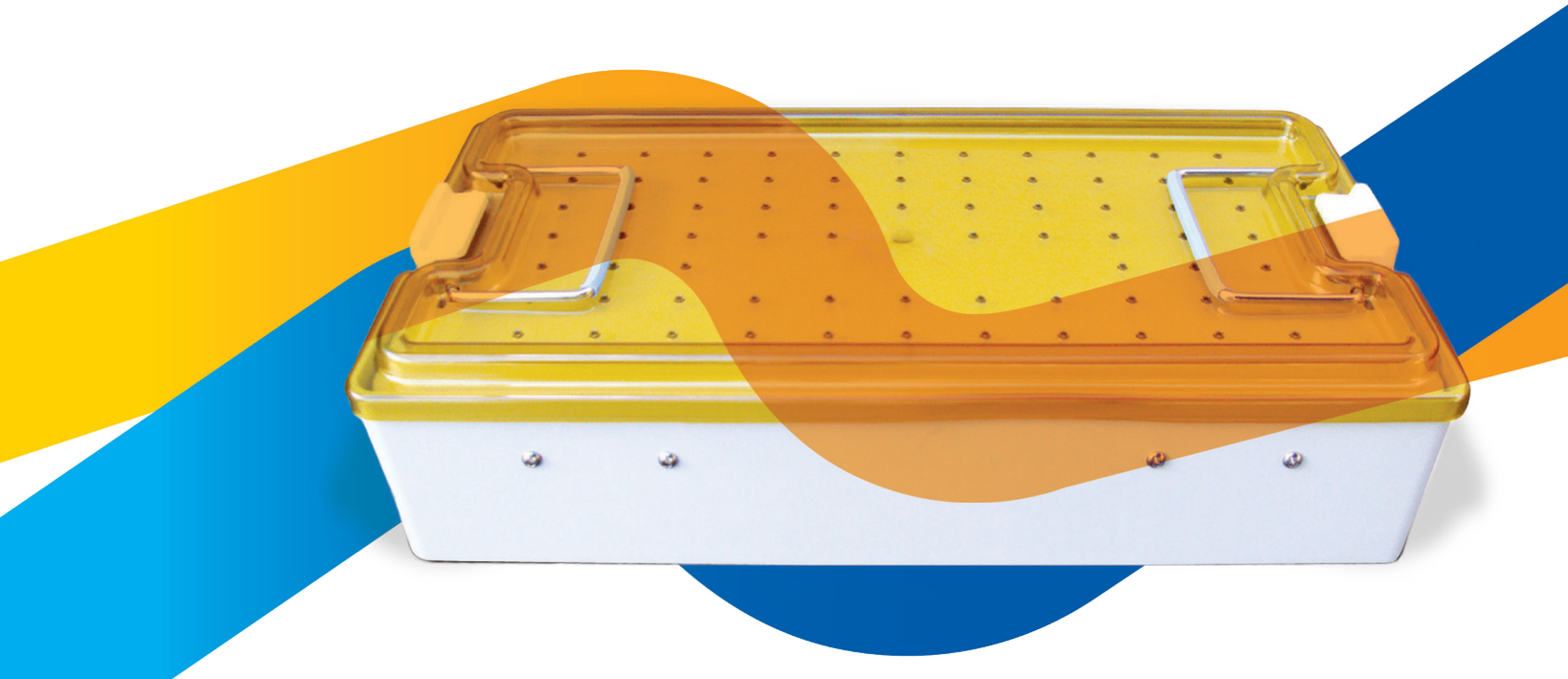
DURABLE+ VERSATILE

ULTEM™ HU1004 RESIN

A high performance resin blend for multiple sterilization environments



CHEMISTRY THAT MATTERS™

SABIC

Founded in 1976, SABIC is today the first public, global multinational enterprise headquartered in the Middle East. Our products range from bulk commodity chemicals to highly engineered plastics for demanding applications. We are a leading producer of polyethylene, polypropylene, glycols, methanol and fertilizers and the world's third largest polyolefin producer.

SABIC's offerings include Chemicals, Polymers, Specialties, Agri-Nutrients and Metals. In Saudi Arabia, the Netherlands, Spain, the USA, India, China and Japan, our dedicated Technology & Innovation centers research ways to meet our customers' needs with excellence.

INNOVATING FOR CUSTOMER SUCCESS

We believe that SABIC customers deserve the full benefit of every advantage our enterprise can offer. After all, our success is defined by our customers' success. And with more than 80 years of experience pioneering advanced engineering thermoplastics, SABIC is positioned to help create new opportunities for growth and breakthrough applications.

We offer expertise and experience to our customers in a variety of ways:

- Material solutions to help drive innovation and market leadership.
- Design, logistics and processing expertise to spark new ideas and better efficiencies.
- Unwavering commitment to build long-term relationships with ingenuity, trust and continuous improvement.

It's what we strive for and work to deliver… a mutual benefit.

Excellence and nothing less.

INTRODUCTION

HARSH STERILIZATION ENVIRONMENTS…

Medical devices and the materials used to construct them must withstand ever increasing in-service demands due to more complex designs, performance requirements and regulations. In particular, the heightened emphasis on infection control is intensifying the spotlight being shined on the range of processes used to sterilize medical and dental equipment and devices. And, trends in the industry are pointing towards designing more inherent functional capabilities into reusable devices, meaning that they are more likely to contain sensitive electronics (vulnerable to heat and moisture) or other features which could require different sterilization options.

Materials must now be able to withstand a number of different potential sterilization processes –such as high temperature steam autoclave (up to 134 °C), gamma irradiation, and an emerging process suitable at low temperatures: hydrogen peroxide gas sterilization. All of these sterilization methods have the potential to degrade devices over time, diminishing their mechanical integrity, interfering with performance, or altering their aesthetics.

…REQUIRE A HIGH PERFORMANCE SOLUTION

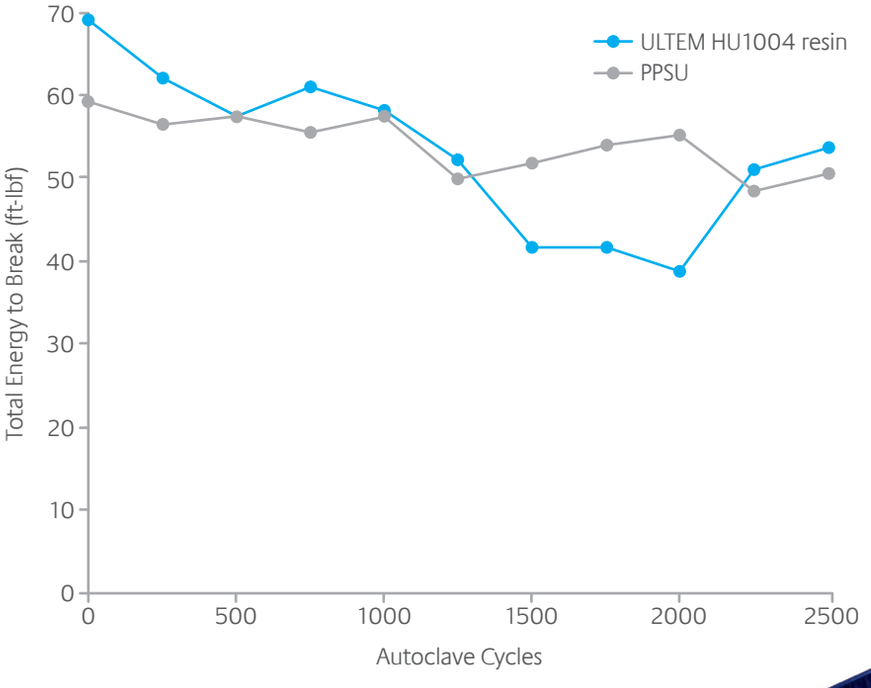
Among the family of high performance engineered thermoplastics offered by SABIC to help healthcare device manufacturers meet these challenges are ULTEM resins, which have proven their capability in each sterilization environment. In particular, SABIC's innovative ULTEM HU1004 resin, a polyetherimide (PEI) resin blend with enhanced hydrolytic stability, has been developed specifically for healthcare applications. This proprietary, patent-pending blend of PEI and another high performance polymer provides synergistic advantages that the individual polymers alone cannot provide while maintaining inherent transparency.

ULTEM HU1004 RESIN: A PROVEN PERFORMER

ULTEM HU1004 resin offers medical device designers and manufacturers a single material solution for the healthcare industry since it is capable of withstanding rigorous sterilization processes such as steam sterilization at 134 °C, gamma irradiation or hydrogen peroxide vapor sterilization (with or without plasma). Additionally, ULTEM HU1004 resin has agency approval of the FDA, biocompatibility (ISO 10993 or USP Class VI) and EUFC.

FIGURE 1

ULTEM HU1004 RESIN AND PPSU SHOW EQUIVALENT PERFORMANCE WITH STEAM STERILIZATION (WITHIN EXPERIMENTAL ERROR).



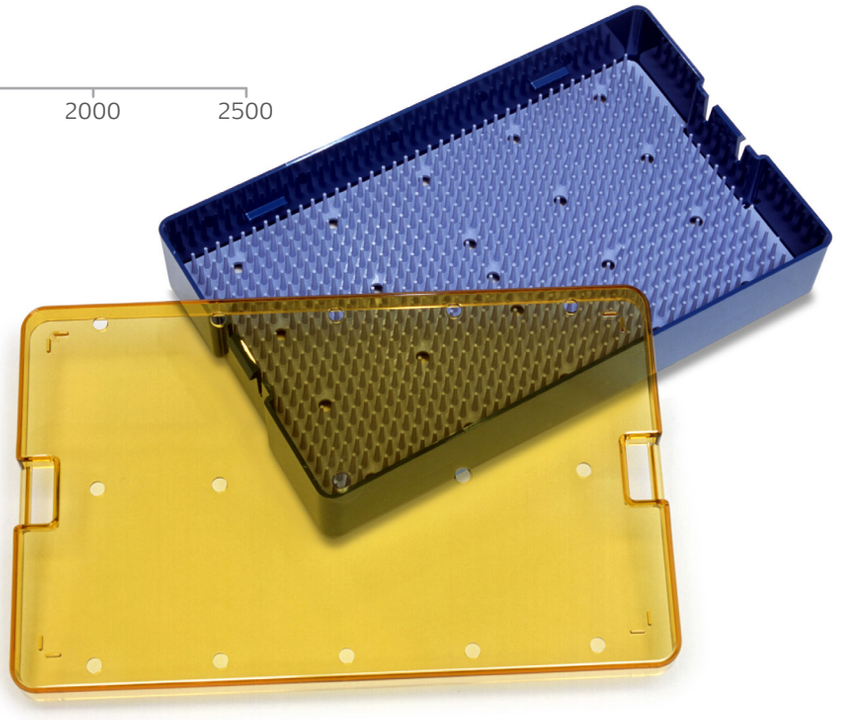


TABLE 1
ASTM PROPERTIES OF ULTEM HU1004 RESIN AND PPSU

MATERIAL PROPERTIES

PROPERTY	UNITS	TEST METHOD	ULTEM HU1004 RESIN	PPSU
MECHANICAL PROPERTY				
Tensile strength @ Yield, Type 1, 0.125”	MPa (kpsi)	ASTM D638	95 (13.7)	71 (10.3)
Tensile Modulus, Type 1, 0.125”	MPa (kpsi)	ASTM D638	3,470 (503)	2,292 (333)
Tensile Elongation @ Break, Type 1	%	ASTM D638	100	100
Flexural Strength, yield, 0.125”	MPa (kpsi)	ASTM D732	151 (22.0)	113 (16.4)
Flexural Modulus, 0.125”	MPa (kpsi)	ASTM D732	2,995 (434)	2,340 (340)
IMPACT PROPERTY				
Izod Impact, Rev. Notch, 23 °C (73 °F)	J/m (ft-lb/in)	ASTM D256	Non-Break	Non-Break
Multi-axial Impact @ 23 °C (73 °F)	–	ASTM D3763	–	–
% Ductile	%	–	100	100
Total Energy to Break	J (ft-lbs)	–	94 (69)	84 (62)
Max Load	N (lbf)	–	8,960 (2,015)	8,200 (1,843)
THERMAL PROPERTY				
HDT, 66 psi, 0.125”, unannealed	°C (°F)	ASTM D648	208 (406)	211 (412)
HDT, 264 psi, 0.125”, unannealed	°C (°F)	ASTM D648	196 (385)	198 (388)
PHYSICAL PROPERTY				
Specific Gravity	–	ASTM D792	1.28	1.29
Transmission @ 0.125”	%	ASTM D1003	63	69
Haze @ 0.125”	%	ASTM D1003	4.6	4.0
Melt Flow Rate @ 337 °C, 6.7kgf	g/10min	ASTM D1238	10.1	9.5

SUPERIOR PERFORMANCE

SUPERIOR PERFORMANCE IN HYDROGEN PEROXIDE PLASMA STERILIZATION SYSTEMS

Our research has shown that ULTEM HU1004 resin maintains tensile strength and ductility – important to extending the useful life of devices – in hydrogen peroxide plasma sterilization systems, outperforming a competitive material, polyphenylsulfone (PPSU). The same study also demonstrated that ULTEM HU1004 resin has a superior ability to retain color and appearance.

The study tested the performance of both ULTEM HU1004 resin and PPSU in at least 300 sterilization cycles in STERRAD† NX†, STERRAD 100NX† plasma and AMSCO† V-PRO† vapor systems. Data shows ULTEM HU1004 resin significantly outperforming PPSU. The results are compiled in the Tables 2 and 3 and Figures 2 – 4 where retention of ductility, in particular, and color stability are clearly demonstrated versus competitive materials.

TABLE 2

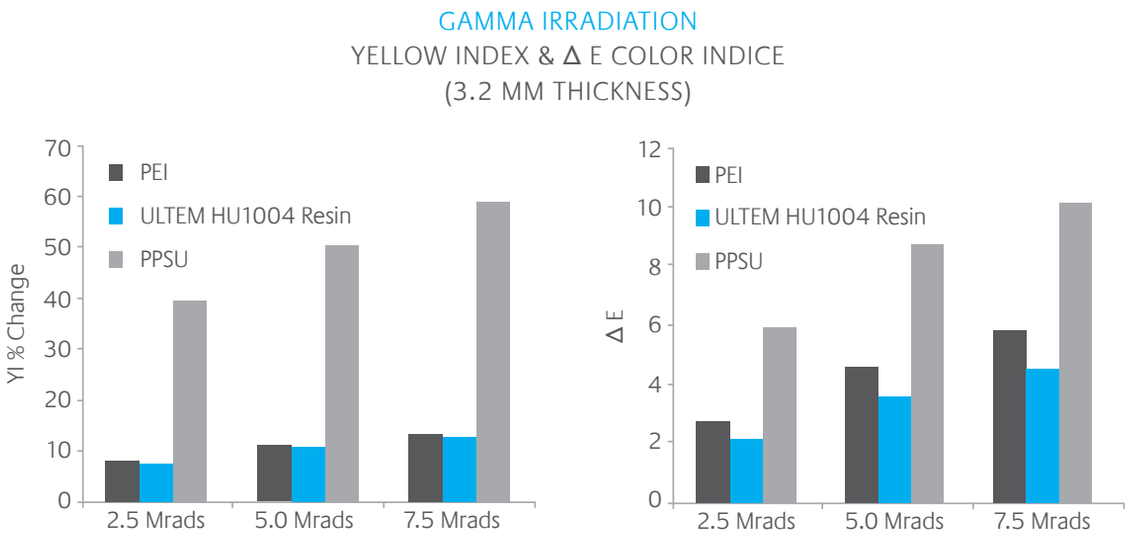
RETENTION OF ASTM PROPERTIES OF ULTEM HU1004 RESIN AND PPSU AFTER 300 STERILIZATION CYCLES

	STERRAD NX		STERRAD 100NX		AMSCO V-PRO	
PROPERTY	ULTEM HU1004 RESIN	PPSU	ULTEM HU1004 RESIN	PPSU	ULTEM HU1004 RESIN	PPSU
Tensile Strength @ Yield, 0.125”	98%	91%	101%	87%	99%	90%
Tensile Modulus, 0.125”	98%	100%	99%	93%	100%	100%
Tensile Elong. @ Break, 0.125”	77%	11%	57%	9%	84%	13%
Mass Retention	99.68%	92.29%	99.40%	91.75%	100.3%	100.5%
Multi-axial Impact @ 23 °C						
Energy to Max Load	90%	7%	69%	43%	92%	21%
Total Energy to Break	91%	7%	75%	49%	94%	23%
Max Load	94%	13%	85%	64%	98%	37%
Failure Type	Ductile	Brittle	Ductile	Ductile	Ductile	Brittle

COLOR STABILITY

FIGURE 2

GAMMA IRRADIATION DATA AT 3 DOSAGE LEVELS SHOWS COLOR STABILITY WITH ULTEM HU1004 RESIN.



COLOR ME...STABLE!

FIGURE 3

COLOR CHANGE AFTER 300 STERRAD NX CYCLES FOR ULTEM HU1004 RESIN AND PPSU

FIGURE 4

MULTI-AXIAL IMPACT OF ULTEM HU1004 RESIN AND PPSU AFTER 300 STERRAD NX CYCLES. THE SAMPLES ON THE LEFT ARE CONTROL SAMPLES, ON THE RIGHT, SAMPLES AFTER EXPOSURE.

ULTEM HU1004 resin

PPSU

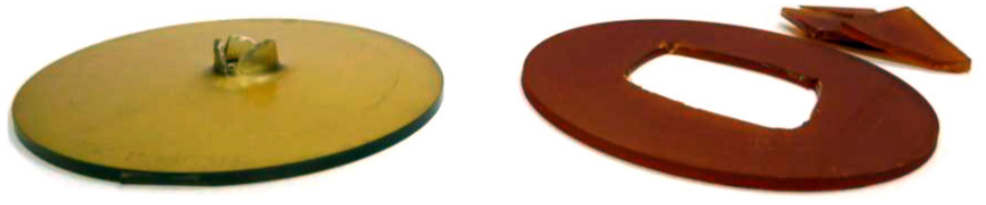


TABLE 3

ΔE COLOR CHANGE AS A FUNCTION OF STERILIZER TYPE AND NUMBER OF STERILIZATION CYCLES FOR ULTEM HU1004 RESIN AND PPSU

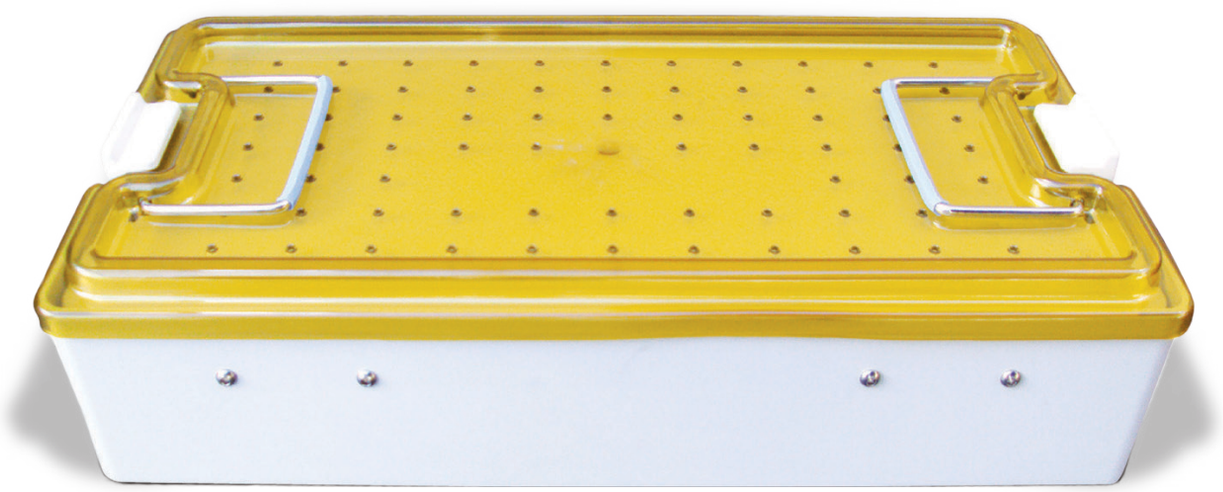
COLOR	STERILIZER TYPE	MATERIAL	ΔE COLOR DIFFERENCE		
			100 CYCLES	200 CYCLES	300 CYCLES
BLUE	STERRAD NX	ULTEM HU1004 Resin	1.4	5.1	5.7
		PPSU	24.7	37.3	50.6
	STERRAD 100NX	ULTEM HU1004 Resin	4.4	2.7	4.7
		PPSU	11.5	31.3	57.2
	AMSCO V-PRO	ULTEM HU1004 Resin	0.8	0.5	1.3
		PPSU	0.8	20.2	46.4
WHITE	STERRAD NX	ULTEM HU1004 Resin	1.2	4.9	5.9
		PPSU	25.8	36.3	36.4
	STERRAD 100NX	ULTEM HU1004 Resin	4.4	2.9	6.8
		PPSU	19.8	30.4	49.1
	AMSCO V-PRO	ULTEM HU1004 Resin	0.7	0.7	0.8
		PPSU	0.7	4.5	29.3
GRAY	STERRAD NX	ULTEM HU1004 Resin	1.4	3.2	4.4
		PPSU	13.9	27.2	33.6
	STERRAD 100NX	ULTEM HU1004 Resin	2.6	3.2	4.9
		PPSU	7.5	25.5	36.6
	AMSCO V-PRO	ULTEM HU1004 Resin	0.2	0.8	1.0
		PPSU	0.2	1.5	10.2

MAKE THE BEST CHOICE

With a broad portfolio of more than 50 healthcare products which adhere to SABIC's stringent healthcare product policy, we offer medical device designers and manufacturers a number of options when considering a balance between properties, performance and methods of sterilization.

Indusbello Sterilization Tray

To address the growing healthcare trend of healthcare associated infections, SABIC has worked closely with Indusbello to develop a differentiated solution for sterilization trays to help improve the safety of patients and clinician healthcare environments. SABIC's ULTEM HU1004 resin is designed to withstand a number of different harsh sterilization processes, including high temperature steam autoclave (up to 134 °C), gamma radiation and an emerging process suitable at low temperatures - hydrogen peroxide gas sterilization. In addition, the material can provide flexibility in design, transparency, superior aesthetics and enhanced productivity through injection molding.

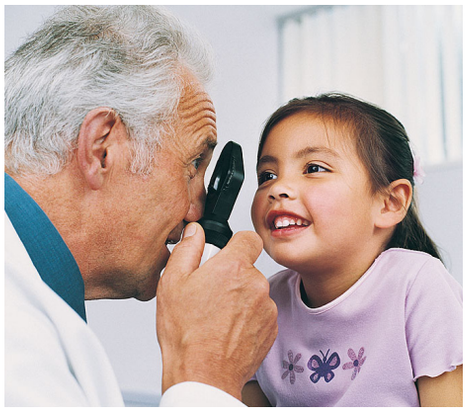


ULTEM HU1004 resin has been pre-assessed for biocompatibility per ISO 10993. The product passed the following tests:

- ISO 10993 Part 5 Tests for In Vitro Cytotoxicity (L929 Neutral Red Uptake)
- ISO 10993 Part 6 Tests for Local Effects After Implantation (2-wk Intramuscular Implantation)
- ISO 10993 Part 10 Tests for Irritation and Skin Sensitization (Kligman Maximization and Intracutaneous Injection)
- ISO 10993 Part 11 Tests for Systemic Toxicity (Systemic Injection and Rabbit Pyrogen)
- ASTM F756-08 Standard Practice for Assessment of Hemolytic Properties of Materials (Hemolysis - Rabbit Blood)
- United States Pharmacopeia 35 Monograph <661> Containers, Physicochemical Tests (Non-Volatile Residue)
- United States Pharmacopeia 35 Monograph <662> Containers, Physicochemical Tests

SABIC does not recommend and will not support the use of any SABIC products in medical devices intended to remain continuously in the human body for longer than 29 days. The customer is in the best position to know the details of the intended conditions of use of their product. It is incumbent on them to carry out the appropriate biocompatibility tests of their product to assure safety, efficacy, and regulatory compliance. SABIC considers the determination of suitability of ULTEM HU1004 resin for a medical device to be the responsibility of the device manufacturer and the drug packager.

To assist in the review of the use of ULTEM HU1004 resin for medical devices and drug packages with the appropriate FDA regulatory personnel, we maintain a Drug Master File (DMF-1562) and a Device Master File (MAF-91) with the FDA. The DMF / MAF contain detailed formulation information and test data on certain grades of ULTEM resins. SABIC considers this information proprietary and does not divulge it without a properly executed secrecy agreement. The FDA holds this information in confidence, but with our specific authorization will review it on behalf of a specific company's application or submittal for the purpose of rendering an opinion about the safety and suitability of the proposed usage.



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