Importance Of Pre-coloured ABS in Inhalation Medical Devices

Medical device bright and intense colours are relevant for patients because they stimulate a positive attitude to take the drug medication, they help the distinction of different device part and facilitate the way how to use the device itself. In addition, they help to distinguish different types of drugs that are targeting to different types of diseases. Despite colour in medical device applications is such a key property, there are strict regulatory limitations in the type of pigments admitted in the colour formulations, and in their maximum allowed concentrations. When the biocompatibility requirement according to ISO 10993 must be met, not only the base ABS material must be biocompatible but also all the additives compounded with the material, including the colour formulation with all its different pigments. No biocompatible pigments must be directly excluded, and maximum allowed pigment concentrations must not be exceeded. Furthermore, special attention must be given to possible mutual interactions among different pigments, ABS material and other additives. ELIX Polymers eliminates those risks to OEMs, processors and developers providing a medical pre-coloured ABS material formulation that includes the complete colour recipe and does not need any further material modification. The complete formulation has been fully reviewed and pre-tested to meet biocompatibility according to ISO 10993 and other regulatory requirements. This is a much safer approach for medical OEMs and moulders instead of choosing a medical ABS in natural colour and compound it themselves with a masterbatch colour, during the injection moulding process.

The ABS market offers mostly natural ABS, forcing processors, OEMs and moulders to buy natural ABS and assume most responsibilities and risks, additional quality control costs and regulatory compliance verifications at different development and production stages.

As mentioned, in the case of pre-tested precoloured medical ABS, the material formulation must not be modified by the customer, reducing responsibilities, supporting the medical device approval process, and avoiding the risk of compounding mistakes during the injection moulding production process. All required medical compliance certifications are already provided by ELIX and are referring to the complete material formulation, including all included colour pigments, additives, and related concentrations.

Regulatory compliance is a pre-requisite for inhalation medical device, but there are also other important quality properties that are strictly related with colour: its homogeneity along the complete device part, its consistency from lot to lot productions, or required colour target contrast in case of surface laser marking (typically for traceability reasons to comply with UDI EU MDR and US CFR regulations). In all these cases colour deviations are not admitted, and a pre-coloured ABS can bring again relevant advantages when compared with natural material post coloured (with masterbatch during the injection moulding process).

Pre-coloured ABS is obtained during a compounding extrusion process, mixing the ABS intermediate materials directly with colour pigments in powder form. Three important elements to consider come into play at this point to optimise dispersion homogeneity in the material compound: the type of technology used (extrusion compounding), the fact that the colour pigments are in powder form, and the mixing step that happens when the base ABS material is not already a compound but still a “set of ingredients” made of different ABS intermediates raw materials, like for example the ABS rubber phase, which also comes in powder form, and the ABS matrix phase (SAN). This combination of factors is not possible in the case of an injection moulding process, as injection moulding machines are not specifically designed to mix optimally different ingredients together but to melt, feed and inject specific types of materials into a mould in a reasonable cycle time. On the other hand, compounding extrusion machines can handle powder recipes and have a specific double screw design that optimises dispersion homogeneity. Twin screw extruders have the right length, L/D relation and helical elements shape to provide adequate compound mixing and better interaction of all ABS intermediate raw materials, but also better interaction with pigments and additives employed. In this way pre-coloured ABS offers better colour pigment dispersion and homogeneous distribution, which is consistent from lot to lot, and also laser marking enhancers benefit of this optimal compounding ability.

In the case of natural ABS post coloured during the injection process, there is also an additional product needed which does not exist in the situation of pre-coloured ABS: a colour masterbatch. This includes a carrier (an additional material to the ones mentioned until now) and a concentration of colour pigments. The carrier is needed to incapsulate the colour pigments and help the pigment distribution with the natural ABS during the injection moulding process. Due to the mentioned compounding limitations during the injection moulding process, the targets of colour dispersion and lot to lot consistence are more difficult to achieve compared to pre-coloured ABS. Masterbatch carrier compatibility with base material and other additives must be assured, and production personnel needs additional training and competences for colouring with masterbatch and managing possible unexpected situations (*e.g.* colour differences in different injection cycles, production stop, colour trouble shooting, specific interactions between ABS with MB carrier or colour formulation). Even when colour targets may be achieved with a masterbatch, there is still the doubt of biocompatibility compliance of the final compound ABS + Masterbatch for the easy reason that no biocompatibility test according ISO 10993 will be conducted on the resulting compound. Such test must be conducted on the final devices for medical approval but not before. Instead, in the case of ELIX pre-coloured medical ABS, the biocompatibility tests are already conducted and passed on the complete compound ABS + colour formulation + additives.

When it comes to sustainable design for medical devices, colour quality turns into an even more critical and sensitive property that needs to be preserved. The demand for new sustainable ABS materials for drug delivery devices applications is growing in the healthcare sector. Due to the risk of cross contamination, medical regulatory compliance cannot be fully fulfilled with mechanically recycled ABS materials. On the other hand, the new scenarios of chemically recycled and bio-based ABS materials are already available and offer the same exact chemical composition and properties of virgin medical ABS, fulfilling the same drug delivery applications along with medical regulations requirements. All the colours that are available in the virgin medical ABS version can be also used in the bio-circular version, guaranteeing not only regulatory compliance, but also the availability of bright and intense colours in chemically recycled ABS formulations. These types of colours cannot be achieved in any case with mechanical recycled content.

ELIX vision is to be a driving force of the new plastics economy in the next years, participating in the redefinition of plastic waste as raw material. The mission is offering top-of-the-line sustainable solutions in our markets, promoting the transformation of the value chain towards a circular economy model.

The company was the first ABS manufacturer to get the International Sustainability and Carbon Certification (ISCC+ certification) for sustainable materials. The certified raw materials content of ELIX M203FC and M205FC medical grades can be adapted according to the customer OEMs' sustainability targets.

ELIX medical ABS formulations with chemically recycled and/or bio-based content have been approved by the FDA for the inclusion in the same Drug Master Files (DMF) of standard virgin ELIX medical ABS formulations M203FC and M205FC. This will support an easier transition towards the use of more sustainable ABS medical materials in drug delivery devices in the coming years.

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Graduated in management engineering at the "Politecnico di Milano" University (Milan, Italy), Luca has 20 years' experience in the fields of plastics, composites and OEMs devices. Luca joined ELIX Polymers in 2017 in the position of Business Development Manager for the healthcare strategic sector. Since 2020 he is actively involved in the development of ELIX E-LOOP sustainable solutions and circular innovations, that include a new growing sustainable ABS and blends material portfolio, with chemically recycled, bio-attributed, bio-based and mechanically recycled content. Luca wrote several technical articles on behalf of ELIX about specialties and sustainable ABS for medical applications that were published on several renowned medical and pharmaceutical magazines. He lived in different European countries and speaks fluently 6 languages (Italian, English, German, Spanish, French and Catalan).