

# ARTICLE

December 2016

## THE IMPORTANCE OF REGULATORY COMPLIANCE FOR STYRENIC MATERIALS IN THE HEALTHCARE INDUSTRY

by

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The patient's wellbeing is the highest priority in regulatory systems for medical products and materials used in healthcare solutions. Thus, authorization procedures for new solutions in the healthcare market are particularly time consuming in order to ensure safety with a detailed risk analysis, compliance with all relevant normative and regulatory demands, execution of a clinical evaluation of the performance, effectiveness and efficiency and finally, a thorough quality management system.

Since the entry of plastics in the healthcare industry, plastics based applications have to comply with the same rules. Today, plastics have become a component that can be found in countless medical applications, from small mobile measurement devices to drug delivery systems, from tubes and connectors to drip chambers for IV sets.

INEOS Styrolution offers various healthcare service packages to healthcare solution providers for a long time. With the broadest range of styrenic based products dedicated to healthcare applications, the company ensures a production environment to deliver products that meet a wide range of compliance requirements and superb quality standards. For certain product lines, production protocols have been implemented so that INEOS Styrolution can offer two different levels of notification of change commitments (up to 12 or 36 months). Consistency in formulation provides another level of assurance to medical device designers that their efforts in qualifying new materials and obtaining the corresponding biocompatibility documentation will be valid for the years to come.

## Compliance testing of styrenics

Testing the raw materials against these common biocompatibility standards (i.e. ISO 10993 and USP class VI), elevates INEOS Styrolution above industry requirement. Medical device manufacturers are required by law to conduct these tests on their final application. Since INEOS Styrolution tests their products against these same standards, medical device manufacturers have greater confidence when these products are used in their final application. They can significantly reduce the risk of failure when introducing new applications in the medical market since their key raw materials are already compliant. Working with a pre-certified raw material would certainly lead to a reduction in time and cost for the application provider.

INEOS Styrolution's styrenic healthcare service packages are designed for use in risk class I and risk class II applications. ABS grades such as Novodur® HD grades and Lustran® ABS, transparent MABS (Terlux® HD), NAS® (SMMA), MBS (Zylar®), Styrolux® (SBC) and Styroflex® (S-TPE) are available with food contact statements in regards to the US (FDA) and European regulations. They meet the requirements of the European and Japanese pharmacopoeia and have tested according to the USP Class Biological Reactivity Tests Class VI and relevant ISO 10993 standards.

Most of the products dedicated to healthcare have a corresponding Drug Master File (DMF). Some of these grades are also available in pre-colored versions and have been or are being assessed according to the above mentioned regulations.

## What is next?

Styrenics are popular materials for a wide range of applications due to their excellent flowability, impact strength, chemical resistance, hard-, softness and surface qualities. They combine excellent physical performance along with aesthetically pleasing attributes. Growing demands require new ideas and grades, and in selected cases optimizing the polymer in order to provide new material properties that allow to meet regulatory compliance.

INEOS Styrolution currently investigates the development of new materials for the healthcare market. One new grade will be tailored to meet the specific needs of IV drip chambers. It was designed to meet the ever increasing demand for products that have superb bonding performance, have excellent flowability for multi cavity tools, and addresses the need of designers who are looking for an alternate grade to those products commonly used in the market space. Another investigation may result in a first fibre filled ABS which will not only meet the challenges of very demanding applications, but also fulfils regulatory requirements as mentioned above. In fact, initial indications are so promising that further results are expected to be announced at the Pharmapack in Paris in February 2017.

## About the author

Bernd Elbert is responsible for new material and application developments within the global healthcare industry team at INEOS Styrolution. He looks back at 25+ years of experience in the polymer industry.

Elbert started his career in 1990 at “The Dow Chemical Company” in Germany. He held various positions in R&D (Senior R&D Specialist), Manufacturing and TS&D (Technical Service & Development Specialist). In 2010, he joined Styron/Trinseo as Application Development Leader for optical media, transparent sheet and medical applications. In 2012, he became Business Development Manager for Healthcare at INEOS Styrolution.

Elbert holds an MSc (Manufacture and Design for Polymer Products) from the London Metropolitan University (UK) and a degree as Industrial Master of Chemistry from the IHK Stade, Germany.