

SECTION 1 – IDENTIFICATION & COMPANY DETAILS

Product Name: **SpermCare® One-Step**
Product Code / Cat #: **2224**
Product Use: A gradient system for semen preparation in ART procedures. Gradient consists of silane-coated colloidal silica particles suspended in HEPES-buffered culture medium.

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 29CFR 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 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/ml gentamicin and 5 mg/ml human serum albumin. TLV not established. Slightly toxic. Possible allergic reaction if ingested or in contact with skin. 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 lactate	312-85-6
Potassium chloride	7447-40-7	Alanyl-glutamine	13115-71-4
Magnesium sulfate heptahydrate	10034-99-8	EDTA, tetra sodium salt	10378.23-1
Potassium phosphate, mono	7778-77-0	Phenol red	34487-61-1
Calcium chloride, dehydrate	10035-04-8	Gentamicin sulfate	1405-41-0
Sodium bicarbonate	144-55-8	Human Serum Albumin	70024-90-7
HEPES, free acid	7365-45-9	Silica Basic Solution (SIBO):	-----
Glucose	50-99-7	Lower Layer 90%	
Sodium pyruvate	113-24-6		

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

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
Relative Density:	For Lower Layer: 1.1050 - 1.1150 g/ml
Viscosity:	For Lower Layer: < 1.65 cP

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, 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.

Meets the requirements of the ISO 10993 guidelines and found to be non-toxic by the following:

Evaluated by an independent test laboratory using USP30-NF25 Agar Diffusing test for cytotoxicity.

Evaluated by an independent test laboratory using the primary vaginal test – repeated exposure for irritating potential.

Evaluated by an independent test laboratory using the Kligman maximization test for sensitizing potential.

Evaluated by an independent test laboratory using the systematic injection test (single dose) for biological reaction.

Contains a human source material, the toxicological properties of which have not been thoroughly investigated.

SECTION 12 – ECOLOGICAL INFORMATION

No information available.

SECTION 13 – DISPOSAL CONSIDERATIONS

Dispose in a safe manner in accordance with all federal, state and local environmental regulations for waste disposal. Avoid release to the environment.

SECTION 14 – TRANSPORT INFORMATION

In accordance with ADR, RID, ADN, IMDG, 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 29CFR 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.