

World-Class Engineering Polymers

- Celanex® thermoplastic polyester (PBT)
- Celcon® and Hostaform® acetal copolymer (POM)
- Celstran®, Compel® and Factor® long fiber reinforced thermoplastic (LFRT)
- Celstran® continuous fiber reinforced thermoplastic (CFR-TP)
- Fortron® polyphenylene sulfide (PPS)
- GUR® ultra-high molecular weight polyethylene (UHMW-PE)
- Impet® thermoplastic polyester (PET)
- Riteflex® thermoplastic polyester elastomer (TPC-ET)
- Thermx® polycyclohexylene-dimethylene terephthalate (PCT)
- Vandar® thermoplastic polyester alloy (PBT)
- Vectra® and Zenite® liquid crystal polymer (LCP)

* Ticona, as a supplier of raw materials, cannot obtain general approval for its polymers for use in medical technology but assists manufacturers of medical technology products by maintaining Drug and Device Master Files with the United States Food and Drug Administration (FDA) for the selected product grades. These FDA files contain confidential information on formulations and biocompatibility documents. With written permission by Ticona, these files can be reviewed for orthopedic device applicants by the FDA.

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Please consult the nearest Ticona Sales Office, or call the numbers listed above for additional technical information. Call Customer Services for the appropriate Materials Safety Data Sheets (MSDS) before attempting to process our products. Ticona engineering polymers are not intended for use in medical or dental implants.

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Contact Information

Americas

Ticona Engineering Polymers
Product Information Service
8040 Dixie Highway
Florence, KY 41042
USA
Tel.: +1-800-833-4882
Tel.: +1-859-372-3244

Customer Service

Tel.: +1-800-526-4960
Tel.: +1-859-372-3214
Fax: +1-859-372-3125

email: proinfo@ticona.com

Europe

Ticona GmbH
Information Service
Professor-Staudinger-Straße
65451 Kelsterbach
Germany
Tel.: +49 (0)180-584 2662 (Germany)*
+49 (0)69-305 16299 (Europe)**
Fax: +49 (0)180-202 1202

See example below for rate information:

* 0.14 €/min + local landline rates

**0.06 €/call + local landline rates

email: infoservice@ticona.de

Ticona on the web: www.ticona.com

Asia

Celanese (China) Holding Co., Ltd.
No. 4560, Jin Ke Road
Zhang Jiang Hi-Tech Park
Shanghai, China
PC, 201203

Customer Service

Tel.: +86-21-3861 9288
Fax: +86-21-3861 9588

email: infohelp@ticona.com

www.ticona.cn

Introducing

GUR® UHMW-PE Vitamin E Filled Premium Grades

For Orthopedic Implants



GUR[®] UHMW-PE For Orthopedic Applications

Our Premium Grades Are Now Available With Vitamin E

Because Ticona's GUR UHMW-PE (ultra-high molecular weight polyethylene) is biocompatible and allows for flexibility of part design, it has been a material-of-choice in orthopedic implants for more than 40 years. GUR 1020 and 1050 are two

of the most frequently used materials for articulating bearing surfaces in orthopedic surgical implant technology.

The extremely high molecular weights of GUR 1020 and 1050 in the range of $5.5\text{--}10 \times 10^6$ g/mol (determined from intrinsic viscosity measurements and using Margolies' equation) are responsible for the desired excellent notched impact strength, wear resistance, stress crack resistance and fatigue strength.

implants, including articulating bearing surfaces for hips, knees and other joints. Ticona has taken into account the special requirements of medical technology for orthopedic implants by ensuring exceptionally high quality, and conforming to regulatory agency criteria based on international standards ASTM F648 and ISO 5834-1/-2 for raw materials and semifinished products.

PERFORMANCE CHARACTERISTICS

- + Improved oxidation resistance
- + High impact strength
- + Excellent low friction properties
- + High energy absorption capacity
- + Excellent abrasion resistance
- + Proven long-term biocompatibility

GUR UHMW-PE Premium Grades

Grades GUR 1020 and 1050 are used for the manufacture of surgical

GUR UHMW-PE Premium Grades With Vitamin E

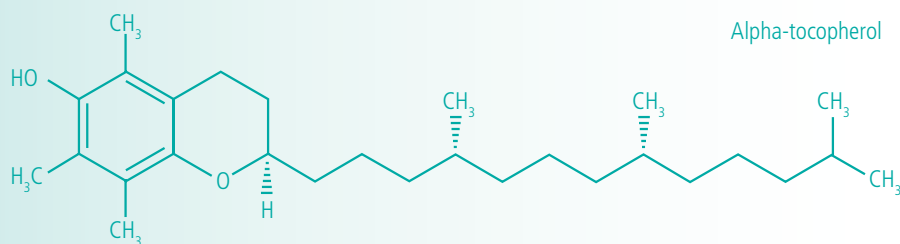
Today, most implants are treated by modern irradiation techniques for sterilization and/or performance improvement. As a result of these

Compression molded parts
made of GUR UHMW-PE
vitamin E filled grades



Illustration of homogeneous
distribution of vitamin E





processes, free radicals are formed in the UHMW-PE which can accelerate *in vivo* oxidation and shelf aging of the implants. Degradation of the material results in reduced mechanical properties, including reduced wear resistance.

Vitamin E is a collective term for the group of tocopherols, of which alpha-tocopherol shows the best properties as an antioxidant. It is a natural substance that already exists in the human body and can be used as a stabilizer for the orthopedic implants made from UHMW-PE. Alpha-tocopherol acts as a radical scavenger and eliminates the free radicals preventing oxidation of the material.

Ticona now provides the first vitamin E powder blend available on a commercial basis. The material is produced in accordance with ASTM F2965 and can be processed like virgin GUR® UHMW-PE premium powder. All mechanical properties remain unchanged compared to

the original GUR UHMW-PE premium grades. The blend follows the typical high standards of product cleanliness and shows a very uniform vitamin E distribution.

Product Stewardship

1. Ticona exclusively supplies grades GUR 1020-E and 1050-E for surgical orthopedic implant applications.
2. Suitable processing methods include compression molding/sintering, ram extrusion and direct compression molding (DCM).
3. These products are not suitable for injection molding.
4. GUR 1020-E and 1050-E resins are in compliance with ISO 5834, ASTM F648 and ASTM F2695.
5. GUR UHMW-PE premium is only supplied for well-documented orthopedic implant parts, such as hip, knee and other joints. Other applications are considered on a case-by-case basis.

CONFORMITY DATA*

GUR® 1020-E UHMW-PE
GUR® 1050-E UHMW-PE

- + FDA Regulation 21 CFR 177.1520
- + USP Class VI (ISO 10993-6; -10; -11)
- + USP <661> Physicochemical Test
- + ISO 10993-3 Genotoxicity
- + ISO 10993-4 Hemolysis
- + ISO 10993-5 Cytotoxicity
- + Drug Master File (DMF) 10904
- + Device Master File (MAF) 588

Performance Driven Solutions

Ticona, a business of Celanese Corporation, is a global company of material scientists, design engineers, technical support experts, account managers and customer service representatives dedicated to helping you achieve your goals in the use of engineering polymers. Ticona is a solutions-driven company that uses advanced polymer technology to produce high-performance plastic materials that are used in a wide spectrum of markets and applications. Our global reach, extensive product portfolio, and engineering and science capabilities enable us to work with you at any stage in your process – be it at early concept or in full production – anywhere in the world.

Technical Properties

	Unit	Test Method	Test Specimen	GUR® 1020-E UHMW-PE	GUR® 1050-E UHMW-PE
Typical Powder Properties					
Viscosity number (VN)	ml/g	ISO 1628, part 3, concentration in decahydronaphthalene 0.0002 g/ml for GUR UHMW-PE grades	Powder	2400	3600
Elongational stress F (150/10)	MPa	ISO 11 542-2	Dumbbell bar	0.24	0.48
Bulk density	g/cm ³	DIN 53 466	Powder	0.43	0.43
Vitamin E concentration	ppm	Internal method	Powder	1000 ± 100	1000 ± 100
Average particle size	µm	Laser refraction	Powder	140 ± 20	140 ± 20
Extraneous matter	#	Internal method	300g	< 3	< 3
Ash content	ppm	ISO 3451-1		< 125	< 125
Typical Properties of Consolidated Sheets					
Density	g/cm ³	ISO 1183 method A	Sheet	0.93	0.93
Charpy notched impact strength (with 14° V-notch on both sides)	kJ/m ²	ISO 11 542, part 2	120-15-10 mm	230	170
Izod notched impact strength (with 15° V-notch on both sides)	kJ/m ²	ASTM F648	63.5-12.7-6.35 mm	≥ 126	≥ 73