



Safety Data Sheet HYALURONIDASE

Revised: 29-Sep-23

SECTION 1 – IDENTIFICATION & COMPANY DETAILS

Product Name: **HYALURONIDASE**
Product Code / Cat #: **2212**
Product Use: An enzymatic solution used in removing cumulus cells surrounding human oocytes (denudation) in preparation for ICSI or other ART procedures. For professional use only.

Manufacturer's Name: INVITROCARE INC
Address: 8415 Progress Drive, Suite F
Frederick, MD 21701
Telephone: 301-360-9660 (Same number to be used in emergencies)

SECTION 2 – HAZARDOUS INGREDIENTS / IDENTITY INFORMATION

To the best of our knowledge, according to the OSHA Hazardous Communication Standard 29 CFR 1910:1200, this product is not considered hazardous.

PLEASE NOTE: Contact with Liquid Media may irritate the eyes, skin, or mucous membranes. In order to limit exposure, exercise caution and wear personal protection equipment when handling this material. Good laboratory and manufacturing procedures are essential for safe use. If exposure occurs, leave the area of contamination immediately. Flush product from eyes or skin with water for at least fifteen minutes. If a reaction such as irritation occurs, consult a Poison Control Center or physician immediately.

HAZARDOUS INGREDIENTS: This product is formulated with 10 mg/L gentamicin and 5 mg/ml human serum albumin (%v/v). TLV not established. Slightly toxic. Possible allergic reaction if ingested or in contact with skin. This could result in skin rash and/or labored breathing.

CHEMICAL NAME: Gentamicin Sulfate Gamma-Irradiated Molecular Biology Reagent Albumin, Human (Human Serum Albumin)

Parent HSA used to formulate this product is derived from blood from CBER licensed Blood Banks. All donors used to obtain the Human Albumin were individually tested and found to be non-reactive for hepatitis B surface antigen (HBsAg), antibodies to hepatitis C virus (HCV), and antibodies to HIV-1 and HIV-2 by approved testing methods.

SECTION 3 – COMPOSITION / INFORMATION ON THE COMPONENTS

Component	CAS-code	Component	CAS-code
Sodium chloride	7647-14-5	Sodium pyruvate	113-24-6
Potassium chloride	7447-40-7	Sodium lactate	312-85-6
Magnesium sulfate heptahydrate	10034-99-8	Alanyl-glutamine	13115-71-4



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Potassium phosphate, mono	7778-77-0	EDTA, tetrasodium salt	10378-23-1
Calcium chloride, dehydrate	10035-04-8	Phenol red	34487-61-1
Sodium bicarbonate	144-55-8	Gentamicin sulfate	1405-41-0
HEPES, free acid	7365-45-9	Human Serum Albumin	70024-90-7
Glucose	50-99-7		

Hyaluronidase - The Hyaluronidase used in this product is derived from bovine testes, is pharmaceutical grade, and is certified with a TSE risk evaluation Certificate of Suitability (CEP). The testes were collected from animals which were found healthy by pre- and post-mortem inspection and which were exempt from Bovine Spongiform Encephalopathy (BSE).

SECTION 4 – FIRST AID MEASURES

INHALATION: Not a likely source of exposure.
INGESTION: Wash out mouth with water. Do NOT induce vomiting. If swallowed, consult a physician.
SKIN: Wash with soap and water after each contact.
EYES: Flush with copious quantities of water. Assure adequate flushing by separating the eyelids with fingers. If irritation develops, consult a physician.
In case of serious hypersensitivity reaction, rush for immediate medical attention.

SECTION 5 – FIRE-FIGHTING MEASURES

FIRE HAZARD: Non-Flammable
EXTINGUISHING MEDIA: Water, Carbon Dioxide, or any other media suitable for surrounding fire.
FIRE FIGHTING PROCEDURES: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

PRECAUTIONS IN HANDLING and STORING: Small spills can be flushed down the drain with a large amount of water. For larger spills, use absorbent material and containerize the collection. Avoid raising dust. Ventilate area and wash spill site after pickup is complete.

SECTION 7 – PRECAUTIONS FOR SAFE HANDLING & USE

Store in original container at 2-8°C, in a well-ventilated place, protected from light. Use aseptic working techniques. Do not mouth pipette. Avoid any unnecessary contact with skin, eyes, or mucus membranes. Keep container closed when not in use. Do not freeze.

SECTION 8 – EXPOSURE CONTROLS – PERSONAL PROTECTION



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Avoid any unnecessary contact with skin. Do not mouth pipette. Store in cold room. Individuals with previous history of allergy (from antibiotics) and/or asthma should avoid potential exposure.

RESPIRATORY PROTECTION: Personal respiratory protective equipment not normally required. Where protection is desired, use NIOSH-approved mechanical dust/mist cartridge respirator or NIOSH-approved single-use dust respirator.

VENTILATION: Local exhaust adequate; mechanical recommended.

PROTECTIVE GLOVES: Compatible chemical-resistance gloves

EYE PROTECTION: Safety glasses

PROTECTIVE CLOTHING: Lab coat

SECTION 9 – PHYSICAL & CHEMICAL PROPERTIES

Physical State:	Liquid, Pink / Orange
Odor:	Odorless
pH:	7.25 – 7.45
Boiling Point:	No data available
Fire Hazards in presence of various substances:	Non-Flammable
Explosive Properties:	No risk
Flash Point:	None
Vapor Pressure:	No data available
Density:	No data available
Solubility:	Soluble in water
Vapor Density:	No data available

SECTION 10 – STABILITY & REACTIVITY DATA

STABILITY:	Stable
CONDITIONS TO AVOID:	Temperatures below 0°C or above 40°C for extended periods of time.
HAZARDOUS POLYMERIZATION:	None known.
HAZARDOUS DECOMPOSITION PRODUCTS:	Toxic fumes of Carbon Monoxide and Carbon Dioxide, Nitrogen Oxides, and Sulfur Oxides when heated to decomposition or under fire conditions.

SECTION 11 – TOXICOLOGICAL INFORMATION

Tested for embryo toxicity using one-cell mouse embryo assay and found to be non-toxic. Contains a human source material, the toxicological properties of which have not been thoroughly investigated. Contains an animal source material, the toxicological properties of which have not been thoroughly investigated.



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SECTION 12 – ECOLOGICAL INFORMATION

No information available.

SECTION 13 – DISPOSAL CONSIDERATIONS

This material is not regarded as hazardous waste. Mix the material with water for disposal. Dispose according to legislation. Observe all federal, state, and local environmental regulations for waste disposal.

SECTION 14 – TRANSPORT INFORMATION

In accordance with ADR, RID, ADN, IMDG, and IATA.
UN number: Not regulated for transport.
Classified as non-hazardous for transport.

SECTION 15 – REGULATORY INFORMATION

IRRITANT

Safety Phrases:	S24/25	Avoid contact with skin and eyes.
	S26	In case of contact with eyes, rinse immediately with plenty of water.
	S36/37/39	Wear suitable protective clothing, gloves, and eye/face protection.
Risk Phrases:	R36/37/38	Irritating to eyes.
Regulations:	The Chemicals (Hazard Information & Packaging for Supply) Regulations 2002. 1999/45/EC Dangerous Preparations Directive. 91/155/EC Safety Data Sheets Directive.	

SECTION 16 – OTHER INFORMATION

Source of key data used to Compile Safety Data Sheet: Component Supplier Safety Data Sheets

The above information and recommendations are believed to be correct, are presented in good faith, and are based upon 29 CFR 1910:1200(d) Hazard Determination. INVITROCARE INCORPORATED does not guarantee the accuracy of this data and shall not be liable for any damage resulting from handling or from contact with the above product. The information shall not be taken as being all-inclusive and is to be used only as a guide with caution. This information is offered solely to you in the advisement for the safe use and handling of the material according to direction for use. (To use this material inconsistent with directions or labeling may constitute a hazard.) The recommendations here bear no legal requirements of Federal, State, Municipal, or Insurance codes.