



VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



SPORE-CURE[®]

Hard Surface Broad Spectrum Disinfectant

Claims, product registrations, and regulatory requirements may vary based on local, regional, and/or national laws and regulations. Please contact your local sales representative for information specific to your region.

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SPORE-CURE Family of Products

Veltek Associates, Inc.

15 Lee Boulevard, Malvern, PA 19355-1234

Tel: 610-644-8335 Fax: 610-644-8335 www.sterile.com

09JUN2025 / MLD25 / DECON, C

PRODUCT OVERVIEW

SPORE-CURE, a 130 PPM hypochlorous acid solution formulated with USP grade sodium hypochlorite and Water for Injection, has been designed for pharmaceutical, medical device, biopharmaceutical, biotechnology, and healthcare facilities that demand maintenance of a clean and critical environment. **SPORE-CURE** is a registered sporicide, virucide, disinfectant, and fungicide. **SPORE-CURE** can also be utilized as a cleaner. This solution can be used as a cleaner on numerous cleanroom surfaces with reduced consequences of corrosion, pitting, and rusting. **SPORE-CURE** has been developed for use in cleaning rotation cycles where hard surface disinfectants are essential for reducing cross-contamination. As an effective one-step, ready-to-use cleaner, **SPORE-CURE** contains no VOCs, reducing concerns seen in VOC containing products.

Sporicide – Disinfectant – Fungicide – Virucide – Cleaner

SPORE-CURE is manufactured via aseptic fill, filtered at 0.2 microns into gamma irradiated sterile components in ISO 5 (Grade A). Each lot of **SPORE-CURE** is sterility tested according to current USP Compendium, is completely traceable, and has been completely validated for sterility and shelf life. **SPORE-CURE** is delivered each time with lot specific analytical and sterility data.

SPORE-CURE is sterile in a 16 oz trigger spray, 32 oz trigger spray, or 1 gallon container. Each sterile container is individually double bagged and packaged in two liner bags using the ABCD Cleanroom Introduction System®.

Quality and Manufacturing

- Formulated with USP Water for Injection
- Filled in an ISO 5 (Grade A)
- Filtered at 0.2 microns
- Components are air washed with 0.2 micron filtered air
- Aseptically filled into components sterilized via gamma irradiation
- Lot sterility tested according to current USP compendium
- Completely traceable from start to finish
- Completely validated for sterility and shelf life

Features and Benefits

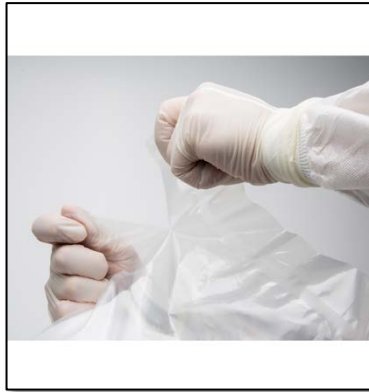
- Spore Cure is registered with Health Canada, DIN 02557150
- SPORE-CURE is an effective sporicide, virucide, disinfectant, and fungicide
- SPORE-CURE disinfects and cleans in one operation
- Each sterile container is double bagged packaged in easy tear bags
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific analytical and sterility data
- Specifically formulated as a sterile cleanroom pharmaceutical formula
- Compatible with common cleanroom surfaces
- 16 oz and 32 oz containers come with an unattached sterile trigger spray
- Very low remaining residue
- Effective against *Clostridioides difficile* spores with a 5 minute contact time

Product Uses

- Hard surface cleaner, disinfectant, fungicide, virucide, and sporicide
- Hard non-porous, inanimate, surfaces in aseptic filling and gowning rooms, general manufacturing areas and laboratories
- Machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves, made of plastic, Plexiglas®, glass, vinyl, glazed porcelain, laminates, glazed tile, and stainless steel.

ABCD Cleanroom Introduction System®

The ABCD Cleanroom Introduction System is a packaging system that allows operators/users to take the package through each level of classified areas by simply removing one bag at a time. Each bag acts as barrier protecting the finished product from becoming a carrier of viable and non-viable contamination. This prevents the need to decontaminate each outer bag prior to entering a cleaner area. In this packaging system, sterilized groups of containers are contained in two outer bags and after each are removed individual containers are each additionally contained in two easy tear bags.



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PRODUCT SPECIFICATIONS

SPORE-CURE – Hard Surface Broad Spectrum Disinfectant	
Certificate of Analysis	Specification
Free Available Chlorine	160 - 270 ppm
Hypochlorous Acid	0.0118 – 0.200%
Appearance	Colorless & Free of Particles
pH	4.5 - 6.0
LAL Result	< 0.25 EU/mL
USP Sterility	PASS

ORDERING INFORMATION

SPORE-CURE – Hard Surface Broad Spectrum Disinfectant		
Part Number	Description	Qty/cs
SPC-02-C	SPORE-CURE, 1 Gallon, RTU, Sterile	4
SPC-16Z-C	SPORE-CURE, 16 oz unattached Trigger Spray, Sterile	12
SPC-32Z-C	SPORE-CURE, 32 oz unattached Trigger Spray, Sterile	12



*SPORE-CURE
Sterile 1 Gallon RTU
SPC-02-C*



LABELING

VAI's Product Label Colors

Product Name	Bottle/Can Color	Label Background Color	Bar & User Info Color	Text Color
DECON-AHOL WFI FORMULA 70% AEROSOL	COOL GREY	PRINTED CAN COOL GREY		
DECON-AHOL WFI FORMULA 70% TRIGGER SPRAY, 1 & 5 GALLON	WHITE	COOL GREY		
DECON-AHOL WFI FORMULA 70% SQUEEZE BOTTLE	WHITE SEMI-TRANSPARENT	COOL GREY		
DECON-AHOL WFI FORMULA 70% ASEPTI-CLEANSE BOTTLE	WHITE SEMI-TRANSPARENT	COOL GREY		
DECON-AHOL WFI FORMULA 60%	WHITE	COOL GREY		
DECON-AHOL WFI FORMULA 91%	WHITE	COOL GREY		
DECON-AHOL FORMULA 99%	WHITE	COOL GREY		
STER-AHOL WFI AEROSOL	WHITE	PRINTED CAN WHITE		
STER-AHOL WFI TRIGGER SPRAY, 1 & 5 GALLON	WHITE	WHITE		
DECON-HAND STERILE	WHITE SEMI-TRANSPARENT	PRINTED BOTTLE		
DECON-HAND NON-STERILE	CLEAR	PRINTED BOTTLE		
DECON-HAND ASEPTI-CLEANSE BOTTLE	WHITE SEMI-TRANSPARENT	WHITE		
STERI-OIL	WHITE	WHITE		
STERI-BUFFER	CLEAR	WHITE		
DECON-PHENE	WHITE	WHITE		
DECON-CYCLE	WHITE	WHITE		
DECON-CLEAN	WHITE	WHITE		
DECON-QUAT 100	WHITE	WHITE		
DECON-QUAT 200C	WHITE	WHITE		
DECON-QUAT 200V	WHITE	WHITE		
HYPO-CHLOR 0.25%	WHITE	WHITE		
HYPO-CHLOR 0.52%	WHITE	WHITE		
HYPO-CHLOR 5.25%	WHITE	WHITE		
HYPO-CHLOR Neutral 0.25%	WHITE	WHITE		
HYPO-CHLOR Neutral 0.52%	WHITE	WHITE		
STERI-PEROX 3%	WHITE	WHITE		
STERI-PEROX 6%	WHITE	WHITE		
DECON-SPORE 200 PLUS (SPORICIDE)	WHITE SEMI-TRANSPARENT	WHITE		
DECON-SPORE 200 PLUS (DISINFECTANT)	WHITE SEMI-TRANSPARENT	WHITE		
STEEL-BRIGHT	WHITE	WHITE		
STERI-SILICON	WHITE	BLACK		
DECON-GLASS	WHITE	WHITE		
VAI WFI QUALITY WATER	WHITE	WHITE		
STERI-WATER	WHITE	WHITE		
SPORE-CURE	WHITE	WHITE		

Product Labeling

SPORE-CURE

For Use in Cleanrooms and Controlled Areas

Hard Surface Broad Spectrum Disinfectant • Hypochlorous acid at 0.013% w/w formulated with USP Water for Injection Quality Water

Sterile • Aseptically Filtered at 0.2 µm • Ready to Use

SPORE-CURE®

For Use in Cleanrooms and Controlled Areas/Utilisable dans les salles blanches et les zones contrôlées

Hard Surface Broad Spectrum Disinfectant/Désinfectant de surface dure à large spectre - USP Water for Injection Quality Water/Eau de qualité injectable USP - Filtered at 0.2 µm and Aseptically Filled into Presterilized Components/Filtré à 0,2 µm et rempli aseptiquement dans des composants pré-stérilisés - Ready to Use/Prêt à l'emploi

Active Ingredients/Ingrédients Actifs:

Hypochlorous Acid CAS# 7790-92-3	0.013%
OTHER INGREDIENTS:	99.987%
TOTAL:	100.00%

*Equivalent to 180 ppm Free Available Chlorine (FAC)/Équivalent à 180 ppm de chlore libre disponible (CLD).

After opening, discard any unused material after 30 days./Après ouverture, jeter tout produit non utilisé après 30 jours.

KEEP OUT OF REACH OF CHILDREN/GARDER HORS DE LA PORTÉE DES ENFANTS

Net Contents/Contenu Net:

473 mL x 12 (5.7 L)
Reorder/Commandez à nouveau # SPC-16Z-C

946 mL x 12 (11.4 L)
Reorder/Commandez à nouveau # SPC-32Z-C

3.79 L x (15.2 L)
Reorder/Commandez à nouveau # SPC-02-C

Label/Étiquette # SPC-00-C - Sterile/Stérile - Rev 05/25
See container for lot number and storage expiration date./Voir le récipient pour le numéro de lot et la date d'expiration de stockage.
US and Foreign Patents: www.sterile.com/patents
DIN: 0255750

Made in USA

Manufactured By/Fabriqué Par:
Veltek Associates, Inc.
15 Lee Blvd. Malvern, PA 19355-1234 USA
Tel: 610-644-8335 • www.sterile.com

Imported by/Au Canada, distribué par:
CCR (Canada Clean Room)
20 Cope Drive, Kanata, ON K2M 2V8
Questions? Comments? (888) 595-8070

PRECAUTIONARY STATEMENTS
PHYSICAL OR CHEMICAL HAZARDS: SPORE-CURE is not compatible with other chemicals such as acids and hydrogen peroxide.

DIRECTIONS FOR USE
This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or 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 which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product can be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

SPORE-CURE® is ready to use. DO NOT DILUTE.

LOCATIONS OF USE: Disinfects cleanrooms and controlled areas such as those in hospitals and health care institutions, and biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing, and cosmetic manufacturing. Use on hard non-porous, nonmetallic surfaces in aseptic filling and gowning rooms, general manufacturing areas and laboratories or: machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves, made of plastic, Plexiglas®, glass, vinyl, glazed porcelain, laminates, glazed tile, and stainless steel. It is compatible with most hard non-porous surface materials. Not for use on food contact surfaces.

SPORICIDAL: SPORE-CURE® is an effective sporicide against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584) on non-porous hard surfaces in 6 hours. Pre-clean all surfaces. Thoroughly wet surface by immersion or soaking with this product and allow surface to soak or remain visibly wet for a minimum of 6 hours. Allow surface to air dry, or after 6 hours rinse and wipe dry with sterilized cloth wiper, if desired.

Sporicidal Clostridioides difficile This product kills and/or inactivates spores of *Clostridioides difficile* on hard, non-porous surfaces that are visibly clean in the presence of organic soil.

Special Instructions for Cleaning Prior to Disinfection Against Clostridioides difficile Spores
Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.

Contact Time: Leave surface wet for 5 minutes.

Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the disinfectant product. The cleaning may be accomplished with any cleaning solution, including this product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

Infectious Materials Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

MISES EN GARDE
RISQUES D'ORIGINE PHYSIQUE OU CHIMIQUE: SPORE-CURE incompatible avec d'autres produits chimiques tels que les acides et le peroxyde d'hydrogène (eau oxygénée).

DIRECTIVES D'UTILISATION
Ce produit ne doit pas être utilisé en tant que stérilisant terminal / désinfectant de haut niveau sur un instrument qui (1) est introduit directement dans le corps humain, soit dans ou en contact avec le flux sanguin ou des zones normalement stériles du corps, ou (2) qui entre en contact avec les membranes intactes mais qui ne pénètre normalement pas la barrière du sang ou s'introduit autrement des zones stériles du corps. Ce produit peut être utilisé pour un pré-nettoyage ou pour une décontamination d'appareils critiques ou semi-critiques avant la stérilisation dans le cadre d'une désinfection de haut niveau.

Le SPORE-CURE est prêt à l'emploi. Ne pas diluer.

LIEUX D'EMPLOI: Désinfecte les salles blanches et les zones contrôlées telles que hôpitaux et celles des établissements de soins de santé, des entreprises biopharmaceutiques, pharmaceutiques, de fabrication d'appareils médicaux et de diagnostic, et de fabrication de produits cosmétiques. Utilisation sur des surfaces inanimées non poreuses de salles de conditionnement aseptique et d'habillage, des zones de fabrication générale et des laboratoires ou sur la machinerie, des outils, des tables, des comptoirs, des bancs à flux laminaire, des planchers, des murs, des chariots, des étagères faites de plastique, Plexiglas®, de verre, de vinyle, de porcelaine émaillée, de laminés, de carreau vernissé et d'acier inoxydable. Il est compatible avec la plupart des matériaux de surfaces dures non poreuses. Ne pas utiliser sur les surfaces en contact avec les aliments.

SPORICIDE: SPORE-CURE® est un sporicide efficace en 6 heures contre *Bacillus subtilis* (ATCC 19659) et *Clostridium sporogenes* (ATCC 3584) sur les surfaces dures non poreuses. Pré-nettoyer toutes les surfaces. Mouiller abondamment la surface par immersion ou trempez avec le produit et laissez la surface tremper ou demeurez visiblement humides pendant au moins 6 heures. Laissez sécher la surface à l'air, ou après 6 heures, essuyer complètement avec un chiffon de tissu stérilisé si nécessaire.

Sporicide pour le Clostridioides difficile Ce produit tue et/ou désactive les spores de Clostridioides difficile sur les surfaces dures et non poreuses qui sont visiblement propres en présence de sol organique.

Instructions spéciales pour le nettoyage avant la désinfection contre le Clostridioides difficile Protection personnelle: Porter une protection adéquate, comme des gants, une blouse de laboratoire, un masque ou des lunettes de protection.

Durée de contact: Laisser la surface humide pendant 5 minutes.

Procédure de nettoyage: Les matières/déchets fécaux doivent être soigneusement nettoyés des surfaces/objets avant la désinfection par application avec un chiffon propre, une vadrouille et/ou une éponge imprégnée du désinfectant. Le nettoyage peut être effectué avec n'importe quelle solution de nettoyage, y compris ce produit. Le nettoyage doit inclure un essuyage et/ou un frottement vigoureux, jusqu'à ce que toute la terre visible soit éliminée. Une attention particulière est requise pour les surfaces à contact élevé. Les surfaces de la salle des patients doivent être nettoyées de manière appropriée, par exemple de droite à gauche ou de gauche à droite, sur les surfaces horizontales et de haut en bas, sur les surfaces verticales, afin de minimiser la propagation des spores. Les toilettes doivent être nettoyées en dernier. Ne pas réutiliser les chiffons sales.

Élimination des matières infectieuses: Les matières utilisées lors du nettoyage qui peuvent contenir des matières fécales/déchets doivent être mises au rebut immédiatement conformément à la réglementation locale relative à l'élimination des matières infectieuses.

SPORE-CURE
Case Label SPC-00-C
Rev 05/25

Any specific product label is available upon request.



Product Labeling (Continued)

SPORE-CURE

For Use in Cleanrooms and Controlled Areas

Hard Surface Broad Spectrum Disinfectant • USP Water for Injection Quality Water • Filtered at 0.2 µm and Aseptically Filled into Presterilized Components • Ready to Use

ACTIVE INGREDIENTS:

Hypochlorous Acid CAS# 7790-92-3.....* 0.013%

OTHER INGREDIENTS:.....99.987%

TOTAL:.....100.00%

*Equivalent to 180 ppm Free Available Chlorine (FAC). After opening, discard any unused material after 30 days.

KEEP OUT OF REACH OF CHILDREN

Label # SPC-00-C • Sterile • Rev 05/25

See container for lot number and storage expiration date.

US and Foreign Patents: www.sterile.com/patents

DIN: 02557150

Made in USA

PRECAUTIONARY STATEMENTS

PHYSICAL OR CHEMICAL HAZARDS: SPORE-CURE is not compatible with other chemicals such as acids and hydrogen peroxide.

DIRECTIONS FOR USE

This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or 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 which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product can be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

SPORE-CURE is ready to use. DO NOT DILUTE.

LOCATIONS OF USE: Disinfects cleanrooms and controlled areas such as those in hospitals and health care institutions, and biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing, and cosmetic manufacturing. Use on hard non-porous, inanimate, surfaces in aseptic filling and gowning rooms, general manufacturing areas and laboratories or: machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves, made of plastic, Plexiglas®, glass, vinyl, glazed porcelain, laminates, glazed tile, and stainless steel. It is compatible with most hard non-porous surface materials. Not for use on food contact surfaces.

Product Labeling (Continued)

SPORICIDAL: SPORE-CURE is an effective sporicide against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584) on non-porous hard surfaces in 6 hours. Pre-clean all surfaces. Thoroughly wet surfaces by immersion or soaking with this product and allow surface to soak or remain visibly wet for a minimum of 6 hours. Allow surface to air dry, or after 6 hours rinse and wipe dry with sterilized cloth wiper, if desired.

Sporicidal *Clostridioides difficile* This product kills and/or inactivates spores of *Clostridioides difficile* on hard, non-porous surfaces that are visibly clean in the presence of organic soil.

Special Instructions for Cleaning Prior to Disinfection Against *Clostridioides difficile* Spores

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.

Contact Time: Leave surface wet for 5 minutes.

Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the disinfectant product. The cleaning may be accomplished with any cleaning solution, including this product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

Infectious Materials Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

***VIRUCIDAL:** The results of ASTM Efficacy Tests show that SPORE-CURE is an effective virucide on inanimate, non-porous, non-food contact surfaces, demonstrated in testing against *Influenza A Virus, H1N1 (Strain A/PR/8/34) in 3 minutes. Pre-clean visibly soiled surfaces. Thoroughly wet surface with this product and allow to remain wet for a minimum of 3 minutes. Allow surface to air dry, or after 3 minutes rinse and wipe dry with sterilized cloth wiper, if desired.

DISINFECTION: SPORE-CURE is an effective hard surface disinfectant on inanimate, non-porous, non-food contact surfaces as demonstrated in testing against *Pseudomonas aeruginosa* (ATCC# 15442), and *Staphylococcus aureus* (ATCC# 6538) in 3 minutes. Pre-clean all surfaces. Thoroughly wet surface with this product and allow to remain wet for a minimum of 3 minutes. Allow surface to air dry, or after 3 minutes rinse and wipe dry with sterilized wiper, if desired.

FUNGICIDAL: SPORE-CURE is an effective fungicide on inanimate, non-porous non-food contact surfaces, demonstrated by the results of AOAC Efficacy Tests against *Trichophyton interdigitale* (ATCC # 9533) in 3 minutes. Pre-clean all surfaces. Thoroughly wet surface with this product and allow to remain wet for a minimum of 3 minutes. Allow surface to air dry, or after 3 minutes, rinse and wipe dry with sterilized wiper, if desired.

SANITIZATION OF NON-FOOD CONTACT SURFACES: SPORE-CURE is an effective sanitizer on inanimate, non-porous non-food contact surfaces demonstrated in testing against *Staphylococcus aureus* (ATCC#6538) and *Klebsiella pneumoniae* (ATCC#4352) in 90 seconds. Pre-clean all surfaces. Thoroughly wet surface with this product and allow to remain wet for a minimum of 90 seconds. Allow surface to air dry, or after 90 seconds, rinse and wipe dry with sterilized cloth wiper, if desired.

Product Labeling (Continued)

Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

Storage: Store in original container in a cool dry area away from direct sunlight and heat to avoid deterioration.

Disposal: For information on disposal of unused, unwanted product, contact the manufacturer or the appropriate municipal/provincial/territorial agency or product stewardship organization.

Container Handling: Non-refillable container. Do not reuse or refill this container to hold materials other than this product. Offer container for recycling if available and dispose of in a sanitary landfill, or by incineration.



*SPORE-CURE
Sterile 16 oz unattached Trigger Spray
SPC-16Z-C*

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TESTING SUMMARY

SPORE-CURE Efficacy Summary

SPORE-CURE has been tested to certified AOAC efficacy standards. The product has achieved passing results supporting claims including bactericidal, fungicidal, sporicidal, & virucidal. Based on the AOAC certified testing presented below, SPORE-CURE is effective as a fungicide, bactericide and virucide at 3 minutes, and sporicide at 6 hours.

AOAC 961.02						
Acceptance Criteria: No visible growth observed in any carrier.						
Conditions: Organic Soil Load – N/A Contact Time: 3 minutes Contact Temperature: 20°C ± 1°C Contact Relative Humidity: 59-60% RH Performed to GLP standards	Test Organism	Carrier Population (Test Geometric mean CFU/Carrier)	Sample Lot	# Carriers	# Positive	
		<i>Trichophyton interdigitale</i> ATCC 9533	6.1 x 10 ⁴	1	10	0/10
				2	10	0/10

AOAC 961.02					
Acceptance Criteria: No visible growth observed in any carrier for each organism.					
Conditions: Organic Soil Load – N/A Contact Time: 3 minutes Contact Temperature: 20°C ± 1°C Contact Relative Humidity: 67-68% RH Performed to GLP standards	Test Organism	Carrier Population (Test Geometric mean CFU/Carrier)	Sample Lot	# Carriers	# Positive
	<i>Staphylococcus aureus</i> ATCC 6538	1.2 x 10 ⁶	1	60	0/60
			2	60	0/60
			3	60	0/60
	<i>Pseudomonas aeruginosa</i> ATCC 15442	6.4 x 10 ⁵	1	60	0/60
			2	60	0/60
			3	60	0/60

Testing Summary (Continued)

AOAC 966.04						
Acceptance Criteria: No visible growth is observed in any subculture broth tubes.						
Conditions: Organic Soil Load – N/A Contact Time: 6 hours Contact Temperature: 20°C ± 1°C Contact Relative Humidity: 40-45.4% RH Performed to GLP standards	Test Organism	Carrier Population (Test Geometric mean CFU/Carrier)	Sample Lot	# Carriers	# Positive	
	<i>Bacillus subtilis</i> ATCC 19659		1.8 x 10 ⁶	1	60	0/60
				2	60	0/60
				3	60	0/60
	<i>Clostridium sporogenes</i> ATCC 3584		5.6 x 10 ⁵	1	60	0/60
				2	60	0/60
				3	60	0/60

ASTM E1053-20					
Acceptance Criteria: Demonstrate at least a 3log ₁₀ reduction in viral titer.					
Conditions: Organic Soil Load – 5.0% Contact Time: 3 minutes Contact Temperature: 20°C ± 1°C Contact Relative Humidity: 46-47% RH Performed to GLP standards	Test Organism	Sample Lot	Carrier Population	Log ₁₀ Reduction per Carrier	
	<i>Influenza A Virus (H1N1)</i> Strain: A/PR/8/34		1	5.68log ₁₀	≥4.48
			2	5.68log ₁₀	≥4.54

Testing Summary (Continued)

ASTM E3218					
Acceptance Criteria: Demonstrate at least a 6log ₁₀ reduction of viable spores.					
Conditions: Organic Soil Load – OECD three-part soil Contact Time: 5 minutes Contact Temperature: 22°C ± 1°C Contact Relative Humidity: 26-52.5% RH Performed to GLP standards	Test Organism	Sample Lot	Carrier Population	Log ₁₀ Reduction per Carrier	
	<i>Clostridioides difficile</i> ATCC 43598		1	6.62 log ₁₀	≥6.62
			2	6.64 log ₁₀	≥6.64
			3	6.76 log ₁₀	≥6.76

Compatibility Study of Various Cleanroom Materials with SPORE-CURE

Table 1: Summary of 30-Day Compatibility Results for Various Cleanroom Materials with SPORE-CURE		
Cleanroom Material – Composition	250ppm HOCl Effect on Cleanroom Material	Maintenance Procedure*
Ceramic Carpet - Quartz	No Effect	None Required
Epoxy	No Effect	None Required
Vinyl	No Effect	None Required
DECOCLEAN – Rigid wall	No Effect	None Required
MIPOLAM - Vinyl	No Effect	None Required
STONHARD® - Resin	No Effect	None Required
GTI Max – Vinyl and polyurethane	No Effect	None Required
PlexiGlas®	No Effect	None Required
Sherwin Williams SofTop® – Epoxy resin	No Effect	None Required

*Procedure required to renew or prevent degradation of surface

ADDITIONAL DOCUMENTATION

Upon request, the following additional documentation is available:

- Product Testing Reports
- Product Labels
- Product Validation
- Safety Data Sheet (SDS)
- Sample lot specific documentation packages delivered with lot specific analytical and sterility data



VAI's SCMD Family of Products

VAI's Sterile Chemical Manufacturing Division (SCMD) manufactures a complete range of cleaning agents and disinfectants that are used daily in cleanroom operations. Overall, VAI's capabilities for manufacturing products include the ability to fill aerosol, bulk, and unit dose packages in ISO 5 or 7 (Grade A/B). Our aseptic filling operations are coupled with the validated and proven ability to irradiate a final product. Assurances are taken in every aspect of SCMD concerning sterility and particulate removal. VAI's operations mirror current GMP's and enforces the adherence to USP specifications. VAI is an EPA and FDA registered facility.

For more information, call 610-644-8335, email sales@sterile.com or visit our website at www.sterile.com. Patents: www.sterile.com/patents