FoamAway™ Irradiated AOF

Catalog Numbers A10369-01, and A10369-02

Pub. No. MAN0007376 **Rev.** 2.0

WARNING! Read the Safety Data Sheets (SDSs) and follow the handling instructions. Wear appropriate protective eyewear, clothing, and gloves. Safety Data Sheets (SDSs) are available from **thermofisher.com/support**.

Product description

Gibco™ FoamAway™ Irradiated AOF is specifically designed to offer high performance and convenience in combating foam in cell culture systems. FoamAway™ Irradiated AOF is formulated to a simethicone concentration supporting less than 15-second de-foaming performance in a USP performance assay and can be used as either an anti-foaming agent (to prevent foam) or as a de-foaming agent (to rid systems of foam that has already formed). FoamAway™ Irradiated AOF saves time and cost in preparation of an anti-foaming agent by being ready to use in culture systems while maintaining reliable performance. FoamAway™ Irradiated AOF is manufactured with 30% Simethicone Emulsion USP containing methylcellulose and does not contain any components derived from human or animal sources.

Product	Catalog No.	Amount	Storage	Shelf Life[1]
FoamAway™ Irradiated AOF[2]	A10369-01 A10369-02	2.5 L (in 5 L bag) 0.5 L (in 1 L bag)	15°C to 30°C (Room temperature)	8 months

[1] Shelf Life duration is determined from Date of Irradiation.

[2] FoamAway™ Irradiated AOF is manufactured with 30% Simethicone Emulsion USP (Dow Corning™, Catalog No. Q7-2587).

Important product information

- Do not filter FoamAway™ Irradiated AOF. FoamAway™ Irradiated AOF has been terminally sterilized through a validated gamma irradiation process and should be aseptically added to sterile cell culture systems. The simethicone particles are too large to be filtered; any attempts to filter FoamAway™ or media containing FoamAway™ will result in the removal of the simethicone particles and reduced performance.
- Shake FoamAway™ Irradiated AOF before use. FoamAway™ Irradiated AOF is a suspension and not a true solution. Some separation of the material will occur during shipping and storage. The media bag must be well shaken prior to use to ensure homogeneity of the suspension. Use immediately following agitation.

Product use

Individual system requirements vary, therefore we recommend determining optimal conditions prior to use. The following instructions are generalized recommendations that may or may not be applicable to your specific cell culture system.

- FoamAway™ Irradiated AOF is an aqueous dilution of a simethicone emulsion. As a result, some separation of the material will occur during shipping and storage. The media bag must be shaken thoroughly prior to use and used immediately following agitation (see **"Important product information" on page 1**).
- This product is sterile and aseptic processes must be followed when connecting the tubing to the bioreactor or other processing equipment.
- FoamAway™ Irradiated AOF must be added aseptically to sterile media. **Do not** filter these products or the cell culture medium containing these products (see **"Important product information" on page 1**).
- Supplement FoamAway™ Irradiated AOF to culture medium at the lowest volume that is effective for specific system requirements for ease of downstream processing. We recommend determining optimal volume of addition for specific applications by performing a titration, starting with a low simethicone volume and increasing as required.

Sterilization information

FoamAway™ Irradiated AOF consists of 30% simethicone diluted with Water for Injection (WFI) grade purified water to a concentration supporting less than 15 second de-foaming performance in a USP Assay. Gamma irradiation sterilization of the FoamAway™ Irradiated AOF has been validated to a sterility assurance level (SAL) of 10^{-6}. The radiation validation study was based on the Association for the Advancement of Medical Instrumentation (AAMI) Technical Information Report (TIR) No. 33:2005 standard, which is titled "Sterilization of Health Care Products – Radiation - Substantiation of a Selected Sterilization Dose – Method VDmax". This process validates a sterilization dose based on the determination of the product bioburden and comparison of that bioburden information to a model population having a defined resistance to radiation. AAMI TIR No. 33:2005 was designed to meet the requirements of ANSI/AAMI/ISO 11137, titled "Sterilization of Health Care Products Radiation Sterilization". The validation documents can be made available for review upon request through on-site audits and under agreement of confidentiality.

Please note that FoamAway™ Irradiated AOF **cannot** be filtered because the size of the simethicone particle is larger than the sterile filter pore size. In order to maintain the sterility of this product, it must be aseptically connected to a bioreactor in-

process. Any mishandling of this product, including but not limited to non-sterile connections, misuse, and improper storage, may result in compromised sterility of this product and systems to which it is added. Life Technologies™ has validated the sterility of the FoamAway™ Irradiated AOF to an SAL of 10^{-6}, but cannot be responsible for the product once it is outside of our physical control. All sales shall be subject to all of the terms and conditions set forth herein and within the Thermo Fisher Scientific's General Terms and Conditions, available at **http://www.thermofisher.com/us/en/home/global/terms-and-conditions.html**, and the Bioproduction Product Terms and Conditions available at **http://www.thermofisher.com/content/dam/LifeTech/Documents/PDFs/Bioproduction-Product-Terms-and-Conditions.pdf** or upon request.

Limited product warranty

Life Technologies Corporation and/or its affiliate(s) warrant their products as set forth in the Life Technologies' General Terms and Conditions of Sale at **www.thermofisher.com/us/en/home/global/terms-and-conditions.html**. If you have any questions, please contact Life Technologies at **www.thermofisher.com/support**.

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For descriptions of symbols on product labels or product documents, go to **thermofisher.com/symbols-definition**.