SAFETY DATA SHEET

Effective Date: 2016 Feb 15

Section 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: Quinn's Advantage® Cryokit Diluent

Catalog Number: Cat. No. ART-8013-12

Manufacturer:
SAGE In Vitro Fertilization
a Cooper Surgical Company
Trumbull, CT 06611
USA
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Product use:
This product is part of the SAGE Quinn's Advantage® Embryo Freeze Kit (ART-8014), Quinn's Advantage® Blastocyst Freeze Kit (ART-8015) and Quinn's Advantage® Thaw Kit (ART-8016), which are intended for use in freezing pronuclear- and cleavage-stage embryos, freezing blastocysts and for thawing frozen pronuclear- and cleavage-stage embryos and blastocysts, respectively.

Section 2 – HAZARD(S) IDENTIFICATION

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 12.0 mg/mL human serum albumin, a derivative of human blood and a potentially bio-hazardous 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 plasma protein fraction.

Section 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Product Description: An aqueous, complex mixture of organic and inorganic salts and simple carbohydrates, at neutral pH intended for the cryopreservation of mammalian oocytes and embryos. Contains 12.0 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 immediately and thoroughly with copious quantities of water. Should serious hypersensitivity reaction occur, seek medical attention immediately. In case of skin contact, wash immediately and thoroughly with soap and water. In case of accidental swallowing, 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, foam, CO_2 or any other media suitable for extinguishing fire
Special Fire Fighting Procedures: None
Unusual Fire & Explosion Hazards: None

Section 6 – ACCIDENTAL RELEASE MEASURES

Spills: Use absorbent material to mop up spilled liquid. Wash area with water.
Waste Disposal: Dispose 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. Use aseptic working techniques at all times. Do not mouth pipette. Store at 2–8 °C and protect from light until the expiration date indicated on the label. Individuals with previous history of allergy to antibiotics and/or asthma, should avoid potential exposure.

Section 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

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
Color: Pink-rose color
Boiling Point: N/Av
Melting Point: N/Av
Vapor Pressure: N/Av
Specific Gravity: 1.0
Vapor Density: N/Av
Evaporation Rate: N/Av
Solubility: 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 and protect from light when not being used.
Incompatibility: N/A
Hazardous Decomposition or Polymerization: Will not occur
Deterioration of the liquid medium may be recognized by any of all of the following: pH change, precipitate or particulates, cloudy appearance, color change.

Section 11 – TOXICOLOGICAL INFORMATION

Toxicity Data: LD_{50} not established for this product.
Effects of Overexposure: Not established for this product. 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

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

United States Food and Drug Administration (FDA): 510(k) **K991390**
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.