



Products and packaging for the medical industry

The results of insight

Contents

Ecdel [™] elastomers Products and packaging for the medical industry 4
General information.
Applications
Regulatory information.
Melt characteristics.
Sealing conditions
Material characteristics.
General extrusion information
Preparation
Drying
Screw design
Filtration
Die design
Film quenching
Auxiliary equipment
Purging
Shutdown procedure
Monolayer film extrusion
Multilayer film extrusion
Extrusion blow molding Ecdel [™] elastomer 9967
Drying
Melt temperature
Screw design
Die head design
Cutoff knife
Mold construction
Mold temperature
Blow pin
Removing part from mold
Purging
Shutdown
Processing conditions

Extruded tubing
Injection molding Ecdel [™] elastomers
Drying
Melt temperature
Mold temperature
Injection pressure
Injection speed
Screw design
Screw speed
Back pressure
Venting
Sprues, runners, and gates
Radii and fillets
Part ejection
Purging
Shutdown and start-up
Typical physical properties

Table 1	Ecdel [™] elastomers
Table 2	Sealing conditions for film extruded from $Ecdel^{\scriptscriptstyle M}$ elastomer 9966 7
Table 3	Effect of gamma radiation on Ecdel [™] elastomer 9966 8
Table 4	Effect of thermal treatment on Ecdel ^{M} elastomer 9966 8
Table 5	Suggested conditions for extrusion of 0.125-mm (5-mil) film from Ecdel [™] elastomer 9966
Table 6	Suggested extrusion blow molding conditions for $Ecdel^{\scriptscriptstyle M}$ elastomer 9967 14
Table 7	Suggested extrusion processing temperatures for $Ecdel^{\scriptscriptstyle M}$ elastomer 9967 15
Table 8	Mechanical properties of Ecdel ^{$**$} elastomer 9966
Table 9	Physical properties of film extruded from $Ecdel^{\scriptscriptstyle \mathbb{M}}elastomer$ 9966 19
Table 10	Electrical properties of Ecdel ^{m} elastomer 9966
Table 11	Permeability properties of Ecdel $^{\!\!\!\!^{M}}$ elastomer 9966
Table 12	Thermal properties of Ecdel ^{M} elastomer 9966
Table 13	Chemical resistance of Ecdel [™] elastomer 9966

Ecdel[™] elastomers Products and packaging for the medical industry

Ecdel[™] elastomers are unique polyester ethers marketed by Eastman Chemical Company. These materials offer clarity and toughness over the extremely wide range of temperatures and chemical resistance required for a variety of demanding applications, including flexible medical and pharmaceutical packaging. Ecdel is widely known for low levels of extractables. It may be autoclave, gamma irradiation, ethylene oxide (EtO), or E-beam sterilized.

Three grades of Ecdel[™] elastomers are commercially available to meet the requirements of the most prevalent polymer processing operations, including extrusion, injection molding, and extrusion blow molding. Additionally, Ecdel can be coextruded with other resins to provide unique solutions to the most difficult needs.

This publication contains information regarding the typical properties of Ecdel[™] elastomers, as well as suggestions for equipment selection and processing conditions to provide optimal performance.

Eastman's Technical Service group is available to assist you during the design and production phases of your application. Our technically trained staff can help you shorten development and commercialization cycles critical to maintaining a competitive edge. Call us to see how we can help. Eastman products have not been designed for nor are they promoted for end uses that would be categorized by the United States Food and Drug Administration (FDA) as implant devices. 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 in order to ensure safety and compliance with requirements of the FDA or other international regulatory agencies.

General information

Applications

Ecdel[™] elastomers may be processed by injection molding, extrusion, and extrusion blow molding. As shown in Table 1, all three formulas may be injection molded and extruded into film and tubing, but only Ecdel elastomer 9967 may be extrusion blow molded. Melt temperatures generally range from 205° to 260°C (400° to 500°F). Optimization of melt temperature for a given process is desirable because the range varies from process to process. Ecdel[™] elastomers may be extrusion blow molded directly into bags or extruded into film for later fabrication into bags. Bags made of Ecdel elastomer usually require an overwrap to maintain drug concentration at the desired level for the shelf life of the product. Barrier properties can be improved through coextrusion with other materials, such as polypropylene or polypropylene/ethylene copolymers. Certain applications involve exposure to conditions ranging from subfreezing temperatures to autoclaving. Ecdel can often provide the heat stability and flexibility needed for use in such environments.

Product	Target inherent viscosity	Extrusion	Injection molding	Extrusion blow molding
9965	1.05	٠	٠	
9966	1.16	٠	٠	
9967	1.23	٠	٠	٠

Table 1. Ecdel[™] elastomers

Regulatory information

ISO 10993 evaluation and testing

The following biological tests for the categories of surface devices and external communicating devices have been conducted on samples of Ecdel[™] elastomer by laboratories independent of Eastman and meet ISO 10993 biocompatibility requirements.

- Cytotoxicity (MEM elution)
- Sensitization
- Irritation/intracutaneous reactivity
- Systemic toxicity (acute)
- In vitro hemocompatibility assay and hemolysis

As required by the U.S. Pharmacopeia (USP) Class VI, the following biological reactivity tests have been conducted on Ecdel[™] elastomers and meet the USP criteria.

- Physicochemical
- Systemic injection
- Intracutaneous injection
- Implantation

Eye irritation tests have also been conducted. Ecdel[™] elastomers were not found to be an eye irritant.

Data from these tests are available on request.

Drug master file (DMF)

Eastman has established Drug Master File No. 4160 with the FDA for Ecdel[™] elastomers and will authorize the FDA's reference to this file at a customer's request.

FDA status

There is no FDA regulation permitting the use of Ecdel[™] elastomers in either direct or indirect food additives.

Additional regulatory information is available on request.

Melt characteristics

Ecdel[™] elastomers have a low melt strength and are extremely tacky during processing. Avoid the use of highly polished chromeplated rolls, molds, and other contact surfaces. Otherwise, sticking will be a problem.

Tackiness can be controlled using matte finishes on metal components and by adjusting roll or tooling temperatures. Adjusting the temperature imparts a degree of crystallinity to the product and improves its release properties. In addition, tooling impregnated with Dupont Teflon[™] fluorocarbon polymer gives good results.

Sealing conditions

Film extruded from Ecdel[™] elastomers has been sealed to itself by conventional heat-sealing methods, such as impulse or radio frequency (RF) sealers, in the Technical Service Laboratory. However, conditions used in the laboratory may not translate into suitable conditions for commercial bag manufacturing processes.

Impulse-sealing conditions were determined on a Sentinel Heat Sealer with a 110-volt power source manufactured by Packaging Industries of Hyannis, Massachusetts, U.S.A. The sealing unit (Model Number 24-679, Serial Number 12-12-ASL) utilized voltage or heat on the top and bottom bars. Impulse conditions, as shown in Table 2, yielded a total cycle time of 2.1 seconds.

Test specimens were 0.2-mm (8-mil) thick and 25.4-mm (1-in.) wide. The flat-seal width was 2.4 mm (³/₃₂ in.). Specimens were peeled using an MTS Systems Sintech[™] testing machine at a speed of 50.8 mm/min (2 in./min). All specimens were conditioned for 24 hours at 23°C (73°F) and 50% relative humidity (RH) prior to testing. Peak T-peel strengths averaged 1.55 kg/cm (8.7 lb/in.) for 5 specimens.

Conventional RF sealing conditions at 27.12 megahertz (MHz), as typically employed with polyvinyl chloride (PVC) films, cannot be used for Ecdel[™] elastomer films. The lack of polarity and different dielectric properties necessitates a high RF power level and higher preseal temperature to obtain a satisfactory bond.

A Kabar 10-kilowatt RF sealer operating at 27.12 MHz was equipped with a flat sealing bar or die that was heated to 177°C (350°F). Films were also sealed using a tear-seal die heated to the same temperature. Seal widths were 2.38 mm (0.09 in.) and 1.59 mm (0.06 in.) for flat and tear seals, respectively. Film specimens, conditioning of specimens, and peeling the specimens were the same as outlined above. RF conditions, as shown in Table 2, yielded a total cycle time of 10 seconds.

The flat-seal specimens yielded peak T-peel values averaging 1.32 kg/cm (7.4 lb/in.) for 5 specimens. The tear-seal specimens yielded peak T-peel values averaging 1.45 kg/cm (8.1 lb/in.) for 5 specimens.

Table 2. Sealing conditions for film extruded from Ecdel[™] elastomer 9966

Impulse sealer		
Film thickness, mm (mil) 0.2 (8)		
Cycle time, s		
Seal	1.1	
Cooling	1.0	
Total	2.1	
Power, volts	25	
Air pressure, kPa (psi)	413 (60)	

Bar RF sealer	
Film thickness, mm (mil)	0.2 (8)
Power level, %	75
Preseal temperature, °C (°F)	177 (350)
Cycle time, s	
Preseal	3
RF seal	6
Cooling	1
Total	10
Air pressure, kPa (psi)	413 (60)

Material characteristics

Effect of sterilization on Ecdel[™] elastomers

Neither ethylene oxide nor autoclave sterilization methods have a significant effect on the properties of Ecdel[™] elastomer films.

When film of Ecdel[™] elastomer 9966 is exposed to increasing levels of gamma radiation, the inherent viscosity (I.V.) of the material decreases and a substantial reduction in tear strength is experienced (see Table 3).

There are no significant differences in film properties when Ecdel[™] elastomer 9966 is subjected to various thermal treatments (see Table 4).

Weatherability

Ecdel[™] elastomer polymers are not inherently stable to continuous, long-term exposure to ultraviolet light as encountered in certain outdoor or industrial uses. If you are interested in weatherability solutions, contact your Eastman sales representative.

Table 3. Effect of gamma radiation on Ecdel[™] elastomer 9966, % change

Exposure dosage, megarads1.53.04.5Film, I.V5-18-20Total extractablesa45215515Tensile stress @ yieldb41224Tensile stress @ breakb-15-17-20				
Total extractablesa45215515Tensile stress @ yieldb41224		1.5	3.0	4.5
Tensile stress @ yieldb41224	Film, I.V.	-5	-18	-20
	Total extractables ^a	45	215	515
Tensile stress @ break ^b −15 −17 −20	Tensile stress @ yield⁵	4	12	24
	Tensile stress @ break [♭]	-15	-17	-20
Elongation @ break ^b 11 3 -2	Elongation @ break ^b	11	3	-2
Tensile modulus, MPa ^b -51 -43 -40	Tensile modulus, MPa ^b	-51	-43	-40
Tear strength ^b −2 −26 −61	Tear strength ^ь	-2	-26	-61

^aExtractables obtained by heating 645 cm² (100 in.²) of film in 200 mL of water @ 121°C (250°F) for 1 hour in a tared beaker; water was evaporated to dryness and beaker was weighed to determine extractables level.

^bProperties were run on 0.125-mm (5-mil) film (machine direction only). Yield stress, break stress, elongation, and tensile modulus were run according to ASTM D882. Tear strength was run according to ASTM D1004.

Table 4. Effect of thermal treatment on Ecdel[™] elastomer 9966, film thickness, 0.125 mm (5 mil), % change

	Tensile strength @ break	Tensile modulus	Elongation @ break	Tear strength
ASTM method	D882	D882	D882	D1004
Conditions 15 min/125°C (257°F) ^a				
M.D.	10	-23	No change	15
T.D.	4	-23	No change	No change
15 min/160°C (320°F)ª				
M.D.	3	-33	-20	40
T.D.	4	-24	8	-30
Autoclaved ^b				
M.D.	13	-20	6	13
T.D.	4	-10	5	10

^aExposed to temperature shown in forced-air oven.

^bExposed @ 121°C (250°F) and 0.10 MPa (15 psi) for 1 hour.

General extrusion information

Preparation

The extruder barrel, screw, and die should be cleaned thoroughly before running Ecdel[™] elastomers. Failure to do so will probably result in excessive die lines, gels, and other visual defects in the finished product.

Drying

Ecdel[™] elastomers must be dried to a moisture level of approximately 0.02% before processing, or like other polyesters, it will undergo excessive hydrolytic degradation while in the melt. A dehumidifying desiccant dryer capable of supplying air at 66°C (150°F) with a dew point not exceeding –30°C (–22°F) and an air volume of 0.062 m³/min/kg (1 cfm/lb) per hour of output will normally dry the material adequately in 4–6 hours. Therefore, the hopper should hold at least 4 times the expected hourly output capacity of the extruder. Longer drying times may be needed if the material has been stored for an extended period.

Drying hoppers, bulk silos, drums, and gaylords provide several means for storing polymer resin. Both poured and vibrated bulk densities have been obtained for Ecdel[™] elastomers. The values are 609 kg/m³ (38 lb/ft³) and 673 kg/m³ (42 lb/ft³), respectively and may be used for any of the Ecdel elastomers.

Screw design

Ecdel[™] elastomers have been shown to process satisfactorily on extruders and screws of a number of different sizes (no special screw design is required to process this material). Extrusion screws having the following characteristics have performed satisfactorily with this material on 63.5-mm (2½-in.) and 88.9-mm (3½-in.) extruders.

- 24:1 minimum L/D ratio
- Approximately the same number of flights in feed and metering sections
- Three or four flight transitions
- Compression ratio of approximately 3:1

If there is a question of suitability of a proposed screw for processing Ecdel[™] elastomers, it is suggested that a drawing be supplied to Eastman's Technical Service and Development Department in Kingsport, Tennessee, U.S.A., for review.

Filtration

Ordinary screen packs and screen pack changers are normally used for extruding Ecdel[™] elastomers. For example, a 24/80/180/80/24 mesh arrangement should be suitable. As the micron rating of a screen pack filtration system is reduced, the filter area must be increased to ensure adequate pack life.

Die design

For film extrusion, a die with a flexible lip is suggested. The die should be tapered to minimize the die-to-chillroll distance. The internal die surfaces should have a 2- to 4-microinch (rms) finish, and the die opening should be 0.6–0.8 mm (25–30 mil) for film thicknesses of 0.025–0.25 mm (1–10 mil).

Film quenching

Ecdel[™] elastomers can be filmed by traditional blown, cast, or sheeting processes. The quench rate will control the optical qualities of the finished films. In blown film processes, controlled chilled air is recommended for the air ring and/or internal bubble cooling (IBC).

When casting or sheeting Ecdel[™] elastomers, a preferred casting system requires a special surface finish on the chill rolls that is different from conventional casting roll systems that employ polished chrome finishes. The nature of Ecdel elastomers melt is such that it vigorously adheres to polished metal finishes. To avoid these problems, the chill rolls should use one of the following finishing methods. The preferred method uses Teflon[™]-impregnated chrome on the roll surface. There are several trademarked processes that provide this kind of service. The second method employs a 25- to 50-rms finish that may be obtained by sandblasting or vapor honing the roll surface. Both methods yield films with excellent clarity. Although the preferred casting system employs a special finish on all rolls, some success has been experienced by using it on the top rolls only (includes the polishing roll if sheeting).

Usually an air knife or vacuum box is utilized when casting film. Chilled air is recommended for the air knife system if one is used for improved chill-roll pinning. The quench water temperature to the top roll should be 10°–25°C (50°–75°F) to quench the film, followed by a water temperature of 55°-65°C (130°-150°F) to the bottom roll to promote crystallization. Temperatures as high as 90°-95°C (190°-200°F) may be required to promote crystallization at high line speeds or if polished chrome rolls are used. The resultant film may be hazy if quenching is performed too slowly or if high roll temperatures are utilized for release. The varying relationships between time and temperature that may be encountered at different throughputs, roll diameters, film thicknesses, and temperatures require conditions to be optimized for each particular operation. Sticking on the top roll, even with a special finish, may suggest insufficient cooling, insufficient roll matte, or both. If the film is too tacky, the bottom roll may be too cool. If, on the other hand, the film is milky in appearance, the bottom roll is probably too hot, resulting in excess crystallization.

Since Ecdel is an elastomer, films may become tacky, particularly when processed with a fast quench rate. If the blocking force or coefficient of friction is too high for processing or the final application, Eastman offers additive concentrates which can be added to improve these properties.

Auxiliary equipment

The film-casting unit will normally be equipped with air jets to pin the edges of the extrudate to the top roll to prevent excessive neck-in. An air knife is used to provide intimate contact of the extrudate across the top of the chill roll. This ensures uniform cooling and prevents slippage of the film across the roll.

Purging

Polypropylene, high-density polyethylene, and many other materials will do a satisfactory job of purging Ecdel[™] elastomers. Because of the good melt stability of this material, purging may not be necessary when the machine is shut down. However, material that is not purged will crystallize in the extruder, and elevated temperatures (approximately 14°C [25°F] above normal) will be required on start-up.

Shutdown procedure

Ecdel[™] elastomers are considered to be heat-stable at the temperatures listed in Table 5. Therefore, the machine can be shut down and later restarted after only a few minutes of purging without any unusual problems. If an extended shutdown is anticipated, it is suggested that the hopper be drained and the extruder run until it is empty. Suitable purging compounds for periodic cleaning of the extruder and die are commercially available.

Table 5. Suggested conditions for extrusion of 0.125-mm (5-mil) film from Ecdel[™] elastomer 9966

Material	Ecdel [™] elastomer 9966	
Equipment	60-mm (2.36-in.), 24:1, L/D extruder Barrier screw 2-Roll stack	
Barrel zone	1, °C (°F)	200 (400)
	2, °C (°F)	230 (450)
	3, °C (°F)	260 (500)
	4, °C (°F)	260 (500)
	5, °C (°F)	260 (500)
	6, °C (°F)	260 (500)
Gate, °C (°F)		260 (500)
Screw speed, rpm	1	17
Water temperatu	ıre, top roll, °C (°F)	10–25 (50–75)
Water temperature, bottom roll, °C (°F)		55–65 (130–150)
Line speed, mpm	(fpm)	9 (30)
Film thickness, m	ım (mil)	0.125 (5)

Monolayer film extrusion

Table 5 gives suggested conditions for extruding Ecdel[™] elastomers into monolayer film. Some changes are usually required to optimize film appearance and physical properties. Ordinarily, this material should be extruded at the lowest melt temperature that will yield a satisfactory product.

Multilayer film extrusion

Ecdel[™] elastomers can be coextruded with other thermoplastic materials having reasonably similar rheological properties and processing temperatures. For example, moisture barrier characteristics can be improved by combining Ecdel elastomers, any of various suitable tie layers, and polyolefins or other polymers.

Commercial tie-layer materials will permit autoclaving without layer separation. The coextrusion process used with Ecdel[™] elastomers is much the same as that used for other materials, utilizing a coextrusion feed block and satellite extruders. The use of a nontacky material coextruded with Ecdel elastomers can simplify some aspects of the casting operation.

Contact your Eastman Technical Service Representative for additional details.

Extrusion blow molding Ecdel[™] elastomer 9967

Drying

See "Drying" on page 9.

Melt temperature

Typical melt temperatures for blow molding Ecdel[™] elastomers are 205°–230°C (400°–445°F). As melt temperature increases, clarity of the molded parts improves. Processing temperatures above 230°C (445°F) can result in excessive parison sag because of reduced melt strength.

Screw design

As discussed in the section on film extrusion, conventional screws have been found to perform satisfactorily with Ecdel[™] elastomers. Eastman's Technical Service and Development Department in Kingsport, Tennessee, U.S.A., can assist on the suitability of a given design on receipt of a drawing or detailed description of the screw being considered. In most cases, the screw will not require a mixing section. If additional melt homogenization or flow-line removal is required, however, a Maddock, Union Carbide, or similar mixer can be used.

Die head design

The die head may be a PVC torpedo, spider, or polyethylene type. Because Ecdel[™] elastomer 9967 is quite viscous under extrusion blow molding conditions, a polyethylene head should have more generous clearances in the restriction areas than those normally associated with polyolefin materials.

Cutoff knife

The cutoff knife is used to cut the hot parison so that the mold can move it away from the die. The cold knife method has been found to provide a reliable cutoff. Sufficient air pressure should be used to provide a rapid swing of the knife.

Mold construction

The mold should be designed to provide good circulation of the cooling water and maximum heat transfer. Aluminum or an alloy of beryllium and copper is the suggested material for the mold. As mentioned previously, Ecdel[™] elastomers polymer melt vigorously adheres to polished metal surfaces. Mold release may be promoted by using fluoropolymer-impregnated metals, which also promote resistance to friction, wear, and abrasion. The finish also prevents entrapment of air. Alternately, a fine matte finish, such as a 220-grit blast, may serve a similar purpose.

All profile changes should be done gradually, and generous draft angles should be provided where possible. This is particularly true for thin cross-sectional parts because an extremely flexible part offers no resistance for pulling free of channels and ledges. Undercut areas must be avoided and ample venting must be used.

The shrinkage allowance for Ecdel[™] elastomers will vary with mold temperature and will usually be from 0.004 to 0.008 mm/mm (4 to 8 mil/in.).

Mold temperature

The optimum degree of crystallization is achieved by using molds fabricated from proper metals and by controlling the temperature of the cooling water. Water temperature of 45°–50°C (110°–120°F) has been found to provide optimum balance between clarity and crystallization when parts are being blow molded.

External handling devices, such as a picker and blow pin, must also be controlled to a similar temperature.

Blow pin

Conventional blow pins that forge the thread finish or other fitting cannot be used because the hot elastomer will stick to the pin and hold it tenaciously. The blow-pin system must be simply designed to penetrate and seal with minimum surface contact.

Removing part from mold

Because the molded article is soft and flexible, part removal requires special considerations. The following are key items to consider when removing your parts from the mold.

- Parts should be held firmly at two places, usually the top and bottom areas.
- After the mold has been opened, one of the holding devices can serve as a robot, or picker, to carry the molded part away and to release it to a conveyor or other handling system.
- A soft, flexible part does not offer enough rigidity for simple removal and may tend to hang on one side of the mold. Consequently, it is necessary to completely control the location of the part at all times during the removal phase.
- To minimize sticking, all flash areas should be thoroughly air-cooled or completely encapsulated by cooled metal surfaces, such as those on the mold or picker.
- Critical surfaces of the mold and handling device can be coated with Teflon[™] fluorocarbon polymer.
- Flash areas can be readily torn or cut free of the molded part if the appropriate pinch lands are built into the mold.
- Automatic in-mold detabbing is difficult or impossible because the tab is needed as a holding part during removal.

Purging

See "Purging" on page 11.

Shutdown

See "Shutdown procedure" on page 11.

Processing conditions

The suggested extrusion blow molding conditions for a 60-mm (2.36-in.) extruder are given in Table 6. These conditions may need to be adjusted, depending on such factors as screw design, output rate, part design, and other variables.

Table 6. Suggested extrusion blow molding conditions for Ecdel[™] elastomer 9967

Equipment	60-mm (2.36-in.) extruder Bekum HBV 120 blow molding machine	
	18-oz widemouthed jar mold	
	Single PVK-50 torpedo die	
	Bushing I.D., mm (in.)	22.87 (0.900
	Mandrel O.D., mm (in.)	22.35 (0.880
Barrel zone	1, °C (°F)	188 (370)
	2, °C (°F)	221 (430)
	3, °C (°F)	193 (380)
	4, °C (°F)	169 (335)
Gate, °C (°F)		182 (360)
Die body, °C (°F)		182 (360)
Die tip, %		80
Melt temperature, °C	(°F)	216 (421)
Mold coolant tempera	ature, °C (°F)	38 (100)
Screw speed, rpm		24
Blowing time, s		12.0
Overall cycle, sª		17

^aDouble shuttle run in single-shuttle mode.

Extruded tubing

Ecdel[™] elastomers can be extruded into semirigid tubing. Additional melt strength can be attained by using Ecdel elastomer 9967. Table 7 shows suggested processing temperatures based on limited experience using a 60-mm (2.36-in.) extruder, an L/D ratio of 24:1, and a conventional screw as described on page 14.

Because Ecdel[™] elastomers are a crystalline material, the tubing must be cooled under controlled conditions to achieve clarity. Otherwise, the appearance of the finished tubing can range from clear to hazy to practically opaque.

As with any polyester or copolyester, there may be a certain degree of residual crystallinity from prior processing or drying. This should be erased by running the melt at a sufficient temperature to destroy the effects of any crystalline history. The tubing should then be quenched as quickly as possible to achieve the desired level of dimensional stability for satisfactory handling. Finally, the tubing should be reheated to obtain a moderate level of crystallinity for improved handling without significantly reducing its clarity.

A number of factors must be considered in determining the maximum operating melt temperature. These include

- Viscosity of the extrudate
- Desired tubing size
- Line speed
- Cooling techniques
- Reheat capability
- Product handling requirements

Normal operation involves adjusting barrel zones 3 and 4 to maximize clarity and control the melt. However, an increase in zones 1 and 2 may allow a reduction in zones 3 and 4, while striking a satisfactory balance between viscosity and clarity.

Since the material will stick to a conventional sizing apparatus, a free extrusion technique is suggested. Excellent control of airflow and utilization of a gear pump are highly desirable. Ecdel[™] elastomers are not a corrosive material, so no particular precautions are necessary with regard to the gear pump.

The presence of residual immiscible resins, such as polyolefin in the gear pump, is likely to contaminate Ecdel[™] elastomers. Purging may be accelerated by heating the

gear pump to a temperature above that of the incoming melt, and in time, the elastomer will purge the olefin material from the gear pump.

The process for cooling and heating tubing extruded from Ecdel[™] elastomers is similar to that used for polyethylene materials. The coolest water available should be used as the material exits the die to quench the tubing and set its shape. If chilled water is available, it would be better than merely cool water.

After the tubing has been quenched, it should be passed through a heated trough to impart a low level of crystallinity and satisfactory handling characteristics. A reasonable starting point for reheating is 52°C (125°F). The reheat temperature may be increased as needed to impart the desired level of crystallinity, but it should not exceed 70°–80°C (160°–170°F). Again, final reheat temperature should be limited to that required to provide satisfactory handling of the finished tubing.

If the tubing exhibits a hazy appearance after reheating, the water is probably too hot for the residence time in the tank. Adjustments may be made by either increasing throughput, lowering water temperature, or a combination of both.

Tubes with large cores should be used in the winding operation. Ecdel[™] elastomers are not as flexible as other materials such as PVC. It yields a semirigid tubing that will kink. Kinking may also be a function of the diameter of the tubing, a lack of crystallinity, or both. If kinking takes place, air will not flow properly and pulsing or ballooning may occur, which could cause quality problems.

Table 7. Suggested extrusion processing temperatures for Ecdel[™] elastomer 9967

		°C	°F
Zone	1	177	350
	2	204	400
	3	204	400
	4	204	400
Melt		219+	425+
Cooling	tank	10–16	50-60
Heating	tank	52	125

Injection molding Ecdel[™] elastomers

Drying

See "Drying" on page 9.

Melt temperature

Ecdel[™] elastomers can be molded with melt temperatures ranging from 225° to 260°C (435° to 500°F). At low melt temperatures, the material flows relatively easily into the mold. At high melt temperatures, the material flows so easily that flashing is generally a problem in any area where the mold is not seated tightly. For molding most items, temperatures in the range of 230°–250°C (450°–480°F) are desirable.

Mold temperature

Mold temperature is usually critical to the production of acceptable parts from Ecdel[™] elastomers. Mold temperatures ranging from 5° to 80°C (40° to 180°F) have been used. Mold temperatures in the range of 50°–80°C (120°–180°F) allow some crystallization of the polymer to occur, resulting in easier ejection from the mold. Better surface finish and shorter cycles result from these higher mold temperatures, although parts appear hazier as a result of polymer crystallization. Mold temperatures on the low end of the range tend to result in severe sticking of parts in the mold unless cooling and overall cycle times are increased. For the most part, temperatures in the range of 40°–65°C (100°–150°F) are suggested, with the higher temperatures preferable when sticking on cores or in cavities and sprue bushings is evident.

Injection pressure

Low injection pressures are usually preferable because Ecdel[™] elastomers flow easily and tend to flash. High pressures tend to reduce mold shrinkage by compressing the rubbery material. Sticking in the mold and on the sprue bushing and cores can result from overpacking with high injection pressures.

Injection speed

Part thickness and design generally dictate the injection speed to be used. Medium to slow injection speeds are generally preferred when molding Ecdel[™] elastomers. Fast speeds tend to overpack and cause sticking and flashing. Also, jetting and backfilling can occur with fast injection speeds, resulting in surface defects.

Screw design

General-purpose screws having compression ratios of 2.5–3.0:1 have been used successfully. The transition zones should have a gradual transition (typically 4–6 diameters) so that the high shear heating of rapid transition is avoided. It is suggested that a free-flowing sliding check ring nonreturn valve at the end of the screw be used instead of a ball check type valve. Vented barrels are not recommended. Unfilled resins are generally mild on screw wear and corrosion of the barrel and screw is not expected with these copolyesters.

Screw speed

Screw speed does not appear to be critical to the successful processing of Ecdel[™] elastomers. Screw speeds of 30–120 rpm have been used successfully.

Back pressure

Back pressure is not normally required when molding natural Ecdel[™] elastomers. If, however, large reground particles are present in the feed or if color concentrates or dry coloring agents are being used, it may be necessary to use a small amount of back pressure to keep the screw full, to plasticate the material properly, and to aid in color dispersion. If back pressure is too high, screw return time may be significantly increased or feeding problems may result.

Venting

Ecdel[™] elastomers give off little or no gas during molding, and vents of 0.01–0.02 mm (0.0004–0.0008 in.) are usually adequate to release air entrapped in the mold. In accordance with good mold design, vents should be relieved to the edge of the mold.

Sprues, runners, and gates

Sprue and runner systems should be as short as possible to minimize pressure drop. The sprue should be large enough in diameter so that it will not freeze before the runner system.

Gates should be as large as practical. It is suggested that gates be at least 1.3 mm (0.05 in.) in diameter for Ecdel[™] elastomers, but a smaller gate should be satisfactory for small, thin-walled parts. Web or tab gates should be considered for large parts. Sprue gating is acceptable for single-cavity molds, but care should be taken in operation not to overpack the cavity.

Radii and fillets

All materials are sensitive to notches to some degree. Whenever possible, sharp corners or angles should be rounded to produce parts more resistant to tearing when they are ejected from the mold or subjected to rigorous end-use conditions.

Part ejection

The rubbery nature of Ecdel[™] elastomers, along with their tendency to adhere to polished metal surfaces, means that it is often difficult to eject parts from the mold. Sufficient draft and knockout pins, larger than those used with conventional plastics, are usually required. Besides being larger, more knockout pins may be necessary. Ejection of parts has also been enhanced through the use of Teflon[™]impregnated nickel, a finish that provides good wear and lubricity. When special tooling finishes do not exist, mold releases of the spray type can be used to aid ejection in prototype work. Also, internal mold releases such as zinc stearate or Acrawax[™] C at a level of 0.3%–1% have been found to help part ejection considerably.

Purging

See "Purging" on page 11.

Shutdown and start-up

If the molding machine is purged, normal shutdown procedures should be used. The screw should be moved to its forward position and the machine operated as an extruder until no more plastic is being extruded. The heat can then be turned off and the screw stopped.

When processing is to be started again, the heater should be turned on and allowed to heat the machine to operating temperature. Then the injection switch should be actuated, even though the screw is already in a forward position. The small motion that results will free the slip ring of the nonreturn valve so that it will operate properly. Rotation of the screw can then begin.

Typical physical properties

Measurements on all formulas for Ecdel[™] elastomers have not demonstrated any significant differences. Ecdel elastomer 9966 has been selected as the material of choice in generating data. Typical physical properties of Ecdel are reported in Tables 8 through 13 and Figure 1. Additional information may be obtained by contacting Eastman at one of the addresses on the back cover of this brochure.

Table 8. Mechanical properties of Ecdel[™] elastomer 9966

Property, ^a units	ASTM method	Typical value
Specific gravity	D792	1.13
Durometer hardness, shore D/A scale	D2240	55/95
Tensile stress @ break	D412 ^b	22 (3,200)
Tensile stress @ yield	D638°	14 (2,030)
Elongation @ yield, %	D638°	38
Elongation @ break, %	D638°	400
Tensile modulus, MPa (psi)	D638	170 (24,650)
Flexural modulus, MPa (psi)	D790	150 (21,750)
Tear strength, N (lbf)	D1004	350 (79)
Izod impact strength, notched, J/m (ft·lbf/in.) @ -40°C (-40°F)	D256	40 (0.75)
Torsional modulus temperature, °C (°F)		
@ 240 MPa (35,000 psi)	D1043	-28 (-18)
@ 930 MPa (135,000 psi)		<-70 (<-94)
Water absorption, 24h, %	D570	0.4

^aUnless noted otherwise, all tests are run @ 23°C (73°F) and 50% RH.

^bD412, Die C specimens, which are equivalent to ASTM D638, Type IV specimens. Specimens were 2.0-mm (0.075-in.) thick and were tested using a crosshead speed of 500 mm (20 in.) per min.

sInjection molded ASTM D638 type I specimens, about 3-mm (1/8-in.) thick, were tested using a crosshead speed of 508 mm (20 in.) per min.

Table 9. Physical properties of film extruded from Ecdel[™] elastomer 9966

Property, ^a units	ASTM method	Typical value
Thickness, mm (mil)		
Minimum		0.11 (4.5)
Maximum		0.14 (5.5)
Haze, %	D1003	1
Gloss at 45°	D2457	85
Transmittance, %		
Regular	D1003	94
Total		93
Refractive index, n _p	D542	1.51
Tensile stress @ yield, crosshead speed, 500 mm (20 in.)/min, MPa (psi)		
M.D.		14 (2,030)
T.D.		12 (1,740)
Elongation @ break, %	 D882	
M.D.		>400
T.D.		>500
Tensile modulus of elasticity, crosshead speed, 25 mm (1 in.)/min, MPa (psi)		180 (26,000)
Coefficient of friction	D1894	>1

°Unless noted otherwise, all tests are run @ 23°C (73°F) and 50% RH.

Table 10. Electrical properties of Ecdel[™] elastomer 9966

Property, ^a units	ASTM method	Typical value
Arc resistance, s (tungsten electrodes)	D495	Fails by melting
Comparative tracking index (CTI), volts	IEC112	Fails by melting
Volume resistivity (in air), ohm·cm	D257	10 ¹⁴
Surface resistivity, ohm/square	D257	10 ¹⁵
Dielectric strength, short time test @ 500 volts/s rate of rise, kV/mm (V/mil)	D149	14 (356) in oil 6 (152) in air
Dielectric constant		
1 kHz		3.9
10 kHz		3.8
1 MHz		3.7
Dissipation factor	D150	
1 kHz		0.02
10 kHz		0.02
1 MHz		0.02

^aAll tests are run @ 23°C (73°F) and 50% RH.

Table 11. Permeability properties of Ecdel[™] elastomer 9966

Property, ^a units	ASTM method	Typical value
Specimen thickness, mm (mil)		0.11–0.14 (4.5–5.5
Water vapor transmission rate		
@ 38°C (100°F) and 90% RH,	F372 ^b	190 (12)
g/m²·24h (g/100 in.²·24h)		
Gas permeability		
cm³·mm/m²·24h·atm		
(cm³·mil/100 in.²·24h·atm)	D1434	
CO ₂ @ 23°C (73°F)		>1,000 (>2,540)
O ₂ @ 30°C (86°F)		130 (330)

^eUnless noted otherwise, all tests are run @ 23°C (73°F) and 50% RH. ^bMocon values; confirmed by ASTM E96E.

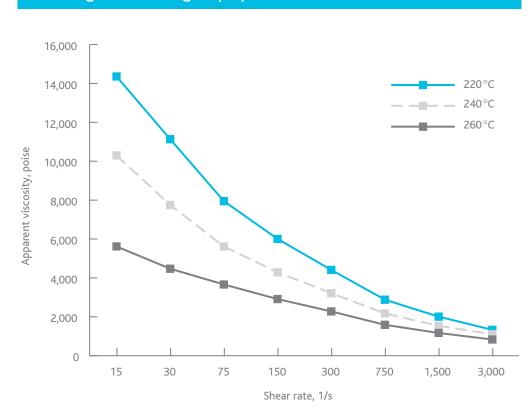


Figure 1. Rheological properties of Ecdel[™] elastomer 9966

Table 12. Thermal properties of Ecdel[™] elastomer 9966

Property, ^a units	ASTM method	Typical value
Flow rate (condition 230°C/2.16 kg load), g/10 min	D1238	10
Crystalline peak melting point, T _m , °C (°F)	D3418	205 (400)
Crystallization temperature on cooling, $T_{cc'}$ °C (°F)		140 (284)
Glass transition temperature, T _g , °C (°F)		-3 (27)
Specific heat, ^b kJ/kg·K (cal/g·°C)		
25°C (77°F)—solid		1.6 (0.382)
100°C (212°F)—solid	DSC	1.8 (0.430)
150°C (302°F)—solid		2.0 (0.478)
175°C (347°F)—solid		2.3 (0.549)
200°C (392°F)—transition		3.1 (0.740) ^c
225°C (437°F)—melt		2.3 (0.549)
Heat of fusion, kJ/kg (Btu/lb)	E793	27 (11.6)
Thermal conductivity, W/m·K (cal/cm·s·°C) 31°C (88°F)	C177	0.19 (0.0004)
Coefficient of linear thermal expansion, 10 ⁵ mm/mm.ºC (10 ⁵ in./in.ºF)	D696	15 (8)
Brittleness temperature, °C (°F)	D746	<-75 (<-103)
Vicat softening temperature (1 kg load), °C (°F)	D1525	170 (338)

°Unless noted otherwise, all tests are run @ 23°C (73°F) and 50% RH.

^bSpecific heat in Btu/lb•°F is numerically equivalent to the value in cal/g•°C.

^cApparent specific heat, including the effects of the heat of fusion.

Conversions of metric/U.S. customary values may have been rounded off and therefore may not be exact conversions.

Table 13. Chemical resistance of Ecdel[™] elastomer 9966

Chemical	Effect ^a
Acetic acid	Severe swelling
Acetone	Severe swelling
Benzyl alcohol	Dissolved
γ-Butyrolactone	Swollen
Cyclohexanone	Severe swelling
1,2-Dichloroethane	Dissolved
Ethanol	Slight swelling
Ethanol, 50%	No effect
Ethyl acetate	Severe swelling
Ethylene glycol	No effect
Ethylene glycol monomethyl ether	Slight swelling
Gasoline	Swollen
Heptane	Slight swelling
Hydraulic fluid	No effect
Isopropanol	Slight swelling
Lipid solution, 20%	No effect
Methanol	Slight swelling
Methyl ethyl ketone	Slight swelling
Methyl isobutyl carbinol	Slight swelling
Methyl isobutyl ketone	Severe swelling
Motor oil	No effect
Nitromethane	Swollen
Sodium hydroxide, 10%	No effect
Sodium hypochlorite bleach, 5%	No effect
Sulfuric acid, 20%	No effect
Tetrahydrofuran	Severe swelling
Toluene	Swollen
Transmission fluid	No effect
Water	No effect
Visual appearance after 4-week immersion @ 23°C (73°F)	

^aVisual appearance after 4-week immersion @ 23°C (73°F).



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. Jingan Branch 1206, CITIC Square No. 1168 Nanjing Road (W) Shanghai 200041, P.R. China

Telephone: (86) 21 6120-8700 Fax: (86) 21 5213-5255

Eastman Chemical Japan Ltd.

MetLife Aoyama Building 5F 2-11-16 Minami Aoyama Minato-ku, Tokyo 107-0062 Japan

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

Eastman Chemical Asia Pacific Pte. Ltd.

#05-04 Winsland House 3 Killiney Road Singapore 239519

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

www.eastman.com

Material 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.

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.

Eastman, Ecdel, and The results of insight are trademarks of Eastman Chemical Company.

Acrawax is a trademark of Lonza Inc., Chas. L. Huisking & Co., Inc.

Sintech is a trademark of MTS Systems Corporation.

Teflon is a trademark of E. I. du Pont de Nemours and Company.

© Eastman Chemical Company, 2011.