# SAFETY DATA SHEET



Laser+<sup>®</sup> (Polyethylene Terephthalate)

### I. CHEMICAL PRODUCT/COMPANY IDENTIFICATION

### **PRODUCT IDENTIFIER:**

Laser+® (Polyethylene Terephthalate) Includes Amorphous and other Resin Products.

### **RECOMMENDED USE AND USE RESTRICTIONS:**

Polymer for plastics industry. See attached "Medical Caution Bulletin No. 1", at end of SDS for use restrictions.

### MANUFACTURER / SUPPLIER:

Alpek Polyester Argentina S.A. Parque Industrial Zarate, Camino Santa Ana S/NRO (B2800OFA) Zarate, Buenos Aires Argentina www.AlpekPolyester.com +54 3487 429900

### **EMERGENCY PHONE NUMBERS:**

For emergency transportation information, call RESTEC at 0810-999-6091 / 54 11 4301 0205.

### 2. HAZARDS IDENTIFICATION

#### **PRODUCT HAZARD CLASSIFICATION:**

This product does not meet the criteria to be classified in a hazard class in accordance to the Labor Risk Superintendence Resolution 801/2015, under the Ministries of Labor, Employment and Social Security. However, an on-demand safety data sheet will be provided.

### **APPROPRIATE LABEL ELEMENTS:**

Pictograms:	NONE
Warning Word:	NO WARNING WORDS
Hazard Indication:	NO DANGER INDICATIONS
Caution Advice:	NO CAUTION ADVICE

#### HAZARDS NOT OTHERWISE CLASSIFIED:

- COMBUSTIBLE DUST WARNING! MAY FORM COMBUSTIBLE DUST CONCENTRATIONS IN AIR.
- CAUTION! MOLTEN MATERIAL WILL PRODUCE THERMAL BURNS. Molten polymer will adhere to skin and can cause severe burns.
- Eye contact with polymer particles may cause mechanical irritation with discomfort, tearing, or blurring of vision.

# 3. COMPOSITION/INFORMATION ON INGREDIENTS

COMPONENTS:		
Material	CAS Number	%
Polyethylene Terephthalate	25038-59-9 / 24938-04-3	>99
Residual additives, modifiers, colorants/impuriti	es -	<1

### 4. **FIRST AID MEASURES**

### GENERAL MEASURES:

Take appropriate protective measures. If necessary, consult a doctor and review this safety data sheet (SDS) with them.

### **DESCRIPTION OF NECESSARY MEASURES:**

<u>INHALATION</u>: No specific intervention is indicated, as the compound is not likely to be hazardous by inhalation. However, if exposed to gases, vapors or fumes from overheating or combustion, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician if necessary.

<u>SKIN CONTACT</u>: The compound is not likely to be hazardous by skin contact, but cleansing the skin after use is advisable. If molten material gets on skin, cool rapidly with cold water. Do not attempt to remove material from skin. Obtain medical treatment for thermal burn.

<u>EYE CONTACT</u>: In case of contact with eyes, rinse with plenty of water, without rubbing the eyes with hands. In the case of use of contact lenses, remove them immediately. Consult a physician if irritation persists. If contact with non-molten material occurs, consult physician.

<u>INGESTION</u>: Ingestion is highly unlikely, because of the shape of pellets of the material. This material does not present a significant degree of toxicity. If considerable quantities of the product are ingested, seek medical attention. This can cause blockage of the gastrointestinal tract. Do not use laxatives. Do not induce vomiting if it is not under medical supervision.

### MOST IMPORTANT SYMPTOMS/EFFECTS, ACUTE AND DELAYED:

Contact with molten product may cause severe skin and/or eye burns.

<u>INHALATION</u>: Dust may cause slight irritation. Inhalation of vapors/fumes from heating/processing can cause irritation of the throat, and in cases of prolonged exposures, nausea and headaches.

<u>SKIN CONTACT</u>: Contact with process vapors/fumes can produce skin irritation. Irritation can also occur by mechanical effects of the dust.

<u>EYE CONTACT</u>: Contact with process vapors/fumes can produce eye irritation. Irritation can also occur by mechanical effects of the dust.

<u>INGESTION</u>: Oral toxicity is very low. There are no deleterious effects of ingestion of small amounts. It may cause a blockage in the event of ingestion. Contact with the molten product can cause severe thermal burns in the eyes and/or skin.

### INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT:

Contact with molten product. Treat burns as thermal burns. The material will come off as healing occurs; therefore, immediate removal from the skin is not necessary. Treat symptomatically. For more information, consult a Poison Control Center: 0800-333-0160.

### 5. FIRE FIGHTING MEASURES

# SUITABLE EXTINGUISHING MEDIA:

Water, Carbon Dioxide ( $CO_2$ ), or Dry Chemical. Use dry chemical, water or  $CO_2$ . Use the product according to the materials of the surrounding area. Do not use direct water jets.

### SPECIFIC HAZARDS ARISING FROM CHEMICAL:

HAZARDOUS COMBUSTION PRODUCTS: Carbon dioxide and carbon monoxide.

### **SPECIAL PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIRE-FIGHTERS:**

Keep personnel removed and upwind of fire. Use self-contained breathing equipment and protective structural clothing for fire fighters.

Spray product/packaging with water to prevent ignition, if exposed to excessive heat or fire. Remove product/packaging if not on fire and can be done safely. Cool product/packaging with water until well after fire is out. Remove debris and extinguish all remaining embers.

Prevent water used for fire control or dilution from entering waterways, drains or springs.

### HAZADOUS DECOMPOSITION PRODUCTS IN CASE OF FIRE:

In the event of a fire, polymer can give off irritating and/or toxic fumes and gases, such as carbon monoxide and other substances derived from incomplete combustion.

# 6. ACCIDENTAL RELEASE MEASURES

### PERSONAL PRECAUTIONS / PROTECTIVE EQUIPMENT / EMERGENCY PROCEDURES

The interior of molten masses may remain hot for some time because of the low heat conductivity of the polymer. Use care when handling/disposing of molten masses.

Review Section 5. FIRE FIGHTING MEASURES and Section 7. PRECAUTIONS FOR SAFE HANDLING before proceeding with clean-up.

Use appropriate Personal Protective Equipment during clean-up. Thermal protective equipment should be used when handling molten material (See Section 8. for further details).

### **ENVIRONMENTAL PRECAUTIONS**

Contain the solid and cover it to prevent its dispersion to the environment. Prevent the product from reaching waterways.

#### METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP:

Sweep up and recover, or mix material with moist absorbent and shovel into suitable chemical waste container.

Dust Deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Non-sparking tools should be used.

# 7. HANDLING AND STORAGE

### **PRECAUTIONS FOR SAFE HANDLING:**

- Do not breathe gases, vapors or fumes that may be evolved during processing. Caution and suitable thermal eyes, face, and body personal protective equipment (PPE) must be used if handling hot/molten material. Contact with molten material can cause burns, so unprotected contact with molten material must be avoided.
- > Do not eat, drink or smoke will handling the product.
- Keep spilled pellets swept up from walkways to minimize slipping hazards. Do not walk on spilled pellets.
- Avoid dust generation and prevent dust accumulations to minimize explosion hazard. Physical operations, such as grinding, can create dust and a potential dust explosion hazard. Under these conditions, follow National Fire Protection Association (NFPA) Codes and Standards for handling combustible dusts.

### CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATABILITIES:

Keep container closed. Incompatible or can react with strong oxidizers. Store in a clean, dry, well-ventilated area. Protect from the sun. Keep containers closed.

# 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### **EXPOSURE LIMITS:**

	Polyethylene Terephthalate	Particles Not Otherwise Specified	Particulates Not Otherwise Regulated (PNOR)
PEL (OSHA):	None Established	-	15 mg/m <sup>3</sup> Total dust 5 mg/m <sup>3</sup> Respirable fraction
TLV (ACGIH):	None Established	3 mg/m³ Respirable particles 10 mg/m³ Inhalable particles	-

\*All exposure limits presented are 8-hour time weighted average (TWA) limits.

CMP (Res. MTESS 295/03): 10 mg/m<sup>3</sup>, PNEOF respirable. – 3 mg/m<sup>3</sup>, PNEOF inhalable

- CMP-CPT (Res. MTESS 295/03): N/D
- CMP-C (Res. MTESS 295/03): N/D

# **APPROPRIATE ENGINEERING CONTROLS:**

- > Use local ventilation to control gases, vapors and fumes from hot processing.
- Use static controls. Static charges can build up and ignite dust or solvent laden atmospheres. Design precautions into processes that can create dust, such as pneumatic conveying systems, grinding and other physical operations. There is the potential for a dust explosion hazard.
- Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

# **INDIVIDUAL PROTECTION MEASURES / PERSONAL PROTECTIVE EQUIPMENT:**

<u>EYE/FACE PROTECTION</u>: Wear coverall chemical splash goggles when the possibility exists for eye or face contact from airborne material. Wear a face shield when working with molten material. Safety goggles should be worn (to comply with EN166).

<u>RESPIRATORY PROTECTION</u>: Respirators are not needed for normal use. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with the OSHA Respiratory Protection Standard (29 CFR 1910.134).

<u>PROTECTIVE CLOTHING</u>: If there is potential for contact with hot/molten material, wear heat-resistant impervious clothing and footwear, and high temperature protective gloves (which comply with IRAM Standards 3607–3608–3609 and in 374). Special protective clothing is not needed for normal use. Gloves and long sleeve work clothes are recommended as good industrial practice.

**<u>RECOMMENDED DECONTAMINATION FACILTIES</u>**: Eyewash station, emergency showers.

# 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Solid, white polymer	Flammability Limits (Upper/Lower):	No data available
Odor:	Odorless	Vapor Pressure:	Not Applicable
Odor Threshold:	No data available	Vapor Density:	Not Applicable
pH:	Not Applicable	Specific Gravity:	>1
Melting Point:	220 – 250 °C	Solubility in Water:	Insoluble
Initial Boiling Point and Boiling Range:	No data available	Partition coefficient (n-octanol/water):	No data available
Flash Point:	Not applicable, combustible solid	Auto-Ignition Temperature:	No data available
Evaporation Rate:	No data available	Decomposition Temperature:	330 ℃
Flammability:	No data available	Viscosity:	No data available
Henry's law constant (20°C):	No data available	Log Koc:	No data available

### **EXPLOSIVE PROPERTIES:**

Dust explosion is possible due to small particle size. Smaller particles present a greater risk for dust explosion, particularly risky are those below 200 mesh. Product in original form is not explosive according to column 2, Annex VII of REACH (no chemical groups are associated with explosive properties).

### **OXIDIZING PROPERTIES:**

In accordance with the column 2, Annex VII of the REACH, this study is not necessary because the substance, by its chemical structure, cannot react exothermically with combustible materials.

# 10. STABILITY AND REACTIVITY

# **REACTIVITY:**

None known.

### CHEMICAL STABILITY:

Stable at normal conditions. Polymerization will not occur.

### **POSSIBILITY OF HAZARDOUS REACTIONS:**

None known.

# CONDITIONS TO AVOID:

Temperatures above 330° C.

### **INCOMPATIBILE MATERIALS:**

Incompatible or can react with strong oxidizers.

### HAZARDOUS DECOMPOSITION PRODUCTS:

Thermal decomposition products caused by overheating polymer can include carbon monoxide, carbon dioxide, acetaldehyde and ethylene. Decomposition products (gases, vapors and/or fumes) may cause skin, eye or respiratory tract irritation, and other adverse health effects.

# II. TOXICOLOGICAL INFORMATION

# **INFORMATION ON LIKELY ROUTES OF EXPOSURE:**

Polymer dust may be inhaled, and come in contact with skin and eyes. Thermal decomposition products may be inhaled.

# SYMPTOMS RELATED TO PHYSICAL, CHEMICAL AND TOXICOLOGICAL CHARACTERISTICS:

- > Skin contact with molten material will produce thermal burns.
- Eye contact with polymer dust may cause mechanical irritation with discomfort, tearing, or blurring of vision. Polyethylene terephthalate is a mild eye irritant.
- Eye contact with molten material will produce thermal burns.
- Decomposition products (gases, vapors and/or fumes) may cause skin, eye or respiratory tract irritation, and other adverse health effects.

# ACUTE, DELAYED, AND CHRONIC EFFECTS FROM SHORT AND LONG-TERM EXPOSURE:

Polyethylene terephthalate animal testing indicates:

- > No carcinogenic, mutagenic, developmental or reproductive effects.
- > No adverse effects from short exposures by inhalation and ingestion.

Polyethylene terephthalate patch tests with humans resulted in no skin irritation or sensitization.

### NUMERICAL MEASURES OF TOXICITY

- Polyethylene Terephthalate: Oral Approximate Lethal Dose (ALD): >10,000 mg/kg in rats
- Acute Toxicity: Oral LD50 (rat, not shown): >10,000 mg/kg ETA-DL50 der (rabbit, calc.): >5000 mg/kg ETA-CL50 inh. (Rat, 4hs., calc.): >5 mg/l
- Skin Irritation or Corrosion: Skin irritation or corrosion: Dermal Irritation (rabbit, estim.): Score: <1.5 Non-irritating</p>
- Serious Injury or Eye Irritation: Eye Irritation (rabbit, estim.): Score: <1 non-irritating
- Skin or Respiratory Sensitization: Skin sensitivity (guinea pig, estim.): no respiratory Sensitivity, respiratory sensitivity (Guinea pig, estim.): not a sensitizer

### CARCINOGENICITY INFORMATION:

None of the components present in this material at concentrations equal to or greater than 0.1% are listed by NTP, IARC, OSHA or ACGIH as a carcinogen.

### 12. ECOLOGICAL INFORMATION

### **ENVIRONMENTAL EFFECTS, BEHAVIOR AND IMPACTS OF THE PRODUCT:**

The product is insoluble in water.

# ECOTOXICITY:

ETA-EC50 (O. mykiss, calc., 48 h): >100 mg/l ETA-EC50 (D. magna, calc., 48 h): >100 mg/l ETA-EC50 (P. subcapitata, calc., 48 h): >100 mg/l ETA-EC50 (T. pyriformis, calc., 48 h): >100 mg/l ETA-NOEC (D. rerio, calc., 14 (d): >1 mg/l ETA-CSEO (D. magna, calc., 14 d): >1 mg/l

### PERSISTENCE AND DEGRADABILITY:

- Biodegradability (-): The product is not biodegradable. Does not contain organic halogens or metals.
- Potential for bioaccumulation: Log Ko/w: N/A
- Bioaccumulation in Fish BCF (OECD 305): N/D
- Mobility in the soil LogKoc: N/D
- Henry's Law constant (20°C): N/D
- Results of PBT and VPVB Assessment: This substance/mixture does not meet the PBT criteria of Annex XIII of the REACH Regulation. This substance/mixture does not meet the criteria vpvb assessment of Annex XIII of the REACH Regulation.

# 13. DISPOSAL CONSIDERATIONS

Treatment, storage, transportation, and disposal must be in accordance with applicable Federal, State/Provincial, and Local regulations.

- Product: The surplus product is classified as non-special industrial waste.
- Procedure of disposal: Incineration or disposal in a landfill. Can be recycled.
- Remains of the Product: Is classified as non-special industrial waste.

# 14. TRANSPORTATION INFORMATION

### **SHIPPING INFORMATION:**

- ➤ U.S. DOT Class Not Regulated.
- Sea IMDG (International Maritime Dangerous Goods) Class Not Regulated.
- > Air ICAO (International Civil Aviation Organization) Class Not Regulated.

Land Transportation:

- > Appropriate name for the Transport: NON-HAZARDOUS GOODS FOR TRANSPORT
- > NO. A/ID: NON-DANGEROUS GOODS FOR TRANSPORT
- Hazard Class: Non-DANGEROUS GOODS FOR TRANSPORT
- Packaging Group: Non-DANGEROUS GOODS FOR TRANSPORT
- Risk Code: Non-DANGEROUS GOODS FOR TRANSPORT
- ▶ LIMITED AND EXCEPT NUMBER: NON-DANGEROUS GOODS FOR AIR
- TRANSPORT (ICAO/IATA) Appropriate name for Shipment: GOODS ARE NOT DANGEROUS FOR TRANSPORT
- > NO. A/ID: NON-DANGEROUS GOODS FOR TRANSPORT
- Hazard Class: Non-DANGEROUS GOODS FOR TRANSPORT
- Packaging Group: Non-DANGEROUS GOODS FOR TRANSPORT

### Air Transportation (ICAO/IATA):

- Instructions for passenger and cargo aircraft: NON-DANGEROUS GOODS FOR TRANSPORT
- Instructions for cargo planes: NON-DANGEROUS GOODS FOR TRANSPORT
- CRE: MERCHANDISE IS NOT DANGEROUS FOR YOUR TRANSPORT

Maritime Transportation (IMO):

- Transport in packaging in accordance with the IMDG code appropriate name for the NON-HAZARDOUS GOODS FOR TRANSPORT
- > A/ID no.: NON-DANGEROUS GOODS FOR TRANSPORT
- Hazard Class: Non-DANGEROUS GOODS FOR TRANSPORT
- Packaging Group: Non-DANGEROUS GOODS FOR TRANSPORT
- EMS: NON-DANGEROUS GOODS FOR TRANSPORT
- Stowage and Segregation: NON-DANGEROUS GOODS FOR TRANSPORT
- Marine Pollutant: No
- > Name for the documentation of transport: NOT CLASSIFIED AS A DANGEROUS GOODS

# 15. **REGULATORY INFORMATION**

### REGULATIONS

- Convention concerning Safety in the Use of Chemicals at Work (Convention 170) International Labor Organization, 1990. International Organization for Standardization – ISO 11014:2009.
- Safety Data Sheet in accordance with the Resolution 801/2015 of the Superintendence of Labor Risks, MTESS, and to the IRAM 41400: 2013 – Safety Data Sheet according to the SGA.
- Resolution 295/2003 of the Ministry of Labor, Employment and Social Security, Republic of Argentina – Environmental exposure controls.
- Resolution 310/2003 Superintendence of Labor Risks, Ministry of Labor, Employment and Social Security, Republic of Argentina – carcinogens.

- National Law No. 24,051 and its regulations, Republic of Argentina Hazardous Waste Law.
- Resolution 195/97 Secretariat of Public Works and Transport of the Republic of Argentina – General Regulations for the Transport of Dangerous Goods by Road.
- Regulation (EC) No 1272/2008 on classification, labelling and packaging of chemical substances and mixtures, and its amendments.
- European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR 2015). The Regulations concerning the International Carriage of Dangerous Goods by Rail (RID 2015). International Maritime Dangerous Goods Code (IMDG 34 ed.), IMO Resolution MSC 90/28/Add.2. IBC/MARPOL, IMO Resolution MEPC 64/23/Add.1.
- Regulations of the International Air Transport Association (IATA 56 ed., 2015) on the transport of dangerous goods by air.
- Globally Harmonized System of Classification and Labelling of Chemicals, Sixth Revised Edition, 2015 2015 (SGA).
- > International Agency for Research on Cancer (IARC), classification of carcinogens.

# **U.S. FEDERAL REGULATIONS:**

- TSCA Inventory Status: In compliance with TSCA Inventory requirements for commercial purposes.
- Under RCRA, it is the responsibility of the product user to determine at the time of disposal whether a material containing the product or derived from the product should be classified as a hazardous waste (40 CFR 261.20-24).
- If discarded in its purchased form, this product does not meet the RCRA characteristic definition for ignitability, corrosivity or reactivity and is not a RCRA listed waste; however, it has not been tested by the Toxicity Characteristic Leaching Procedure (TCLP).
- > SARA, Title III: This material is not known to contain extremely hazardous substances.

# **INTERNATIONAL REGULATIONS:**

- DSL (Canadian Domestic Substances List) and CEPA (Canadian Environmental Protection Act): This product is listed on the DSL or otherwise complies with CEPA new substance notification requirements.
- > No components of this product are on the Mexican Raw Materials Regulation.

# 16. ADDITIONAL INFORMATION

The data in this Safety Data Sheet relates only to the specific material designated herein and does not relate to use in combination with any other material or in any process.

This SDS was prepared based on current knowledge of the chemical product and provides information relating to the safety, security, health and the environment. It should be noted that the handling of any substance requires prior knowledge of their dangers on the part of the user. Because the conditions or methods of use are beyond our control, we do not assume any liability for the use, intake or any type of inappropriate handling or different to detail under instructions of this product. Compliance with all the regulations at the national, provincial, and municipal is the responsibility of the user.

### Abbreviations:

ACGIH - American Conference of Governmental Industrial Hygienists

- BCF Bioconcentration Factor
- CAS Chemical Abstracts Service
- CL50 Lethal Concentration 50%
- LD50 Lethal Dose 50%

- EC50 Concentration Medium effect
- NOEC No observed effect concentration
- ETA Estimation of acute toxicity
- IDLH Immediately Dangerous to Life or Health
- NIOSH National Institute for Occupational Safety and Health
- OSHA Occupational Safety and Health Administration
- OECD Organization for Economic Co-operation and Development
- PEL Permissible Exposure Limit
- TLV Threshold Limit Value
- TWA Time Weighted Average

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# SDS Revision Date: September 1, 2023

End of SDS



# **MEDICAL CAUTION BULLETIN NO.I**

DO NOT USE MATERIALS PRODUCED BY ALPEK POLYESTER BUSINESSES IN MEDICAL APPLICATIONS INVOLVING **PERMANENT, BRIEF, OR TEMPORARY IMPLANTATION** IN THE HUMAN BODY OR PERMANENT CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES, UNLESS THE MATERIAL HAS BEEN PROVIDED DIRECTLY FROM AN ALPEK POLYESTER BUSINESS UNDER A CONTRACT WHICH EXPRESSLY ACKNOWLEDGES THE CONTEMPLATED USE.

ALPEK POLYESTER MAKES NO REPRESENTATION, PROMISE, EXPRESS WARRANTY OR IMPLIED WARRANTY CONCERNING THE SUITABILITY OF THESE MATERIALS FOR USE IN THE HUMAN BODY OR IN CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES.

### THE CONTENT OF ALPEK POLYESTER MATERIAL IS NOT CERTIFIED FOR IMPLANTS.

Alpek Polyester materials are not designed or manufactured for use in implantation in the human body or in contact with internal body fluids or tissues. Alpek Polyester has not performed clinical testing of these materials for implantation. Alpek Polyester will not provide to customers making implantable devices any notice concerning its materials, as specified under 21 CFR section 820.50, or any other information necessary for medical device use of the materials under any other statue or FDA regulation. Alpek Polyester has neither sought, nor received, approval from the FDA for the use of these materials in implantation in the human body or in contact with internal body fluids or tissues.

# ALL IMPLANTABLE MEDICAL DEVICES CARRY A RISK OF FAILURE AND ADVERSE CONSEQUENCES.

The medical judgment of a physician, a medical device seller and the FDA should be relied upon for identification of both harmful consequences and life-saving benefits from an implantation device comprised of specific materials. These benefits and risks can be found in published medical cases performing clinical medical studies of an implantable medical device. Alpek Polyester does not support the use of its products in these applications and cannot weigh the benefits against the risk defined in these articles. Alpek Polyester cannot offer a medical judgment on the safety or efficacy of the use of its materials in such devices.

# DO NOT MAKE REFERENCE TO THE ALPEK POLYESTER NAME OR ANY ALPEK POLYESTER BUSINESS TRADEMARK IN ASSOCIATION WITH AN IMPLANTABLE MEDICAL DEVICE.

Do not use a trademark or licensed trademark from Alpek Polyester or any of its businesses as the descriptive name of an implantable medical device (e.g. do not call it the "Delcron®" prosthesis, or do not call it a "Laser+® device").

End of Bulletin