TABLE 1. Accel TB One-Step Surface Cleaner and Disinfectant. (*Note: Registered in USA only.*)

MANUFACTURER AND LOCATION
Virox Technologies Inc. Oakville, Ontario, Canada
TYPE OF DISINFECTANT
Oxidizing disinfectant
FEATURES
A sanitizer, bactericide, virucide, tuberculocide, and fungicide that is appropriate for use in the daily and/or monthly cleaning and disinfection of pharmacy and laboratory areas to reduce the potential for cross-contamination and the spread of pathogenic microorganisms.
Contains germicidal detergent?
Yes.
Exerts sporicidal effect?
No.
Requires precleaning of the target surface?
Only surfaces that are grossly soiled with organic matter require precleaning.
Requires rinsing?
No. This product is for use only on nonfood-contact surfaces.
Inactivated by
A heavy organic soil load (i.e., greater than 5%).
Presentation
Available as a wipe in multiple counts/sizes and as a solution in a 32-oz spray bottle and in 1-gal and 5-gal containers. Accel TB wipes and solution are not offered sterile. The compatibility of wipes for the required ISO class must be verified before they are used.
USP Chapter <797> compliant?
Yes.
CGMP compliant?
Yes.
EPA registered?
Yes.
Applications
Use on environmental surfaces in pharmaceutical cleanrooms, work stations, and laboratories. Also appropriate for use on isolator hoods, work tables, and compounding equipment and for the cleaning of floors, ceilings, and walls in segregated compounding areas and in buffer, anteroom, and cleanroom areas. A surface (especially floors) treated with Accel TB should be rinsed with sterile water to remove trace surfactants.
Effective against
Gram-negative and gram-positive vegetative bacteria, enveloped and nonenveloped viruses, fungi, and mycobacteria. Please see www.viroxhealthcare.com for a complete list of the pathogens against which this product is effective.
When to use this disinfectant
During cleaning and disinfection according to the pharmacy's SOP or in accordance with state and federal guidelines.
Minimum contact time
The nonalcohol formulation ensures that the treated surface remains adequately wet for the entire required contact time of 30 sec for the broad-spectrum nonfood-contact sanitizing of hard surfaces, 1 min for virucidal and bactericidal disinfection, 1 min for sanitizing soft surfaces, 5 min for tuberculocidal disinfection, and 10 min for fungicidal disinfection.
Residue
Trace amounts of nonactive residue remain after this product has been used.
Preparation for use (dilution, etc., required)
Ready to use; requires no mixing or dilution.

TABLE 1. Continued.

Cautions or special instructions about storage and use

Keep out of reach of children. Do not store in direct sunlight. Avoid storing this product at an elevated temperature (recommended long-term storage temperature range, 15°C-30°C). PPE is not required if the product is used as directed, but avoid contact with eyes and wash hands after using the product and before eating. Do not use on heavy metals such as copper, brass, etc. Do not use with Delrin (E. I. du Pont de Nemours and Company, Wilmington, Delaware). Do not mix with other chemicals or concentrated bleach products.

Contraindications for use

Compatible with most materials, but check the material compatibility chart and/or test the product in an inconspicuous area on the target surface to confirm material suitability.

Expiration date

Three years from the date of manufacture.

PROCEDURE FOR USE

Before applying Accel TB, clean (with Accel TB or detergent and either potable water or pyrogen-free water) all target surfaces that are grossly soiled with organic matter.

*Disinfection of **hard** surfaces (disinfection plus sanitization)*

Use a cloth or a disposable wipe to apply Accel TB to the target surface. Ensure that the treated surface remains sufficiently wet for 1 min if used as a bactericide or virucide, 5 min if used as a tuberculocide, and 10 min if used as a fungicide. For broad-spectrum nonfood-contact sanitizing, apply Accel TB to the target surface with a cloth or a disposable wipe and ensure that the treated surface remains wet for 30 sec. Wipe the treated surface or object dry with a cloth or a disposable wipe. The rinsing of nonfood-contact surfaces is not required after this product has been applied, although periodic damp wiping is considered best practice for treated surfaces and high-risk equipment. ***Note: If this product is used before sterile compounding, then sterile cloths, sterile disposable wipes, and sterile water for irrigation must be used. Disinfection must be followed by a rinse with sterile water, and the treated surface must be wiped dry with a sterile cloth.***

*Disinfection of **soft** nonsterile surfaces (sanitization)*

- Hold the bottle upright 6-8 inches from the target surface.
- Spray until the fabric is wet. Do not saturate the fabric.
- Let the treated fabric stand for 1 min. Allow to air dry.

VALIDATION OF EFFECTIVENESS

To ensure that Accel TB is effective against specific organisms, perform environmental monitoring per *USP* Chapter <797> guidelines.

MANUFACTURER'S CONTACT INFORMATION

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CGMP = current good manufacturing practice; EPA = Environmental Protection Agency; ISO = International Organization for Standardization; PPE = personal protective equipment; SOP = standard operating procedure; *USP = United States Pharmacopeia*

TABLE 2. Peridox RTU and Peridox RTU Sterile Sporicidal Disinfectants.

MANUFACTURER AND LOCATION

BioMed Protect, LLC
St. Louis, Missouri
USA

TYPE OF DISINFECTANT

Peroxide-based cleaning products /sporicidal disinfectants.

FEATURES

- Exert broad-spectrum sporicidal, bactericidal, virucidal, fungicidal, and tuberculocidal effects.
- Can be used daily, weekly, or monthly as sporicidal disinfectants to meet facility cleaning and disinfecting requirements.
- Contain no alcohol or bleach.
- Ready to use; no mixing or dilution required.

Contain germicidal detergent?

Yes. Peridox RTU and Peridox RTU Sterile contain cleaning agents (surfactants) that allow the product to simultaneously clean and disinfect.

Exert surface sporicidal effect?

Yes.

Require precleaning of the target surface?

Areas that are heavily contaminated with soil loads must be precleaned before either Peridox RTU or Peridox RTU Sterile is applied. Surfaces can be precleaned with either Peridox RTU or Peridox RTU Sterile.

Require rinsing?

Rinsing is not required unless specified by the facility's SOP. Treated surfaces and objects can be allowed to air dry or can be wiped dry with an appropriate disposable sterile wipe. However, *USP* Chapter <797> suggested best practice for Peridox RTU, Peridox RTU Sterile, and all disinfectant products registered with the EPA that are used in or on PECs requires rinsing treated surfaces and objects with sterile IPA and/or sterile water.

Inactivated by

Heavy or excessive soil.

Presentation

- Peridox RTU is available in nonsterile 1-gal and 32-oz bottles.
- Peridox RTU Sterile is terminally sterilized and validated to a sterility assurance level of 10^{-6} in 1-gal and 32-oz bottles.

USP Chapter <797> compliant?

Yes; both Peridox RTU and Peridox RTU Sterile.

CGMP compliant?

Yes; both Peridox RTU and Peridox RTU Sterile.

EPA registered?

Yes; both Peridox RTU and Peridox RTU Sterile (EPA Reg. No. 88089-4).

Applications

Independent laboratory testing[1] has shown that both Peridox RTU and Peridox RTU Sterile, when properly used, are effective in cleaning and decontaminating stainless steel surfaces contaminated by hazardous drugs. Those products can be used in compounding pharmacies (including on and in PECs and SECs, in laboratories, and in processing facilities) to clean and disinfect the surfaces of isolators, laminar flow hoods, biological safety cabinets, work tables, and other equipment. Depending on the requirements of the target area (i.e., sterile or nonsterile), Peridox RTU and Peridox RTU Sterile can be used for the cleaning and disinfection of floors, walls, and ceilings in buffer zones, anteroom areas, and any segregated compounding area without damage to surfaces when used according to the product-label instructions.

Effective against

Both Peridox RTU and Peridox RTU Sterile eliminate spores, viruses, mycobacteria, fungi, and bacteria from surfaces when used according to label instructions. To access the complete list of pathogens against which those products are effective, visit www.contechealthcare.com. http://www.contechealthcare.com/files/documents/dis011_peridox_rtu_efficacy_data.pdf.

TABLE 2. Continued.

When to use Peridox RTU and Peridox RTU Sterile

Daily, weekly, and monthly for cleaning and disinfection or according to the facility's SOP and/or state and federal guidelines.

Minimum contact time

- For both Peridox RTU and Peridox RTU Sterile, the minimum contact times are as follows:
- Mold and fungi = 1 min
- Bacteria and viruses = 2 min
- Spores = 3 min
- Tuberculocidal effects = 5 min

Residue

These products require no rinsing unless stated by the applicable *USP* guidelines or pharmacy's SOP. A small percentage of nonvolatile residue that is usually not visible to the naked eye will remain on the treated surface.

Preparation for use

Ready-to-use; no dilution or rinsing required.

Cautions or special instructions about storage and use

- Store containers in an upright position away from direct sunlight and heat at a temperature range between 32°F and 104°F (0°C and 40°C).
- Do not return either Peridox RTU or Peridox RTU Sterile to the original container. Empty all containers as thoroughly as possible before discarding them.
- Best practices state that appropriate gloves and safety glasses should be worn when either Peridox RTU or Peridox RTU Sterile is handled.
- Do not mix Peridox RTU or Peridox RTU Sterile with other chemicals.
- Do not allow Peridox RTU or Peridox RTU Sterile to remain in prolonged contact with copper, brass, bronze, or other heavy metals.

Contraindications for use

Peridox RTU and Peridox RTU Sterile are compatible with most materials including stainless steel, but check for material compatibility on an inconspicuous area of the target surface or consult the material compatibility chart[2] for either product.

Expiration date

Opened or unopened in the original container:

- Peridox RTU = Two-year shelf-life from the date of manufacture.
- Peridox RTU Sterile = One year shelf-life from the date of irradiation, not to exceed the original expiration date of manufacture.

PROCEDURE FOR USE IN STERILE COMPOUNDING AREAS

- Always follow the product label directions.
- Wear appropriate PPE.
- Preclean the target surface, if necessary.
- Apply Peridox RTU or Peridox RTU Sterile and ensure that the entire target surface is thoroughly wet.
- Leave the surface wet for the required contact time.
- Rinse the treated surface or object with sterile IPA or sterile water if necessary to comply with current *USP* guidelines and/or the pharmacy's SOP.
- Allow treated surfaces and objects to air dry or wipe them dry with an appropriate disposable sterile wipe according to the pharmacy's SOP.

VALIDATION OF EFFECTIVENESS

To ensure that Peridox RTU and Peridox RTU Sterile are effective against specific organisms, perform environmental monitoring per *USP* Chapter <797> guidelines.

MANUFACTURER'S CONTACT INFORMATION

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TABLE 2. Continued.

MANUFACTURER'S CONTACT INFORMATION CONTINUED

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REFERENCES

1. Personal communication. Meiners MJ. Lake Zurich Industrial Hygiene Laboratory. Bureau Veritas North America, Inc., Lake Zurich, Illinois. January 31, 2014. Available at: www.contechealthcare.com/files/documents/Peridox_RTU_Hazardous-Drug-Cleaning-Removal-Test-Summary.pdf. Accessed April 14, 2015.
2. Contec, Inc. *Peridox sporicidal disinfectant and cleaner material compatibility.* [Contec, Inc. Website.] Available at: www.contechealthcare.com/files/documents/dis018_peridox_materialcompatibility.pdf. Accessed June 6, 2015.

EPA = Environmental Protection Agency; IPA = isopropyl alcohol; PPE = personal protective equipment; PECs = primary engineering controls; RTU = ready to use; SECs = secondary engineering controls; SOP = standard operating procedure; *USP = United States Pharmacopeia*

TABLE 3. TX6466 Bru-Clean TbC Disinfectant.

MANUFACTURER AND LOCATION

Manufactured by Medentech, Clonard Road, Wexford, Ireland, for Brulin & Co., Inc., Indianapolis, Indiana.
Distributed by ITW Texwipe, Kernersville, North Carolina.

TYPE OF DISINFECTANT

Chlorine-based compound.

FEATURES

- Effervescent premeasured tablets.
- Provides effective cleaning, deodorizing, and disinfection in areas in which controlling the hazards of cross-contamination on precleaned, hard, nonporous inanimate surfaces (work surfaces, equipment, walls, floors, ceilings, etc.) is of prime importance.
- An alternative to bleach but emits less odor.
- Due to its neutral pH, is much less corrosive to metals and less hazardous for users than liquid bleach.
- The active ingredient has a 2-year shelf life.
- Concentration in a daily-prepared solution remains consistent.
- Functional-use label on each bottle can be used to document (for usage control) the date opened and the operator's initials.

Contains germicidal agent?

Yes.

Exerts sporicidal effect?

No.

Requires precleaning of the target surface?

Yes.

Requires rinsing?

Yes.

Inactivated by

Organic or inorganic matter and reducing agents (e.g., thiosulfate).

Presentation

Each bottle of 270 tablets yields 270 gal of solution (2 bottles/case).

USP Chapter <797> compliant?

Yes.

CGMP compliant?

Yes.

TABLE 3. Continued.

EPA registered?
Yes (71847-2-106).
Applications
For use in sterile and nonsterile compounding areas, hospitals, nursing homes, medical and dental offices and clinics, operating rooms, isolation wards, and medical research facilities. Can also be used to preclean or decontaminate critical or semicritical medical devices before their sterilization or high-level disinfection.
Effective against
For a complete list of the bacteria, viruses, fungus, and diseases against which this product is effective, please see the product label.
When to use this disinfectant
During cleaning and disinfection according to the pharmacy's SOP.
Minimum contact time
Allow the disinfectant solution to remain wet on the treated surface for 10 min or until the treated surface has dried.
Residue
The residue must be removed with sterile water for irrigation or with sterile 70% IPA.
Cautions or special instructions about storage and use
Store in a properly labeled container to protect against contamination. Avoid breathing the dust that is generated when the tablets rub against each other in the product container. Prevent contact with eyes, skin, and clothing by wearing appropriate PPE (e. g., rubber gloves, safety glasses, a face shield) when preparing the solution. Wash hands thoroughly with soap and water after handling the product or solution. Other reasonable precautions not included on the EPA label are: - Do not reuse the empty container. - Keep this product under locked storage and ensure that it is inaccessible to children and people unfamiliar with its proper use. - Do not use or store near heat or an open flame.
Contraindications for use
This product is not to be used as a terminal sterilant or a high-level disinfectant on any surface or on any instrument that: (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.
Factors that inactivate this disinfectant
Organic and inorganic matter deactivate the active ingredient; thus precleaning the target surface is required.
Expiration date
Two years after manufacture.
PROCEDURE FOR USE IN STERILE COMPOUNDING AREAS
Add 1 tablet to 1 gal of sterile water for irrigation (25°C/77°F) to obtain a concentration of 937 ppm (mg/L) of available chlorine. This solution should be freshly prepared. Use on the same day of preparation and discard any unused solution. Apply the solution to precleaned, hard, nonporous inanimate surfaces and use a sterile brush, spray device, sponge, cloth, or mop to wet all surfaces thoroughly. Allow the treated surfaces to remain wet for 10 min; then wipe the treated surfaces with a sterile brush, sponge, or cloth. For sprayer application, fill a coarse-spray device with the solution, spray 6-8 inches from the target surface, and then rub the treated area with a sterile brush, sponge, or cloth. After treatment with TX6466 Bru-Clean TbC, all surfaces in the area must be thoroughly rinsed with sterile water for irrigation.
VALIDATION OF EFFECTIVENESS
Disinfection-effectiveness validation should be performed according to the pharmacy's SOP for established frequency.
CONTACT INFORMATION
ITW Texwipe Customer service: 800-839-9473 Customer service fax: 336-996-2297 info@texwipe.com

CGMP = current good manufacturing practice; EPA = Environmental Protection Agency; IPA = isopropyl alcohol; PPE = personal protective equipment; SOP = standard operating procedure; *USP = United States Pharmacopeia*

TABLE 4. TX650 TexQ Disinfectant and TX651 TexQ Disinfectant.

MANUFACTURER AND LOCATION

ITW Texwipe, Kernersville, North Carolina.

TYPE OF DISINFECTANT

Quaternary ammonium compounds.

FEATURES

- Appropriate to use before and after preparing sterile or nonsterile compounds.
- Effective for hard-surface one-step cleaning plus disinfection.
- Available in both ready-to-use and concentrate solutions. The ready-to-use solution is designed to be applied without mixing or activation. The concentrate must be diluted before application (the dilution rate is 2 oz of concentrate per 1 gal of sterile water for irrigation). In sterile compounding areas, sterile water for irrigation must be used for rinsing either form of this product.
- Can be used to clean and disinfect walls, floors, ceilings, work surfaces, and equipment.
- Provide uniform and complete surface coverage.
- Inhibit the growth of mold and mildew and their odors when used as directed.
- Contain no phosphorous or abrasives.
- Free of dye and fragrance.
- Manufactured in the U.S.
- Sterile-validation documents available on request.
- Gamma irradiated.
- Effective against the pathogens listed on the product label.

Contain germicidal agent?

Yes.

Exert sporicidal effect?

No.

Require precleaning of the target surface?

Only for areas that are heavily soiled with organic or inorganic matter or when visible soil is present.

Require rinsing?

Yes.

Inactivated by

Anionic soaps and detergents (e.g., the anionic surfactant sodium lauryl sulfate) in some cleaning products, polysorbate(s), lecithin, and excessive (i.e., visible) organic or inorganic soil.

Presentation

Available in 2 forms: a ready-to-use spray solution (TX650 TexQ disinfectant) in 22-oz bottles (12 or 4 bottles/case) for small surfaces (tables, equipment, etc.) and a concentrate solution (TX651 TexQ disinfectant) (4 bottles/case) in 1-gal containers for large surfaces. One gal of concentrate makes 64 gal of ready-to-use solution. The bottles and the containers have a functional-use label to document (for usage control) the date opened and the operator's initials.

USP Chapter <797> compliant?

Yes.

CGMP compliant?

Yes. Manufactured under ISO 9001, 13485, and 14001 compliance.

EPA registered?

Yes.

Applications

These products can be used on hard nonporous surfaces, objects, and equipment such as:
Glass; Plexiglas; laminated surfaces; metal; stainless steel; glazed porcelain or ceramic; sealed granite, marble, slate, stone, terra cotta, limestone, or terrazzo; plastics such as polycarbonate, polyvinylchloride, polystyrene, or polypropylene; chrome; vinyl; shelves; racks; vanity tops; carts; tables; chairs; desks; folding tables; work stations, lifts; washable walls; cabinets; doorknobs; garbage cans and pails; trash barrels, cans, and containers; cuspidors and spittoons; enameled surfaces; painted or otherwise finished woodwork; Formica (the Diller Corporation, a Fletcher Building [Auckland, New Zealand] company); washable wallpaper; windows; mirrors; and external lenses for vision correction, including eyeglasses.

TABLE 4. Continued.

Effective against
For a complete list of the bacteria, viruses, and fungi against which these products are effective, please see the product label.
When to use these disinfectants
TexQ disinfectants should be used during cleaning and disinfection according to the pharmacy's SOP.
Minimum contact time
Leave the treated surface wet for at least 10 min or until the surface dries.
Residue
Yes; the residue should be removed with 70% IPA or sterile water for irrigation.
Preparation for use
Spray the ready-to-use solution from the 22-oz bottle onto a sterile wipe and wipe the surface. Avoid spraying the product directly onto the target surface (doing so may spread contamination from the spray pressure). The concentrated solution must be diluted as follows: 2 oz of concentrate per 1 gal of sterile water for irrigation.
Cautions or special instructions about storage and use
- Store only in the original container. - Do not reuse empty containers. - Keep these products under locked storage and ensure that they are inaccessible to children and people unfamiliar with their proper use. - Avoid contact with eyes, skin, and clothing by wearing appropriate PPE during the use of either the diluted form of this product or the concentrate. After contact with either form of this product (and especially before eating, drinking, using tobacco, or using the toilet), wash hands thoroughly with soap and potable water. - Do not use or store near heat or an open flame. - Do not breathe the product-generated spray mist. - Prevent the ingestion of either the concentrate (which is corrosive and also causes irreversible eye damage and skin burns) or the diluted product.
Contraindications for use
Not for use on contact lenses.
Factors that inactivate these disinfectants
Anionic compounds such as soaps and detergents, polysorbate(s), lecithin, and visible organic soil or inorganic soil.
Expiration date
One year after the production date.
PROCEDURE FOR USE IN STERILE COMPOUNDING AREAS
Note: Use only sterile products or tools (water, mops, buckets, 70% IPA) for the treatment of sterile compounding areas.
TX650 TexQ disinfectant ready-to-use spray solution
1. Spray the disinfectant onto a sterile wipe to the needed level of wetness. 2. Wipe the target surface with that sterile wipe. 3. Allow the treated surface to remain wet for the 10-min contact time. 4. Remove the residue with a sterile wipe and either sterile 70% IPA or sterile water for irrigation.
TX651 TexQ disinfectant concentrate solution
1. Pour 1 gal of sterile water for irrigation into a sterile bucket. 2. Add 2 oz of TexQ concentrate per 1 gal of sterile water for irrigation and mix. 3. Use a sterile mop to apply the solution to the target surface (floor, wall, etc.). 4. Allow the treated surface(s) to remain wet for the 10-min contact time. 5. Use another sterile mop to remove the residue with either sterile water for irrigation or sterile 70% IPA.
VALIDATION OF EFFECTIVENESS
Disinfection-effectiveness validation should be performed with an established frequency according to the pharmacy's SOP. TX650 TexQ and TX651 TexQ are validated for sterility, and their certificates of validation are available to customers.
MANUFACTURER'S CONTACT INFORMATION
ITW Texwipe Customer service, 800-839-9473 Customer service fax, 336-996-2297 info@texwipe.com

CGMP = current good manufacturing practice; EPA = Environmental Protection Agency; IPA = isopropyl alcohol; PPE = personal protective equipment; SOP = standard operating procedure; *USP = United States Pharmacopeia*

TABLE 5. Quality System Requirements: CGMP Versus *USP* Chapter <797>.

QUALITY SYSTEM REQUIREMENT	CGMP	*USP* CHAPTER <797>
Cleaning validation	Yes	No
Use of sterile disinfectants	Yes	Only isopropyl alcohol

CGMP = current good manufacturing practice; *USP = United States Pharmacopeia*

Adapted from: Kastango ES, Douglass KH. Quality standards for large-scale sterile compounding facilities. [The Pew Charitable Trusts Website] May 21, 2014. Available at: www.pewtrusts.org/en/research-and-analysis/analysis/2014/05/21/ensuring-the-safety-of-compounded-drugs. Accessed March 18, 2015.