



MATERIAL SAFETY DATA SHEET

Bilirubin Oxidase

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Bilirubin Oxidase

Product Number: 70-1021-00; 70-1021-01; 70-1021-88; BIOX-70-1021

Synonym(s): BO; Bili Ox; Bilirubin:oxygen oxidoreductase

Product Use: For In Vitro Diagnostic Use Only.

Description: Lyophilized powder containing enzyme (protein), carbohydrate and buffering salts.

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

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

Distributor

Genzyme Diagnostics
One Kendall Square
Cambridge, MA 02139
USA
Phone: 1-800-332-1042

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 yellow to light blue powder.

Routes of Exposure:

Typical occupational exposure routes are inhalation, eye 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. |



MATERIAL SAFETY DATA SHEET

Bilirubin Oxidase

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)
Bilirubin oxidase EC R-Phrases: R42	80619-01-8	Not Assigned	50 - 60
Ammonium sulfate EC R-Phrases: None	7783-20-2	231-984-1	10 - 20
Potassium phosphate, monobasic EC R-Phrases: None	7778-77-0	231-913-4	10 - 20
Sucrose EC R-Phrases: None	57-50-1	200-334-9	10 - 20

NOTE - Bilirubin oxidase - Enzyme source: Myrothecium verrucaria, Enzyme Commission number: 1.3.3.5

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.



MATERIAL SAFETY DATA SHEET

Bilirubin Oxidase

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.

Specific Hazards Arising from the Chemical:

Irritating or highly toxic gases may be generated by combustion, including ammonia (NH₃), carbon dioxide (CO₂), carbon monoxide (CO), phosphorus oxides (PO_x), potassium oxides (KO_x) and sulfur oxides (SO_x).

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



MATERIAL SAFETY DATA SHEET

Bilirubin Oxidase

Exposure Guidelines:

ACGIH - Threshold Limits Values - Time Weighted Averages (TLV-TWA)

Sucrose 57-50-1 10 mg/m³ TWA

ACGIH - Threshold Limits Values - TLV Basis - Critical Effects

Sucrose 57-50-1 lung

Australia - Occupational Exposure Standards - TWAs

Sucrose 57-50-1 10 mg/m³ TWA

Belgium - Occupational Exposure Limits - TWAs

Sucrose 57-50-1 10 mg/m³ VLE

Canada - Quebec - Occupational Exposure Limits - TWAEVs

Sucrose 57-50-1 10 mg/m³ TWAEV

France - Occupational Exposure Limits - TWAs (VMEs)

Sucrose 57-50-1 10 mg/m³ VME

Ireland - Occupational Exposure Limits - STELs

Sucrose 57-50-1 20 mg/m³ STEL

Ireland - Occupational Exposure Limits - TWAs

Sucrose 57-50-1 10 mg/m³ TWA

Israel - Occupational Exposure Limits - TWAs

Sucrose 57-50-1 10 mg/m³ TWA

Korea - Occupational Exposure Limits - STELs

Ammonium sulfate 7783-20-2 20 mg/m³ STEL

Korea - Occupational Exposure Limits - TWAs

Ammonium sulfate 7783-20-2 10 mg/m³ TWA

Sucrose 57-50-1 10 mg/m³ TWA

Netherlands - Occupational Exposure Limits - TWAs (MACs)

Sucrose 57-50-1 10 mg/m³ MAC

NIOSH - Pocket Guide - TWAs

Sucrose 57-50-1 10 mg/m³ TWA (total dust); 5 mg/m³ TWA (respirable dust)

OSHA - Final PELs - Time Weighted Averages (TWAs)

Sucrose 57-50-1 15 mg/m³ TWA (total dust); 5 mg/m³ TWA (respirable fraction)

Spain - Occupational Exposure Limits - TWAs (VLA-ED)

Sucrose 57-50-1 10 mg/m³ VLA-ED

United Kingdom - Occupational Exposure Standards (OES) - TWAs

Sucrose 57-50-1 10 mg/m³ TWA

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, OSHA's eye and face protection regulations 29 CFR 1910.133 and/or European Standard EN 166.

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.



MATERIAL SAFETY DATA SHEET

Bilirubin Oxidase

Personal Protective Equipment (PPE):

- 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 yellow to light blue powder	pH:	Not available
Odor:	Slight odor	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.

Physical Properties - Chemical Incompatibilities

Ammonium sulfate	7783-20-2	Aqueous solution is acidic; reacts with bases forming ammonia. Attacks metals. Hot material reacts with nitrates, nitrites, chlorates.
Sucrose	57-50-1	Reacts with potassium hydroxide, strong acids, strong oxidizers.

Hazardous Decomposition Products:

Thermal decomposition can lead to release of irritating gases and vapors.

Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION



MATERIAL SAFETY DATA SHEET

Bilirubin Oxidase

Acute Effects:

NIOSH - Selected LD50s and LC50s

Ammonium sulfate	7783-20-2	Oral LD50 Rat: 2840 mg/kg; Oral LD50 Mouse: 640 mg/kg
Potassium phosphate, monobasic	7778-77-0	Dermal LD50 Rabbit: >4640 mg/kg
Sucrose	57-50-1	Oral LD50 Rat: 29700 mg/kg

Chronic Effects:

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

Carcinogenicity:

Argentina - Occupational Exposure Limits - Carcinogens

Sucrose 57-50-1 A4 - Not classifiable as a human carcinogen

Canada - New Brunswick - Occupational Exposure Limits - Carcinogens

Sucrose 57-50-1 A4 - Not Classifiable as a Human Carcinogen

Sensitization:

May cause sensitization by inhalation.

12. ECOLOGICAL INFORMATION

Ecotoxicity:

Ecotoxicity - Water Flea Data

Ammonium sulfate 7783-20-2 24 Hr LC50 water flea: 423 mg/L

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)

Ammonium sulfate	7783-20-2	Present
Potassium phosphate, monobasic	7778-77-0	Present
Sucrose	57-50-1	Present



MATERIAL SAFETY DATA SHEET

Bilirubin Oxidase

US State Regulations:

Massachusetts - Toxics Use Reduction Act

Ammonium sulfate 7783-20-2 313 chemical (solution)

New Jersey - Right to Know Hazardous Substance List

Ammonium sulfate 7783-20-2 sn 2892

Pennsylvania - RTK (Right to Know) List

Ammonium sulfate 7783-20-2 Environmental hazard

Sucrose 57-50-1 Present

International Regulations:

Canada - WHMIS - Classifications of Substances

Ammonium sulfate 7783-20-2 Uncontrolled product according to WHMIS classification criteria

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

Sucrose 57-50-1 Uncontrolled product according to WHMIS classification criteria

Canada - WHMIS - Ingredient Disclosure List

Ammonium sulfate 7783-20-2 1 % (English Item 95, French Item 1512)

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

Ammonium sulfate 7783-20-2 hazard class 1, low hazard to waters

Inventory - Australia - Inventory of Chemical Substances (AICS)

Ammonium sulfate 7783-20-2 Present

Potassium phosphate, monobasic 7778-77-0 Present

Sucrose 57-50-1 Present

Inventory - Canada - Domestic Substances List (DSL)

Ammonium sulfate 7783-20-2 Present

Potassium phosphate, monobasic 7778-77-0 Present

Sucrose 57-50-1 Present

Inventory - Canada - Organisms on the Domestic Substances List (DSL)

Bilirubin oxidase 80619-01-8 IUB #1.3.3.5

Inventory - China

Ammonium sulfate 7783-20-2 Present

Potassium phosphate, monobasic 7778-77-0 Present

Sucrose 57-50-1 Present

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

Ammonium sulfate 7783-20-2 231-984-1

Potassium phosphate, monobasic 7778-77-0 231-913-4

Sucrose 57-50-1 200-334-9

Inventory - Japan Existing and New Chemical Substances (ENCS)

Ammonium sulfate 7783-20-2 1-400

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

Inventory - Korea - Existing and Evaluated Chemical Substances

Ammonium sulfate 7783-20-2 KE-01743

Potassium phosphate, monobasic 7778-77-0 KE-28622

Sucrose 57-50-1 KE-17258

Switzerland - Toxic Substances Classification

Ammonium sulfate 7783-20-2 Class 5

Potassium phosphate, monobasic 7778-77-0 Class 5

Canadian Hazardous Products:

WHMIS Status Controlled

Classification

D2B - Other Toxic Effects-TOXIC

MATERIAL SAFETY DATA SHEET
Bilirubin Oxidase



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.

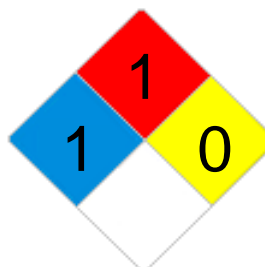
HMIS® RATINGS

HEALTH	*	2
FLAMMABILITY		1
PHYSICAL HAZARD		0

Target Organ(s):

Respiratory system

NFPA RATINGS



MSDS Origination Date: September 12, 2005

Version #: 1

Revision Date: Not Applicable



MATERIAL SAFETY DATA SHEET

Bilirubin Oxidase

Disclaimer:

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Genzyme be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Genzyme has been advised of the possibility of such damages.