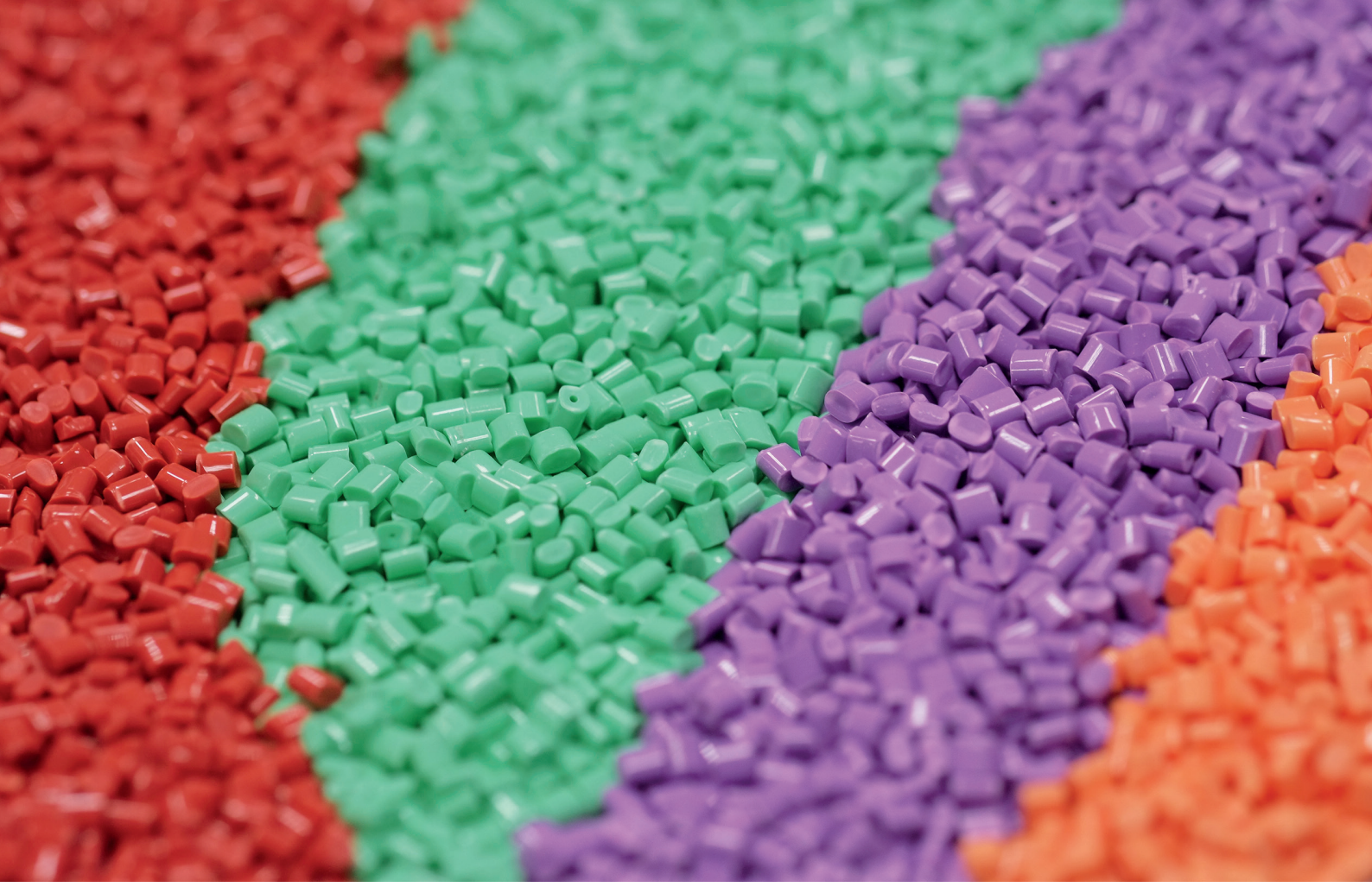

IMPORTANCE OF PRE-COLOURED ABS IN INHALATION MEDICAL DEVICES

ELIX POLYMERS | A member of Sinochem International

Luca Chiochia of **ELIX Polymers** discusses the vital role of coloured plastics in medical devices and how the use of pre-coloured, pre-tested solutions can provide not only a significantly reduced regulatory burden for device developers and manufacturers but also a higher quality end product, going on to explain how the company is approaching the critical subject of producing more sustainable polymers.

Medical devices with bright and intense colours are relevant for patients because they stimulate a positive attitude to taking their medications, as well as helping to differentiate device parts and indicate how to use the device correctly. Additionally, distinct colours help to distinguish different types of drugs that target different disease areas.

However, despite colour in medical device applications being such a crucial property, there are strict regulatory limitations on the types of pigments permitted to be used in colour formulations and on their maximum concentrations. According to the requirements set out in ISO 10993, not only the base acrylonitrile butadiene styrene (ABS) material must be biocompatible but also all the additives compounded with the material, including the colour formulation with all its various 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 between different pigments, ABS and other additives. ELIX Polymers eliminates those risks for original equipment manufacturers (OEMs), processors and developers by providing a pre-coloured medical-grade ABS material formulation that includes the complete colour recipe and does not need any further material modification. As such, it is invaluable for OEMs to have access to a reviewed and pre-tested formulation that meets biocompatibility standards according to ISO 10993 and other regulatory requirements.

"PRE-COLOURED ABS IS A MUCH SAFER APPROACH FOR MEDICAL OEMS AND MOULDERS, RATHER THAN USING A MEDICAL-GRADE ABS IN NATURAL COLOUR AND COMPOUNDING IT THEMSELVES WITH A MASTERBATCH COLOUR DURING THE INJECTION MOULDING PROCESS."

PRE-COLOURED ABS

Pre-coloured ABS is a much safer approach for medical OEMs and moulders, rather than using a medical-grade ABS in natural colour and compounding it themselves with a masterbatch colour during the injection moulding process. However, the ABS market primarily offers 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 prior, in the case of pre-tested and pre-coloured medical ABS, the material formulation is not modified by the customer, which reduces their responsibilities, facilitating the medical device approval process and avoiding the risk of compounding mistakes during the injection moulding production process. For ELIX's pre-coloured ABS, all required medical compliance certifications can be provided with reference to the complete material formulation, including all included colour pigments, additives and related concentrations.

Regulatory compliance is a prerequisite for medical devices, but there are also other important quality properties that are strictly related to colour, including homogeneity throughout the complete device part, consistency from lot-to-lot productions and required colour target contrast in case of surface laser marking (typically for traceability reasons to comply with unique device identification regulations). In all of these cases, colour deviations are not permitted, and a pre-coloured ABS can offer advantages compared with natural materials 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 come into play at this point to optimise dispersion homogeneity in the material compound:

- The type of technology used, such as extrusion compounding
- The fact that the colour pigments are in powder form
- 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, such as the ABS rubber phase (which also comes in powder form) and the ABS matrix phase.

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 different ingredients together optimally, but rather to melt, feed and inject specific types of materials into a mould within a reasonable cycle time. On the other hand, extrusion compounding machines can handle powder recipes and have a specific double-screw design that optimises dispersion homogeneity. Twin-screw extruders not only have the right length, length/diameter relationship and shape of helical elements to provide adequate compound mixing and a better interaction between the ABS intermediate and raw materials, but also have a better interaction with the 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. Furthermore, laser-marking enhancers benefit from this optimal compounding ability.

In the case of natural ABS post-coloured during the injection process, there is also an additional product needed that is not required for pre-coloured ABS: a colour masterbatch. This includes a carrier (an additional material to the ones mentioned prior) and a concentration of colour pigments. The carrier is needed to encapsulate the colour pigments and help the pigment distribution within the natural ABS during the injection moulding process. Due to the compounding limitations during the injection moulding process, the targets of colour dispersion and lot-to-lot consistency are more difficult to achieve compared with pre-coloured ABS.

Masterbatch carrier compatibility with base material and other additives must be ensured, and production personnel need additional training and competencies for colouring with masterbatch and managing possible unexpected situations, such as colour differences between different injection cycles, production stop, colour troubleshooting and specific interactions between ABS and the masterbatch carrier or colour formulation.

Even when colour targets may be achieved with a masterbatch, there remains room for doubt with regard to the biocompatibility compliance of the final compound ABS and masterbatch, due to the fact that no biocompatibility tests in accordance with ISO 10993 will have been conducted on the resulting compound. Such tests must be conducted on the final devices and not before. However, in the case of pre-coloured medical ABS,

"IN THE CASE OF PRE-COLOURED MEDICAL ABS, THE BIOCOMPATIBILITY TESTS HAVE ALREADY CONDUCTED AND PASSED ON THE COMPLETE COMPOUND OF ABS, COLOUR FORMULATION AND ADDITIVES."

the biocompatibility tests have already conducted and passed on the complete compound of ABS, colour formulation and additives.

COLOUR AND SUSTAINABILITY

When it comes to sustainable design for medical devices, colour quality turns into an even more critical and sensitive property. The demand for new, more sustainable ABS materials for drug delivery device 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 novel approaches 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 regulation 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 mechanically recycled content.

"THE NOVEL APPROACHES 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."

ELIX's vision is to be a driving force of the new plastics economy in the upcoming years, participating in the redefinition of plastic waste as a raw material. The company's mission is to offer top-of-the-line sustainable solutions, promoting the transformation of the value chain towards a circular economy model. Towards this goal, ELIX was the first ABS manufacturer to earn the International Sustainability and Carbon Certification (ISCC+ certification) for sustainable materials.

In pursuit of more sustainable ABS materials, ELIX has launched E-LOOP, a new brand name that covers all the company's circular economy initiatives, including a circular plastics portfolio and responsible innovation programmes. ELIX's E-LOOP ABS portfolio includes new medical and biocompatible ABS grades with chemically recycled and/or bio-based content. The certified raw materials content of ELIX M203FC and M205FC medical grades can be adapted according to the customer OEMs' sustainability targets.

ELIX's medical-grade ABS formulations with chemically recycled and/or bio-based content have been approved by the US 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.

Luca Chiochia

Luca Chiochia, Business Development Manager at ELIX Polymers, graduated in Management Engineering at the Polytechnic University of Milan (Milan, Italy). Mr Chiochia has 20 years' experience in the fields of plastics, composites and devices, joining ELIX Polymers in 2017 as Business Development Manager for the healthcare strategic sector. Since 2020, he has been actively involved in the development of ELIX's E-LOOP sustainable solutions and circular innovations, including a new, broadening sustainable ABS and blends material portfolio, with chemically recycled, bio-attributed, bio-based and mechanically recycled content. Mr Chiochia has written several technical articles on behalf of ELIX about specialties and sustainable ABS for medical applications that have been published in several renowned medical and pharmaceutical magazines.

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