

MATERIAL SAFETY DATA SHEET

(Effective date: April 27, 2004)

SECTION I. MANUFACTURER AND PRODUCT

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Manufactured by: SAGE IVF, Inc.
1979 E. Locust St.
Pasadena, CA 91107

Product: **Name:** **Hyaluronidase, 80 U/mL in HEPES-HTF**
Cat. No: **4007-A**

Description: An aqueous, isotonic, complex mixture of organic and inorganic salts, simple carbohydrates, and amino acids, at neutral pH. Contains the bovine enzyme, hyaluronidase which randomly attacks the hexosaminidic linkage of hyaluronic acid, the glycosaminoglycan that makes up the extracellular matrix of certain cells and tissues, including the cumulus cells surrounding mammalian oocytes. Also contains 0.010 mg/mL gentamicin, 0.003 mg/mL phenol red as a pH indicator, and 5 mg/mL human serum albumin.

SECTION II. PHYSICAL DATA

| | |
|--|------------------------|
| Boiling Point: n/av | Specific Gravity: 1.0 |
| Melting Point: n/av | Vapor Density: n/av |
| Vapor Pressure: n/av | Evaporation Rate: n/av |
| Appearance: Pink-rose color, clear liquid, particle free | Solubility: n/a |

SECTION III. HAZARDOUS INGREDIENTS

Product contains the aminoglycoside, gentamicin sulfate. This broad spectrum antibiotic has been associated with nephrotoxicity and/or ototoxicity when administered I.V. and serum concentrations are maintained at static levels above 10 mcg/mL for extended periods.

Contains 5.0 mg/mL human serum albumin, a derivative of human blood and a potentially biohazardous material. All donors used in its manufacture were individually tested and found to be nonreactive for hepatitis B surface antigen (HBsAg) and antibodies to hepatitis C virus (HCV) and human immunodeficiency virus (HIV) by approved testing methods. Donors of the source material have been screened for Creutzfeldt-Jakob disease (CJD). Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of CJD is also considered extremely remote. No cases of transmission of viral disease or CJD have ever been identified for albumin.

All Bovine glands, organs and tissue raw materials used for further processing originate from certified USDA inspected plants, where animals are given ante and post-mortem inspections and are deemed fit for human consumption.

SECTION IV. FIRE AND EXPLOSION HAZARD DATA

Fire Hazard: Non-flammable
Extinguishing Media: Water, CO₂ or any other media suitable for extinguishing fire
Special Fire Fighting Procedures: None

Unusual fire and Explosion Hazards: None

SECTION V. HEALTH HAZARD DATA

Toxicity data: LD₅₀ not established for this product.
Effects of Overexposure: Not established for this product
Emergency and First Aid Procedures: In case of eye contact, flush with copious quantities of water, In case of serious hypersensitivity reaction, rush for immediate medical attention. If swallowed, wash out mouth with water provided the person is conscious. Call a physician. Toxicity data for human serum albumin and bovine hyaluronidase have not been thoroughly investigated. This material should be treated as a potentially biohazardous product.

SECTION VI. REACTIVITY DATA

Stability: Stable
Conditions to avoid: : Do not expose product to elevated temperatures (above 40° C) for extended periods. Store product at or below -20°C upon receipt. After thawing, unused product may be kept refrigerated at 2° - 8°C when not being used.
Incompatibility: n/a
Hazardous Decomposition Products: n/a
Hazardous Polymerization: Will not occur

SECTION VII. SPILL OR LEAK PROCEDURES

Spills: Use absorbent material to mop up spill. Wash area with water.
Waste Disposal: Disposed of in an approved land fill or incinerate providing local environmental regulations permit.

SECTION VIII. SPECIAL PROTECTION INFORMATION

Product contains Human Serum Albumin and bovine hyaluronidase, potentially biohazardous materials. Universal precautions for handling potentially biohazardous materials should be taken when using this product. Use disposable gloves, lab coat and eye protection.

SECTION IX. SPECIAL PRECAUTIONS

Precautions to be taken in handling and storing: Avoid any unnecessary contact with skin, eyes or mucus membranes. Do not mouth pipette. Store the product at or below -20°C upon receipt. After thawing, unused product may be kept refrigerated at 2° - 8°C. Individuals with previous history of allergy to antibiotics and/or asthma, should avoid potential exposure.

SECTION X. DISPOSAL CONSIDERATIONS

Disposal should be in accordance with existing disposal practices employed at your institution. Observe all federal, state and local environmental regulations.

SECTION XI. DISCLAIMER

The above information is believed to be correct and reported in good faith. The information shall not be taken as being all inclusive and is to be used only as a guide with caution. SAGE IVF, Inc. shall not be held liable for any damage resulting from handling or from contact with the above product.

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DOCUMENT HISTORY REVISION

| DCN Number | Revision Number | Effective Date | Nature of Revision |
|-------------------|------------------------|-----------------------|--|
| 04-010 | 01 | 12/14/01 | 1.Add Particle free 2. Change Biopharma to IVF 3. Change to CooperSurgical-SAGE letterhead. 4.Delete original BSE information and replace with Worthington's Certificate of Analysis description. 5. Delete emergency telephone number 6. Revise albumin cautionary statement |