



PHARMACEUTICAL



ECOLAB[®]

A COMPREHENSIVE APPROACH TO CLEANING & DISINFECTION

Designed Specifically for Pharmaceutical Manufacturers



Addressing Your Specific Needs with Our **Total Plant Solutions**

The **Ecolab** Benefit

At Ecolab, we provide our customers with the support of a global organization renowned for the most effective programs combined with the highest levels of service.

- ▲ Founded in the US in 1923
- ▲ Operational in over 170 countries
- ▲ Over 48,000 employees
- ▲ Over 3,000,000 customers worldwide
- ▲ Largest sales and service force in the industry

Experienced, highly trained and backed by the full resources of the global leader in sanitation, our dedicated Life Sciences team will deliver the proven solutions customers need to:

- ▲ Produce safe, compliant products that exceed your customers' standards
- ▲ Continuously and measurably improve operational efficiency
- ▲ Help achieve sustainability goals, including reducing water and energy consumption

WE ARE A TRUSTED PARTNER TO OVER 20 OF THE WORLD'S TOP PHARMACEUTICAL MANUFACTURING COMPANIES.

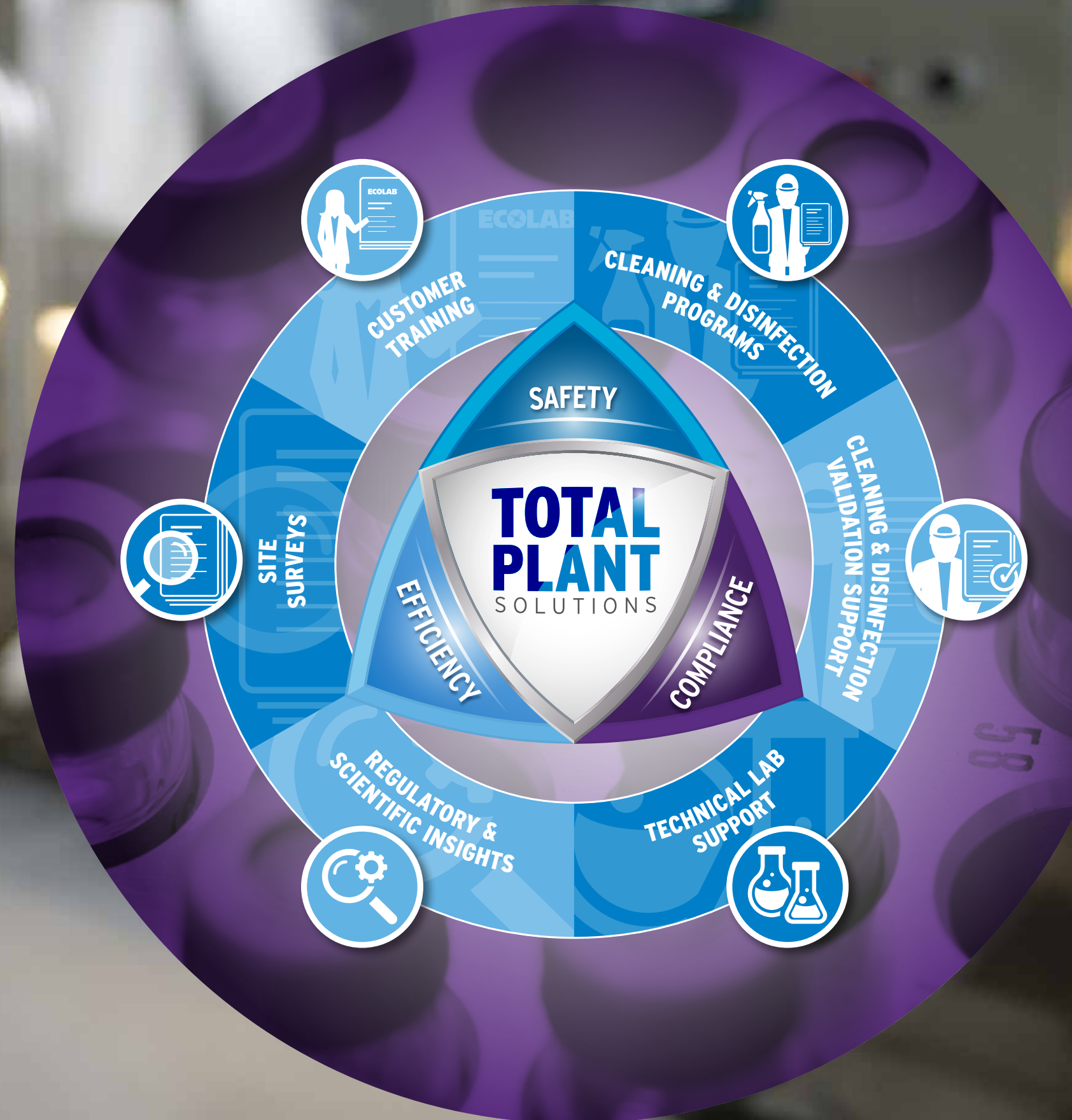
EXPERTISE IN LIFE SCIENCES

Our business has a strong track record in Europe where we are leaders in the cleaning and disinfection market for the Pharmaceutical industry, including partnerships with the leading global Pharmaceutical, Biopharma and Contract Drug Manufacturing organizations.

We provide our customers with complete cleaning and disinfection programs for external surfaces of manufacturing equipment and cleanrooms, and for direct product contact surfaces.

These programs meet the latest regulatory standards and our dedicated products are manufactured in fully auditable and traceable production facilities.

With years of industry experience, our Validation and Technical Support teams will assist you in developing and implementing the best programs for your facilities.



Our Programmatic Approach



Cleaning & Disinfection Programs

Ecolab provides you with site-specific cleaning and disinfection programs to help manage risk and improve process efficiency for external surfaces of manufacturing equipment and cleanrooms, in addition to direct product contact surfaces.

CLEANROOMS

Cleaning and disinfection solutions for external surfaces of manufacturing equipment and rooms.

This program includes:

- ▲ Sterile products as part of the **Klercide™ range**
- ▲ Products manufactured in cleanrooms using sterility assurance best practices to ensure sterility. This provides the reassurance that your process validation is secure, using products with substantiated quality
- ▲ Plant maintains full validated batch traceability and can be audited on request
- ▲ Innovative packaging solutions, such as our patented **SteriShield Delivery System (SDS)** on the trigger spray bottles, which works as a closed system designed to preserve the sterility of the contents throughout use
- ▲ Certificates of Analysis available for all chemical SKUs



KLERCIDE™ RANGE

Manufactured in our state-of-the-art facility, our extensive range of sterile alcohols and biocides provides control of contamination on cleanroom surfaces.

APPLICATION TOOLS
TRIPLE BUCKET SYSTEM
MOP WIPE FRAMES

PRODUCT FORMATS
READY-TO-USE
PRESATURATED WIPES
CONCENTRATES

DISINFECTANT ROTATION
ALCOHOLS
DISINFECTANTS
SPORICIDES

CIP (CLEAN IN PLACE) & COP (CLEAN OUT OF PLACE)

Cleaning and disinfection solutions for direct product contact surfaces.

This program provides:

- ▲ A specific product range for the pharmaceutical industry - **COSA™ Range**
- ▲ Formulations providing high rinsability
- ▲ No silicate, perfume, silicone or coloring
- ▲ Products manufactured to GMP quality with fully documented work instructions and procedures
- ▲ Fully validated batch traceability and can be audited on request
- ▲ Certificates of Analysis available for all chemical SKUs
- ▲ A comprehensive Ecolab Cleaning Validation support web page, which has been designed to help our customers with their cleaning validation processes or revalidation in the pharmaceutical industry
- ▲ CIP Optimization: An evaluation and recommendation on methods to optimize time, temperature, mechanical action, chemistry and chemistry residuals in CIP systems
- ▲ We offer installations for automatic cleaning and disinfection. After an assessment of your process, we are able to recommend the equipment installation to meet your requirements. These installations could cover a variety of equipment, such as: storage stations, pump systems, conductivity dosing systems, CIP Kits, etc.



We go beyond identifying the right chemistry - we develop site-specific hygiene programs to maximize process efficiency and help manage risk.

ALKALINE CLEANERS

ACID CLEANERS

ADDITIVES/BOOSTERS

MANUAL CLEANING

SANITIZERS & DISINFECTANTS



COSA™ RANGE

Manufactured in a pharmaceutical GMP production facility, our comprehensive range of cleaners and additives provides process optimization in your CIP and COP systems.

Global Technical Consultants

TECHNICAL EXPERTISE TO SUPPORT AND ACHIEVE cGMP COMPLIANCE, DRIVE EFFICIENCIES AND ENABLE A HARMONIZED APPROACH ACROSS MANUFACTURING SITES

An Ecolab partnership gives you access to experienced technical experts that partner with you to deliver sustained compliance and operational excellence.

Your account manager works closely with you and our skilled technical team to tackle your unique challenges, providing you with the best-in-class service and solutions to deliver on your key goals – patient safety, product safety and quality, productivity and regulatory compliance.

Our Global Technical Consultants offer:



**CLEANING & DISINFECTION
VALIDATION SUPPORT**



SITE SURVEYS
by IRCA-accredited
SMEs



**REGULATORY
& SCIENTIFIC
INSIGHTS**



From laboratory sample testing to site surveys, you can count on Ecolab to help you maximize product quality, while driving safety, regulatory compliance and operational efficiency.

PHARMACEUTICAL

Our Programmatic Support



Cleaning & Disinfection Validation Support

We assist you in navigating the complex validation processes and change controls, through optimization based on environmental and economic targets, and assistance with validation efficacy project management.

CLEANING VALIDATION SUPPORT

This support includes:

- ▲ Laboratory testing on the most challenging soils
- ▲ Toxicology Data (LD⁵⁰ or PDE)
- ▲ Allowable residue limit calculation for cleaning and disinfection agents
- ▲ Validated analytical methods for testing residues of cleaning/disinfection agents (ICH Guidelines)

Specific and non-specific methods available:

- ▲ HPLC (High-Performance Liquid Chromatography)
- ▲ TOC (Total Organic Carbon)
- ▲ Photometric
- ▲ Conductivity
- ▲ Test strips
- ▲ Surface tension

VALIDATION EFFICACY PROJECT MANAGEMENT

By partnering with customers to coordinate laboratory studies, we accelerate the validation process. We also provide on-site training and guidance to assure a smooth transition from laboratory studies to practical, real-world application. This includes:

- ▲ Protocol development and coordination with accredited contract testing laboratories

- ▲ A review of draft reports for data accuracy and alignment with protocol intent
- ▲ Consultation on documentation required to meet regulatory expectations

Our Programmatic Support



Site Surveys

We have a service available from our International Register of Credited Auditors (IRCA) to assess the compliance and effectiveness of your cleaning and disinfection programs.

SITE SURVEYS

Conducted on-site, the surveys include an in-depth analysis of cleaning and disinfection processes to determine:

- ▲ Compliance with cGMP and alignment with inspection expectations
- ▲ Opportunities for improvement, cost savings and complexity reduction

- ▲ Operator safety and environmental impact
- ▲ The risks of non-compliance with emerging standards

Following the site survey, a detailed report provides site and consolidated findings together with preliminary recommendations to help you prioritize your opportunities for improvement.



THE COMPREHENSIVE SITE REVIEW SERVICE

Provided by accredited (IRCA) subject matter experts experienced in offering technical support and regulatory guidance to pharmaceutical facilities.



Regulatory & Scientific Insights

Our expert team has knowledge of the regulations and regulatory environment to ensure compliance with cGMP, assure product safety and quality, and help implement validations that meet regulatory expectations.

We:

- ▲ Continuously survey the regulatory landscape for changes in cGMP requirements and standards for cleaning and disinfection

- ▲ Conduct deep analysis of global inspection trends in cleaning and disinfection (EU, US, PIC/S)
- ▲ Lead the development of optimal methods for efficacy determinations, engaging with the scientific and regulatory community to drive acceptance
- ▲ Support customer validation implementation that meets regulatory expectations



Technical Lab Support

Ecolab offers support to identify the right cleaning procedure for your specific processes and products.

Testing may include:

1. Soil removal studies on your most challenging soils
2. Studies to assess product compatibility with customer surface materials
3. Performance analysis to compare procedures and techniques
4. Residue analysis for customer surfaces to help determine changes required



Our **Programmatic** Support



Customer Training



Our technical teams conduct on-site training programs to ensure that best practices are understood and implemented correctly to meet the quality and safety standards at customer facilities.

Our comprehensive training covers a variety of topics such as those listed below:

- ▲ Optimal cleaning and disinfection application techniques
- ▲ Safety training
- ▲ Regulatory requirements and standards
- ▲ CIP optimization
- ▲ Validation guidance

We also organize and participate in various industry seminars to educate the industry as well as define and improve regulatory standards to achieve optimal process solutions and outcomes.

Dedicated Resources at the Corporate and Local Level

Our customers are at the center of all we do. From customized cleaning and disinfection programs to validation support and beyond, our global account management team partners with you to create customized solutions that meet your needs and exceed your plant goals.

We achieve this by working closely with you at both the local plant and corporate level to design and provide a consistent approach for your facilities that unifies our Ecolab resources and expertise to deliver what you need to be successful.



ACCOUNT MANAGER

- ▲ Connects routinely with your local teams
- ▲ Ensures alignment on plant drivers and KPIs
- ▲ Reviews cleaning and disinfection programs for the facility
- ▲ Identifies opportunities and provides recommendations
- ▲ Executes continuous improvement projects
- ▲ Provides you with our full suite of service standards called Six Star Services
- ▲ Trains plant employees



CORPORATE ACCOUNT MANAGER

- ▲ Connects with customers at corporate level
- ▲ Manages performance KPIs and escalations
- ▲ Drives best practices and portfolio standardization
- ▲ Accelerates progress towards continuous improvement opportunities
- ▲ Drives value delivery

OUR ASSURANCE

Ecolab is committed to providing exceptional service, total plant solutions and unsurpassed industry expertise to help you achieve your business goals.

Our breadth of resources and integrated business model ensure consistency across your operations. We look forward to the opportunity to partner with you on your transformation journey.

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





ECOLAB®

THE STERISHIELD DELIVERY SYSTEM

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

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

FEATURES



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





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

-  **Employee Health and Safety**
-  **Cost of Use / Profitability**
-  **Product Quality**
-  **Regulatory Compliance**

"Disinfectants should be shown to be effective for the duration of their in use shelf-life."

STERISHIELD DELIVERY SYSTEM (SDS)

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

-  **▲ Closed System**
No air suck back ensures sterility
-  **▲ Validated System**
Sterile in-use shelf life
-  **▲ Variable Spray Pattern**
Ensures optimum surface coverage
-  **▲ Reduced Airborne Particulates**
Safer compared to aerosols



TRIGGER SYSTEMS



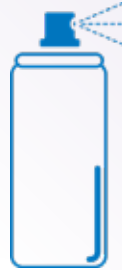
- 
- 
- 
- 

Do 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-bottle and standard trigger spray systems. This puts your product quality and compliance at risk due to potential loss of sterility of the contents and increases in-use cost.

AEROSOLS

Can pose a safety risk due to the generation of higher levels of small airborne particulates and may result in an increase in overall cost given their higher disposal costs. Aerosols also lack an adjustable spray pattern that may limit the coverage of surface areas.

- 
- 
- 
- 



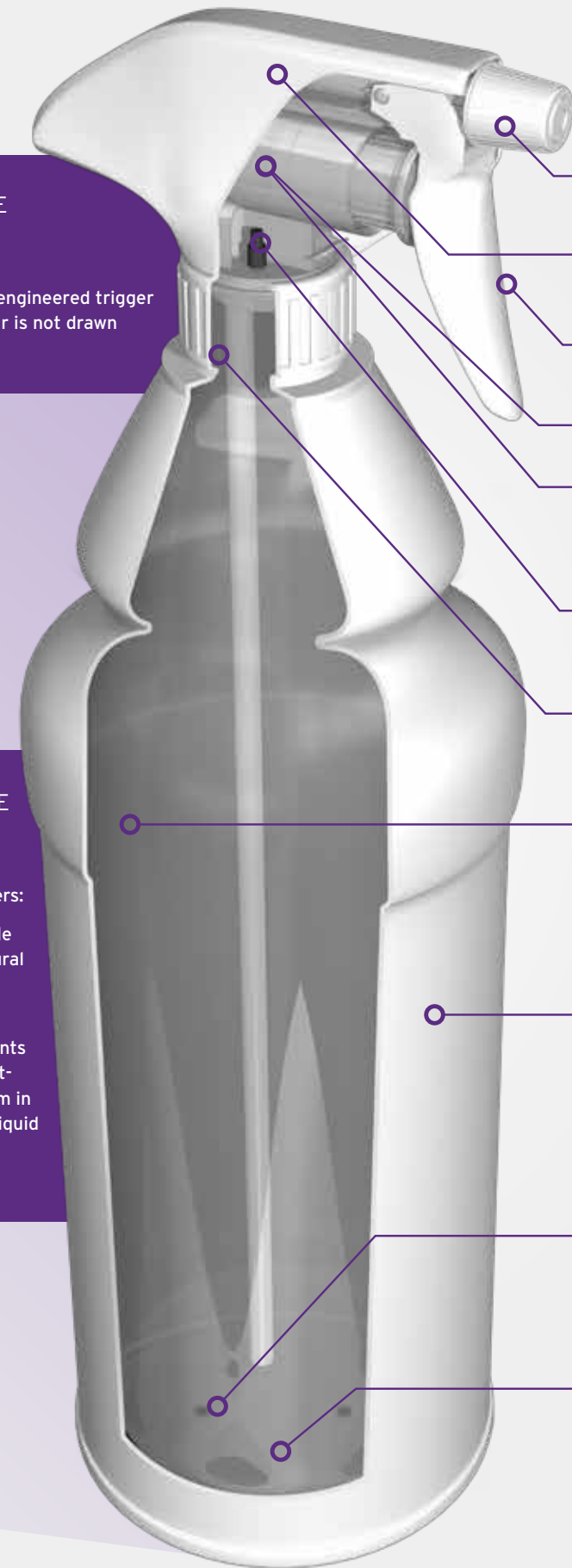
WHAT MAKES THE TRIGGER SO EFFECTIVE?

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 integral bag** protects its contents and creates a post-dispensing vacuum in which remaining liquid is stored and kept sterile



A variable rotating nozzle to deliver the desired spray pattern

A shroud that is smooth, simple and easy to disinfect

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

Optimum dosing volume

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

A unique venting system, fitted with a '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 that is co-extruded with the bottle when manufactured

A plastic outer bottle which provides 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, enabling the inner bag to collapse around the fluid

An inner bag is sealed to the outer bottle at the centre of the base to allow it to collapse around the dip tube

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

The SteriShield Delivery System trigger spray delivers the benefits of sterility by preserving the integrity of the product, minimising 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 pressurised content



COST OF USE

- ▲ Uses the entire volume of product
- ▲ Product can be used for the entire in-use shelf life



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 content sterility and shelf life
- ▲ Validated trigger spray



With the SteriShield Delivery System (SDS), every feature 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 with the bottle, preventing any air from being drawn back inside. This not only eliminates the risk of microbial contamination in critical fill / finish areas but also chemical contaminants, for example where powders or aerosols are present, assuring users of uncompromised, sterile fluid dispensing every time.

EFFICACY ASSURED

The variable nozzle allows the liquid to 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 programme. The system has undergone in-depth validation, including microbiology media broth tests to detect any potential ingress of viable contamination from the external environment.

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

OPERATOR SAFETY

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 vapour inhalation by operators, while also reducing false positives in air sampling.

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 a closed system, the SDS offers reduced cost by eliminating expensive, pressurised containers with their associated waste disposal requirements and wastage of unused product which cannot be dispensed.

The system also removes the risk of contamination associated with other trigger systems.

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:

- ▲ The same quality product from start to finish
- ▲ An adjustable nozzle
- ▲ Variable spray pattern for specific requirements
- ▲ 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 the SteriShield Delivery System



How do you prove the 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 summarised 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 our spray products - ensuring long in-use shelf life and peace of mind.

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

Note: The successful validation test results for the SDS are not applicable to any other trigger spray system.

VACUUM TEST

Identical transparent bottles are tested to ensure a vacuum was maintained by our trigger. Coloured 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.



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 and thereafter

Vacuum - fluid level maintained - system is closed



The SDS is an "air-tight" closed system

NUTRIENT BROTH TEST

Bottles are filled with microorganism growth promotion media (both FTM and TSB), periodically used (sprayed) over a six month period and the contents regularly tested for continued sterility. In total 90 bottles were tested to ensure robust data.



All test samples showed no growth, indicating sterility

The SDS provides a fully protective environment



A trigger spray without the SDS showed growth with 1/10th of volume usage.

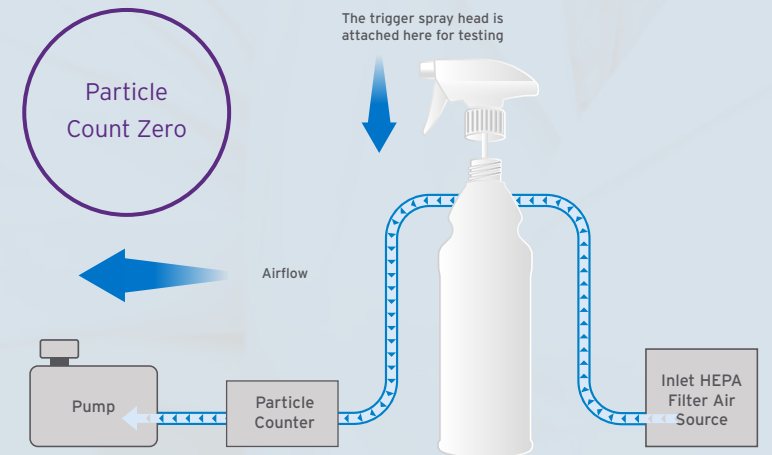
PARTICLE TEST

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.

Various leading competitor products were subjected to the same particle test and all failed (as shown in the table bottom right).

- ▲ The system was self validating (as 0 was required before each test)
- ▲ The test is a demonstration of real time in-use situations
- ▲ The results highlight the risk of not using the SDS



TRIGGER	> 0.5 microns particles			> 5 microns particles		
	Test 1	Test 2	Test 3	Test 1	Test 2	Test 3
SDS Trigger Spray	0	0	0	0	0	0
Competitor 1	421	15	103	4.2	1.1	0
Competitor 2	249	64	123	0	2.1	2.1
Competitor 3	28	26	74*	4	4	15*
	62	353	56	0	21	8
	189	25	251	21	1	29

*In these two tests it was noted that the trigger and bottle combination were unable to clean up after use. This indicated that the use of the trigger had compromised it permanently. (There was no evidence of any damage to the trigger.)



The SDS maintains an internal sterile environment



ECOLAB KLERCIDE PROGRAMME

Our programme consists of a wide array of products and services that meet your key needs for cleanroom cleaning and disinfection to ensure patient safety, product quality, regulatory compliance, employee health and safety and operational efficiency.

PLEASE SPEAK TO YOUR ECOLAB ACCOUNT MANAGER FOR FURTHER INFORMATION

WORLDWIDE HEADQUARTERS

1 Ecolab Place
St. Paul, MN 55102
USA

www.ecolab.com/lifesciences

EUROPE HEADQUARTERS

Richtistr. 7
8304 Wallisellen
Switzerland

www.ecolablifesciences.com

