MATERIAL SAFETY DATA SHEET

Section 1 – Identification of the Substance and Company / Undertaking

Product Names/ Part Numbers: LACTEL® Absorbable Polymers

This MSDS applies to the following lactide-glycolide containing polymer products:

Part #	Polymer / Product Description	Inherent Viscosity Range, dL/g
B6017-1	50:50 Poly(DL-lactide-co-glycolide), Ester Terminated	0.15-0.25
B6010-1	50:50 Poly(DL-lactide-co-glycolide), Ester Terminated	0.26-0.54
B6010-2	50:50 Poly(DL-lactide-co-glycolide), Ester Terminated	0.55-0.75
B6010-3	50:50 Poly(DL-lactide-co-glycolide), Ester Terminated	0.76-0.94
B6010-4	50:50 Poly(DL-lactide-co-glycolide), Ester Terminated	0.95-1.20
B6013-1	50:50 Poly(DL-lactide-co-glycolide), Acid Terminated	0.15-0.25
B6013-2	50:50 Poly(DL-lactide-co-glycolide), Acid Terminated	0.26-0.54
B6001-1	65:35 Poly(DL-lactide-co-glycolide), Ester Terminated	0.55-0.75
B6001-2	65:35 Poly(DL-lactide-co-glycolide), Ester Terminated	0.83-0.93
B6007-1	75:25 Poly(DL-lactide-co-glycolide), Ester Terminated	0.55-0.75
B6007-1	75:25 Poly(DL-lactide-co-glycolide), Acid Terminated	0.70-0.90
B6006-1	85:15 Poly(DL-lactide-co-glycolide), Ester Terminated	0.55-0.75
B6006-2	85:15 Poly(DL-lactide-co-glycolide), Ester Terminated	0.76-0.85

Synonyms: Polylactide – glycolide copolymer
Chemical Family: Polymer
Intended Use: Bioabsorbable polymer

Company: DURECT Corporation
Address: 2685-A Pelham Parkway
Pelham, AL 35124

In case of Emergency, contact: 205-620-0025 or 205-515-0192

The following MSDS applies to the finished product only (as a polymer granule or pellet). If handling the monomers to form the final polymeric product, consult the MSDS for the individual components and take appropriate precautions.

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Section 2 –Hazards Identification

Appearance: Varies depending on product from white to light gold to tan granules or pellets depending on product

Signal Word: CAUTION

Hazard Overview: Bioabsorbable polymer for pharmaceutical application**.** Direct contact may cause reversible skin, eye or mucous membrane irritation. Avoid skin contact, eye contact, and inhalation.

Statement of Known Hazard: Product not considered hazardous under US OSHA hazard communication, EU Directives and GHS criteria.

EU Indicator of Danger: None applicable

EU Risk Phrases: None applicable

Section 3 – Product Composition

Ingredient	EINECS / ELINCS #	CAS #	% (by wt)	EU Classification
Poly(lactide-co-glycolide)	Exempt/polymer	26780-50-7	100	None applicable

Section 4 – First Aid Precautions

Eye Contact
Immediately flush eyes thoroughly with water for at least 15 minutes. If an irritation develops, notify medical personnel and supervisor.

Skin Contact
Immediately wash thoroughly with soap and water for 15 minutes. If an irritation develops, contact medical personnel and notify supervisor.

Inhalation
Immediately move to fresh air and notify medical personnel and supervisor.

Ingestion
Immediately notify medical personnel and supervisor. Drink 2-3 glasses of water and contact medical personnel.

Medical Conditions Aggravated by Exposure
None known or reported.

Section 5 – Fire Protection

Flammability/Explosivity
Not considered flammable. No explosivity data available. High concentrations of finely divided organic particles are potentially explosive if ignited. Avoid dispersions of dust in the air to reduce dust explosion hazard potential.

Extinguishing Media
Use water fog or fire extinguishing media suitable for Class A fires (e.g., multipurpose dry chemical or foam).

Special Fire Fighting Procedures
Wear full structural fire fighting protective clothing and NIOSH/MSHA-approved positive pressure, self-contained breathing apparatus. Decontaminate after use.

Section 6 – Spill and Release Measures

If material is released or spilled, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment. For small spills (such as in a laboratory), dampen surface and wipe material away with paper towels; wash spill area thoroughly with soap and water. For large spills, use an industrial vacuum cleaner equipped with a high efficiency particulate (HEPA) filter. Dispose of collected material in accordance with applicable waste disposal regulations.

Section 7 – Handling and Storage

Avoid contact with skin, eyes or clothing. Store at –10 ° C or below with a dessicant in original containers. The polymer is shipped at ambient temperature. When maintained in the original unopened packaging, the polymer is stable to excursions (<4 weeks) up to 40 ° C. Keep container closed until ready for use. Purge container with high-purity dry nitrogen before resealing Wash thoroughly after handling.

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Section 8 – Exposure Control/Personal Protection

Eye 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.

Respiratory Protection
When possible, handle material in enclosed processes or containers. If it is 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.

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.

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

Other
Wash hands, face and other potentially exposed areas immediately after handling material (especially before eating, drinking, or smoking). Decontaminate all protective equipment after use.

Section 9 – Physical/Chemical Properties

Molecular Weight:	Varies by product; check product specification sheet for further information
pH:	Not applicable / solid
Boiling Point:	Not applicable / solid
Melting Point:	None (amorphous)
Vapor Pressure:	No data available
Solubility in Water:	Reacts slowly with water to become soluble

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Evaporation Rate: No data available.
Specific Gravity: Varies depending on product
Vapor Density and Percent Volatile: No data available

Section 10 – Stability/Reactivity

Stability: Stable
Incompatability: Not known
Hazardous Polymerization or Decomposition Products: Already a polymer

Section 11 – Toxicological Information

Acute and chronic toxicity – No specific data; this polymer class is considered to have low acute and chronic toxicity.

Reproductive toxicity (fertility impairment) and developmental toxicity (birth defects) – No specific data; this polymer class is not considered to be reproductive of developmental toxicants.

Genotoxicity and Carcinogenicity – No specific data; this class of polymers are not considered to be genotoxicants or carcinogens. This polymer class is not listed by IARC, NIOSH or OSHA as carcinogens.

Section 12 – Environmental Information

Persistence and Degradability
No data available.

Aquatic Toxicity
No data available.

Section 13 – Waste Disposal Methods

All wastes containing the material should be properly labeled. Dispose of any waste residues according 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 – Transportation Information

DOT Hazard Class
Not applicable – Not considered hazardous for shipment.

Proper Shipping Name
Not applicable.

UN Number
Not applicable.

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Section 15 – Labeling/Regulatory Information

US OSHA: This MSDS complies with the requirements under 29 CFR 1910.1200

Shipments of this material should have affixed the following label (in addition to the identity label): (in addition to the identity label):

OSHA Label
CAUTION. Avoid skin contact, eye contact, and inhalation.

EU Hazard Symbol: None applicable.

EU Risk Phrases: None applicable

EU Safety Phrase(s):
S 24/25 Avoid contact with skin and eyes
S 36/37/39 Wear suitable protective clothing, gloves and eye/face protection

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The following provides further regulatory information on the product formulation ingredients. This information is not meant to be inclusive of all regulations that may apply.

California Proposition 65: None of the ingredients are listed as reproductive or developmental toxicants or carcinogens.

SARA 313: None of the ingredients are listed under SARA 313 requirements.

SARA 311/312: Acute: No Chronic: No Fire: No Pressure: No

CERCLA: None of the ingredients are listed under this regulation.

RCRA: None of the ingredients are listed under this regulation.

TSCA: All ingredients are listed under TSCA or are exempt as a polymer.

Section 16 – Other Information

No additional information.
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Abbreviations

ACGIH:	American Conference of Governmental Industrial Hygienists
CAS#:	Chemical Abstract Services Number
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act of 1980
CFR	Code of Federal Regulations
DOT:	Department of Transportation
EU:	European Union
GHS:	Globally Harmonized System
IARC:	International Agency for Research on Cancer
IATA:	International Air Transport Association
OSHA:	Occupational Safety and Health Administration
NTP:	National Toxicology Program
RCRA:	Resource Conservation and Recovery Act
SARA:	Emergency Planning and Community Right-to-Know Act.
TSCA:	Toxic Substances Control Act

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The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions.

No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material..