

Effective Date: 2016 Feb 15

Section 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: Hyaluronidase, 80 U/mL in HEPES-HTF

Catalog Number: ART-4007-A

Manufacturer:

SAGE In Vitro Fertilization
a Cooper Surgical Company
Trumbull, CT 06611
USA
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Product use:

This product is intended for in vitro procedures involving the necessary removal of cumulus cells from the oocyte prior to intracytoplasmic sperm injection (ICSI). This is done to create a clean surface on the zona pelucida to permit the easy handling of the oocyte with microtools for holding and injection.

Section 2 – HAZARD(S) IDENTIFICATION

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 mg/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 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Product 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 4 – FIRST-AID MEASURES

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 5 – FIRE FIGHTING MEASURES

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 6 – ACCIDENTAL RELEASE MEASURES

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 7 – HANDLING AND STORAGE

Use care in handling/storage. Avoid any unnecessary contact with skin, eyes or mucus membranes. Do not mouth pipette. Store the product at 2° - 8°C upon receipt. 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 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory Protection: None Required
Ventilation: Local exhaust is adequate; mechanical (general) ventilation is recommended
Protective Gloves: Disposable medical gloves, such as disposable nitrile gloves
Eye Protection: Safety glasses
Other Protective Equipment: Work clothes, including standard precautions for healthcare workers.

Section 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Particle-free, clear liquid	Specific Gravity: 1.0
Color: Pink-rose color	Vapor Density: N/Av
Boiling Point: N/Av	Evaporation Rate: N/Av
Melting Point: N/Av	Solubility: N/Av
Vapor Pressure: N/Av	

Section 10 – STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: Do not expose product to elevated temperatures (above 40 °C) for extended periods of time. Store product at 2° - 8°C when not being used.
Incompatibility: N/A
Hazardous Decomposition or Polymerization: Will not occur
Deterioration of the liquid medium may be recognized by any or all of the following: pH change, precipitate or particulates, cloudy appearance, color change.

Section 11 – TOXICOLOGICAL INFORMATION

Toxicity Data: LD₅₀ not established for this product.
Effects of Overexposure: Not established for this product.

Section 12 – ECOLOGICAL INFORMATION

No information available.

Section 13 – DISPOSAL CONSIDERATIONS

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

Section 14 – TRANSPORT INFORMATION

United States Department of Transportation (DOT) Primary Hazard Class/Division: Non-Hazardous

Section 15 – REGULATORY INFORMATION

United States Food and Drug Administration (FDA): 510(k) **K991393**

Section 16 – OTHER INFORMATION

SAGE In Vitro Fertilization, a CooperSurgical Company, warrants that its products conform to the information designated herein. The information, data, and recommendations contained herein are believed to be accurate and reported in good faith. The information may not be all inclusive and is to be used only as a guide with caution. SAGE In Vitro Fertilization shall not be held liable for any damage resulting from handling, or from contact with the product. We reserve the right to revise this MSDS periodically as new information becomes available.