

Effective Date: 2016 Feb 15

## Section 1 – PRODUCT AND COMPANY IDENTIFICATION

**Product Name: Polyvinylpyrrolidone (PVP) 7% (w/v) in HEPES-HTF**

**Catalog Number: ART-4005-A**

**Manufacturer:**

SAGE In Vitro Fertilization  
a Cooper Surgical Company  
Trumbull, CT 06611  
USA  
+45 46 79 02 00

**Product use:**

This product is intended for the ICSI procedure to decrease the motility of spermatozoa, prevent their sticking to the injection pipette during the procedure, and to give more control over the flow of fluid in the ICSI needle.

## Section 2 – HAZARD(S) IDENTIFICATION

Product contains the polymer, PVP of av. MW 360,000. The compound in powder form may be harmful by inhalation, ingestion, or skin absorption. It may cause eye and/or irritation. The material in powder form may be irritating to mucous membranes and upper respiratory tract. To the best of our knowledge, the chemical, physical, and toxicological properties of this material have not been thoroughly investigated. 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.

## 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. The effective ingredient is polyvinylpyrrolidone (PVP) of average molecular weight 360,000 at a concentration of 7% (w/v), the purpose of which is to decrease the motility of spermatozoa. The solution also contains 5 mg/mL human serum albumin, 0.010 mg/mL gentamicin, and 0.003 mg/mL phenol red as a pH indicator.

## 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.

## Section 5 – FIRE FIGHTING MEASURES

Fire Hazard: Non-flammable  
Extinguishing Media: Water, CO<sub>2</sub> or any other media suitable for extinguishing fire  
Special Fire Fighting Procedures: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.  
Unusual fire and Explosion Hazards: Emits toxic fumes under fire conditions.

## 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. Individuals with previous history of allergy to antibiotics and/or asthma, should avoid potential exposure.

## Section 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Product contains Human Serum Albumin, a potentially biohazardous material. Universal precautions for handling potentially biohazardous materials should be taken when using this product.

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: 1.015

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: Strong oxidizing agent.

Hazardous Decomposition or Polymerization: Thermal decomposition may produce carbon monoxide, carbon dioxide, and nitrogen oxides.

Hazardous Polymerization: Will not occur

## Section 11 – TOXICOLOGICAL INFORMATION

Toxicity data: (for solid PVP-360)

Orl-Rat LD50: 100gm/kg

Orl-Mus LD50:>40 gm/kg

Ipr-Mus LD50: 12 gm/kg

Orl-Rbt LD50: 1040 mg/kg

Orl-Gpg LD50: 100 gm/kg

Only selected Registry of Toxic Effects of Chemical Substances (RTECS) data are presented here. See actual entry in RTECS for complete information.

Effects of Overexposure: Unexcreted particles may be phagocytized by cells of the reticuloendothelial system and deposited in storage sites in the liver, spleen, lung, bone marrow resulting in the storage disease thesaurosis. Severity and symptoms depend on storage site and nature of the particle. Pathological changes are not necessarily attributed to the thesaurosis, but in some cases an inflammation or granulomatoma have occurred. This material is classified by IARC (International Agency for Research on Cancer) as Group 3 with limited animal evidence for carcinogenicity and no adequate data for human carcinogenicity classification.

Toxicity data for human serum albumin have not been thoroughly investigated. This material should be treated as a potentially biohazardous 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

EU Additional Classification

S: 22 24/25

Safety Requirements: Do not breathe dust. Avoid contact with skin and eyes.

US Classification and Label Text

US Statements: Caution: Avoid contact and inhalation

United States Regulatory Information

SARA Listed: No

TSCA Inventory Item: Yes

Canada Regulatory Information

WHMIS Classification: This product has been classified in accordance with the hazard criteria of the CPR, and the MSDS contains all the information required by the CPR.

DSL: Yes

NDSL: No

Note: Additional information on file from original equipment manufacturer (OEM) for PVP in bulk form. Other constituents are known to be non-toxic having no known safety requirements.

United States Food and Drug Administration (FDA): 510(k) **K991391**

Full Quality Assurance No. **CE 82107**

## 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.