

Instructions for Use

Recombinant Trypsin Solutions

An Animal Components-free Cell Dissociation Solution, Designed as an Alternative to Porcine Trypsin for the Dissociation of Cells




2740231-000-01



SARTORIUS

An animal components-free cell dissociation solutions, designed as an alternative to porcine trypsin for the dissociation of cells

	Recombinant Trypsin Solution	Recombinant Trypsin-EDTA Solution
REF	03-078-1A	03-079-1A
	03-078-1B	03-079-1B
	03-078-1C	03-079-1C

	Room Temperature (15 - 25°C)
--	------------------------------

Contents

1	Product Description	4
2	Source	4
3	Features.....	5
4	Intended Use and Safety.....	5
5	Storage and Stability.....	6
6	Instructions for use.....	6
7	Quality Control	6
8	Quality Assurance.....	7
9	Auxiliary Products.....	8

1 Product Description

Animal components-free (ACF) recombinant trypsin solutions, developed as an alternative to porcine trypsin. The solutions do not contain any chymotrypsin, carboxypeptidase A, and other protease contaminant.

Recombinant Trypsin Solution formulations were developed for efficient dissociation of adherent cell types from surfaces and tissues and were optimized for sensitive cells, such as primary human mesenchymal stem cells (hMSC). The addition of EDTA usually accelerates the dissociation phase.

Recombinant Trypsin Solutions are pure enzyme solutions, which help maximize the yield of functionally viable cells from cultureware, while preventing the toxicity effect induced by other non-desirable proteases. In addition, recombinant trypsin eliminates the risk of viruses, or other potential adventitious agents found in animal-derived components.

2 Source

Recombinant Trypsin raw material is produced by submerged microbial fermentation. Solutions are derived from a production process which does not utilize any raw materials and/or processing aids of animal origin.

3 Features

- Ready-to-use
- Non-animal or human origin
- Increased specificity
- Eliminates contaminating activities found in bulk production of enzymes
- Free from undesirable proteases such as carboxypeptidase A and chymotrypsin
- Optimized for hMSC (from a variety of sources), cultured in both serum-free and serum-containing systems
- Sterile

4 Intended Use and Safety

- For research or further manufacturing use as ancillary material in manufacturing of cell, gene or tissue-based products
- Intended for in vitro diagnostic use
- Not intended for human in vivo applications
- Do not use if visible particles and | or precipitate are observed.
- Do not use beyond the expiration date indicated on the product label.
- Maintain aseptic work conditions.
- Do not use if there is any package leakage or any exposure to environmental conditions as the sterility of the product might be compromised.
- Refer to the Material Safety Data Sheet (MSDS) for hazard information.

5 Storage and Stability

- Stable at room temperature (15–25°C)
- Protect from direct light.
- Shelf life: refer to product label for expiration date.

6 Instructions for use

The following instructions are applicable for most cell lines. Actual procedures and concentrations should be determined by experience with individual cell lines (see notes below).

1. Wash the cells with DPBS w/o Ca, Mg (Cat. No. 02-023-1).
2. Add 1 mL of Recombinant Trypsin Solution to each T-25 tissue culture flask.
3. Incubate the flask at 37°C for 2 min or longer as necessary. Verify cell's detachment using inverted microscope.

NOTE The time needed to dislodge cells will vary depending upon cell type, cell density and medium used.

4. When cells are completely detached, add 5–10 mL of culture medium MSC NutriStem® XF (Cat. No. 05-200-1). Alternatively use diluted (1:50, in DPBS) Soybean Trypsin Inhibitor (SBTI) (Cat. No. 03-048-1).
5. Pellet the cells by centrifugation, and discard the supernatant.
6. Resuspend the cells in growth medium, and seed as desired.

7 Quality Control

Recombinant Trypsin Solution performance is tested on hMSC. Additional standard evaluations are pH, Osmolality, sterility and endotoxin tests. For full specifications, please check the lot specific Certificate of Analysis (CoA).

8 Quality Assurance

- Listed in Europe under CE IVD class I, thus comply with European In-Vitro Diagnostic Devices Directive (98/79/EC) requirements.
- Notified under US FDA IVD part 864.4400 Cell-freezing apparatus and reagents for in vitro diagnostic use. 864.4400
- Manufactured under ISO 13485 QMS and ISO 9001 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 – Cleanrooms and associated controlled environments



Authorized Representative in the European Community:

MedNet GmbH

Borkstraße 10, 48163 Münster, Germany



Manufacturer

Biological Industries Israel Beit Haemek Ltd.

Kibbutz Beit Haemek 2511500, Israel

Product Label Symbols



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



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.



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



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



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.

9 Auxiliary Products

Product	Cat. No.
MSC NutriStem [®] XF Basal Medium	05-200-1
MSC NutriStem [®] Supplement Mix	05-201-1
Soybean Trypsin Inhibitor	03-048-1
NutriFreez [®] D10 Cryopreservation Medium	05-713-1
Dulbecco's PBS (w/o Ca & Mg)	02-023-1

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen, Germany

Phone: +49 551 308 0
www.sartorius.com

The information and figures contained in these instructions correspond to the version date specified below.

Sartorius reserves the right to make changes to the technology, features, specifications and design of the equipment without notice.

Masculine or feminine forms are used to facilitate legibility in these instructions and always simultaneously denote all genders.

Copyright notice:

These instructions, including all components, are protected by copyright.

Any use beyond the limits of the copyright law is not permitted without our approval.

This applies in particular to reprinting, translation and editing irrespective of the type of media used.

Last updated:

03 | 2024

© 2024

LH | Publication No.: SCM6032-e240302
DIR No.: 2740231-000-01