

SECTION 1. IDENTIFICATION

Product identifier

Trade name : PURASORB® PDLG

Other means of identification :

- PURASORB® PDLG 5002
- PURASORB® PDLG 5002A
- PURASORB® PDLG 5002A Y
- PURASORB® PDLG 5004
- PURASORB® PDLG 5004A
- PURASORB® PDLG 5008
- PURASORB® PDLG 5010
- PURASORB® PDLG 5505G
- PURASORB® PDLG 7502
- PURASORB® PDLG 7502A
- PURASORB® PDLG 7504
- PURASORB® PDLG 7504A
- PURASORB® PDLG 7507
- PURASORB® PDLG 7507 Y
- PURASORB® PDLG 7509
- PURASORB® PDLG 7509 Y
- PURASORB® PDLG 7510
- PURASORB® PDLG 75016A
- PURASORB® PDLG 8503
- PURASORB® PDLG 8505A
- PURASORB® PDLG 8508
- PURASORB® PDLG 8531
- CAS: 26780-50-7
- Poly(Lactide-co-Glycolide)
- 1,4-Dioxane-2,5-dione, 3,6-dimethyl-, polymer with 1,4-dioxane-2,5-dione

Recommended use of the chemical and restrictions on use

Recommended use : Medical device and/or pharmaceutical applications.

Manufacturer or supplier's details

Company name of supplier : PURAC America Inc.
 Address : 8250 Flint Street
 Lenexa KS 66214
 USA
 Telephone : +18006694092
 Telefax : +19138884970
 E-mail address of person responsible for the SDS : sds@corbion.com

Emergency telephone

CHEMTREC: +1 703-741-5970 / 1-800-424-9300

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

GHS label elements

Signal Word : Warning

Hazard Statements : May form combustible dust concentrations in air.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Substance

Components

No hazardous ingredients

SECTION 4. FIRST AID MEASURES

General advice : Keep warm and in a quiet place.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If breathed in, move person into fresh air.

In case of skin contact : If on skin, rinse well with water.

In case of eye contact : Rinse immediately with plenty of water and seek medical advice.
If easy to do, remove contact lens, if worn.

If swallowed : Rinse mouth.
Do NOT induce vomiting.

Most important symptoms and effects, both acute and delayed : No symptoms known or expected.
None known.

Notes to physician : Treat symptomatically.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray
Dry powder
Foam
Carbon dioxide (CO₂)

Unsuitable extinguishing media : High volume water jet

Specific hazards during fire fighting : Exposure to decomposition products may be a hazard to health.

Hazardous combustion products : Carbon oxides
toxic fumes
Organic acids

Further information : Use a water spray to cool fully closed containers.
Prevent fire extinguishing water from contaminating surface water or the ground water system.

Special protective equipment for fire-fighters : Use personal protective equipment.
In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Refer to protective measures listed in sections 7 and 8.

Environmental precautions : Should not be released into the environment.

Methods and materials for containment and cleaning up : Collect as much of the spill as possible with a suitable absorbent material.
Contain spillage, soak up with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and transfer to a container for disposal according

to local / national regulations (see section 13).
Sweep up and shovel into suitable containers for disposal.
Do not create a powder cloud by using a brush or compressed air.
After cleaning, flush away traces with water.
To clean the floor and all objects contaminated by this material, use plenty of water.

SECTION 7. HANDLING AND STORAGE

Advice on safe handling	:	Use only with adequate ventilation. Avoid inhalation, ingestion and contact with skin and eyes. Wear personal protective equipment. Do not eat, drink or smoke when using this product. Do not breathe vapors/dust. Wash skin thoroughly after handling. Dust must be collected and disposed of carefully. Avoid formation of dust and aerosols.
Conditions for safe storage	:	Keep containers tightly closed in a cool, well-ventilated place.
Further information on storage conditions	:	Product is hygroscopic. Store the closed package in a freezer. Content must be at room temperature before opening.
Further information on storage stability	:	Keep in a dry place. Stable under normal conditions.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection	:	No personal respiratory protective equipment normally required. Suitable respiratory equipment: Equipment should conform to NIOSH Respirator Standard 42 CFR part 84
Filter type	:	Particulates type
Hand protection	:	
Directive	:	Equipment should conform to ANSI/ISEA 105
Wearing time	:	8 h
Material	:	butyl-rubber
Glove thickness	:	0.5 mm
Material	:	Chloroprene
Glove thickness	:	0.5 mm
Material	:	PVC
Glove thickness	:	0.5 mm
Material	:	Nitrile rubber
Glove thickness	:	0.35 mm
Eye protection	:	Wear safety glasses or goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. Equipment should conform to ANSI/ISEA Z87.1

Skin and body protection	:	Long sleeved clothing Boots
Protective measures	:	The Personal Protective Equipment listed in Section 8 are recommendations. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	granules
Color	:	white, light tan
Odor	:	odorless
Odor Threshold	:	No data available
pH	:	No data available
Melting point/range	:	Not applicable
Boiling Point	:	No data available
Flash point	:	Not applicable
Flammability (solid, gas)	:	Not classified as a flammability hazard
Self-ignition	:	No data available
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapor pressure	:	No data available
Relative density	:	No data available
Density	:	1.1 - 1.54 g/cm ³
Solubility(ies)	:	
Water solubility	:	insoluble, hydrolyzes
Partition coefficient: n-octanol/water	:	No data available
Decomposition temperature	:	> 392 °F / > 200 °C
Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable
Oxidizing properties	:	Not applicable
Particle size	:	No data available
Particle Size Distribution	:	No data available

Specific surface area : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.
Decomposes when moist.

Possibility of hazardous reactions : No dangerous reaction known under conditions of normal use.

Conditions to avoid : Extremes of temperature and direct sunlight.
Direct heating, dirt, chemical contamination, sunlight, UV or ionizing radiation.
Exposure to moisture.
Avoid dust formation.

Incompatible materials : Oxidizing agents
Bases
Acids
Metals
water

Hazardous decomposition products : toxic fumes
Carbon dioxide (CO₂)
Carbon monoxide
Organic acids

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified due to lack of data.

Skin corrosion/irritation

Not classified due to lack of data.

Serious eye damage/eye irritation

Not classified due to lack of data.

Respiratory or skin sensitization

Skin sensitization

Not classified due to lack of data.

Respiratory sensitization

Not classified due to lack of data.

Germ cell mutagenicity

Not classified due to lack of data.

Carcinogenicity

Not classified due to lack of data.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified due to lack of data.

STOT-single exposure

Not classified due to lack of data.

STOT-repeated exposure

Not classified due to lack of data.

Aspiration toxicity

Not classified due to lack of data.

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity**

No data available

Persistence and degradability**Product:**

Biodegradability : Remarks: Hydrolyzes slowly on contact with water. Hydrolysis product: readily biodegradable

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects**Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : In accordance with local and national regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION**Domestic regulation****49 CFR**

Not regulated as a dangerous good

International Regulations**UNRTDG**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Combustible dust

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMII Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

The ingredients of this product are reported in the following inventories:

TSCA : Product contains substance(s) not listed on TSCA inventory.

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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Separators: Comma is applied as a thousand separator; Dot is used as a decimal separator; Example 1,234,567.89

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