



Quinn's Advantage® SPS Serum Protein Substitute

**For laboratory procedures only;
other uses must be qualified by the end user.**

Product Description	REF Number	Unit Size
Quinn's Advantage® SPS	ART-3010	12 X 12 mL
Quinn's Advantage® SPS	ART-3011	100 mL

INTENDED USE

A variety of protein supplements have been added to ART media, ranging from maternal serum to preparations of albumin purified to varying degrees to plasma expanders such as Albuminar, Plasmatin, and Plasmanate (Weathersbee et al, 1995; Adler et al, 1993). The routine functions of albumin in tissue culture include trace metal binding, osmotic stability, and carrier activity. In addition to these beneficial effects of albumin on cellular physiology, it is thought that the presence of α and β globulins in certain preparations of plasma expanders provides additional benefits for the culture of preimplantation mammalian embryos in vitro (Pool & Martin, 1994). These additional benefits have been ascribed to the high content of poly-hydroxy domains present in the α - and β -globulins producing a weak gel-like environment that enhances embryonic development (Weathersbee et al, 1995). A protein supplement and possibly any bound embryotrophic components associated with it is still necessary, however, to enhance blastocyst production in vitro (Pool et al, 2000).

Quinn's Advantage® SPS is a protein supplement that provides the beneficial growth-promoting activities of albumin and α and β globulins.

PRODUCT DESCRIPTION

Product contains 50 mg/mL total protein (weight/volume) in saline solution; the protein is in the form of 88% normal human serum albumin and 12% α and β globulins. Each lot is tested for pH (7.4 ± 0.2), osmolality (280 ± 10 mOsm/kg water), sterility (no detectable contamination), and biocompatibility ($> 80\%$ mouse zygote development to blastocysts).

This product contains 10mg/L of gentamicin, an aminoglycoside antibiotic.

PRECAUTIONS AND WARNINGS

Do not use product that shows evidence of particulate matter or cloudiness.

The Quinn's Advantage® SPS Serum Protein Substitute (REF#3010) contains 50 mg/mL human serum albumin.

Caution: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when testing for antibodies to HIV-1/HIV-2, HCV and non-reactive for HBsAg, HCV RNA and HIV-1 RNA. No known test methods can offer assurances that products derived from human blood will not transmit infectious agents. Donors of the source material have been screened for Creutzfeldt-Jacobs 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 diseases or CJD have ever been identified for albumin.

Single use: To avoid problems with contamination, handle using aseptic techniques and discard any excess product that remains in the bottle or vial after procedure is completed.

Note: Embryo is considered a general term. More precisely, SAGE considers the period of time initiating when a single diploid cell results from the fusion of male and female genome resulting in zygote formation with subsequent development from repeated mitotic divisions forming a solid mass or morula (typically day 4-5) and after which a fluid-filled cavity develops resulting in blastocyst formation (typically day 5-6) ending with embryo implantation that begins the end of the first week and is completed by the end of the second week post conception.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

This product contains the antibiotic gentamicin sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.

QUALITY ASSURANCE

One-cell MEA tested and passed with 80% or greater blastocyst. USP Endotoxin tested and passed with <1 EU/mL.

A Certificate of Analysis is available for this product.

DIRECTIONS FOR USE

For sperm preparation and embryo culture: Use at 10% (v/v). For 10 mL of medium, add 1.0 mL of SPS solution to 9.0 mL of bicarbonate-buffered medium (eg, Quinn's Advantage® Fertilization Medium (REF #1020/1021) or Quinn's Advantage® Cleavage Medium (REF #1026/1027). NOTE: for washed sperm samples for IUI, use Quinn's™ Sperm Washing Medium (REF #1005/1006), which already contains 5 mg/mL Human Serum Albumin.

For embryo transfer: Use at 50% (v/v). For 10mL of medium, add 5.0 mL of SPS solution to 5.0 mL of Quinn's Advantage® Medium with HEPES (REF #1023/1024).

For embryo cryopreservation: Use at 20% (v/v). For 10 mL of medium, add 2.0 mL of SPS solution to 8.0 mL of Quinn's Advantage® Medium with HEPES (REF #1023/1024).

For micromanipulation (ICSI and Assisted Hatching): Use at 10% (v/v). For 10 mL of medium, add 1.0 mL of SPS solution to 9.0 mL of Quinn's Advantage® Medium with HEPES (REF #1023/1024).

Laboratories may establish through appropriate testing that higher or lower concentrations than those suggested above are optimal for specific applications.

NOT INTENDED FOR INJECTION BY USUAL PARENTERAL ROUTES IN HUMANS OR ANIMALS.

Each laboratory should make its own determination of which medium and protocol to use for each particular procedure.

Information on specific aspects of IVF, embryo culture, and cryopreservation is available in our Product Catalog.

STORAGE INSTRUCTIONS AND STABILITY

Store unopened containers refrigerated at 2 °C to 8 °C. Warm to ambient or incubator (37 °C) temperature prior to use. Do not freeze or expose to temperatures greater than 39 °C. The product is stable until the expiration date shown on the label.

- A. Remove desired volume of product using aseptic procedures.
- B. Once removed, do not return any volume of product to the original container.
- C. Do not use if the product becomes discolored, cloudy, turbid, or shows any evidence of microbial contamination.

RELATED PRODUCTS

SAGE In Vitro Fertilization™ has a full line of products for the Reproductive Medicine Specialist. Please call or write for specific information or to receive a copy of our current catalog. For technical questions, or to reach our Customer Service Department, call the SAGE Support Line.

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REFERENCES

Adler et al. Plasmanate as a medium supplement for in vitro fertilization. *J Assisted Reprod Genetics*. 1993;10:67-71.

Pool & Martin. High continuing pregnancy rates after in vitro fertilization-embryo transfer using medium supplemented with a plasma protein fraction containing α and β globulins. *Fertil Steril*. 1994;61:714-719.

Pool et al. The role of macromolecules in human blastocyst production in vitro. In: *Program of the International Symposium on ART and the Human Blastocyst*; 2000; Dana Point, Calif.

Weathersbee et al. Synthetic serum substitute (SSS): a globulin-enriched protein supplement for human embryo culture. *J Assisted Reprod Genetics*. 1995;12:354-360.

Call the SAGE SUPPORT LINE:
In the U.S.: (800) 243-2974
International: (203) 601-9818

EXPLANATION OF SYMBOLS

Catalog Number



Batch Number



Use By (year, month, day)



Do Not Reuse



Temperature Limitation



Aseptic Technique Sterilization
 Membrane Filtered (SAL 10⁻³)

**ATTENTION:**

See instructions for use.



Manufacturer

Rx ONLY

U.S. Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).



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