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., 4th edition 2002). Under 3.1 "Materials used for the manufacture of containers", 3.2 "Containers" and 3.2.2 "Plastic containers and closures for pharmaceutical use", 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, it is necessary to distinguish between primary and secondary packaging:

1. Secondary packaging

According to the German Federal Institute for Risk Assessment (BfR, formerly BgVV), substances are considered suitable in Germany if they conform to applicable food and drugs regulations. Packaging that does not come into direct contact with the packed goods, in this case pharmaceuticals, is not subject to any further legal requirements or official recommendations.

We recommend for this purpose products that:
- are physiologically safe
- do not migrate,
- meet the requirements of Recommendation IX of BfR with regard to contents of heavy metals and comply with the European Directive 94/62/EC (CONEG Regulation)

2. Primary packaging

Plastic containers for pharmaceutical purposes are intended to hold medicinal products. They are or they can be in direct contact with these products. 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.

To ensure compatibility of containers and packed goods (preparations), manufacturers of containers must perform several tests: Adsorption behaviour of a preparation in respect of the plastic container, migration behaviour 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 polyolefins (3.1.3), provided this is not ruled out by more specific requirements in another section.
3. Pharmaceuticals and medical devices

For the following reasons, no statements can be issued confirming the physiological safety of colorants for the purpose of coloring infusion tubes, suture materials or other medical materials and equipment that come into contact with body fluids or internal organs:

- There are no general purity requirements to colorants for these applications.
- The specifications in the various monographs on specific substances (e.g. iron oxide, titanium oxide etc.) are not part of normal quality control.
- Colorants are produced in large-scale industrial processes and not primarily for the medical sector.
- All regulations relevant to the above-mentioned applications specify testing of the final product, i.e. the ultimate responsibility lies with the manufacturer of the final product. The final product should be tested according to the Medical Devices Directive 93/42/EEC and ISO 10993.

Additional information

As masterbatch manufacturers have no influence on downstream processing conditions, it is up to processors to perform with their final products the tests regarding compliance with national and international laws, regulations and any other applicable provisions.