

MATERIAL SAFETY DATA SHEET

(Effective date: September 22, 2000)

SECTION I.

MANUFACTURER AND PRODUCT

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Manufactured for Conception Technologies by:

InVitroCare Incorporated
San Diego, CA 92121

Product:

Name: PVP 10% Ready to Use Solution
Cat. No: PVP

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 10% (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: 0.91
Melting Point: n/av	Vapor Density: n/av
Vapor Pressure: n/av	Evaporation Rate: n/av
Appearance: Pink color, clear liquid	Solubility: n/a

SECTION III.

HAZARDOUS INGREDIENTS

Contains the polymer, PVP of av. MW 360,000. This compound may be harmful by inhalation, ingestion, or skin absorption. It may cause eye irritation. It 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.

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 potentially biohazardous material.

SECTION IV.

FIRE AND EXPLOSION HAZARD DATA

Fire Hazard: Non-flammable

Extinguishing Media: Water, CO₂ or 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.

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SECTION V.

HEALTH HAZARD DATA

Toxicity data: (for solid PVP-360)
Ori-Rat LD50: 100gm/Kg
Ori-Mus LD50:>40 gm/Kg
Ipr-Mus LD50: 12 gm/Kg
Unr-Mus LD50: 16 gm/Kg
Ori-Rbt LD50: 1040 mg/Kg
Ori-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. After thawing, unused product can be kept refrigerated at 2° - 8°C when not being used.

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.

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

SECTION VIII. SPECIAL PROTECTION INFORMATION

Respiratory Protection: NIOSH/MSHA approved mechanical dust/mist cartridge respirator.

Ventilation: Local exhaust adequate; mechanical recommended

Protective Gloves: Rubber gloves

Eye Protection: Chemical safety goggles

Other Protective Equipment: Overalls, etc.

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. After thawing, unused 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

European Information: **CAUTION** – Substance not yet fully regulated.

Reviews, Standards, and Regulations:

OEL=MAK

IARC Cancer Review: Animal - limited evidence IMEMDT 19,461,79

IARC Cancer Review: Human - no adequate data IMEMDT 19,461,79

IARC Cancer Review: Group 3 IMSUDL 7,56,87

NOHS 1974: HZD 81235; NIS 50; TNF 7856; NOS 63; TNE 102100

NOES 1983: HZD X7211; NIS 46; TNF 7688; NOS 63; TNE 161259; TFE 84819

EPA TSCA Section 8 (B) Chemical Inventory

EPA TSCA Section 8 (D) Unpublished Health/Safety Studies

EPA TSCA Test Submission (TSCATS) Data Base, April 1997

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. Neither Conception Technologies nor InVitroCare Incorporated shall be held liable for any damage resulting from handling or from contact with the above product.



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