry, thickness). These conditions are not part of our knowledge and therefore not under control of the masterbatch producer.

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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).