

**MATERIAL SAFETY DATA SHEET****GlyPro® R2****1. PRODUCT AND COMPANY IDENTIFICATION****Product Name:** GlyPro® R2**Product Number:** 70-5126-01; 70-5126-05; 70-5526-50**Synonym(s):** GlyPro Reagent 2**Product Use:** Component of the GlyPro® Reagent kit. For use in the quantitative determination of glycated serum proteins. For In Vitro Diagnostic Use Only.**Description:** Dry pellet containing enzyme, salt, sugar and buffer.**Corporate Headquarters****Genzyme Corporation**500 Kendall Street
Cambridge, MA 02142
USA**Phone:** 617-252-7500**Manufacturer/Distributor****Genzyme Diagnostics**50 Gibson Drive
Kings Hill, West Malling
Kent, ME19 4AF

UK

Phone: 44 (0) 1732 220022**Emergency Telephone Numbers****Genzyme (U.S.):** 617-562-4555**CHEMTREC (U.S.):** 800-424-9300**CHEMTREC (Outside U.S.):** 703-527-3887**2. HAZARDS IDENTIFICATION****Precautionary Statements:**

CAUTION! The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: pale yellow pellet.

Routes of Exposure:

Occupational exposure routes may include eye and skin contact.

Potential Health Effects:

Inhalation	No data available. Although there is no evidence that the enzyme(s) in this preparation induces specific respiratory hypersensitivity, all proteins are potential respiratory allergens and may result in respiratory sensitization in certain individuals after repeated and/or prolonged inhalation exposure, producing mild to severe symptoms similar to pollen allergy or asthma, including mucous membrane or eye irritation, itching of the skin or eyes, sneezing, nasal or sinus congestion, coughing, and tightness in the chest. These symptoms may develop as late as 12 hours after exposure.
Eye	No data available. Eye exposure may cause irritation.
Skin	No data available. Skin contact may cause irritation, redness and discomfort.
Ingestion	No data available.
Chronic Effects	No data available.
Target Organs	Unknown.

Regulatory Status:

This preparation is classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIP 2002 No. 1689; and/or U.N. GHS ST/SG/AC 10/30. Refer to Sec. 15, Regulatory Information, for details regarding hazard classification.

None of the components present in this preparation at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

Potential Environmental Effects:

Unknown.



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3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS #	EC #	% (wt/wt)
Mannitol	87-78-5	201-770-2	44 - 50
EC R-Phrases: None	EC Hazard Class: None		
EDTA tetrasodium, dihydrate	10378-23-1	Not Assigned	26 - 31
EC R-Phrases: None	EC Hazard Class: None		
4-(2-Hydroxyethyl)-1-piperazinepropanesulfonic acid (EPPS)	16052-06-5	240-198-8	16 - 21
EC R-Phrases: None	EC Hazard Class: None		
4-Aminoantipyrine	83-07-8	201-452-3	1 - 4
EC R-Phrases: None	EC Hazard Class: None		
Ketoamine oxidase	Not Assigned	Not Assigned	< 1
EC R-Phrases: None	EC Hazard Class: None		

NOTE - Ketoamine oxidase - Enzyme source: Fusarium oxysporum, Enzyme Commission number: Not registered

4. FIRST AID MEASURES

Inhalation:

If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

Eye Contact:

Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

Skin Contact:

In case of contact, flush skin with copious amounts of cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.

Ingestion:

In case of ingestion, contact a poison control center or physician for instructions.

5. FIRE FIGHTING MEASURES

Flammable Properties:

Material may burn when exposed to sufficient heat.

Suitable Extinguishing Media:

Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry chemical or water spray.

Unsuitable Extinguishing Media:

Unknown.

Specific Hazards Arising from the Chemical:

Irritating or highly toxic gases may be generated by combustion, including carbon monoxide (CO), carbon dioxide (CO₂), nitrogen oxides (NO_x) and sulfur oxides (SO_x).

Standard Protective Equipment and Precautions for Firefighters:

Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.



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6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:

Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material. Wash hands thoroughly after handling.

Environmental Precautions:

No information available.

Methods and Materials for Containment and Clean-Up:

Scoop up released material. Decontaminate the spill site following standard procedures. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

7. HANDLING AND STORAGE

Handling:

Follow good laboratory hygiene practices. See Section 8, Engineering Controls. Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.

Storage:

Store at 2 to 8°C (36 to 46°F). Do not store with incompatible substances; see Section 10.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines:

There are no ACGIH, NIOSH, OSHA or country-specific occupational exposure limits currently established for components present in this preparation at concentrations equal to or greater than 1% (0.1% if carcinogen).

Engineering Controls:

Use in well ventilated areas. If handling large quantities or there is a potential for dust or aerosol generation, use local exhaust ventilation. Facilities storing or using this preparation should be equipped with an eyewash fountain.

Personal Protective Equipment (PPE):

Respiratory	A respirator is not required under normal conditions of use.
Eye/Face	Wear appropriate protective chemical safety glasses.
Skin	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Gloves	Wear chemical resistant protective gloves.
General	Follow company-specific safety procedures.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Pale yellow pellet	pH:	7.97 - 7.99 (in solution)
Odor:	Unknown	Solubility:	Water-soluble
Boiling Point:	Not applicable	Evaporation Rate:	Not applicable
Melting Point:	Not available	Density:	Not available
Freezing Point:	Not applicable	Vapor Pressure:	Not applicable
Viscosity:	Not applicable	Partition Coefficient (n-octanol/water):	Not available
		Vapor Density:	Not applicable



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Flammability/Explosivity Limits in Air, Lower: Not applicable
Flammability/Explosivity Limits in Air, Upper: Not applicable
Auto-Ignition Temperature: Not available
Flash Point: Not applicable

10. STABILITY AND REACTIVITY

Chemical Stability:

Stable under ordinary conditions of use and storage. See Section 7.

Conditions to Avoid:

Unknown.

Incompatible Materials:

Unknown.

Hazardous Decomposition Products:

None expected under normal conditions of use.

Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Effects:

Toxicology Data - Selected LD50s and LC50s

4-Aminoantipyrine

83-07-8

Oral LD50 Rat: 1700 mg/kg

Chronic Effects:

No data available.

Carcinogenicity:

No data available.

Mutagenicity:

No data available.

Teratogenicity:

No data available.

Reproductive Effects:

No data available.

Sensitization:

No data available.

12. ECOLOGICAL INFORMATION

Ecotoxicity:

No data available.

Persistence and Degradability:

No data available.

Bioaccumulative Potential:

No data available.



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Mobility in Environmental Media:

No data available.

13. DISPOSAL CONSIDERATIONS

Methods of Disposal:

Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations.

14. TRANSPORT INFORMATION

Basic Shipping Description:

Not classified as dangerous goods. Not regulated per IATA and DOT regulations.

15. REGULATORY INFORMATION

US Federal Regulations:

This preparation is a component of an FDA-regulated in vitro diagnostic device.

Inventory - United States - Section 8(b) Inventory (TSCA)

4-(2-Hydroxyethyl)-1-piperazinepropanesulfonic acid (EPPS)	16052-06-5	Present
4-Aminoantipyrine	83-07-8	Present
Mannitol	87-78-5	Present



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International Regulations:

If approved for European Communities use, this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

Canada - WHMIS - Classifications of Substances

4-Aminoantipyrine	83-07-8	Uncontrolled product according to WHMIS classification criteria
EDTA tetrasodium, dihydrate	10378-23-1	Uncontrolled product according to WHMIS classification criteria

Inventory - Australia - Inventory of Chemical Substances (AICS)

4-(2-Hydroxyethyl)-1-piperazinepropanesulfonic acid (EPPS)	16052-06-5	Present
4-Aminoantipyrine	83-07-8	Present
EDTA tetrasodium, dihydrate	10378-23-1	Present
Mannitol	87-78-5	Present

Inventory - Canada - Domestic Substances List (DSL)

4-Aminoantipyrine	83-07-8	Present
Mannitol	87-78-5	Present

Inventory - Canada - Non-Domestic Substances List (NDSL)

4-(2-Hydroxyethyl)-1-piperazinepropanesulfonic acid (EPPS)	16052-06-5	Present
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Inventory - China

4-(2-Hydroxyethyl)-1-piperazinepropanesulfonic acid (EPPS)	16052-06-5	Present
4-Aminoantipyrine	83-07-8	Present
EDTA tetrasodium, dihydrate	10378-23-1	Present
Mannitol	87-78-5	Present

Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

4-(2-Hydroxyethyl)-1-piperazinepropanesulfonic acid (EPPS)	16052-06-5	240-198-8
4-Aminoantipyrine	83-07-8	201-452-3
Mannitol	87-78-5	201-770-2

Inventory - Japan Existing and New Chemical Substances (ENCS)

4-Aminoantipyrine	83-07-8	9-62
Mannitol	87-78-5	9-1375

Inventory - Korea - Existing and Evaluated Chemical Substances

4-Aminoantipyrine	83-07-8	KE-01297
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Canadian Hazardous Products:

WHMIS Status Exempt

European Communities Dangerous Substances/Preparations:

EC Hazard Class None

Risk Phrases None

Safety Phrases None

16. OTHER INFORMATION

Further Information:

This MSDS has been prepared in accordance with the ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, Canadian Controlled Products Regulation (CPR), UK Chemical Hazard Information and Packaging Regulations, European Communities REACH Regulation, and UN Globally Harmonized System of Classification and Labelling of Chemicals.



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Version #: 3

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