



MATERIAL SAFETY DATA SHEET

α -Amylase Test Reagent (CNP3)

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: α -Amylase Test Reagent (CNP3)

Product Number: 80-3500-20; 80-3500-50; 80-3603-01; 80-3844-03; 80-5260-00; 80-5383-00; 80-5451-00

Synonym(s): Liquid Select Amylase; Direct Amylase Reagent; Amylase Direct; alpha-Amylase Test Reagent (CNP3)

Product Use: For the quantitative determination of alpha-amylase activity in serum and plasma; to assist in the diagnosis of acute pancreatitis. For In Vitro Diagnostic Use Only.

Description: Aqueous solution containing chromogenic substrate, buffer, preservative and salts.

Corporate Headquarters

Genzyme Corporation

500 Kendall Street
Cambridge, MA 02142
USA

Phone: 617-252-7500

Distributor

Genzyme Diagnostics

50 Gibson Drive
Kings Hill, West Malling
Kent, ME19 4AF
UK

Phone: 44 (0) 1732 220022

Manufacturer/Distributor

Genzyme Diagnostics

31 New York Avenue
Framingham, MA 01701-9322
USA

Phone: 800-332-1042

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. May be irritating to eyes, respiratory system and skin. May be harmful in contact with skin and if swallowed. Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: clear, faint yellow liquid.

Routes of Exposure:

Occupational exposure routes may include eye contact, skin contact, skin absorption and inhalation.

Potential Health Effects:

Inhalation	Symptoms of acute potassium thiocyanate exposure may be similar to acute cyanide toxicity: Acute inhalation may cause coughing, mucosal irritation and dyspnea (shortness of breath).
Eye	No data available. Eye exposure may cause irritation, redness, watering and pain.
Skin	Symptoms of acute potassium thiocyanate exposure may be similar to acute cyanide toxicity: Skin contact may cause irritation, redness, itching and pain. Dermal absorption and eye contact may result in systemic effects.
Ingestion	Symptoms of acute potassium thiocyanate exposure may be similar to acute cyanide toxicity: Low oral doses of cyanides produce symptoms of weakness, headache, confusion, and occasionally nausea and vomiting.



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Potential Health Effects:

Chronic Effects Symptoms of potassium thiocyanate intoxication may be similar to chronic cyanide toxicity. Subchronic and chronic effects of cyanide inhalation include: CNS effects, such as vertigo (dizziness), nystagmus (abnormal eye movement), nervousness, headache, weakness, loss of appetite, and changes in smell and taste; CVS effects, such as precordial (central chest) pain, EKG abnormalities, and breathing difficulties; GI tract effects, such as nausea, vomiting, and gastritis (stomach lining inflammation); enlarged thyroid/goiter; and skin effects, such as dermatitis, itching, scarlet rash, papules (bumps) and severe irritation of the nose and throat. Symptoms of chronic ingestion of cyanide include: CNS effects, such as neuropathies (nerve problems) and amblyopia (lazy eye); and thyroid abnormalities. Subchronic dermal exposure symptoms include itching, rash, papules, dermatitis, skin and nail discoloration, diarrhea, headache, and body and limb numbness, weakness and pain.

Target Organs Potassium thiocyanate: central nervous system, cardiovascular system and thyroid.

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:

See Section 12.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS #	EC #	% (wt/wt)
Water	7732-18-5	231-791-2	81 - 91
EC R-Phrases: None	EC Hazard Class: None		
Potassium thiocyanate	333-20-0	206-370-1	7 - 8
EC R-Phrases: R20/21/22, R52/53	EC Hazard Class: Xn		
Sodium chloride	7647-14-5	231-598-3	1 - 2
EC R-Phrases: None	EC Hazard Class: None		
4-Morpholineethanesulfonic (MES) monohydrate, free acid	4432-31-9	224-632-3	1 - 8
EC R-Phrases: None	EC Hazard Class: None		
2-Chloro-4-nitrophenyl maltotrioxide (CNP3)	Not Assigned	Not Assigned	< 0.2
EC R-Phrases: None	EC Hazard Class: None		
Calcium acetate	62-54-4	200-540-9	< 0.1
EC R-Phrases: None	EC Hazard Class: None		
Sodium azide	26628-22-8	247-852-1	< 0.1
EC R-Phrases: R28, R32, R50, R53	EC Hazard Class: T+, N		

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.



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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:

Dilute aqueous solution not considered a fire hazard.

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:

Unknown.

Standard Protective Equipment and Precautions for Firefighters:

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

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:

This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. Follow proper disposal procedures.

Methods and Materials for Containment and Clean-Up:

Absorb spill with inert material/sorbent. 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 - 8°C (36 - 46°F). Do not freeze. Do not store with incompatible substances. See Section 10.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION



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Engineering Controls:

Minimize potential for aerosolization. Handle within a containment system, with local exhaust ventilation, or with dilution ventilation at a minimum. 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:	Clear, faint yellow liquid	pH:	6.0
Odor:	Not available	Solubility:	Water-soluble
Specific Gravity:	1.04	Evaporation Rate:	Not available
Boiling Point:	Not available	Vapor Pressure:	Not available
Melting Point:	Not applicable	Partition Coefficient (n-octanol/water):	Not available
Freezing Point:	Not available	Vapor Density:	Not available
Viscosity:	Not available		
Flammability/Explosivity Limits in Air, Lower:	Not available		
Flammability/Explosivity Limits in Air, Upper:	Not available		
Auto-Ignition Temperature:	Not applicable		
Flash Point:	Not available		

10. STABILITY AND REACTIVITY

Chemical Stability:

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

Conditions to Avoid:

There are no physical conditions known to result in a hazardous situation.

Incompatible Materials:

Avoid strong oxidizing agents, acids, heavy metals and their salts. Thiocyanates can develop toxic gas in contact with strong acids.

Hazardous Decomposition Products:

None expected under normal conditions of use.

Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION



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Acute Effects:

Toxicology Data - Selected LD50s and LC50s

Potassium thiocyanate	333-20-0	Oral LD50 Rat: 854 mg/kg
Sodium chloride	7647-14-5	Inhalation LC50 Rat: >42 g/m ³ /1H; Oral LD50 Rat: 3 g/kg; Dermal LD50 Rabbit: >10 g/kg

Local Effects:

No data available.

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:

Ecotoxicity - Freshwater Fish Species Data

Sodium chloride	7647-14-5	96 Hr LC50 <i>Lepomis macrochirus</i> : 9675 mg/L [flow-through]; 96 Hr LC50 <i>Lepomis macrochirus</i> : 12946 mg/L [static]; 96 Hr LC50 <i>Pimephales promelas</i> : 7650 mg/L [static]
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Ecotoxicity - Water Flea Data

Sodium chloride	7647-14-5	48 Hr EC50 <i>Daphnia magna</i> : 1000 mg/L
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Persistence and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Environmental Media:

No data available.

13. DISPOSAL CONSIDERATIONS

Methods of Disposal:

This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. If preparation enters drain, flush with a large volume of water to prevent azide build-up. 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



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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-Morpholineethanesulfonic (MES) monohydrate, free acid	4432-31-9	Present
Potassium thiocyanate	333-20-0	Present
Sodium chloride	7647-14-5	Present

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

Potassium thiocyanate	333-20-0	Uncontrolled product according to WHMIS classification criteria
Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria

Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes

Sodium chloride	7647-14-5	ID Number 270, hazard class 1 - low hazard to waters
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Inventory - Australia - Inventory of Chemical Substances (AICS)

4-Morpholineethanesulfonic (MES) monohydrate, free acid	4432-31-9	Present
Potassium thiocyanate	333-20-0	Present
Sodium chloride	7647-14-5	Present

Inventory - Canada - Domestic Substances List (DSL)

4-Morpholineethanesulfonic (MES) monohydrate, free acid	4432-31-9	Present
Potassium thiocyanate	333-20-0	Present
Sodium chloride	7647-14-5	Present

Inventory - China

4-Morpholineethanesulfonic (MES) monohydrate, free acid	4432-31-9	Present
Potassium thiocyanate	333-20-0	Present
Sodium chloride	7647-14-5	Present

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

4-Morpholineethanesulfonic (MES) monohydrate, free acid	4432-31-9	224-632-3
Potassium thiocyanate	333-20-0	206-370-1
Sodium chloride	7647-14-5	231-598-3

Inventory - Japan Existing and New Chemical Substances (ENCS)

Potassium thiocyanate	333-20-0	1-152
Sodium chloride	7647-14-5	1-236

Inventory - Korea - Existing and Evaluated Chemical Substances

4-Morpholineethanesulfonic (MES) monohydrate, free acid	4432-31-9	KE-25529
Potassium thiocyanate	333-20-0	KE-29216
Sodium chloride	7647-14-5	KE-31387

Canadian Hazardous Products:

WHMIS Status	Exempt
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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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