

Instructions for Use

Bio-Pure Human Serum Albumin (HSA), 10%, 20%

Human Serum Albumin, optimized for human embryonic stem cells
and induced pluripotent stem cell culture




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Human Serum Albumin, optimized for human embryonic stem cells
and induced pluripotent stem cell culture

REF	05-720-1	Bio-Pure Human Serum Albumin (HSA), 10%
	05-730-1	Bio-Pure Human Serum Albumin (HSA), 20%

	2-8°C
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1 Product Description and Important Notes

- Bio-Pure Human Serum Albumin is a xeno-free supplement, especially qualified for the growth and expansion of undifferentiated pluripotent human embryonic stem (hES) cells and induced pluripotent stem (hiPS) cells, in both feeder-dependent and feeder-free conditions. Human Serum Albumin (HSA) is a medium supplement containing a highly soluble osmolytic protein with a high molecular weight.
- HSA is effective in maintaining hES cell growth and expansion. It is particularly valuable in maintaining cell membrane stability. HSA is useful both for binding anionic, cationic and neutral molecules, as well as its ability to sequester and stabilize a wide array of ions and other small molecules.

2 Precaution and Disclaimer

- Do **not** use if a visible precipitate is observed in the medium.
- Do **not** use Bio-Pure solution beyond the expiration date indicated on the product label.
- Please refer to the Safety Data Sheet (SDS) for hazard information.

3 Storage and Stability

- Bio-Pure Human Serum Albumin should be stored at 2–8°C.
- Once removed from the bottle, do not return any excess or leftover amounts of the product to the original container. Preferably, prepare aliquots for future use. Once the product has been opened, store the resealed container at 2–8°C.

4 Features

- Xeno-free (XF) solution.
- Support culture of hPSC and hMSC from different sources.
- The raw material (Albumin) used for the manufacturing of Bio-pure is an EU licensed medicinal product, therefore complies with relevant EU blood derived medicinal products regulation including Directives 2003/63/EC, 2002/98/EC and 2004/33/EC.

5 Instructions for use

- Take a bottle of Bio-Pure Human Serum Albumin (HSA), 10% Solution from proper storage conditions (2 – 8°C) and read the label to verify identity and expiration date.
- Warm to room temperature.
- Ensure that the cap of the bottle is tight.
- Gently swirl the solution in the bottle to allow for uniformity.
- Wipe the outside of the bottles with a disinfectant solution such as 70% ethanol.
- Using aseptic | sterile techniques under a laminar-flow culture hood, work according to established protocols.
- Remove the desired volume using aseptic techniques
- The optimal concentration of albumin for cell culture varies with cell line and particular cell culture media utilized.

6 Quality Control

- Bio-Pure performance is tested for the growth and expansion of undifferentiated pluripotent human embryonic stem (hES) cells.
- Additional tests are pH, osmolality, endotoxins and sterility tests.
- For full specifications please check the lot specific Certificate of Analysis (CoA).

7 Quality Assurance

- For in vitro diagnostic use, research use or for use as ancillary material in manufacturing cell, gene and tissue-based products.
- Listed in Europe under CE IVD class I, thus comply with European In-Vitro Diagnostic Devices Directive (98/79/EC) requirements.
- Listed in the US FDA under IVD Class I.
- Manufactured under ISO 13485 QMS and in compliance with applicable cGMP guidelines.
- Manufactured under controlled environments and processes in accordance with:
 - ISO 13408 – Aseptic Processing of Health Care Products
 - ISO 14644 – Airborne Particulate Cleanliness Classes in Clean Rooms and Clean Zones



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Kibbutz Beit Haemek 2511500, Israel

7.1 Product Label Symbols

REF

Indicates the manufacturer's catalogue number so that the product can be identified.

LOT

Indicates the manufacturer's batch code so that the batch or lot can be identified.

NOTE Synonyms for batch code are lot number and batch number.



Indicates the date after which the product is not to be used.



Indicates the temperature limits to which the product can be safely exposed.

STERILE A

Indicates a product that has been manufactured using accepted aseptic techniques.



Indicates that the product meets the requirements of the applicable EC directives.

IVD

Indicates a product that is intended to be used as an in vitro diagnostic medical device.



Indicates the need for the user to consult the instructions for use.

8 Related Products

Product	Cat. No.
MSC Attachment Solution	05-752-1
NutriFreez® D10 Cryopreservation Medium	05-713-1
Recombinant Trypsin Solution	03-078-1
Recombinant Trypsin-EDTA Solution	03-079-1
Soybean Trypsin Inhibitor (SBTI)	03-048-1
Dulbecco's PBS (w/o Ca & Mg)	02-023-1
NutriCoat™ Attachment Solution	05-760-1

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Masculine or feminine forms are used to facilitate legibility in these instructions and always simultaneously denote the other gender as well.

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