



Proven reliability

High-performance cellulosics for demanding medical device applications



A time-tested solution

In a world that is constantly changing due to technological advancements and rapid innovation, Tenite[™] cellulosics have remained relevant—and effective—decade after decade, since 1932. Apart from excellent clarity and toughness, the features that allow this material to continue to meet the needs of today's demanding medical device market include:

- Sustainability
- Chemical resistance
- Ease of processing
- Customizability

Furthermore, select formulas of the Tenite propionate 360 family have undergone USP Class VI testing after gamma sterilization.

Sustainability

Tenite is manufactured from 100% renewable softwood trees that are harvested utilizing sustainable forestry management practices. For every pound of Tenite produced, approximately 40% to 50% by weight is renewable content.



Chemical resistance

So important to the medical market, Tenite exhibits first-in-class chemical resistance to lipids, disinfectants, and oncology drugs.

Retention of impact energy

Sample	Lipids	IPA	Bleach	Quat	Phenolic	Virex [®] TB	3% Hydrogen peroxide	CaviCide™	Vesphene [®] IISE	Wex-Cide®	Sani-Cloth® AFIII	Etoposide
	% Retention in impact properties											
Tenite CAP360-07												
Tenite CAP360-12												
Tenite CAP360-16												
Eastman Tritan MX731 high flow												
PC (13 g/10 min MFR) standard flow									•		•	
PC (20 g/10 min MFR) high flow									•		•	•

KEY

80%–110% Good retention of impact energy

▲ 60%–79% Significant decrease in impact energy

0%–59% Severe decrease in impact energy

Retention of impact energy to break (%) against various disinfectants (exception: lipids are used as a therapeutic or body fluid simulant, and Etoposide is an oncology drug). Chemical resistance refers to resistance to environmental stress cracking and chemically induced embrittlement. (Chemicals were applied for 24 hours with the materials being held under 1.5% constant strain.

COMMON APPLICATIONS

Tenite is ideal for devices with thin walls or long flow lengths that pose processing challenges, but also require toughness and chemical resistance.

- Cannulas
- IV components
- Connectors
- Drug delivery devices

Ease of processing

Tenite also exhibits high flow for thin-walled, long flow length molding applications.



Typically, to increase flow or processability within a particular family of resins, toughness and chemical resistance are sacrificed. Tenite is an exception to the ordinary. The best combination of high flow processing while maintaining chemical resistance is only possible with Tenite.

Tenite CAP360-16



Spiral flow experiment utilizing slow-to-moderate injection speed and a 0.0625 in. mold wall thickness

Customizability

The mechanical properties of Tenite can be tailored for the requirements of many different applications by selecting an appropriate plasticizer content.

CAP360 property comparison as a function of bis(2-ethylhexyl) adipate plasticizer loading

	ASTM Method	CAP360-07	CAP360-12	CAP360-16
Flexural modulus (MPa)	D 790	1862	1448	1241
Yield strength (MPa)	D 638	41.4	31.7	30.3
Notched Izod (23°C) (J/m)	D 256	203	416	>533
Vicat softening temp. (°C)	D 1525	107	96	92

Note: Eastman makes no representation that the material in any particular shipment will conform exactly to the values given.

For more information, contact your Eastman representative or visit us online at www.eastman.com/tenite.



Eastman Chemical Company

Corporate Headquarters P.O. Box 431 Kingsport, TN 37662-5280 U.S.A.

Telephone: U.S.A. and Canada, 800-EASTMAN (800-327-8626) Other Locations, (1) 423-229-2000 Fax: (1) 423-229-1193

Eastman Chemical Latin America

9155 South Dadeland Blvd. Suite 1116 Miami, FL 33156 U.S.A.

Telephone: (1) 305-671-2800 Fax: (1) 305-671-2805

Eastman Chemical B.V.

Fascinatio Boulevard 602-614 2909 VA Capelle aan den IJssel The Netherlands

Telephone: (31) 10 2402 111 Fax: (31) 10 2402 100

Eastman (Shanghai) Chemical

Commercial Company Ltd. Building 3, Yaxin Science & Technology Park Lane 399 Shengxia Road, Pudong New District 201210, Shanghai, P.R. China

Telephone: (86) 21 6120-8700 Fax: (86) 21 5027-9229

Eastman Chemical Japan Ltd.

Anzen Building 16F 1-6-6 Moto Akasaka Minato-ku, Tokyo 107-0051 Japan

Telephone: (81) 3-3475-9510 Fax: (81) 3-3475-9515

Eastman Chemical Asia Pacific Pte. Ltd.

9 North Buona Vista Drive #05-01 The Metropolis Tower 1 Singapore 138588

Telephone: (65) 6831-3100 Fax: (65) 6732-4930

www.eastman.com

Safety Data Sheets providing safety precautions that should be observed when handling and storing Eastman products are available online or by request. You should obtain and review the available material safety information before handling any of these products. If any materials mentioned are not Eastman products, appropriate industrial hygiene and other safety precautions recommended by their manufacturers should be observed.

It is the responsibility of the medical device manufacturer ("Manufacturer") to determine the suitability of all component parts and raw materials, including any Eastman product, used in its final product to ensure safety and compliance with requirements of the United States Food and Drug Administration (FDA) or other international regulatory agencies.

Eastman products have not been designed for nor are they promoted for end uses that would be categorized either by the United States FDA or by the International Standards Organization (ISO) as implant devices. Eastman products are not intended for use in the following applications: (1) in any bodily implant applications for greater than 30 days, based on FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" tests (including any cosmetic, reconstructive, or reproductive implant applications); (2) in any cardiac prosthetic device application, regardless of the length of time involved, including, without limitation, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass assisted devices; or (3) as any critical component in any medical device that supports or sustains human life.

For manufacturers of medical devices, biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The ranges of tests under FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" include cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), subchronic toxicity (subacute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information is available on request. The Manufacturer of the medical device is responsible for the biological evaluation of the finished medical device.

The suitability of an Eastman product in a given end-use environment is dependent on various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is the responsibility of the Manufacturer to evaluate its final product under actual end-use requirements and to adequately advise and warn purchasers and users thereof.

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