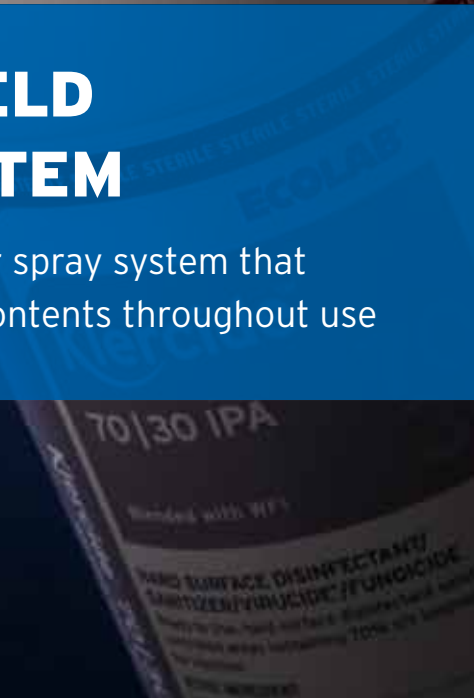


PHARMACEUTICAL



THE STERISHIELD DELIVERY SYSTEM

A closed and validated trigger spray system that ensures the integrity of the contents throughout use



An **Ideal Solution** for Cleaning and Disinfection of Critical Areas



An effective cleaning and disinfection program in controlled areas is critical to maintain product quality and safety in the pharmaceutical manufacturing industry.

Typical spray solutions such as conventional trigger spray systems and standard aerosols can compromise various areas of your business, including:



Employee Health and Safety



Cost of Use / Profitability



Product Quality

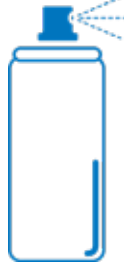


Regulatory Compliance

"To prevent introduction of contamination in critical environments¹ disinfectants should be sterile²"

STANDARD AEROSOLS

Can pose a safety risk due to higher volatile content release and can result in an increase in overall cost given their disposal costs. Aerosols also lack an adjustable spray pattern that may limit the coverage of surface areas.



CONVENTIONAL TRIGGER SYSTEMS



May not form a closed system and are unable to prevent air from being drawn back into the bottle, posing a risk of contaminating the contents of the bottle during use. This is applicable to both bag in the bottle and standard trigger spray systems. This puts your product quality and compliance at risk due to potential loss of sterility and increases in-use cost as product cannot be used beyond a single session in critical areas.

STERISHIELD DELIVERY SYSTEM (SDS)

Specifically designed to address these challenges, the SteriShield Delivery System's unique combination of bag in the bottle design and patented trigger system provides a closed system and ensures contamination cannot enter the bottle during use. Unique features of this revolutionary product include:

- ▲ **Closed System**
No air suck back ensures sterility
- ▲ **Validated System**
In use shelf life of three months
- ▲ **Variable Spray Pattern**
Ensures optimum surface coverage
- ▲ **Reduced volatile content**
Safer compared to aerosols



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FEATURES

WHAT MAKES THE TRIGGER SO EFFECTIVE?

A patented precision engineered trigger head to ensure that air is not drawn back into the bottle.

WHAT MAKES THE BOTTLE SO EFFECTIVE?

A bottle with dual layers:

- ▲ A rigid outer bottle to provide structural stability
- ▲ An inner flexible bag protects its contents and creates a post-dispensing vacuum in which remaining liquid is stored

A variable rotating nozzle to deliver the desired spray pattern as required

A shroud that is smooth, simple, and easy to wipe and disinfect

An ergonomically designed trigger to provide ease of use and consistency for every operator

A precision engineered pump system, lubricated with medical grade silicone, to eliminate air ingress around the plungers

A unique venting system, fitted with 'duck billed valve', to ensure ONLY one way venting during irradiation

An inner bag that is sealed to the outer bottle all around the top of the bottle neck

An inner flexible bag is attached to the outer bottle when manufactured

A plastic outer bottle to provide structural rigidity

Two holes drilled into the base of the outer bottle to allow air to move freely into the space between the flexible bag and the outer bottle allowing the inner bag to collapse around the fluid

An inner bag that is sealed to the outer bottle at the center of the base to prevent the dip tube from being blocked by the back collapsing, allowing the complete dispensing of the contents

1. FDA's Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice, September 2004. 2. Including ISO Class 5 environments

Why use the Ecolab **SteriShield Delivery System** Trigger Spray?

The SteriShield Delivery System trigger spray delivers the benefits of key cleaning and disinfection criteria by preserving the integrity of the product, minimizing risk to operators, fulfilling regulatory requirements and providing a cost-effective solution.



HEALTH & SAFETY

- ▲ The variable nozzle allows for a larger spray droplet size to reduce atmospheric concentration of products such as alcohol
- ▲ No pressurized content



COST OF USE

- ▲ Uses the entire volume of product
- ▲ Product can be used beyond a session - up to three months after opening



PRODUCT QUALITY

- ▲ Closed system eliminating contamination risk
- ▲ Adjustable spray pattern ensuring optimum surface coverage
- ▲ Easy to clean shroud and bottle



REGULATORY COMPLIANCE

- ▲ Validated in-use sterility and shelf life
- ▲ Validated trigger spray

With the SteriShield Delivery System (SDS), every feature - including the trigger - is designed to prevent air return, assuring users of sterile fluid dispensing, every time.

STERILITY ASSURED

The patented and unique trigger head works by forming a complete seal, preventing any air from being drawn back into the bottle. This not only eliminates the risk of microbial contamination in critical fill / finish areas but also chemical contaminants, for example air pollutants, in other areas where powders or aerosols are present, assuring users of sterile fluid dispensing every time.

EFFICACY ASSURED

Because of its variable nozzle, the liquid can be dispensed as required and the correct application can be obtained for each procedure enabling thorough wetting of the surface so that all disinfection procedures are effective.

TESTED AND VALIDATED

The SDS has been subjected to a stringent and comprehensive validation testing program. The system has undergone in-depth validation, including microbiology media broth tests to detect any potential ingress of contamination from the external environment.

Additionally, Ecolab has undertaken vacuum and particulate testing to prove without reservation that the trigger and bottle combination creates and maintains a closed system, protecting the sterility of the contents in use for a minimum of three months.

OPERATOR SAFETY

For alcohol and some of the other products, the SDS offers improved safety compared to aerosol sprays. The larger droplet size dispensed from the trigger spray reduces the level of atmospheric alcohol created at the time of use, consequently reducing the risk of excessive vapor inhalation by operators.

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OPTIMUM SURFACE COVERAGE

The fully adjustable trigger spray nozzle allows the liquid to be dispensed in any configuration, from a jet to a wide spray, allowing the user to select the most appropriate method of application.

REDUCED COST OF USE

By providing the same 'closed system' benefits of an aerosol, the SDS offers reduced cost by eliminating expensive, pressurized metal containers with their associated waste disposal requirements and wastage of unused product which cannot be dispensed.

In addition, product is validated for an in-use shelf life of three months as opposed to a single session for conventional trigger systems. This again reduces product wastage and further cost.

From purchase to disposal, the SDS can offer a significant advantage by reducing the total cost of use.

EASY TO USE

The development of our user friendly trigger provides:

- ▲ A variable nozzle
- ▲ At maximum, a broad spray pattern; at minimum, a jet
- ▲ An easy to clean shroud
- ▲ Negligible wastage
- ▲ Ergonomic design ensuring comfortable use for a range of hand sizes



Always look for the SDS stamp on our packaging - the patented and validated trigger spray system

Validation Studies for SteriShield Delivery System



Note: Our validation testing data is not applicable to any other trigger spray system

How do you prove SteriShield System is a closed system?

As part of our development of the SteriShield Delivery System, the system was subjected to rigorous testing to ensure its performance as a closed system.

A combination of vacuum tests, nutrient broth tests and particle tests have been conducted with results summarized below. A full set of data is available for each of these tests.

The results provide the assurance of a fully validated dispensing system which is fitted to all of our spray products - ensuring long in-use shelf life and peace of mind.

"The combination of our unique trigger head and bottle are what makes the SDS a truly closed system."

VACUUM TEST

Identical transparent bottles are tested in combination with a selection of in-market triggers. Colored fluid contents are used and 25% of the liquid expelled. These are left to stand for 24 hours and observed for change in fluid level.



The SDS is an "air-tight" closed system



Standard Trigger Spray

No vacuum - fluid level drops - system is not closed

25%
Liquid expelled

No vacuum - fluid level drops - system is not closed



SteriShield Delivery System Trigger Spray

Vacuum maintained after 24 hours

Vacuum - fluid level maintained - system is closed

NUTRIENT BROTH TEST

Bottles are filled with microorganism growth promotion media (both FTM and TSB), periodically used (sprayed) over a three month period and the contents regularly tested for continued sterility.

All test samples showed no growth, indicating sterility



The SDS provides a protective environment for up to three months



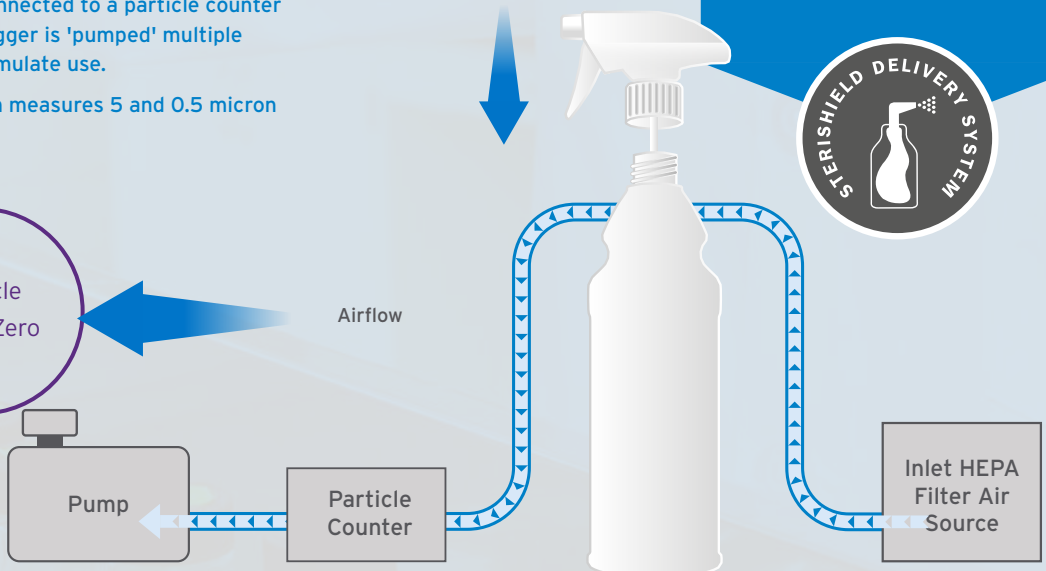
PARTICLE TEST

An empty SDS bottle with a trigger spray is connected to a particle counter and the trigger is 'pumped' multiple times to simulate use.

The system measures 5 and 0.5 micron particles.

The trigger spray head is attached here for testing

Particle Count Zero



The SDS prevents even 0.5µm particles from entering the bottle



Klercide™ Products in SteriShield Delivery System

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	PRODUCT NAME	DESCRIPTION
1	Klercide 70 30 IPA	Sterile IPA Blended with WFI Spray
2	Klercide 70 30 Pharma Ethanol	Sterile Pharma Ethanol Blended with WFI Spray
3	Klercide Cleanroom Quat	Sterile Low Residue Quat Blended with WFI Spray
4	Klercide Low Residue Peroxide	Sterile Low Residue Peroxide Blended with WFI Spray
5	Klercide Neutral Detergent	Sterile IPA Blended with WFI Spray
6	Klercide WFI Quality Water	Sterile WFI Quality Water



PLEASE SPEAK TO YOUR ECOLAB ACCOUNT MANAGER FOR FURTHER INFORMATION

WORLDWIDE HEADQUARTERS

1 Ecolab Place
St. Paul, MN 55102
USA

www.ecolab.com/lifesciences
www.ecolab.com/pharmaceutical

