

Safety Data Sheet

Section 1: Identification

Product identifier

- Product Name** • **Vitrace® (hyaluronidase injection), Ovine**
Product Code • AB50926; AB50999; NDC 24208-0002-01; NDC 24208-002-01; NDC 67425-0002-10

Relevant identified uses of the substance or mixture and uses advised against

- Recommended use** • Hyaluronidase is a spreading or diffusing substance which modifies the permeability of connective tissue.
Restrictions on use • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

- Manufacturer** • Bausch & Lomb
 1400 North Goodman Street
 Rochester, NY 14609
 United States
 bausch.com
Telephone (General) • 1-800-553-5340

Use only in accordance with label instructions.

Emergency telephone number

- Manufacturer** • 1-800-535-5053

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

- UN GHS** • Skin Irritation 2
 Eye Irritation 2A

Label elements

UN GHS

WARNING



- Hazard statements** • May cause skin irritation
 Causes serious eye irritation

May be harmful if swallowed
Ingestion of enzyme liquid may induce sensitization and cause allergic reactions in sensitized individuals.

Precautionary statements

- Prevention** • Use only in accordance with label instructions and supplied prescribing information. Wash thoroughly after handling.
- Response** • IF ON SKIN: Wash with plenty of soap and water.
IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
- Storage/Disposal** • Store unopened vial in refrigerator at 2-8C (35-46F). After admixture with drug, store at 15-25C (59-77F) and use within 6 hours. Protect from light. DO NOT FREEZE. Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Other hazards

UN GHS

- No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition		
Chemical Name	Identifiers	%
Hyaluronidase	CAS:37326-33-3 EINECS:253-464-3	55% TO 65%
Potassium Phosphate Dibasic Anhydrous	CAS:7758-11-4 EINECS:231-834-5	< 0.1%
Potassium Phosphate Monobasic	CAS:7778-77-0 EINECS:231-913-4	< 0.1%
Sodium chloride	CAS:7647-14-5 EINECS:231-598-3	< 1%
Water	CAS:7732-18-5 EINECS:231-791-2	< 40%
Lactose Monohydrate	CAS:63-42-3 EINECS:200-559-2	< 0.1%

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- Remove to fresh air. If signs/symptoms develop, get medical attention.

Skin

- IF ON SKIN: Wash with plenty of soap and water.

Eye

- Flush eyes with water for at least 15 minutes.

Ingestion

- If swallowed, rinse mouth with water (only if the person is conscious) Get medical attention immediately if symptoms occur.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed

Other information

- Additional details are provided on the product packaging and/or the product insert.

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media • Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media • No data available

Firefighting Procedures • Fire fighters should wear complete protective clothing including self-contained breathing apparatus.

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards • None known.

Hazardous Combustion Products • None known.

Advice for firefighters

- No data available

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions • No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8. No special precautions expected to be necessary if material is used under ordinary conditions and as recommended. Avoid any skin contact.

Emergency Procedures • Keep unauthorized personnel away. Ventilate closed spaces before entering. Stop leak if you can do it without risk.

Environmental precautions

- Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

Methods and material for containment and cleaning up

Containment/Clean-up Measures • Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Use appropriate Personal Protective Equipment (PPE) Avoid generating dust. Wash away spilled liquid remainder with plenty of water.

Prohibited Materials • None known.

Reference to other sections

- Refer to Section 8 - Exposure Controls/Personal Protection and Section 13 - Disposal Considerations.

Section 7 - Handling and Storage

Precautions for safe handling

Handling

- Use only in accordance with product literature. Wash thoroughly with warm water and soap after handling.

Conditions for safe storage, including any incompatibilities

Storage

- Store unopened vial in refrigerator at 2-8C (35-46F). After admixture with drug, store at 15-25C (59-77F) and use within 6 hours. Protect from light. DO NOT FREEZE. Use before expiration date marked on carton and/or container.

Special Packaging Materials

- Maintain product in original container only.

Other Information

- Refer to product literature.

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines

- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure controls

Engineering

Measures/Controls

- Not required during normal clinical use. No special controls are required under conditions of intended use. Local exhaust ventilation should be provided when handling bulk product.

Personal Protective Equipment

Pictograms



Respiratory

- No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, a NIOSH-certified air-purifying respirator equipped with HEPA -organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits and when adequate oxygen is present. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

Eye/Face

- No special personal protection required under conditions of intended use. In the event of a bulk spill, appropriate eye protection should be worn.

Hands

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear rubber or nitrile gloves.

Skin/Body

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

Thermal hazards

- None known.

General Industrial Hygiene Considerations

- Avoid contact with skin and eyes. Wash thoroughly with soap and water after handling.

Environmental Exposure Controls

- No special controls are required under conditions of intended use. In the event of a bulk spill, prevent spilled material from entering storm sewers or drains, waterways, and contact with the soil.

Other Information

- Use only in accordance with product literature.

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Color	Clear Colorless .
Odor	No odor.	Odor Threshold	No data available
General Properties			
Boiling Point	No data available	Melting Point	No data available
Decomposition Temperature	No data available	pH	No data available
Specific Gravity/Relative Density	No data available	Water Solubility	Dissolves readily in water.
Viscosity	No data available		
Volatility			
Vapor Pressure	No data available	Vapor Density	No data available
Evaporation Rate	No data available		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	Not flammable.		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze. Protect from light and heat.

Incompatible materials

- No data available.

Hazardous decomposition products

- None known.

Section 11 - Toxicological Information

Information on toxicological effects

Other Material Information • Toxicological information refers to raw materials only. Concentrations and toxicological effects are substantially reduced in the product.

Components		
Potassium Phosphate Monobasic (< 0.1%)	7778-77-0	Acute Toxicity: Ingestion/Oral-Rat LDLo • 4640 mg/kg; Behavioral: Somnolence (general depressed activity); Gastrointestinal: Other changes; Skin-Rabbit LD50 • >4640 mg/kg
Sodium chloride (< 1%)	7647-14-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 3000 mg/kg; Irritation: Skin-Rabbit • 500 mg 24 Hour(s) • Mild irritation

GHS Properties

Classification

Acute toxicity	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Skin Irritation 2
Skin sensitization	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Classification criteria not met
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Eye Irritation 2A

Potential Health Effects

Inhalation

- Acute (Immediate)**
 - Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)**
 - No data available.

Skin

- Acute (Immediate)**
 - May cause irritation.
- Chronic (Delayed)**
 - Repeated and prolonged exposure may cause sensitization.

Eye

- Acute (Immediate)**
 - Causes serious eye irritation.
- Chronic (Delayed)**
 - No data available

Ingestion

- Acute (Immediate)**
 - Not expected to be an exposure route. However, may cause gastric and intestinal irritation if ingested.
- Chronic (Delayed)**
 - Ingestion of enzyme liquid may induce sensitization and cause allergic reactions in sensitized individuals.

Reproductive Effects

- 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.

Other information

- Symptoms of toxicity: Local edema or urticaris (swelling), erythema, chills, nausea, vomiting, dizziness, tachycardia, and hypotension.

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- Substance is readily biodegradable.

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Product waste

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	NDA	Not Regulated	NDA	NDA	NDA
TDG	NDA	Not Regulated	NDA	NDA	NDA
IMO/IMDG	NDA	Not Regulated	NDA	NDA	NDA
IATA/ICAO	NDA	Not Regulated	NDA	NDA	NDA

Special precautions for user

- No special precautions.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

- No data available

Section 15 - Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

SARA Hazard Classifications

- No data available

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Hyaluronidase	37326-33-3	No	Yes	No
Lactose Monohydrate	63-42-3	Yes	Yes	Yes
Potassium Phosphate Monobasic	7778-77-0	Yes	Yes	Yes
Potassium Phosphate Dibasic Anhydrous	7758-11-4	Yes	Yes	Yes
Sodium chloride	7647-14-5	Yes	Yes	Yes
Water	7732-18-5	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

- Potassium Phosphate Dibasic Anhydrous

7758-11-4

Uncontrolled product
according to WHMIS

• Potassium Phosphate Monobasic	7778-77-0	classification criteria Uncontrolled product according to WHMIS classification criteria
• Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria
• Lactose Monohydrate	63-42-3	Uncontrolled product according to WHMIS classification criteria
• Hyaluronidase	37326-33-3	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria

Europe

Other

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification

• Potassium Phosphate Dibasic Anhydrous	7758-11-4	Not Listed
• Potassium Phosphate Monobasic	7778-77-0	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Lactose Monohydrate	63-42-3	Not Listed
• Hyaluronidase	37326-33-3	Not Listed
• Water	7732-18-5	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling

• Potassium Phosphate Dibasic Anhydrous	7758-11-4	Not Listed
• Potassium Phosphate Monobasic	7778-77-0	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Lactose Monohydrate	63-42-3	Not Listed
• Hyaluronidase	37326-33-3	Not Listed
• Water	7732-18-5	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases

• Potassium Phosphate Dibasic Anhydrous	7758-11-4	Not Listed
• Potassium Phosphate Monobasic	7778-77-0	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Lactose Monohydrate	63-42-3	Not Listed
• Hyaluronidase	37326-33-3	Not Listed
• Water	7732-18-5	Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List

• Potassium Phosphate Dibasic Anhydrous	7758-11-4	Not Listed
• Potassium Phosphate Monobasic	7778-77-0	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Lactose Monohydrate	63-42-3	Not Listed
• Hyaluronidase	37326-33-3	Not Listed
• Water	7732-18-5	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Potassium Phosphate Dibasic Anhydrous	7758-11-4	Not Listed
• Potassium Phosphate Monobasic	7778-77-0	Not Listed

• Sodium chloride	7647-14-5	Not Listed
• Lactose Monohydrate	63-42-3	Not Listed
• Hyaluronidase	37326-33-3	Not Listed
• Water	7732-18-5	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Potassium Phosphate Dibasic Anhydrous	7758-11-4	Not Listed
• Potassium Phosphate Monobasic	7778-77-0	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Lactose Monohydrate	63-42-3	Not Listed
• Hyaluronidase	37326-33-3	Not Listed
• Water	7732-18-5	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Potassium Phosphate Dibasic Anhydrous	7758-11-4	Not Listed
• Potassium Phosphate Monobasic	7778-77-0	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Lactose Monohydrate	63-42-3	Not Listed
• Hyaluronidase	37326-33-3	Not Listed
• Water	7732-18-5	Not Listed

Other Information

- REACH: All components have been pre-registered. No component is a SIN or SVHC. NOTE: PR (Pre-registered), SVHC (Substance of Very High Concern), SIN (Substitute It Now)

Section 16 - Other Information**Relevant Phrases (code & full text)**

- EUH208 - Contains sensitising substance. May produce an allergic reaction.

Last Revision Date

- 17/April/2013

Preparation Date

- 17/April/2013

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