ADVANCED MATERIALS HANDLING

Mixing Systems

Complete recirculation and mixing process system

Two of the most significant benefits to single-use bioprocessing over reusable manufacturing equipment are lower cost and simpler operation. And yet some processing steps, such as mixing, have not been able to realize these benefits.

Many single-use mixing systems on the market use expensive stainless steel vessels, components, and control systems that are unnecessary for most applications.

The Entegris mixing system is designed to maximize simplicity, ease-of-use, and affordability. This single-use bag system creates a completely sterile mixing and recirculation process from start to finish. Our mixing system is designed to store, recirculate, and mix all types of media within a sterile single-use bag. With the properly fitted bag, the only additional equipment is a reusable Entegris conical drum and a pump. The rapid recirculation design will mix almost any component to a homogeneous mixture within 5-15 minutes, saving time and money without sacrificing quality or consistency.

APPLICATIONS

- Buffer preparation
- Media preparation
- Recirculation of homogeneous solutions
- · Liquid to liquid
- Powder to liquid



Custom sizes, configurations, and materials available to meet your needs

FEATURES & BENEFITS

Simplest single-use mixing system	Peristaltic pump operation minimizes capital costs
	Streamlined single-use consumables require less operator training and minimize risk of mishandling
	Flexible and mobile design allows easy integration into any process step
Customizable system design	Provides design flexibility and allows the system to fit the process rather than the process adapt to the system
Quick-turn customer service	Consistently fast development and delivery minimizes the risk of production delays
	Personalized timely and useful attention ensures the solution meets your unique needs



MATERIALS OF CONSTRUCTION

Standard 3-ply film*

This multilayer design provides strength and low gas permeability for single-use mixing applications.

- Total 13 mil thickness
- Inner product contact barrier: Flex 100 low density polyethylene (LDPE)
- Middle barrier: Flex 100 LDPE
- Outer barrier: Flex 150 ethylene vinyl alcohol (EVOH)/nylon

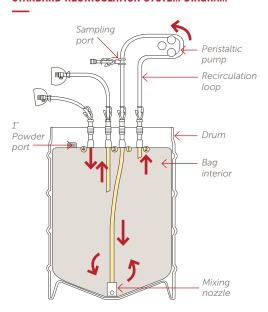
METHOD OF OPERATION

Entegris' mixing system uses a disposable mixing nozzle to direct recirculating fluids and powders throughout the single-use bag, which is fitted inside a reusable mixing system drum. Using the mixing nozzle design, multiple tubing sizes, and a conical-shaped bottom drum, the mixing system creates either a gentle or robust turbulent mixing that sweeps and lifts the contents from the container bottom. There are no moving parts in the system; fluid and other media recirculation is accomplished via an external pump. If needed, the mixing system can be combined with our temperature-controlled mixing drum.

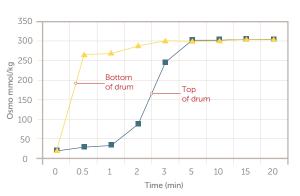
Standard Features

- Entegris mixing bags and associated components are sterilized using gamma irradiation between 25 – 40 kGy unless requested otherwise
- Extractables and leachables (E&I) data available for all contact materials
- Full traceability for all materials
- Certificates of Analysis provided for each lot
- Entegris' mixing system is manufactured under a quality system designed to be compliant to 21 CFR Part 820: Quality System Regulation

STANDARD RECIRCULATION SYSTEM DIAGRAM



PERFORMANCE DATA



Results: The test data demonstrates rapid mixing of the test media achieving 99% homogeneity within 5 minutes and 100% or complete mixture within 15 minutes.

^{*3-}ply includes two inner LDPE barriers and an outer barrier of LDPE/EVOH/NYLON/LDPE, with the inner barriers placed inside the outer to create a 3-ply chamber.

ORDERING INFORMATION

Part number	Description
FSE00419.01	50-liter single-use bag
FSE00419.02	100-liter single-use bag
FSE00419.03	200-liter single-use bag
FSF00019.01	50-liter drum
FSF00019.02	100-liter drum
FSF00019.03	200-liter drum
FSA00491.03	Tank liner (one size fits all, 50 – 200 L)
FSF00010.03	Drum dolly (one size fits all, 50 – 200 L)

FOR MORE INFORMATION

Please call your Regional Customer Service Center today to learn what Entegris can do for you. Visit <u>entegris.com</u> and select the <u>Contact Us</u> link to find the customer service center nearest you.

TERMS AND CONDITIONS OF SALE

All purchases are subject to Entegris' Terms and Conditions of Sale. To view and print this information, visit entegris.com and select the Terms & Conditions link in the footer.



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