SAFETY DATA SHEET

Effective Date: 2017 Sep 12

Section 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name / Catalog Number:

Vitrification Kit, ART-8025/ART-8026
Equilibration Solution, ART-8025-A/ART-8026-A
Vitrification Solution, ART-8025-B/ART-8026-B
MOPS Solution, ART-8025-C/ART-8026-C
Vitrification Solution with 8 Straws, ART-8025-HSV/ART-8026-HSV
Vitrification Solution with 20 Straws, ART-8025-HSV-20/ART-8026-HSV-20

Manufacturer:
SAGE In Vitro Fertilization
a Cooper Surgical Company
Trumbull, CT 06611
USA
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Product use:
These products are intended for the ultra-rapid freezing and containment of human embryos (pronuclear zygotes through day 3, cleavage stage embryos and blastocyst stage embryos) in A.R.T. procedures. The kit is designed to be used in conjunction with the SAGE Vitrification Warming Kit (ART-8030/ART-8031) for warming and recovery of specimens.

Section 2 – HAZARD(S) IDENTIFICATION

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 12 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 non-reactive 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.

Contains DMSO which may cause skin irritation. May cause hives, skin rashes and dermatitis. DMSO is readily absorbed through skin and may carry other dissolved chemicals into the body. An unusual garlic-onion oyster odor may develop on breath and body/skin. Absorption through skin may also cause diarrheas, and affect respiration, blood behavior (fatigue, dizziness, sedation, headaches), vision (transient photophobia, and disturbances of color vision), urinary system (hematuria). DMSO causes eye irritation and may cause blurred vision, corneal opacity and chemical conjunctivitis.

Contains Ethylene glycol. Prolonged skin contact is unlikely to result in absorption of harmful amounts. Repeated skin exposure to large quantities may result in the absorption of harmful quantities. Repeated excessive ingestion may affect the liver (hepatitis, hepatocellular necrosis), kidneys (kidney damage, with or without deposits of calcium oxalate in the kidneys) behavior/central nervous system/peripheral nervous system and blood.

Section 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Product Description:
Equilibration Solution (Ref. # ART-8025-A/ART-8026-A) is a sterile, aqueous MOPS buffered solution of containing organic and inorganic salts, non-essential and essential amino acids, gentamicin sulfate (0.01 g/L), 7.5% (v/v) each of DMSO, and ethylene glycol and 12 mg/mL human albumin.

Vitrification Solution (Ref. # ART-8025-B/ART-8026-B) is a sterile, aqueous MOPS buffered solution containing organic and inorganic salts, non-essential and essential amino acids, gentamicin sulfate (0.01 g/L), 15% (v/v) each of DMSO and ethylene glycol, 12 mg/mL human albumin, and 0.6 M sucrose.

MOPS Solution (Ref. # ART-8025-C/ART-8026-C) is a sterile, aqueous MOPS buffered solution containing organic and inorganic salts, non-essential and essential amino acids, gentamicin sulfate (0.01 g/L), and 12 mg/mL human albumin.

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_2 or any other media suitable for extinguishing fire
Special Fire Fighting Procedures: None
Unusual fire and Explosion Hazards: None

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^{o} - 8^{o}C upon receipt.

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: N/A
Vapor Density: N/Av
Evaporation Rate: N/Av
Solubility: N/A

Section 10 – STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: Do not expose product to elevated temperatures (above 40 ℃) for extended period s of time. Store product at 2^{o} - 8^{o}C when not being used.
Incompatibility: N/A
Hazardous Decomposition or Polymerization: Will not occur
Deterioration of the liquid medium may be recognized by any or 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) **K073522**
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.

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(Effective date: 2017 Sep 12)

DOCUMENT HISTORY REVISION

DCN Number	Revision Number	Effective Date	Nature of Revision
N/A	03	2017 Sep 12	1. ART-8026 added to sections 1 and 3.
N/A	02	2016 Feb 15	2. Updated document to SDS format.
012-007	01	15 Feb 12	1. Updated document to new MSDS format.
08-022	New	10 Apr 08	1. New Document