Chemical Recycled ABS Materials for the Transition to a Circular Economy Model

The demand for new, sustainable ABS materials for drug delivery device applications is growing in the healthcare sector. However, because of the risk of cross-contamination, medical regulatory compliance requirements cannot be fully met with mechanically recycled ABS materials. Fortunately, new chemically recycled and bio-based ABS materials are already available, which possess the same chemical composition and properties of virgin medical ABS. This means that they fulfil the same medical applications and meet medical regulation requirements. All the colours that are available as virgin medical ABS can also be 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 with mechanical recycled content.

Some clarifications are needed to understand how it is possible for chemical recycled medical ABS to fully comply with medical applications and which are their main sustainability advantages versus medical ABS with entire fossil origin.

There are several types of chemical recycling technologies and different kinds of waste that can be chemically recycled. In this case we are talking about conversion chemical recycling, which is breaking down the target waste through pyrolysis (a thermal decomposition process without the presence oxygen) to obtain an oil like feedstock. Very important is the entrance point of this pyrolysis oil into the ABS polymer supply chain, which is at its very start (upstream). This means, not only before the production of ABS starting raw materials (Acrylonitrile, Butadiene and Styrene), but also before all the steps that are needed to produce such raw materials, without introducing any process change in them. The ISCC+ certification with a mass balance approach guarantees the sustainable non-fossil content, and the whole supply chain can benefit of this with the already existing

production processes, without making first huge investments which would make this impossible from an economical perspective. Already the chemical recycling processes themselves, the transformations from waste into pyrolysis oil, are represented by different types of expensive alternative technologies that depend on the type of considered waste and that need to be optimised and scaled up to make chemical recycling economically feasible.

An example is the incorporation of pyrolysis oil obtained from used tires in the supply chain production of Styrene. The only change is the partial substitution of Nafta oil with Pyrolysis oil to feed the steam cracking process, that is needed to convert large hydrocarbons contained in the oil into smaller ones. As it happens in the case of 100% fossil oil, the same molecules such as Ethylene and Benzene can be extracted, as it occurs for several other ones. These can be used as reagents in the production of Ethylbenzene and use the same exact processes that is used since many years for the fossil version of these input substances. The next step in the supply chain is the production of Styrene, which is obtained starting from Ethylbenzene with its standard production process which is also the same and has been also optimised since many years. The only difference is that, if chemical recycled content from used tires is present instead of fossil content, each one of these supply chain steps must be certified by ISCC+ with a mass balance approach. The same occurs in the following production passage at the ABS manufacturer, where Styrene is used as raw material to be polymerised with Butadiene and Acrylonitrile to obtain ABS.

It has been possible to obtain the ISCC+ certification with a mass balance approach and to offer ABS grades with chemical recycled content to the market. Medical grades are already used since many years in medical applications such as drug delivery devices and medical device housings, and now are available with up to 70% ISCC+ certified raw materials content (chemical recycled + bio-based content), ISCC+ certified with a mass balance approach. The same special GMP procedures implemented for medical ABS with fossil content are used, and there is no difference in the chemical composition, process, or properties between the fossil and chemical recycled version.

Medical devices need approval from authorities before market introduction. Specific and confidential information about material formulation must be included in the requested documentation to support the approval process. Medical ABS FC composition is registered in a Drug Master File (DMF) by the material manufacturer at the FDA and can be accessed by regulatory authorities to verify medical device compliance for the specific medical device application. A Letter of Authorization is released by the material manufacturer to grant the medical OEM the right to incorporate the information contained within the DMF into their medical device application. This also grants FDA reviewers permission to review the proprietary information within the DMF in reference to that specific medical device application. Each DMF contains all formulation detailed information regarding not only the medical ABS FC composition, but also all the biocompatible colour formulations that are available for that ABS FC grade. Periodically, when a new medical ABS FC colour is developed on customer demand, the FDA is contacted to get permission to include that specific colour formulation in the corresponding ABS FC Drug Master File. Only authorised colour pigments within the maximum allowed concentrations can be

used, pigments which have been previously biocompatibility tested at recognised laboratories according to ISO 10993.

The formulations with chemical recycled content (ISCC+ certified) go through the same process and are finally registered at the FDA in the same DMF M203FC or M205FC, in a similar way as it happens for new medical FC colours. In this way, all information regarding the specific ABS material composition with exact chemical recycled content and in the requested colour is included in DMF #25288 (or #25284 in the case of ELIX M205FC).

Once discussed how it is possible for a medical ABS ISCC+ certified with chemical recycled content to fully comply with medical regulations and healthcare applications, it is important to consider which are the sustainability advantages in comparison with a full fossil-based medical ABS. The key variables to take into account are the type of waste used, the level CO_2 emissions related with the waste recycling process, the efficiency of the process (which % of the waste can be exploited) and the possible presence of biogenic content in the waste itself. In addition, from an end-of-life perspective, also the CO_2 emission reduction due to the avoided waste incineration process can be also considered, since this step is eluded when creating circularity.

When the waste is methodically separated and sorted by type, the related recycling process can be fine-tuned on that specific type of waste, with a consistent reduction of energy inputs required and consequent CO_2 emissions outputs. If we compare for example used tire waste with undefined mixed plastic waste, the first one has recently implemented

a much more efficient chemical recycling process, with much lower CO_2 emissions and no solid/liquid residues generated. In addition, the controlled source used (only tires) improves the traceability of the process, which would solve a big problem in the European tire industry.

The average tire composition from this source of used waste includes synthetic rubber but also natural rubber, carbon black, textile fiber and steel. With the identified recycling process, also carbon black can be recovered, representing an additional positive environmental impact. The volatiles generated during the process can be reincorporated to feed energy into the same recycling process, reducing the related CO_2 process emissions. Furthermore, the natural rubber content in the used tires has great importance. Natural rubber was extracted from plants in the past, and those plants where absorbing CO_2 emissions during their previous life instead of emitting CO_2. This biogenic content in tires provides therefore a relevant contribution in CO_2 emissions reduction.

The percentage content of sustainable certified raw materials in the medical ABS composition can be adapted to the OEMs sustainability and economic targets. For example, ABS grades with 25%, 50% or up to 70% ISCC+ certified raw material contents (chemical recycled and/or bio-based) are possible but also any specific customer percentage configuration is possible. Even 100% is in theory possible option, and it depends on available chemical recycled raw material sources, incremental environmental contribution, recycling technology state of the art, scale synergies and related cost.

Most important is to start adopting this type of solution including recycled waste as raw materials, even with low percentages. This would be the correct attitude that will support an easier transition towards the use of more sustainable ABS medical materials in drug delivery and other medical devices in the coming years.

Luca Chiochia

Luca joined ELIX Polymers in February 2017 and works in the position of Business Development Manager for the Healthcare and Consumer sectors. He is responsible for the identification, development and validation of new market/segments, products & applications opportunities and for translating customer needs into practice. Luca graduated in management engineering at the "Politecnico di Milano" University (Milan, Italy) and has at present over 15 years' experience in the fields of thermoplastics, thermoset plastics, composites, electrical insulation, and electronics. He worked in the past in different positions as Business Development Manager, Head of Sales Energy & Composite Materials, Export Manager Europe & Asia and Sales Application Engineer Iberia & South France.

Email: luca.chiochia@elix-polymers.com