



## SAFETY DATA SHEET (MSDS)

**Date of Preparation or Revision:** November 29, 2004

### IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND COMPANY:

NDC Number: 67425-002-10  
Product Name: Vitrase<sup>®</sup> (hyaluronidase injection), Ovine  
Supplier: ISTA Pharmaceuticals, Inc.  
15295 Alton Parkway  
Irvine, CA 92618  
Telephone: (949) 788-6000  
Fax: (949) 788-6010  
Emergency Contact: 24 hours; Infotrac 1-800-535-5053

### COMPOSITION/INFORMATION ON INGREDIENTS:

Chemical Name: Hyaluronate 4-glycanohydrolase  
Synonyms: None  
Hazardous Ingredient: Enzyme protein (approximately 60%)  
CAS Registry Number: 37326-33-3

### HAZARDOUS IDENTIFICATION:

Enzyme liquid. Ingestion of enzyme liquid resulting from handling may induce sensitization and cause allergic reactions in sensitized individuals.

### FIRST AID MEASURES:

If swallowed, wash out mouth with water, provided the person is conscious. Call a Physician.  
If inhaled, remove to fresh air. If symptoms of irritation or sensitization occur (wheezing, shortness of breath, labored coughing, etc.) call a Physician.  
In case of skin contact, immediately wash skin with soap and copious amounts of water,  
In case of accidental eye contact, immediately flush eyes with copious amounts of water for at least 15 minutes

### FIRE-FIGHTING MEASURE:

Extinguishing Media: Water Spray. Carbon dioxide, dry chemical or appropriate foam.  
Special Fire Fighting Procedures: As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke. Product is not expected to present a fire hazard concern.  
Unusual Fire and Explosive Hazards: None

### ACCIDENTAL RELEASE MEASURES:

Steps to be Taken if Material is Released or Spilled: Wear protective equipment. Spilled material should be carefully wiped up or moisten with water and removed.

### HANDLING AND STORAGE:

Store unopened vial in refrigerator at 2-8°C (35-46°F). Avoid prolonged or repeated exposure. Wash thoroughly after handling.

### EXPOSURE CONTROLS/PERSONAL PROTECTION:

Protective Equipment: Wear suitable protective clothing, such as chemical resistant gloves and eye protection.



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### PHYSICAL AND CHEMICAL PROPERTIES:

Appearance: Clear colorless solution.  
Odor: None  
Solubility: Dissolves readily in water.

### STABILITY AND REACTIVITY:

Stability: Stable under normal handling procedures.  
Incompatibilities and Conditions to Avoid: Consult a doctor regarding potential drug interactions.  
Hazardous Combustion or Decomposition Products: None

### TOXICOLOGICAL INFORMATION:

Ingestion of enzyme liquid may induce sensitization and cause allergic reactions in sensitized individuals.

Carcinogenicity/ mutagenicity: Long-term studies have not been performed to assess carcinogenic or mutagenic potential, however, hyaluronidase is found in most tissues in the body.

Fertility: Male: Testicular degeneration may occur with the production of organ-specific antibodies against this enzyme following repeated injections. Female: Fertility may not be adversely affected.

Teratogenicity: There have not been adequate reproductive studies. If absolutely necessary, precautions should be used when administering during pregnancy.

Symptoms of Toxicity: Local edema or urticaria (swelling), erythema, chills, nausea, vomiting, dizziness, tachycardia, and hypotension. Immediately discontinue use if symptoms appear.

### ECOLOGICAL INFORMATION:

No information available, however the substance is readily biodegradable.

### DISPOSAL CONSIDERATIONS:

Country, federal, state, and local regulations are varied and change frequently. For this reason, we recommend that you contact your local Department of Health Services for information on the disposal of this product or arrange for disposal by a licensed disposal company.

### TRANSPORTATION INFORMATION:

Not Classified as hazardous by DOT regulations.

### REGULATORY INFORMATION:

DOT designations: Not classified as hazardous by DOT Regulations  
EPA Designations: RCRA Hazardous waste (40 CFR 261.33) Not Listed  
FDA Designations: Prescription only medication. NDC No. 67425-001-01  
OSHA Designations: (29 CFR 1910.1000, Table Z) Not Listed  
SARA Title III: Not listed under Section 313 of Toxic Release Reporting.

### OTHER INFORMATION:

Avoid contact with material. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Material should only be handled by qualified, experienced professionals. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide for experienced personnel. **ISTA Pharmaceuticals, Inc.** shall not be held liable for any damage resulting from the handling or from contact with the above product.