



MATERIAL SAFETY DATA SHEET

Cholesterol Esterase - N

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Cholesterol Esterase - N

Product Number: 70-6221-00; 70-6221-01; 70-6221-20

Synonym(s): CEN; Sterol esterase; Steryl-ester acylhydrolase

Product Use: For In Vitro Diagnostic Use Only.

Description: Lyophilized powder containing enzyme (protein) and buffering salt.

Corporate Headquarters

Genzyme Corporation

500 Kendall Street
Cambridge, MA 02142-1108
USA

Phone: +1 617-252-7500

Distributor

Genzyme Diagnostics

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

UK

Phone: +44 (0) 1732 220022

Distributor

Genzyme Diagnostics

One Kendall Square
Cambridge, MA 02139
USA

Phone: 1-800-332-1042

Emergency Telephone Numbers

Genzyme (U.S.): +1 617-562-4555

CHEMTREC: (Transport-related)

--within U.S.: 1-800-424-9300

--outside U.S.: +1 703-527-3887

2. HAZARDS IDENTIFICATION

Emergency Overview:

The chemical, physical and toxicological properties of this preparation, pertaining directly to occupational exposures, have not been thoroughly characterized.

Precautionary Statements:

WARNING! May be irritating to eyes, respiratory system and skin. May cause sensitization by inhalation. Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: light brownish powder.

Routes of Exposure:

Typical occupational exposure routes are inhalation and skin contact.

Potential Health Effects:

Inhalation	Inhalation may be irritating to the nasal passages and throat. Respiratory sensitization may develop in certain individuals after repeated 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, wheezing and tightness in the chest. These symptoms may develop as late as 12 hours after exposure.
Eye	Eye exposure may cause irritation, redness and watering.
Skin	As with all enzymes, skin irritation is possible, particularly at high enzyme concentrations, with prolonged enzyme contact, and under moist conditions. Skin contact may cause irritation, dryness, redness and itching.
Ingestion	Effects of ingestion are unknown, but may include digestive system irritation nausea, vomiting or diarrhea.
Chronic Effects	Repeated and/or prolonged inhalation by certain individuals may result in respiratory sensitization and possibly permanent decreases in lung function.



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Potential Health Effects:

Medical Conditions Aggravated By Exposure Individuals with preexisting allergies to enzyme products may be more susceptible to health effects from accidental exposure and should be evaluated for their suitability for working with this product. Medical supervision for all employees who handle or come in contact with respiratory sensitizers is recommended.

Target Organs Respiratory system.

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. CHIPS 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.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS #	EC #	% (w/w)
Cholesterol esterase EC R-Phrases: R42	9026-00-0 EC Hazard Class: Xn	232-808-6	82 - 98
Potassium phosphate, monobasic EC R-Phrases: None	7778-77-0 EC Hazard Class: None	231-913-4	2 - 18

NOTE - Cholesterol esterase - Enzyme source: Pseudomonas sp., Enzyme Commission number: 3.1.1.13

4. FIRST AID MEASURES

Inhalation:

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

Eye Contact:

Immediately flush eyes with plenty of tepid water while separating eyelids with fingers, removing contact lenses if worn. Continue to flush for at least 15 minutes. 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. Wash material from skin with soap and water and rinse thoroughly with clean water. Obtain medical attention if needed or if irritation or other symptoms develop.

Ingestion:

In case of ingestion, drink 4 to 8 ounces (120 to 240 mL) of water to dilute. Seek medical attention if symptoms of digestive irritation or discomfort occur.

5. FIRE FIGHTING MEASURES

Flammable Properties:

Like most organic solids, material will burn when exposed to sufficient heat or upon contact with an ignition source.

Suitable Extinguishing Media:

Carbon dioxide, chemical foam, dry chemical or water spray.



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Specific Hazards Arising from the Chemical:

None expected.

Standard Protective Equipment and Precautions for Firefighters:

As in any fire, 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. Ensure adequate ventilation. Avoid physical contact with material and avoid generating or inhaling dust. Wash hands thoroughly after handling.

Methods and Materials for Containment and Clean-Up:

Carefully vacuum up powdered spill with a HEPA-filtered vacuum and transfer into an appropriate clean, dry container. (If vacuuming is not possible lightly mist the spill to keep the dust down, taking care to avoid slipping, and scoop up.) After material pickup is complete, wash spill site to remove any residual material and dry completely. Dispose of spilled material and contaminated waste 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. Wear proper Personal Protective Equipment (PPE) and employ exposure controls as indicated in Section 8. Avoid physical contact. Minimize dust generation during use. Wash hands thoroughly after handling.

Storage:

Refer to product label and/or literature for specific storage conditions. The recommended storage temperature(s) at the time of MSDS preparation/revision is: Store desiccated at -20°C (-4°F). Keep container tightly closed. Do not store with incompatible substances or under avoidable conditions identified in 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:

Provide adequate ventilation by means of mechanical exhaust, to keep airborne concentrations low. Local exhaust is preferred, because it can control the emissions of the contaminant at its source, preventing dispersion into the general work area. Ventilation systems should be fitted with High Efficiency Particulate Air (HEPA) filters or other proper exhaust control at mixing and filling sites and where operations can create dust or aerosols. Facilities storing or utilizing this preparation should be equipped with an eyewash fountain and a safety shower.

Personal Protective Equipment (PPE):

Respiratory

A respiratory protection program that meets U.S. Federal OSHA 29 CFR 1910.134 and ANSI Z99.2, Canadian CSA Standard Z94.4-93, European Standard CR 529, or other applicable regulatory standards must be followed whenever exposure limits are exceeded and engineering controls are not feasible, or if insufficient ventilation or workplace conditions warrant a respirator's use. In such cases an air purifying respirator equipped with particulate filter cartridges, (42 CFR 84 - NIOSH Part 84 particulate filter, EN 141/143 particulate "P" filter), selected to provide a filtration efficiency appropriate to your workplace is recommended.

Eye/Face

Wear appropriate protective safety eye wear as described in the ANSI standard 787.1-2003.



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Personal Protective Equipment (PPE):

Skin	Wear appropriate protective clothing, such as a lab coat or other long-sleeved garment over your clothes, to minimize contact and contamination of clothing. Change into clean clothes promptly if clothing becomes contaminated. Wash contaminated clothing before reuse.
Gloves	Prevent skin exposure by wearing protective gloves impermeable to this material/preparation. Change gloves regularly or immediately if they are contaminated, torn or punctured. Latex or nitrile gloves are recommended for incidental handling. Heavy (30 mil) butyl rubber gloves are recommended for extended handling and spill clean-up.
General	Consult your company's safety manager/industrial hygienist or your safety equipment manufacturer/supplier for assistance with your selection of appropriate PPE.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Light brownish powder	pH:	7.5 (in solution)
Odor:	Not available	Solubility:	Water-soluble
Specific Gravity:	Not available	Vapor Pressure:	Not applicable
Boiling Point:	Not applicable	Partition Coefficient (n-octanol/water):	Not available
Melting Point:	Not available	Other:	Minimum Ignition Energy (MIE) for dust not available
Freezing Point:	Not applicable	Other:	Minimum Ignition Temperature (MIT) for dust not available
		Vapor Density:	Not applicable

Chemical Family: Protein mixture

10. STABILITY AND REACTIVITY

Chemical Stability:

Stable under ordinary conditions of use and storage; (see handling and storage information in Section 7).

Conditions to Avoid:

Avoid heat, flames, sparks and ignition sources. Avoid prolonged exposure to direct sunlight. Excessive heat may damage the product.

Incompatible Materials:

Avoid strong oxidizing agents, strong acids and bases.

Hazardous Decomposition Products:

None expected under normal conditions of use.

Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Effects:

NIOSH - Selected LD50s and LC50s

Potassium phosphate, monobasic

7778-77-0

Dermal LD50 Rabbit: >4640 mg/kg

Chronic Effects:

Chronic respiratory exposures in sensitized individuals may result in permanent decrease in lung function.



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Sensitization:

May cause sensitization by inhalation.

12. ECOLOGICAL INFORMATION

Ecotoxicity:

No information available for product. Not expected to exhibit ecotoxic characteristics at any stage of use.

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.

Packaging:

Containers of this material may retain product residues. Handle contaminated packaging in the same way as the substance itself, by disposing in accordance with all applicable federal, state, local, and provincial environmental and hazardous waste regulations. If not officially specified differently, non-contaminated packaging may be treated like household waste or recycled.

Waste Classification:

Chemical waste generators must refer to the relevant hazardous waste regulations to ensure complete and accurate classification. Disposal regulations may vary according to geographic location.

14. TRANSPORT INFORMATION

Basic Shipping Description:

Contact Genzyme for shipping information.

15. REGULATORY INFORMATION

US Federal Regulations:**Inventory - United States - Section 8(b) Inventory (TSCA)**

Cholesterol esterase	9026-00-0	XU
Potassium phosphate, monobasic	7778-77-0	Present



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International Regulations:

Canada - WHMIS - Classifications of Substances

Potassium phosphate, monobasic 7778-77-0 Uncontrolled product according to WHMIS classification criteria

Inventory - Australia - Inventory of Chemical Substances (AICS)

Cholesterol esterase 9026-00-0 Present
Potassium phosphate, monobasic 7778-77-0 Present

Inventory - Canada - Domestic Substances List (DSL)

Cholesterol esterase 9026-00-0 Present
Potassium phosphate, monobasic 7778-77-0 Present

Inventory - Canada - Organisms on the Non-Domestic Substances List (NDSL)

Cholesterol esterase 9026-00-0 IUB #3.1.1.13

Inventory - China

Potassium phosphate, monobasic 7778-77-0 Present

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

Cholesterol esterase 9026-00-0 232-808-6
Potassium phosphate, monobasic 7778-77-0 231-913-4

Inventory - Japan Existing and New Chemical Substances (ENCS)

Potassium phosphate, monobasic 7778-77-0 1-452

Inventory - Korea - Existing and Evaluated Chemical Substances

Cholesterol esterase 9026-00-0 KE-05951
Potassium phosphate, monobasic 7778-77-0 KE-28622

Switzerland - Toxic Substances Classification

Potassium phosphate, monobasic 7778-77-0 Class 5

Canadian Hazardous Products:

WHMIS Status Non-controlled

European Communities Dangerous Substances/Preparations:

EC Hazard Class Xn - Harmful

Symbols



Risk Phrases

R42 May cause sensitization by inhalation.

Safety Phrases

S22 Do not breathe dust.
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

16. OTHER INFORMATION

Recommended Use:

For In Vitro Diagnostic Use Only. Not for human or drug use.

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 US OSHA Hazard Communication Standard, European Communities Safety Data Sheets Directive, Canadian Controlled Products Regulations, UK Chemical Hazard Information and Packaging Regulations, and UN Globally Harmonized System of Classification and Labelling of Chemicals.

The hazard ratings on this MSDS are for appropriately trained workers using a Hazardous Materials Identification System (HMIS®) or a National Fire Protection Association (NFPA) 704 program. The ratings are estimates and should be treated as such. The hazard rating scales range from (0) minimal hazards to (4) significant hazards or risks. Chronic (long-term) health effects are indicated in the HMIS® by an asterisk (*). HMIS® is a registered trade and service mark of the NPCA. For details on HMIS® ratings visit www.paint.org/hmis. For details on NFPA 704 visit www.nfpa.org.



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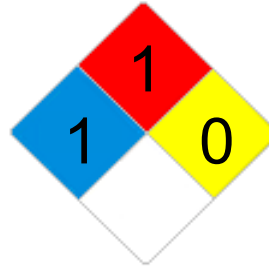
HMIS® RATINGS

HEALTH	*	2
FLAMMABILITY		1
PHYSICAL HAZARD		0

Target Organ(s):

Respiratory system

NFPA RATINGS



MSDS Origination Date: June 17, 2005

Version #: 1

Revision Date: Not Applicable

Disclaimer:

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