



SAFETY DATA SHEET

TELEPHONE CONTACTS:

Product Technical and Medical Information: (949) 310-4469

SECTION 1: PRODUCT IDENTIFICATION

Compound Name: poly(2,3)Glucose, T1-35 (T013501020300)
Chemical Class: Biopolymer
Manufacturer's Name: TRGel LLC
Address: 30 Hughes Suite 204, Irvine, CA 92618
Revision Date: June 7, 2018

SECTION 2: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: poly(2,3)-Glucose, is a polymer synthesized from natural sugars, has been shown to form a hydrogel depot when injected as a liquid solution into laboratory animals subcutaneously. Preformed hydrogel particles of this polymer (spheroid capsules) have been implanted into the abdominal cavity and into the renal capsule of laboratory animals. The maximum dose the laboratory animals were exposed to in these experiments was 2000 mg/kg. No acute toxicity, local inflammation or histological abnormality, or long term toxicity with implants was observed over a 3 month period. Based on these observations, the compound can be considered to have subcutaneous LD50 >2 g/kg thus being of low toxicity. However, the knowledge of the material is limited, it is advised to observe all precautions for safe handling and protective equipment use described in this document.

Hazard Classification (GHS): Not a dangerous substance

Signal Word and Hazard Statements (GHS): Not dangerous

Potential Health Effects:

EYE CONTACT: Contact with the eyes may result in mild irritation. Use appropriate eye protection.

SKIN CONTACT: The effect of the prolonged contact with the skin is unknown. Transdermal absorption is possible. Mild irritation is possible. Use gloves.

INHALATION: The result of inhalation of dust or aerosol is unknown. Use a respirator when dust or aerosol is generated

INGESTION: The health effects of ingestion are unknown, both gastrointestinal blockage due to gelation and a laxative effect (similar to poly ethylene oxide) are possible.

CHRONIC EFFECTS: Not known



SECTION 3: COMPOSITION/HAZARDOUS INGREDIENTS

Chemical Name	CAS Number	Percent (By Weight)	Exposure Limits in Air (8 hr. TWA)
poly(2-3)1,6 anhydro β -D glucose 4-O-glyme	N/A	100	N/E

SECTION 4: FIRST AID MEASURES

Eye Contact:	If contact or irritation occurs, flush eyes with plenty of cold water for at least 15 minutes. Obtain medical attention if irritation or other symptoms occur.
Skin Contact:	Wash skin with soap and cold water. If irritation develops consult a physician
Inhalation:	If symptoms occur, move to fresh air and obtain medical attention. Treat symptomatically.
Ingestion:	No information is available on ingestion in humans. Consult a physician if symptoms (e.g. blockage or diarrhea) develop.

SECTION 5: FIRE FIGHTING MEASURES

Autoignition Temperature:	Decomposition begins at 180 C. Combusts in air at about 300 C
Flashpoint	In the range 180-230° C in a closed container.
Fire-Extinguishing Materials:	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
Fire fighting Procedures:	Toxic, corrosive or flammable vapors might be evolved from fires involving product contents or packaging, Use self-contained breathing apparatus in enclosed or confined spaces. For multiple packages/pallets of product full protective equipment is recommended for firefighters.
Unusual Fire and Explosion:	None known

SECTION 6: ACCIDENTAL RELEASE MEASURES

Use wet methods or HEPA vacuum to pick up spilled solids. Do not sweep or use other methods which generates dust. After clean up, flush spill area with water. For spill clean up, use disposable Tyvek or equivalent protective coveralls, chemical resistant gloves and half-face or full-face respirator with HEPA cartridges.

SECTION 7: HANDLING AND STORAGE

Handling:	Handle in a sterile manner.
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Storage:

Store dry material at a temperature of +4° C to +25° C, with the contents sealed under a nitrogen blanket. Keep container closed when not in use. Avoid direct sunlight.

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Engineering Controls:	The sterile material should be handled in a sterile laminar flow hood to maintain sterility and reconstituted with sterile water solutions.
Respiratory Protection:	This material does not have established exposure limits. For large quantities or where dust generation is likely, use a respirator.
Eye Protection:	When handling small quantities, wear safety glasses.
Protective Clothing:	Wear natural rubber, nitrile or other chemical-resistant gloves when handling. For small quantities, wear a lab coat or other protective clothing.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor:	White to off-white solid, no odor
pH:	Non ionic
Melting Point/Freezing Point:	This non-crystalline polymer has a glass transition temperature of about 100° C in dry form. The lower critical solution temperature is 35° C in water.
Solubility in Water:	Soluble in cold water up to 30%. Forms insoluble hydrogel at 35° C.
Specific Gravity:	Approximately 1.
Vapor Pressure :	<0.01 mm Hg at 20° C. This material is non-volatile.

SECTION 10: Stability and Reactivity

General:	This product is stable when used as directed. It is unreactive.
Incompatible Materials/Conditions:	Store away from oxidizers and heat. Store at 4-25° C.
Hazardous Decomposition:	Hazardous decomposition products formed under fire conditions. - Carbon oxides Other decomposition products - No data available. In the event of fire: see section 5

SECTION 11: TOXICOLOGICAL INFORMATION

Oral:	No data is available
Intravenous:	No data is available
Subcutaneous:	In a single dose study, subcutaneous administration to mice of 1000 and 2000 mg/kg resulted in no lethality, clinical signs of



toxicity, or microscopic tissue abnormalities and no other treatment-related effects with up to 3 month of observations.

Ocular:	No data is available
Implants:	Mice were implanted with a single dose of 2000 mg/kg of poly(2,3)Glucose gel in the renal capsule and the abdominal cavity. No toxic effect or abnormality was observed in up to 1 month of observations.
Mutagenicity:	No data is available
Reproduction:	No data is available
Cellular/in vitro:	Human islets of Langerhans function normally while encapsulated in poly(2,3)Glucose. Cultures of human lymphoblastoid TK6 cells show no toxicity effects (MTS assay) from dissolved poly(2,3)Glucose, up to 15 mg/ml. Murine macrophage j774 cells show no inflammatory response (Interlukin 6 assay) from dissolved poly(2,3)Glucose, up to 10 mg/ml.

SECTION 12: ECOLOGICAL INFORMATION

No ecological information available for the material.

SECTION 13: DISPOSAL CONSIDERATIONS

This product is not classified as a hazardous waste when disposed of. Landfill or incineration is recommended for dry poly(2,3)Glucose. Sewer disposal is recommended for liquid solutions. If biohazardous materials are also present, then dispose in accordance with the biohazard.

SECTION 14: TRANSPORT INFORMATION

Not a hazardous material for DOT, IATA, IMO or TDG shipment.

SECTION 15: REGULATORY INFORMATION

TSCA (Toxic Substances Control Act):	As defined by U.S. Code Title 15, Chapter 53 (TSCA), Section 2602 and TSCA Regulations at 40CFR, Subchapter R, Part 710, this product is exempt from regulations under TSCA.
CERCLA (Comprehensive Environmental Response, Compensation, and Liability Act):	This product contains no components subject to reporting or notification requirements
SARA Title III (Superfund Amendments and Reauthorization Act):	311/312 Hazard Categories: none 313 Reportable Ingredients: None



WHMIS (Workplace
Hazardous Materials
Information System - Canada):

Not Regulated

European Information In
Accordance With EU
Classification and Packaging
Directives:

Hazard Symbol: None (not harmful)

Risk Phrases:

R22: Harmful if swallowed.

Safety Phrases:

S 22 – Do not breathe dust

S 36/37 – Wear suitable protective clothing and gloves

SECTION 16: OTHER INFORMATION

Revision Summary: MSDS revised June 7, 2018

HMIS Rating

Health hazard: 0

Chronic Health Hazard:

Flammability: 1

Physical Hazard: 0

NFPA Rating

Health hazard: 0

Fire Hazard: 1

Reactivity Hazard: 0

Legal information

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