

## **MATERIAL SAFETY DATA SHEET**

(Effective date May 6, 2004 )

### **SECTION I. MANUFACTURER AND PRODUCT**

Page 1 of 3

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

**Product:**                   **Name: 7% PVP Ready to Use Solution**  
                                  **Cat. No:           4005-A**

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 II. PHYSICAL DATA**

Boiling Point: n/av	Specific Gravity: 1.015
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**

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.

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Page 2 of 3

**SECTION IV.           FIRE AND EXPLOSION HAZARD DATA**

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 V.           HEALTH HAZARD DATA**

Toxicity data: (for solid PVP-360)  
                  Orl-Rat LD50: 100gm/kg  
                  Orl-Mus LD50:>40 gm/kg  
                  lpr-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.

Emergency and First Aid Procedures:    In case of eye contact, immediately flush with copious quantities of water for at least 15 minutes. Flush skin with 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 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 2° - 8°C upon receipt.  
Incompatibility:    Strong oxidizing agent.  
Hazardous Decomposition Products:    Thermal decomposition may produce carbon monoxide, carbon dioxide, and nitrogen oxides.  
Hazardous Polymerization:    Will not occur

**SECTION VII.           SPILL OR LEAK PROCEDURES**

Spills:    Use absorbent material to mop up spill. Wash area with water.

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Page 3 of 3

Waste Disposal: Disposed of in an approved land fill providing local environmental regulations permit.

#### **SECTION VIII.           SPECIAL PROTECTION INFORMATION**

Product contains Human Serum Albumin a potentially biohazardous material. Universal precautions for handling potentially biohazardous materials should be taken when using this product. Use disposable gloves 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 2° - 8°C upon receipt. Product can 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.           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.

#### **SECTION XII.           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**

<b>DCN Number</b>	<b>Revision Number</b>	<b>Effective Date</b>	<b>Nature of Revision</b>
04-010	New	10/10/01	1.Add Particle free 2. Change Biopharma to IVF 3. Change to CooperSurgical-SAGE letterhead.. 4.Update regulatory section 5. Add Note: Additional information on file from original equipment manufacturer (OLM) for PVP in bulk form. Other constituents are known to be non-toxic having no known safety requirements.
00237	New	10-10-01	New Document