

HyClone™ ADCF antifoam solution

HyClone™ ADCF antifoam solution products are formulated to contain ~ 3% active simethicone. Sterilization of these products is performed using a validated gamma-irradiation process. The products are delivered in single-use bags designed with tubing lines and fittings to enable easy connection and delivery to various cell culture systems (Fig 1). HyClone ADCF antifoam solution has been shown to effectively prevent foam from occurring in cell culture systems, as well as to quickly eliminate foam already formed.

Key features of antifoam products include:

- Easy to use and ready for immediate application
- Validated gamma-irradiation process to a sterility assurance level (SAL) of 10^{-6}
- Provided in single-use bags with convenient tubing and fitting designs (customization possible)
- Animal-derived component free (ADCF) for improved batch-to-batch consistency and reduced risk of viral contamination

Specifications

HyClone ADCF antifoam solution are formulated to contain ~ 3% active simethicone concentration. The products are formulated by dilution of 30% simethicone emulsion using water for injection (WFI) quality water. Gamma-irradiation treatment of these products has been validated to a sterility assurance level (SAL) of 10^{-6} . The gamma-radiation process is based on the Association for the Advancement of Medical Instrumentation (AAMI) technical information report (1). A sublethal sterilization dose was determined according to AAMI/ANSI/ISO11137-2, method V_Dmax25. This process validates a radiation dose based on the determination of the product bioburden and a comparison of that bioburden with a model population having a defined resistance to radiation.

Our antifoam products are provided in single-use bags with convenient tubing and fitting designs (Fig 2 to 4). The single-use bags can also be customized to fit your specific needs.

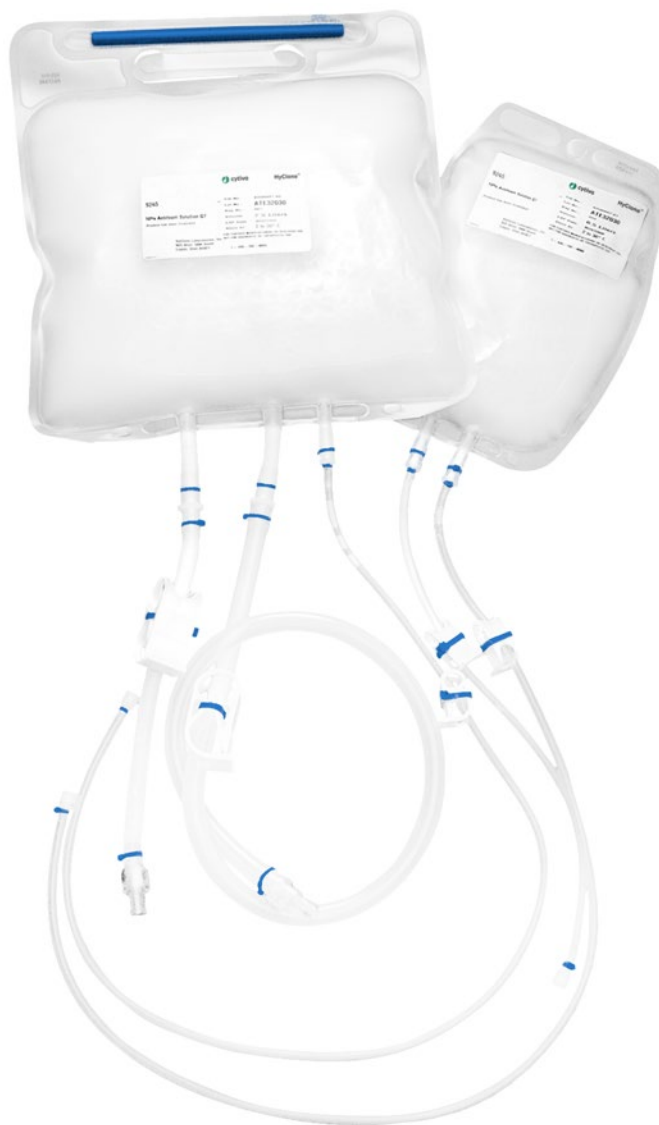
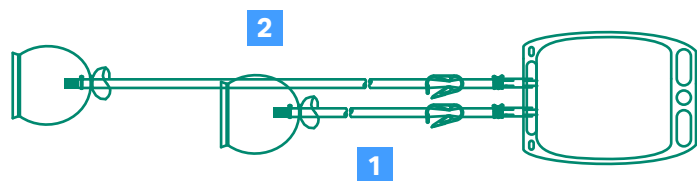
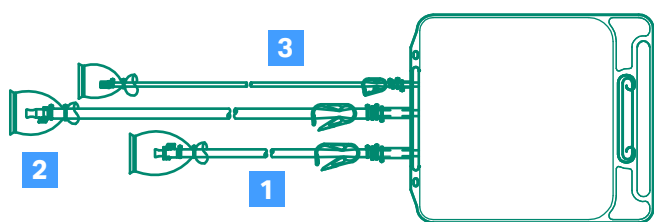


Fig 1. HyClone ADCF antifoam solution products are supplied ready to use in packaging from 500 mL to 10 L.



| 1 L container* | Size | Material | Tubing size | Fittings |
|----------------|-----------------|----------|---------------------------|------------------|
| Line 1 | 56 cm (22 in.) | Silicone | 1/8 in. i.d. x 1/16" wall | Female luer lock |
| Line 2 | 107 cm (42 in.) | C-Flex | 1/8 in. i.d. x 1/16" wall | Female luer lock |

Fig 2. Diagram of a 1 L single-use container system*.



| 5 and 10 L containers* | Size | Material | Tubing size | Fittings |
|------------------------|------------------|----------|------------------------------|----------------------|
| Line 1 | 27 cm (10.5 in.) | Silicone | 3/8 in. i.d. x 1/8 in. wall | Female quick connect |
| Line 2 | 91 cm (36 in.) | C-Flex | 3/8 in. i.d. x 1/8 in. wall | Male quick connect |
| Line 3 | 104 cm (41 in.) | C-Flex | 1/8 in. i.d. x 1/16 in. wall | Female luer lock |

Fig 3. Diagram of 5 and 10 L single-use container systems*.

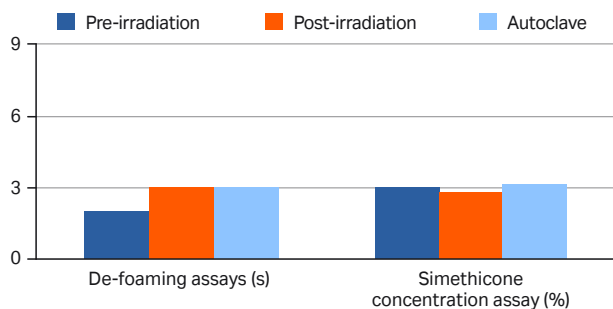


Fig 4. Comparison of HyClone ADCF antifoam solution with an autoclaved simethicone solution. HyClone ADCF antifoam solution provides the same level of de-foaming activity as an autoclaved antifoam solution.

Suggested preparation

HyClone ADCF antifoam solution products are delivered ready for immediate application. Due to the characteristics of simethicone emulsions, some product separation can occur during shipping and storage. Shake antifoam products vigorously before use. Note that some residue might remain in the filling tube upon receipt, and is inherent to the filling process. The residue has no impact on the product or its performance.

General culture recommendations

HyClone ADCF antifoam solution has been demonstrated to directly replace autoclaved simethicone solutions (Fig 4). As individual systems might vary, optimal concentrations and conditions should be determined prior to use. As the solutions are not filterable, aseptic techniques and processing are required to deliver HyClone ADCF antifoam solution products to cell culture systems and media.

Reference

1. Technical information report: Sterilization of healthcare products — radiation — substantiation of a selected sterilization dose — Method VDmax, AAMI TIR33:2005, ISBN 1-57020-270-2, Association for the Advancement of Medical Instrumentation, Arlington, VA, USA (2006).

Ordering information

| Product | Description | Size* | Product code |
|--------------------------------|-------------------------------------------------------------------------------------------------------------------|------------|--------------|
| HyClone ADCF antifoam solution | Raw material Dupont Q7-2587, simethicone emulsion USP manufactured to deliver 3% active simethicone concentration | 500 mL | SH30897.01 |
| | | 8 x 500 mL | SH30897.04 |
| | | 2.5 L | SH30897.02 |
| | | 2 x 2.5 L | SH30897.05 |
| | | 5 L | SH30897.07 |
| | | 10 L | SH30897.08 |

* Antifoam solution 500 mL is supplied in a 1 L single-use container system.
Antifoam solution 2.5 L is supplied in a 5 L single-use container system.
Antifoam solutions 5 L and 10 L are supplied in a 10 L single-use container system.

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