A wide portfolio of high-purity PE, PP and Metocene PP products is used for sensitive applications in medical technology and the pharmaceutical sector

Safety, Innovation, Service

Healthcare Sector. Highly specialized polyolefins meet the high requirements for the healthcare market. Close collaboration between polymer producer and distributor provides an exceptional service for processors in terms of supply flexibility, formulation consistency and individual on-site consulting, which forms the basis for attractive, long-term successful projects.

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Because healthcare products can have direct effects on the health of users, they require particular care. For this reason, national and international guidelines specify extremely high requirements for purity and formulation consistency. These apply not only to the product itself but also to the containers in which it is transported, stored or dispensed. Successful applications require the materials used to meet strictest quality criteria, while also offering documented manufacture, long-term formulation consistency, guaranteed security of supply and expert on-site consulting. With its continually updated, application-oriented Purell concept and close collaboration with distributors, LyondellBasell, Frankfurt, Germany, fully satisfies these requirements.

When it comes to selecting materials for the bags, pouches, sachets, bottles, syringes etc. used in the medical, pharmaceutical and cosmetics sectors, the trend

Translated from Kunststoffe 2/2010, pp. 72–75
Article as PDF-File at www.kunststoffe-international.com; Document Number: PE110343

Fig. 1. The storage conditions for high-purity polyolefins comply with the high requirements of the healthcare sector

is moving in the direction of polypropylene (PP) and polyethylene (PE). These materials are replacing the previously dominant PVC here because of their universal and largely problem-free suitability for processes such as injection molding, extrusion and co-extrusion, blow molding, injection blow molding and blown film manufacture. Other key reasons for their success in this sector include their wide range of available mechanical properties from flexible to stiff, high transparency, high to very high chemical purity and, last but not least, attractive cost efficiency.

The positive material properties characteristic of the polyolefins form the basis for their use in the healthcare sector. However, these properties alone are not sufficient when it comes to choosing the best polymer for such applications. Because of the complexity and protracted nature of the approval procedures, with their expensive toxicological and microbiological tests, the appropriate certificates along with guaranteed formulation consistency and security of supply are additional requirements.

Any Time in Any Delivery Form and Quantity

The specially optimized material portfolio of LyondellBasell and market penetration of distributors such as Ultrapolymers of Augsburg, Germany, have made a vital contribution to the established and continually growing importance of the polyolefins in the medical and pharmaceutical sectors. Raw material producers have tended to concentrate on major customers and global support. The distributors, on the other hand, mainly ensure local presence on the ground within Europe and an individually tailored service to the customer – often a supplier to the large medical technology companies. They cater for individual customer needs in terms of delivery date, form and scope, without any restrictions as regards the required quantities and container sizes. So the producers and distributors together cover the entire value chain of the industry.

For example, Ultrapolymers offers its customers express delivery, which guarantees arrival of the goods, even small quantities, within 24 hours of order receipt. In cases of the utmost urgency, the distributor can provide even faster delivery from the nearest of its Europe-wide warehouses, so that in an extreme case the distance from the customer is the only time-determining factor.

Approval Certificates Speed Up Development Time

The physical and chemical properties of the polyolefins marketed under the Purell service concept meet the specifically stipulated conditions for packaging and containers used in the healthcare sector. So these polyolefins come with test certificates verifying compliance with the requirements of, for example, the European Pharmacopeia (in which specifications for plastic materials are also listed) or the United States Pharmacopeia. LyondellBasell also works with agencies in other countries to ensure compliance with their regulations. If product manufacturers use a suitably certified material, they can generally expect a simplified approval procedure.

The comprehensive application support provided by LyondellBasell and Ultrapolymers involves more than just obtaining approvals and certificates. As a complete service package, it also includes discussions that go way beyond the usual technical questions to consider the specific application in the context of the medical protocol developed by LyondellBasell and adopted by Ultrapolymers. As a management tool, this systematic and extremely detailed probing of all the boundary conditions helps identify and exclude the potential risks of an application well in advance and also to unlock possible cost savings.

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Long-term Security of Supply – Globally and Locally

When the approval procedures have been completed, processors/manufacturers must be able to rely absolutely on the required amount of material being available for supply in consistent composition over very long periods of time without any bottlenecks. LyondellBasell and Ultrapolymers give their customers this essential guarantee for all Purell products. The products are manufactured in selected production sites under consistent, GMP-like conditions, so that customers can largely discount the possibility of batch variations in processing properties.

The producer will as far as possible avoid changes to the formulation. If a change should be necessary, when, for example, the use of a certain process aid or additive is prohibited by legislation, then LyondellBasell and its partners promise their customers that they will continue to supply the affected product in unchanged form for two years following notification of the forthcoming change.

While this promise goes way beyond that which producers of standard polyolefins are normally prepared to offer, Ultrapolymers will guarantee this batch consistency for even longer periods of time on request. In cases where customers with particularly challenging applications are not satisfied with the promise of 24 months' unchanged supply, the distributor will extend the security of supply guarantee for up to a further three years by placing the required quantity in their own warehouse ready for delivery on call. If required, the distributor will even store the products in two geographically separate warehouses to cover all eventualities **(Fig. 1)**.

Another additional service provided by the distributor involves storing a certain product batch recognized as being optimum for the specific application and process over quite long periods of time, decided by the customer. Delivery then takes place at specified intervals or on call. →

This allows processors to avoid the possible and often contractually agreed variation in flow properties to which polyolefins are particularly prone and which is especially noticeable in the production of small parts. It saves them having to compensate for this problem by post-adjustment of machine parameters and also prevents the associated material losses that would otherwise have to be accepted.

Fig. 2. Disposable syringes made from high-purity polyolefins

Material Portfolio Covering Wide Range of Application

Purell polyolefins comprise homopolymers as well as block and random copolymers. In terms of flow properties, transparency and stiffness, they cover a very wide property spectrum and can be processed into both very thin films and robust housing components, while also being sterilizable by a variety of methods. The PP grades are suitable for the manufacture of thin-walled products, because of their good flowability, and permit fast cycles. In addition, they are characterized by good toughness at low temperature. PE-LD can be steam sterilized, is produced without additives, and strikes a good balance between stiffness and crack propagation resistance.

The diversity of the Purell product portfolio reflects the wide range of application. This includes

- bottles and ampoules for infusions produced by the blow-fill-seal process, for which the flexible PE-LD grades Purell PE 3020D, PE 3040D and PE 3220D and the much stiffer PP random copolymer grade RP270G are used, while the more flexible Purell PE-LD grades PE 1810E and the easier flowing PE 1840H are selected for ampoules and smaller bottles, e.g. for eye drops. All these blow molding grades were optimized for the production process in close collaboration with machinery manufacturers. Another recently available grade is Purell PE 3420F, which has the highest heat resistance and density (0.933 g/cm^3) of all PE-LD grades currently on the market. As a result, the new material withstands high sterilization temperatures up to 115 °C, allowing shorter sterilization times. It also enables extremely thin-walled containers to be produced (for examples see **Title picture**).
- Injection molded parts for unfilled disposable syringes of various design, suitable for different sterilization methods **(Fig. 2)**. For the syringe cylinder, the highly transparent PP homopolymer grades HP570R (general-purpose grade) and HP371P (gamma sterilizable) and the random copolymer grades RP373R (good sliding properties) and RP374R (sterilizable in an autoclave and with ethylene oxide) are suitable. For the plunger, the PE-LD grade GA7760 (high stiffness and warpage-free) and Purell HP570R are used.
- Blown and cast films for infusion bags **(Fig. 3)** and secondary packaging of syringes or diagnostic equipment, for which the high-purity, additive-free PE-LD grades Purell PE 2420F and the stiffer PE 3020H (blown films) are used, as well as the highly stiff PP homopolymer grade HP570M (cast films).
- Extruded or injection blow molded bottles **(Fig. 4)** made from PE-HD grades with very low additive content, such as Purell PE GF4750 (higher stress cracking resistance) and GF4760 (higher stiffness), ACP6031D and ACP5231D (very high stiffness combined with very good stress cracking resistance), and the stiff PP random copolymer grade RP270G. For lid applications, the very easyflowing and flexible Purell PE-LD grade 2410T is used.
- Other polyolefins are used for bottles, lids, tubes, caps, test tubes, inhalers **(Fig. 5)** and a range of laboratory requisites from pipette tips to microtiter plates **(Fig. 6)**.

Close Customer Contact Is Crucial

For potential and existing users, close contact between the customer and material supplier or distributor provides the foundation for future, long-term success. Direct exchange of application and processing experience and reports on the results of current research and development work together form the basis for need-oriented provision of materials, which meet current and foreseeable future market requirements and combine cost efficiency with top-quality, application-tailored performance.

Fig. 3. Infusion bags made from high-purity polyolefins

Fig. 4. Extrusion blow molded parts made from high-purity polyolefins

Fig. 5. Inhaler made from high-purity polyolefins

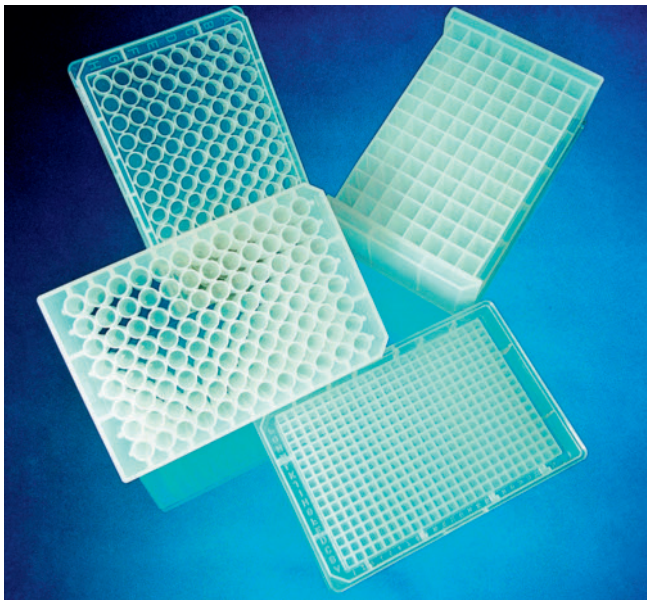

Fig. 6. Microtiter plates made from high-purity polyolefins

In the healthcare sector, it is particularly crucial to establish this contact during the initial planning phase, because this is just when mistakes can result in especially protracted and expensive corrective measures. The experienced technical consultants from both LyondellBasell and Ultrapolymers maintain this close contact. Right from the start of a development, they employ their technical expertise to help assess and evaluate the potential risks and speed up globally required approval procedures by selecting the right material. They also optimize applications by advising on correct design for the selected material, so minimizing production costs. And they provide on-site support for such developments right up to the serial production stage by helping set up the machines, being personally present during mold proving, and optimizing process parameters for cost-efficient, trouble-free production. ■

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