



SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

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Product identifier	Direct LACTEL® Absorbable Polymers
Synonyms	Part # B6015-1 [25:75 Poly(DL-lactide-co-ε-caprolactone), Ester Terminated] or Part # B6016-1 [80:20 Poly(DL-lactide-co-ε-caprolactone), Ester Terminated]
Trade names	Not applicable
Chemical family	Lactide-caprolactone-containing copolymer
Relevant identified uses of the substance or mixture and uses advised against	Bioabsorbable polymer for pharmaceutical/biomedical applications, packaged in final form for use as a bulk excipient.
Note	This SDS for LACTEL® Absorbable Polymers is written to address potential worker health and safety issues associated with the handling of the formulated final product. This SDS applies to the finished product only (as a polymer granule or pellet). If handling the monomers used to form the final polymeric product, consult the SDS for the individual components and take appropriate precautions.
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SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Regulation (EC) 1272/2008 [GHS] None required.

Directive 67/548/EEC or 1999/45/EC None required

Label elements

CLP/GHS hazard pictogram None required

SECTION 2 - HAZARDS IDENTIFICATION ...continued

CLP/GHS signal word	None required
CLP/GHS hazard statements	None required.
CLP/GHS precautionary statements	None required
EU symbol/indication of danger	None required
Risk (R) Phrase(s)	None required
Safety Advice	None required
Other hazards	Direct contact may cause reversible skin, eye, or mucous membrane irritation.
US Signal word	None required
US Hazard overview	Product not considered to be hazardous under US OSHA hazard communication.
Note	This substance is not classified as dangerous/hazardous according to Directive 67/548/EEC, Regulation EC No 1272/2008 (EU-CLP), and applicable US regulations. The EU symbol/indicator of danger, R Phrases and Safety Advice are based on Directive 67/548/EEC or 1999/45/EC. The GHS classifications are based on Regulation (EC) 1272/2008.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ELINCS#</u>	<u>Amount</u>	<u>EU Classification</u>	<u>GHS Classification</u>
Poly(DL-lactide-co-ε-caprolactone), Ester Terminated	N/A	N/A	~100%	Not classified	Not classified
Note	The ingredient listed above is not considered hazardous. See Section 16 for full text of EU and GHS classifications. The EU classification is based on Directive 67/548/EEC and the GHS classification is based on Regulation (EC) 1272/2008.				

SECTION 4 - FIRST AID MEASURES

Description of first aid measures

Immediate Medical Attention Needed	Yes
Eye Contact	If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.

SECTION 4 - FIRST AID MEASURES ...continued

Skin Contact	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
Inhalation	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.
Ingestion	If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.
Protection of first aid responders	See Section 8 for Exposure Controls/Personal Protection recommendations.
Most important symptoms and effects, both acute and delayed	See Sections 2 and 11.
Indication of immediate medical attention and special treatment needed, if necessary	Treat symptomatically and supportively.

SECTION 5 - FIREFIGHTING MEASURES

Extinguishing media	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
Specific hazards arising from the substance or mixture	No information identified. May emit carbon monoxide and carbon dioxide in a fire.
Flammability/Explosivity	No explosivity or flammability data identified. High concentrations of finely divided airborne organic particles can potentially explode if ignited.
Advice for firefighters	Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated.
Environmental precautions	Do not empty into drains. Avoid release to the environment.

SECTION 6 - ACCIDENTAL RELEASE MEASURES ...continued

Methods and material for containment and cleaning up For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice with an appropriate solvent (see Section 9).

Reference to other sections See Sections 8 and 13 for more information.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling.

Conditions for safe storage including any incompatibilities The polymer is shipped at ambient temperature. Store at -10°C or below with a dessicant in original containers. Keep container closed until ready for use. Purge container with high-purity dry nitrogen before resealing.

Specific end use(s) No information identified.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Control**Parameters/Occupational****Exposure Limit Values**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Poly(DL-lactide-co-ε-caprolactone), Ester Terminated	--	--	--

DNELs/PNECs None identified.

Exposure/Engineering controls None normally required. When practicable, handle material in enclosed or contained processes or in processes with effective local exhaust ventilation.

Respiratory protection When possible, handle material in enclosed processes or containers. If properly handled with effective ventilation or containment, respiratory protection should not be needed. For aerosol-generating procedures, an air-purifying respirator with NIOSH/MSHA approval for dusts/mists may be needed.

Hand protection Wear rubber or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued

Skin protection	Rubber gloves are recommended to minimize potential for skin contact when handling as a solid. If the material is dissolved in an organic solvent, wear gloves that provide protection against the solvent. In laboratory or manufacturing setting, wear lab coat or other protective overgarment at a minimum to minimize skin contact. Base the choice of protection on the job activity and potential for skin contact.
Eye/face protection	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face.
Environmental Exposure Controls	Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.
Other protective measures	Wash hands in the event of contact with this substance, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors). Decontaminate all protective equipment following use.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Granules or pellets.
Color	White to yellowish, light gold.
Odor	No information identified.
Odor threshold	No information identified.
pH	Not applicable (N/A).
Melting point/freezing point	No information identified.
Initial boiling point and boiling range	No information identified.
Flash point	No information identified.
Evaporation rate	No information identified.
Flammability (solid, gas)	No information identified.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued

Upper/lower flammability or explosive limits	No information identified.
Vapor pressure	No information identified.
Vapor density	No information identified.
Relative density	No information identified.
Water solubility	Reacts slowly with water to become soluble.
Solvent solubility	No information identified.
Partition coefficient (<i>n</i>-octanol/water)	No information identified.
Auto-ignition temperature	No information identified.
Decomposition temperature	No information identified.
Viscosity	No information identified.
Explosive properties	No information identified.
Oxidizing properties	No information identified.
Other information	
Molecular weight	Product molecular weight varies by part number and lot number.
Molecular formula	No information identified.

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	No information identified.
Chemical stability	Stable. When maintained in the original unopened packaging, the polymer is stable to excursions (<4 weeks) up to 40° C.
Possibility of hazardous reactions	Not expected to occur.
Conditions to avoid	Elevated temperatures.
Incompatible materials	No information identified.
Hazardous decomposition products	No information identified.

SECTION 11 - TOXICOLOGICAL INFORMATION

Information on toxicological effects

Route of entry May be absorbed by inhalation, skin contact and ingestion.

Acute toxicity

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Poly(DL-lactide-co-ε-caprolactone), Ester Terminated	--	--	--	--

Additional acute toxicity information No data on product formulation; this class of polymers is considered to have low acute toxicity.

Irritation/Corrosion No data on product formulation.

Sensitization No data on product formulation, however sensitization is not expected to occur.

STOT-single exposure No data on product formulation.

STOT-repeated exposure/Repeat-dose toxicity No data on product formulation; this class of polymers is considered to have low chronic toxicity.

Reproductive toxicity No data on product formulation; this class of polymers is not considered to be reproductive toxicants.

Developmental toxicity No data on product formulation; this class of polymers is not considered to be developmental toxicants.

Genotoxicity No data on product formulation; this class of polymers is not considered to be genotoxic.

Carcinogenicity No data on product formulation; this class of polymers is not considered to be carcinogenic. This substance is not listed by NTP, IARC, ACGIH or OSHA as a carcinogen.

Aspiration hazard No data available.

Human health data See "Section 2 - Other Hazards"

SECTION 12 - ECOLOGICAL INFORMATION

Toxicity

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Poly(DL-lactide-co-ε-caprolactone), Ester Terminated	--	--	--

Additional toxicity information No data available.

Persistence and Degradability No data available.

SECTION 12 - ECOLOGICAL INFORMATION ...continued

Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Results of PBT and vPvB assessment	Not performed.
Other adverse effects	No data available.
Note	The environmental characteristics of the formulated product have not been fully investigated. Releases to the environment should be avoided.

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste treatment methods	Used product should be disposed of according to local, state, and federal regulations. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.
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SECTION 14 - TRANSPORT INFORMATION

Transport	This product is not regulated as a hazardous material/dangerous good under US DOT, Canada TDG, IATA, IMDG or EU ADR/RID.
UN number	None assigned.
UN proper shipping name	None assigned.
Transport hazard classes and packing group	None assigned.
Environmental hazards	Based on the available data, this substance is not regulated as an environmental hazard or a marine pollutant.
Special precautions for users	No special precautions needed.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

SECTION 15 - REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture	This SDS complies with the requirements under US, EU and GHS (EU CLP - Regulation EC No 1272/2008) guidelines.
Chemical safety assessment	Not conducted.
OSHA Hazardous	No
EU label pictogram(s)	None required
EU classification	None required
Risk phrases	None required
Safety phrases	None required
WHMIS classification	Not considered hazardous.
WHMIS symbol(s)	None required
GHS pictogram(s)	None required
GHS signal word	None required
GHS H and P phrases	None required
TSCA status	Considered to be a polymer under TSCA.
SARA section 313	Not listed.
California proposition 65	Not listed.

SECTION 16 - OTHER INFORMATION

Full text of R phrases and EU Classifications	Not available.
Full text of H phrases, P phrases and GHS classification	Not available.
Sources of data	Information from published literature and internal company data.
Abbreviations	ACGIH - American Conference of Governmental Industrial Hygienists ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail AIHA - American Industrial Hygiene Association CAS# - Chemical Abstract Services Number DNEL - Derived No Effect Level DOT - Department of Transportation EINECS - European Inventory of New and Existing Chemical Substances

SECTION 16 - OTHER INFORMATION ...continued

Abbreviations ...continued ELINCS - European List of Notified Chemical Substances
EU - European Union
GHS - Globally Harmonized System of Classification and Labelling of Chemicals
IARC - International Agency for Research on Cancer
IDLH - Immediately Dangerous to Life or Health
IATA - International Air Transport Association
IMDG - International Maritime Dangerous Goods
LOEL - Lowest Observed Effect Level
LOAEL - Lowest Observed Adverse Effect Level
NIOSH - The National Institute for Occupational Safety and Health
NOEL - No Observed Effect Level
NOAEL - No Observed Adverse Effect Level
NTP - National Toxicology Program
OEL - Occupational Exposure Limit
OSHA - Occupational Safety and Health Administration
PBT - Persistent, Bioaccumulative and Toxic
PNEC - Predicted No Effect Concentration
SARA - Superfund Amendments and Reauthorization Act
STEL - Short Term Exposure Limit
TDG - Transport of Dangerous Goods
TSCA - Toxic Substances Control Act
TWA - Time Weighted Average
WHMIS - Workplace Hazardous Materials Information System

Revisions Updated formatting in accordance with General US, EU, and GHS (EU CLP) requirements.

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