

# SAFETY DATA SHEET

Effective Date: 2016 Feb 15

## Section 1 - PRODUCT AND COMPANY IDENTIFICATION

Product Name: Quinn's Advantage® Serum Protein Supplement (SPS)

Catalog Number: ART-3010, ART-3011

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

#### Product use:

Quinn's Advantage SPS is a protein supplement that provides the beneficial growth-promoting activities of albumin and  $\alpha$  and  $\mbox{\ensuremath{\mathbb{G}}}$  globulins..

## Section 2 – HAZARD(S) IDENTIFICATION

Product contains 50 mg/mL human serum protein, a derivative of plasma and a potentially bio-hazardous material. The proteins used in this product were derived from plasma which was collected from centers located in the United States and licensed by the United States Food and Drug Administration. Each individual plasma unit has been tested by FDA approved methods 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.

## Section 3 – COMPOSITION / INFORMATION ON INGREDIENTS

**Product Description:** An aqueous solution containing 50 mg/mL of selected plasma proteins consisting of approximately 88% normal human albumin and 12% alpha and beta globulins in saline solution. Intended as a protein supplement for *in vitro* mammalian cell culture media.

## 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<sub>2</sub> 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  $2^{\circ}$  -  $8^{\circ}$ C upon receipt. Individuals with previous history of allergy to antibiotics and/or asthma, should avoid potential exposure.

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# 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, colored liquid

Color: Clear amber color

Boiling Point: N/Av

Evaporation Rate: N/Av

Melting Point: N/Av Solubility: N/Av

Vapor Pressure: 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 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<sub>50</sub> 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) K003734

#### 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.