SAFETY DATA SHEET

Effective Date: 2016 Feb 15

Section 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name / Catalog Number:

In Vitro Maturation Kit, ART-1600
Oocyte Washing Media, ART-1600-A
Oocyte Maturation Media, ART-1600-B
Embryo Maintenance Medium, ART-1600-C

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

Product use:
These products are intended for the preparation of oocytes for use in A.R.T. procedures..

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 5 mg/mL plasma protein fraction 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 plasma protein fraction.

Section 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Product Description: An aqueous, isotonic, complex mixture of organic and inorganic salts and simple carbohydrates, at neutral pH intended for *in vitro* mammalian cell culture. Contains 5 mg/mL plasma protein fraction, 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_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. 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: N/Av
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^{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.

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) **K053646**
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.