



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 # B6002-1 [Poly(L-lactide), Ester Terminated] or Part # B6002-2 [Poly(L-lactide), Ester Terminated] or Part # B6005-1 [Poly(DL-lactide), Ester Terminated] or Part # B6005-2 [Poly(DL-lactide), Ester Terminated] or Part # B6014-1 [Poly(DL-lactide), Acid Terminated] or Part # B6014-2 [Poly(DL-lactide), Acid Terminated] |
| Trade names | Not applicable |
| Chemical family | Lactide-containing polymer |
| 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. |
| Issue Date | 22 October 2010 |

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

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

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

Label elements

CLP/GHS hazard None required
pictogram

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| 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/ELIN</u> <u>CS#</u> | <u>Amount</u> | <u>EU</u> <u>Classification</u> | <u>GHS</u> <u>Classification</u> |
|-------------------|--|----------------------------------|---------------|------------------------------------|-------------------------------------|
| Poly(lactide) | 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

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| 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

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| 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

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| 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

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| 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(lactide) | -- | -- | -- |

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

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| 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

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| 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

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| 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

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| 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(lactide) | -- | -- | -- | -- |

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(lactide) | -- | -- | -- |

Additional toxicity information No data available.

Persistence and Degradability No data available.

SECTION 12 - ECOLOGICAL INFORMATION ...continued

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| 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

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| 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

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| 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

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| 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

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| 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.

Disclaimer 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 because it is a pharmaceutical product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.