

SOLUTIONS

sterile

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Sterile disinfectants

Alcohol

DEC-AHOL WFI® and STER-AHOL WFI® are based on tried and trusted sterile isopropanol and ethanol solutions, respectively. These solutions are produced with WFI (water for injection) quality water to minimize the risk of endotoxin contamination. Sterile closed systems are employed during manufacture. The DEC-AHOL® series (70% isopropanol in WFI) and the STER-AHOL® series (70% ethanol in WFI) are both available sterile, double-bagged and ready for use in Class A and B zones and in a variety of presentations – aerosols (both mist and stream), trigger-sprays, squeeze-bottles and the ingenious “Inverta-spray” that allows inverted spraying procedures in difficult to reach areas. Every assurance is taken to ensure sterility and particulate removal. Each batch is accompanied by the appropriate certificates and documentation, including certificates for irradiation, analysis and sterility.

Disinfectants

A complete range of sterile disinfectants is available, filtered at 0.2 microns and gamma irradiated. All are accompanied by appropriate documentation and certificates of sterility, analysis and irradiation.

DEC-PHENE® is a high pH sterile germicidal disinfectant based on a sodium phenol compound. It is phosphate-free and strong enough to kill a wide spectrum of pathogenic and non-pathogenic bacteria. DEC-PHENE® is employed as a disinfectant in a wide range of applications, including the disinfection of walls, ceilings and floors.

DEC-CYCLE® is a phosphate free, low pH germicidal detergent. DEC-CYCLE® is recommended for use in pharmaceutical, biotechnology and medical device manufacturing. It is strong enough to kill a broad spectrum of bacteria, whilst mild enough to have no harmful effects on most common surfaces.

DEC-QUAT® is a sterile disinfectant based on a quaternary ammonium solution. DEC-QUAT® is used as a disinfectant in a wide spectrum of applications (which includes its use as a fungicide) in the pharmaceutical industry, in hospitals and in the food manufacturing industry. It is often employed when treating solid, non-porous surfaces and is effective against viruses such as Hepatitis B Virus (HBV) and Human Immuno-deficiency Virus Type 1 (HIV)*, when used at concentrations 1oz/1 gallon.

Sporicide

DEC-SPORE 200® PLUS is a sterile sporicide. Its active ingredient is a mixture of peracetic acid, acetic acid and hydrogen peroxide. When used as a 5% solution (1:20 dilution) it has a very strong sporicidal effect. The 0.4% solution is often used as a disinfectant.

DEC-SPORE 200® PLUS is filtered at 0.2 microns and then aseptically filled into pre-sterilized containers. It is used to sterilize production, packing and filling areas and has a sporicidal effect.

STERI-PEROX® and HYPO-CHLOR®

STERI-PEROX® is designed for pharmaceutical and biotechnology operations that demand a sterile hydrogen peroxide solution. STERI-PEROX® is an effective one step, ready to use product that is available in pre-mixed concentrations of 3% and 6%.

HYPO-CHLOR® is designed for pharmaceutical and biotechnology operations that demand a sterile sodium hypochlorite solution. HYPO-CHLOR® is an effective one step, ready to use product that is available in pre-mixed concentrations of 5.25%, 0.52% and 0.25%.

Formulation is accomplished with WFI. Both products are produced sterile by aseptic filtration at 0.2 microns and are delivered with lot specific Certificate of Analysis and Sterility Report.

SimpleMix®

SimpleMix® is a patented mixing system and guarantees proper mixing and sterility.

The SimpleMix® twin-chamber system consists of an upper chamber (which contains the active ingredient) and a lower reservoir (which contains a WFI quality diluent). Activating the SimpleMix® system at the point of use starts the mixing process, ensuring dilutions are made easily and correctly within an enclosed system, therefore avoiding the handling of concentrated chemicals.

Sterile WFI quality water is used as the dilutant. The concentrates are derived from the DEC- family.

- Sterile production: registered with the FDA and the EPA
- Complete range of disinfectants
- Double packaging / sterile products
- Products used by over 300 pharmaceutical and biotechnology companies all over the world
- Complete documentation



* Special instructions and precautions for such cleaning applications should be employed.



DEC-CLEAN®

DEC-CLEAN® is a specialist cleaning agent designed to remove residues and build-ups from repeated use of disinfectants. It is designed for use on washable, non-porous surfaces. DEC-CLEAN® ensures that noticeable and often unnoticeable residues are removed, therefore returning the surface to its original form and allowing subsequent efficient cleaning and disinfection to be maintained.

STERI-SILICON® and STERI-OIL®

STERI-SILICON® Sterile Lubricant and Releasing Spray is a sterile silicon lubricant designed for use within the aseptic manufacturing area. Machinery lubrication is essential for trouble-free equipment operation. STERI-SILICON® is colourless, inert and temperature stable from -40 to 500 degrees Fahrenheit.

STERI-OIL® 200 Sterile Lubricant is a sterile mineral oil for use within the aseptic manufacturing area. The use of a sterile USP grade mineral oil lubricant is important to assure environmental conditions. STERI-OIL® 200's heavy consistency provides lubrication and prevents metal to metal contact, withstands high friction without displacement, and reduces metal fatigue. STERI-OIL® 200 penetrates and lubricates mechanisms and can be used for moisture displacement. Packaged in 1oz unit dose squeeze bottles, STERI-OIL® 200's sterility and analytical makeup is assured for each lot.

Both products are aseptically filtered, double-bag packaged and then gamma irradiated. Each product is delivered with lot specific documentation and certificates.

Applications of sterile disinfectants

Core2Clean®

The Core2Clean® cleaning system is designed for cleaning and disinfecting surfaces in controlled environments. It creates a system that can be integrated into a well-defined, repeatable cleaning SOP. The Core2Clean® system can be sterilized in an autoclave and is a progression from the traditional cleaning methods (2 pail system). The system allows effective cleaning to be achieved much more rapidly. The active ingredients can also be applied using spray and atomization techniques, as well as with the mop head. In so doing, Core2Clean® brings together several cleaning techniques in one appliance.

Asepti-Cleanse®

ASEPTI-CLEANSE® was developed specifically for use within the pharmaceutical and biotechnology industries. The device's touchless dosing and dispensing system works with infrared sensors and fulfils the cGMP requirements for clean rooms. Applying the correct dose of disinfectants DEC-AHOLWFI® and DEC-HAND®, which are both available in containers designed specifically for this device, has never been so easy.

Application:

ASEPTI-CLEANSE® applies a pre-established dose of an alcohol-based disinfectant using a touchless system. The dosing device does not come into contact with the hand.





Disinfectant Wipes

ALCOH-Wipes® & ALCOH-Gloves®

ALCOH-Wipe® is a superior sterile polyester flat wipe pre-saturated with 70% IPA and 70% Ethanol solution. Both products are inherently low in particulate and shedding features for use in pharmaceutical and biotechnology operations. The ALCOH-Glove® is a unique wipe shaped like a mitten, and pre-saturated with 70% IPA. The shape allows complete coverage of the hand, allowing accurate cleaning of awkward places.

Dry wipes

WipeDown®10 is a superior dry cleaning wipe for aseptic wipe downs of filling and packaging machinery, stainless steel surfaces, glass and any critical surface requiring to be cleaned. The wipe is a laundered polyester dry wipe that incorporates Class 10 cleanliness and sealed edges. WipeDown®10 is manufactured from 100% continuous filament polyester double-knit interlock. It is chemically engineered to achieve maximum cleanliness features and sorbency. The edges are laser cut leaving no abrasive borders, reducing particles and shedding from the edges. The wipe is available in a 12"x12" size, both sterile and non-sterile.

WipeDown®HC is a superior dry cleaning wipe used for surface cleanups, IPA wipe downs, cleaning and decontaminating critical surfaces. The wipe incorporates Class 100 cleanliness with low particulates and non-shedding features. The wipe is available in a sterile 9"x9" size and uses a 55% polyester/45% cellulose spun-laced blend that is especially clean and absorbent. Particulates, residues and foreign

matter are effectively entrapped in the engineered design of the material.

PROCESS2Wipe®

Process2Wipe® IPA70 is a 70% USP IPA saturated wipe used for both aseptic and non-aseptic wipe downs of stainless steel surfaces, glass and any critical surface requiring to be cleaned. The wipe incorporates the Class 10 cleanliness and sealed edges of the WipeDown®10 dry wipe and is then saturated with a USP 70% IPA solution in WFI. Process2Wipe® IPA70 clean room wipes are extremely low in particle shedding. They are packaged in ultra clean packages containing multiple wipes and are then double-wrapped.

STERI-PEROX® and HYPO-CHLOR® Wipes

STERI-PEROX® Wipe 6% or 3% is a superior saturated Hydrogen Peroxide wipe used for aseptic wipe downs of critical surfaces. The wipe is a laundered polyester dry wipe that incorporates the Class 10 cleanliness and sealed edges of the WipeDown®10 wipe. The wipe is available in a 12"x12" size, and saturated with either 6% or 3% hydrogen peroxide solution in WFI.

HYPO-CHLOR® Wipe 0.25% or 0.52% is a superior saturated Sodium HypoChlorite wipe used for aseptic wipe downs of critical surfaces. The wipe is a laundered polyester dry wipe that incorporates the Class 10 cleanliness and sealed edges of the WipeDown®10 wipe. The wipe is available in a 12"x12" size, and saturated with either 0.25% or 0.52% sodium hypochlorite solution in WFI.

Detergents

Process2Clean products have been specifically designed for the cleaning of critical processes. The appropriate selection and use of process cleaners is key. Firstly, the detergent must remove product residues that may exist in either open or closed process manufacturing equipment. Secondly, there must be the ability to rinse free any product residue or potential contamination that has entered the process, and also the process cleaning agent itself, to assure surfaces are clean prior to the formulation and manufacturing of a new batch.

If contamination of any kind is introduced, be it viable, non-viable or residual, then its removal must be assured. To assist in reducing possible contamination, Process2Clean products are available in both sterile and non-sterile formats. The sterile versions are filtered at 0.2 microns in a GMP Class 100 manufacturing area into pre-sterilized containers. Each lot is tested for sterility via current USP compendium. The sterile version eliminates concerns for any unwanted particles, micro-organisms and pyrogens that may be introduced through the process cleaning agent.

Products Engineered to Your Specific Cleaning Needs

Process2Clean products have been optimally engineered to remove a multitude of product residues typically encountered in pharmaceutical and biotechnology applications.

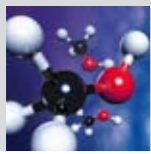
All products are formulated under the highest quality standards to assure the highest level of quality and cleanliness of the final product. Each product is supported by a comprehensive cleaning validation package.

The Process2Clean product line includes:

- Acid Detergents
- Alkaline Detergents
- Speciality Additive Detergents
- Sanitizing Agents

In addition, we can work with you and assist in cleaning validation studies and therefore the selection of the most appropriate detergent for your process.





Collection of airborne micro-organisms over extended periods

SMA™ Atrium

With the SMA™ Atrium system, we extend traditional airborne microbial collection to encompass long-term microbiological monitoring. SMA Atrium® systems are used in sterile environments and inside isolators. The system allows sampling for up to three hours at multiple sampling points (up to a maximum of ten sampling points) - and all can be achieved simultaneously.

The SMA Atrium® system consists of separate component parts. The sampling chambers (atriums) are fully autoclavable, and use 90mm petri-dishes containing appropriate culture medium. The air path inside the chambers is designed to produce a capture efficiency of 95% - when validated with bacteria and particles.

The design of the sampling atrium allows them to be placed near critical production zones where space is at a premium, and inside isolators. The diameter of the apertures can be selected to achieve the desired sampling times. The atrium design ensures that the desiccation process of the culture medium can be controlled even during long sampling times.

EMTEK Products®

The EMTEK range of Microbial Air Samplers uses standard 90mm agar plates and includes the VI100 Controller, with options of Remote-Slit-Sampler (R2S), Remote Autoclavable Sampler (RAS) and the Compressed Gas/Confined Space Sampler (RCG).

The **VI100 Controller** is the most versatile air sampler controller on the market today. With a colour LCD and touch-screen interface, the VI100 can operate R2S, RAS and RCG samplers. With IR remote control (Start/Stop/Reset, Pause/Resume) and controlled sampling rates of 28.3, 50 and 100 LPM, it allows sampling with heads placed from 1 metre up to 25 metres away from the VI100. With a 0.2 micron filtered HEPA exhaust, it is easily portable at only 6 kg in weight.

The **Remote-Slit-Sampler (R2S)** Microbial Air Sampler incorporates Slit-to-Agar methodology, offering a highly accurate analysis of air quality. The R2S is designed for monitoring clean rooms, isolators and other critical environments, and can be easily sanitized. The **Remote Autoclavable Sampler (RAS)** is based on sieve impaction with microbial recovery comparable to Slit-to-Agar samplers. Constructed of 316L stainless steel, it can be sterilized by autoclave or chemicals. The **Compressed Gas/Confined Space (RCG)** is a remote slit-to-agar impaction device that allows sampling of compressed air and gas systems. It also allows sampling in critical areas where a sampling device cannot be placed directly.



Rapid Microbial Detection

BioTrak™ Real-Time Viable Particle Counter

The BioTrak™ Real-Time Viable Particle Counter offers best-in-class features and versatility in the exciting new field of real time airborne viable particle detection. The BioTrak™ particle counter detects total and viable particle counts in real time and incorporates TSI field proven, patented Laser Induced Fluorescence (LIF) technology to determine particle viability, combining viable particle detection, total particulate detection and integrated particle collection functionality into a single portable instrument. This combination with multiple parameter optical detection and discrimination algorithms reduces the chance of false positives.

Features:

- 0.5 to 25 µm size range
- Integrated particle collection filter for off line specification analysis
- Full optical particle counter functionality
 - Complies with all requirements of ISO 21501-4
 - 1CFM (28.3 L/min) sample flow rate
 - Icon driven touch screen Graphical User Interface
 - Recipe based storage and recall of sampling protocols
 - Reports: ISO-14644-1, EU GMP Annex 1 and FS209E
- Stand-alone operation or can integrate into a facility monitoring system
- Stainless steel enclosure



Portable Monitoring

AeroTrak™ Series

The AEROTRAK™ line of Airborne Particle Counters - including portables, handhelds and remotes - are designed to meet the rigid requirements for clean room applications, and comply with the stringent requirements set forth in ISO 21501-4. They are calibrated to NIST traceable PSLs using TSI's world-class Classifier and Condensation Particle Counters, the recognised standard for particle measurements.

A complete line of Portable Particle Counters is available. The 100 LPM version allows sampling 1m³ of air in just 10 minutes, shortening the time required to perform classifications. AEROTRAK™ Portable Particle Counters offer instant Pass/Fail reporting on ISO 14644-1 and EU GMP Annex.

AEROTRAK™ Handheld Particle Counters offer an icon-driven colour touch screen for simple configuration and feature a unique variable binning option. When used as survey tools, these products can help you save time and money when looking for the early identification of problem areas.

Handheld Particle Counters are an excellent choice for:

- Tracking down particle contamination sources
- Classifying clean areas
- Looking for filter leaks
- Conducting IAQ investigations.





Management of electrostatic loads

Ionization blowers 6442

The workplace ionization blower - Model 6442 - incorporates two blower levels in order to ensure optimal ESD protection, regardless of the required application and workplace environment. Its compact design requires very little space.

The blower has a universal stand, allowing it to be set up in many different positions.

The automatic cleaning system (Auto-Clean system) is equipped with a brush mechanism that cleans the emitter points whenever the apparatus is switched on and off. This ensures efficient ionization during long periods with minimum maintenance.

Sterile solutions from PMT comply with high regulatory requirements.

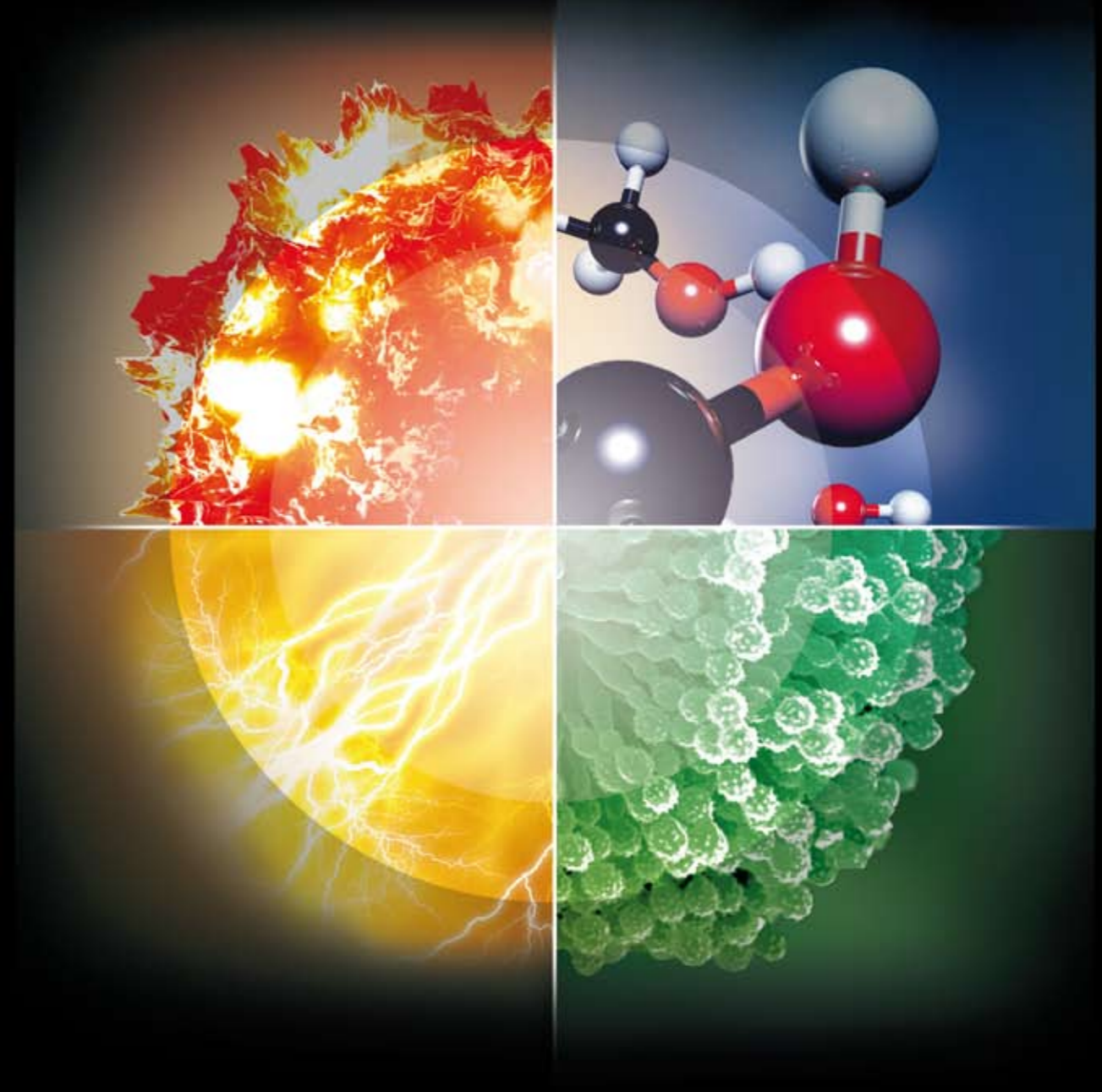
Sterile Solutions from PMT comply with high regulatory requirements.

PMT locations are ISO 9001 certified:



Particle Identification

Microcontamination Control



Electrostatic Management

Sterile Solutions