



## 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:**

<b>Inhalation</b>	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.
<b>Eye</b>	No data available. Eye exposure may cause irritation.
<b>Skin</b>	No data available. Skin contact may cause irritation, redness and discomfort.
<b>Ingestion</b>	No data available.
<b>Chronic Effects</b>	No data available.
<b>Target Organs</b>	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 EC R-Phrases: None	87-78-5 EC Hazard Class: None	201-770-2	44 - 50
EDTA tetrasodium, dihydrate EC R-Phrases: None	10378-23-1 EC Hazard Class: None	Not Assigned	26 - 31
4-(2-Hydroxyethyl)-1-piperazinepropanesulfonic acid (EPPS) EC R-Phrases: None	16052-06-5 EC Hazard Class: None	240-198-8	16 - 21
4-Aminoantipyrine EC R-Phrases: None	83-07-8 EC Hazard Class: None	201-452-3	1 - 4
Ketoamine oxidase EC R-Phrases: None	Not Assigned EC Hazard Class: None	Not Assigned	< 1

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 (CO<sub>2</sub>), nitrogen oxides (NO<sub>x</sub>) and sulfur oxides (SO<sub>x</sub>).

**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):**

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

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Pale yellow pellet	<b>pH:</b>	7.97 - 7.99 (in solution)
<b>Odor:</b>	Unknown	<b>Solubility:</b>	Water-soluble
<b>Boiling Point:</b>	Not applicable	<b>Evaporation Rate:</b>	Not applicable
<b>Melting Point:</b>	Not available	<b>Density:</b>	Not available
<b>Freezing Point:</b>	Not applicable	<b>Vapor Pressure:</b>	Not applicable
<b>Viscosity:</b>	Not applicable	<b>Partition Coefficient (n-octanol/water):</b>	Not available
		<b>Vapor Density:</b>	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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**MSDS Origination Date:** August 10, 2004

**Version #:** 3

**Revision Date:** October 29, 2008

**Disclaimer:**

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