

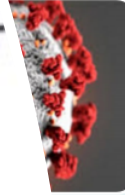
PPDC Fall Meeting Emerging Pathogens Implementation Committee (EPIC) Updates

- Chairs/Presenters
- **Tajah Blackburn, USEPA**
 - **Rhonda Jones, SRC**
- **Anastasia Swearingen, CBC**

Agenda

- Brief Background/Timeline
- Formation of New Workgroup/Members
- Updates/Next Steps for Sub-Workgroups
 - Communication/Education
 - Policy
 - Technical
- Next Steps
- Questions

TO REGISTRANTS: PROCES
 NST EMERGING VIRAL PATI
 REGISTERED DISINFECTANT



nd Purpose
 Classification
 ility Criteria
 r Using the Process
 ria Associated with Emerging Pathogens P
 onal Terms of Registration
 ss Example

Objective #1:

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Objective #2:

Assess the user experience with antimicrobial disinfection products registered by the EPA for infection control

Objective #3:

Pro
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 gap

Category N: Disinfectants for Coronavirus (COVID-19)

Find a Product to Kill Coronavirus (COVID-19)

Background/Timeline

2020

- Emerging Pathogen Workgroup (EPWG) was proposed in Fall 2020 to conduct a retrospective analysis of the Emerging Viral Pathogen Policy and EPA's antimicrobial response to COVID-19 pandemic.
- EPWG was formed in December 2020 with 1st meeting occurring in January 2021, comprising of > 20 members representing regulated industry, academia, trade associations, regulatory/technical consultants, transportation industry, and CDC.

2021-2022

- Met Biweekly to address 4 charge questions
- EPWG provided >85 recommendations to EPA for consideration and prioritization

2022-2023

- Antimicrobials Division (AD) prioritized the recommendations for consideration in the implementation phase (presented at the May 2022 Spring PPDC Meeting)
- PPDC voted to (1) form a new workgroup to refine and implement the recommendations, and (2) focus on how to expand to other types of antimicrobial pathogens

Formation of Emerging Pathogens Implementation Committee (EPIC)

- Meetings began in July 2022 for 2-year assignment; with several members from the initial EPWG seeking participation in EPIC.
- Focus on the prioritized recommendations regarding the (1) Emerging Viral Pathogen (EVP) Guidance (**Technical Workgroup**), (2) Communication/Educational gaps from several sectors (**Comms/Education Workgroup**), and (3) policy changes proposed and retained during the pandemic and normal operations (**Policy Workgroup**).
- EPIC small workgroups were formed to address each of the prioritized recommendations for the 3 main headings identified.
- Large group meetings (every 2 months) were conducted to bring all members up-to-date following small workgroup discussions.

EPIC Core Members

Matt Arduino, CDC

Ellen Baldassare, LANXESS

Steve Bennett, HCPA

Diane Boesenberg, Exponent

Alex Cook, First Group

Patti Costello, AHA

Lisa Dreilinger, Arxada

Seth Goldberg, Steptoe

James Kim, Cleaning Institute

Pat Quinn, The Accord Group

Kate Sande, Ecolab

Tajah Blackburn, EPA (Chair)

Rhonda Jones, SRC (Chair)

Anastasia Swearingen, CBC (Chair)

Revised Emerging Viral Pathogen (EVP) Guidance Update



Reviewed all proposed revisions
(Completed October 2023)



Options for implementing changes
(Completed October 2023)



Brief AD Management and routes for
implementation (Nov/Dec 2023)

PPDC EPIC Communications/Education Work Group Status Report

- **Roster To Date:**
- Tajah Blackburn, USEPA, Lead
- Alex Cook, First Group
- Matt Arduino, CDC
- Ellen Baldassare, LANXESS
- Steve Bennett, HCPA
- Jim Kim, ACI
- Anastasia Swearingen, CBC
- Rhonda Jones, SRC

EPWG Charge Question #3



What education is needed during a pandemic or other emergency for the public, end users, and other regulating authorities?



Issue: There was ineffective messaging across several sectors due to information and education gaps.



Response: Develop targeted resources and references for general and specialized messaging for key sectors at different stages of a pandemic/emergency gathered through planned outreach tools (surveys, etc.) and lessons learned.

Sources Used for Acquiring Sector Information



Published Literature/
Sector Centric Documents



Conversations



Emails



Other Resources

Sector Information

- Migrant Clinicians Network (MCN)
- Healthcare Professionals
- Pharmacies
- Public Transportation/Ground Transportation
- Air Transportation
- Vessels/Cruise Ships
- Schools
- Migrant Farmworkers
- Migrant Workers
- Food Establishment /Processing
- Small Businesses and their workers
- Hospitality
- Detention Centers



Recurring Themes Across Different Sectors



Exposure Issues

Overuse

No Worker Protections Standard (WPS) Information for Antimicrobial Pesticides



Confusion/misinterpretations for the use of “disinfectants” and “sanitizers”



Language barriers

Dialect issues

Overall literacy challenges



Incompatibility issues with exposed surfaces



Wrap-up Sector
Information Gathering

**(COMPLETED IN
AUGUST)**



Complete Spanish
Translations For
Certain Aspects Of
EVP Guidance And
Instructions For List Q
Websites

(DECEMBER 2023)



Propose
Products/Locations
(Infographics, Centralize
Information, etc.)

(MAY 2024)

Communication/Education Work Group: Future Activities

PPDC EPIC Policy Work Group Status Report

- **Roster To Date:**
- Anastasia Swearingen, CBC, Lead
- Rhonda Jones, SRC
- Diane Boesenberg, Exponent
- Pat Quinn, Accord Group
- Lisa Dreilinger, Arxada
- Seth Goldberg, Steptoe & Johnson
- Matt Arduino, CDC
- Ellen Baldassare, LANXESS
- Patti Costello, AHA
- Tajah Blackburn, USEPA, AD

Policy Work Group Activities



Explore Options for On-Label/Point of Sale Information on EVP Products

Developed preliminary proposal for use of QR code to convey EVP language from updated EVP policy—*Still under exploration with AD*

Reviewed previous proposal for icons on packaging—*De-prioritized based on current regulatory hurdles*



Explore Options for Streamlining Incident Reporting

Learning more from OECA on Enforcement and Compliance History Online (ECHO) database statistics and capabilities



Evaluate Policy Options to Address Feedback from User Groups

Tools for understanding surface compatibility questions (with Technical WG)

Explore communications tools for sharing use information targeted at specific use sites (e.g., daycares, farms) (with Communications WG)

Policy Work Group: Future Activities

Develop policy
recommendations
for deploying
additional
resources during
public health
emergencies

Product
compatibility with
common surface
materials
+ Technical Group

Interface with PR
Notice 98-10 to
address
emergencies for
faster submission
processing
+ Technical Group

Assist with Section
18 Efficacy
Guidance
+ Technical Group

PPDC EPIC Technical Work Group Status Report

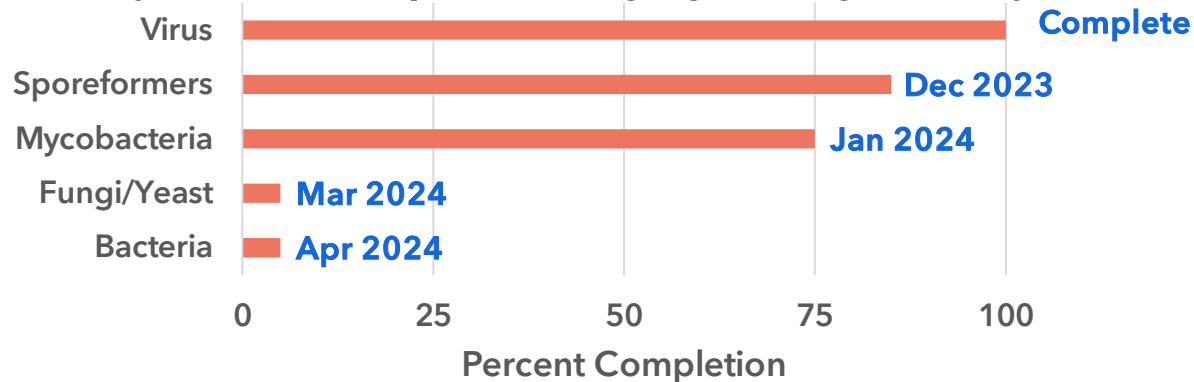
Rhonda Jones, RM (AAM)
Scientific & Regulatory Consultants, Inc.

Expanded Team:

- Rhonda Jones, SRC, Lead
- Tajah Blackburn, PhD, EPA AD
- Anastasia Swearingen, CBC
- Kristie Restrepo, Ecolab
- Shanen Conway, Element
- Milady Brutofsky, TSG
- Diane Boesenberg, Exponent
- Pat Quinn, Accord Group
- Lisa Dreilinger, PhD, Arxada
- Matt Arduino, PhD, CDC
- Ellen Baldassare, LANXESS
- Patti Costello, AHA
- Nicole Karikari, EPA AD
- Syed Sattar, PhD, CREMco
- J. Hudson Garrett, PhD, U of Louisville
- Vipin Rastogi, PhD, EPA ORD
- Judith Noble-Wang, CDC
- Tony Buhr, PhD, US Navy
- Mrudula Srikanth, Clorox
- Karen Ramm, Microchem Laboratory
- Grace Rapai, Neogen

EPIC Technical Workgroup Task Status/Deliverables

- **High Priority: Revise & Expand Emerging Pathogen Policy:**



- **Medium/Low Priority:**

- Identify any gaps in current EVP Landing Page - *ongoing*
- Draft revisions to 810 guidelines for ESS/Residual guides - *EPA to confirm need*
- Extend Residual Guidance to other microorganism types
- Policy Work Group: Material compatibility; Section 18 Efficacy Guide

Outcome of Consensus Building

- **Viral:**

- Updated and expanded per PPDC request
- Viral prerequisites remain the same but added sporeformers

- **Sporeformers:**

- Established prerequisites for hard porous/hard non-porous/soft surfaces - spores and prions
- Proposed new supportive species based on US military research
- General Recommendations on test methodology
- Likely very few products will meet requirements - provided case-by-case recommendations

- **Mycobacteria:**

- Established prerequisites for hard porous/hard non-porous/soft surfaces - spores, prions, *C. auris*, and *M. bovis*
- General Recommendations on test strain replacement

Question to PPDC



Is it possible to expand the workgroup's operational period for another 6 months?

Instead of terminating in May 2024, propose to sunset in November 2024



This additional period with allow for adequate resolution of ongoing projects without creating a new group



Appendix

Bacterial Sporeformers Summary

Emerging Pathogen is...	PROPOSED Qualifying Claim Options	Final Draft Recommendations
HARD NON-POROUS SURFACE CLAIMS: Pre-cleaning required for all surfaces		
Bacterial Sporeformer	Protozoa (No 810 guide/method)	We do not recommend this as a prerequisite for an EP policy as there are currently no registration guidelines or registered products for hard surfaces.
	Prions (810.2700)	Recommend use as a prerequisite to support a bacterial sporeforming EP claim; no/few registrations available currently
	Sterilant (810.2100): B. subtilis + C. sporogenes Porcelain penicylinders + suture loops	Recommend use to support a bacterial sporeforming EVP claim for Clostridia spores only.
	Sporicidal (810.2100): B. subtilis + C. sporogenes Porcelain pen., SS pen., OR suture loops	Recommend use to support a bacterial sporeforming EP claim for Clostridia spores only.
	C. difficile Spore Disinfectant (810.2100), C. difficile; Brushed SS discs	Propose Cdif registrations should NOT be used as a prerequisite for emerging Bacillus sporeformers Policy. EPA may consider this for support for Clostridia EPs on a case-by-case basis - may be needed due to supply chain.
	B. anthracis Decontaminant (810.2100); B. anthracis; ; porcelain peni + sutures./SS discs	Recommend use as a prerequisite to support a bacterial sporeforming EP claim; no/few registrations available currently
	B. thuringiensis Al Hakam, B. thuringiensis kurstaki HD-1 cry-, B. anthracis Sterne, or B. anthracis ΔSterne: Testing of any one species (spore form) in the AOAC Sporocidal Activity Test 966.04, ASTM E2197, or ASTM E2839 + ASTM E3218	Recommend any of these individual spore tests to be used as the prerequisite to support a bacterial sporeforming EP claim; no registrations available currently; A new PRIA Protocol review may be necessary for this.
	Spore Suspension Testing	We do not recommend this as a prerequisite for an EP policy as it is not sufficiently stringent. In a public health crisis, EPA may elect to rely on this information on a case-by-case basis.

Bacterial Sporeformers Summary

Emerging Pathogen is...	PROPOSED Qualifying Claim Options	Final Draft Recommendations
PROPOSED: HARD POROUS SURFACE CLAIMS: Pre-cleaning required for all surfaces		
Bacterial Sporeformer	Protozoa (No 810 guide/method)	We do not recommend this as a prerequisite for an EP policy as there are currently no registration guidelines or registered products for hard porous surfaces.
	Prions (810.2700)	We do not recommend this as a prerequisite for an EP policy as there are currently no registration guidelines or registered products for hard porous surfaces.
	Sterilant (810.2100): B. subtilis + C. sporogenes Porcelain penicylinders + suture loops	Recommend use to support a bacterial sporeforming EP claim for Clostridia spores only based on porcelain penicylinders testing.
	Sporicidal (810.2100): B. subtilis + C. sporogenes Porcelain pen. , SS pen., OR suture loops	Recommend use to support a bacterial sporeforming EP claim for Clostridia spores only based on porcelain penicylinders testing.
	C. difficile Spore Disinfectant (810.2100), C. difficile; SS disc carriers	We do not recommend this as a prerequisite for an EP policy as there are currently no registration guidelines or registered products for hard porous surfaces. EPA may consider this for support for Clostridia EPs on a case-by-case basis due to the brushed steel discs - may be needed due to supply chain.
	B. anthracis Decontaminant (810.2100); B. anthracis; porcelain peni + sutures./SS discs	Recommend use as a prerequisite to support a bacterial sporeforming EP claim based on porcelain penicylinders testing in the AOAC method; no/few registrations available currently. EPA may consider on a case-by-case basis relying on the brushed steel discs surface in the ASTM method as needed to respond to supply chain issues.
	B. thuringiensis Al Hakam, B. thuringiensis kurstaki HD-1 cry-, B. anthracis Sterne, or B. anthracis ΔSterne: <small>Testing of any one species (spore form) in the AOAC Sporocidal Activity Test 966.04, ASTM E2197, or ASTM E2839 + ASTM E3218</small>	Recommend any of these individual spore tests to be used as the prerequisite to support a bacterial sporeforming EP claim when porcelain penicylinders and AOAC test method are used for testing; no registrations available currently; A new PRIA Protocol review may be necessary for this. EPA may consider on a case-by-case basis relying on the brushed steel disc surface in the ASTM E2197 method as needed to respond to supply chain issues.
Spore Suspension Testing	We do not recommend this as a prerequisite for an EP policy as it is not sufficiently stringent. In a public health crisis, EPA may elect to rely on this information on a case-by-case basis.	
General Recommendation	The Work Group recommends that work be undertaken to develop a variety of hard porous carriers that are good simulants of the range of hard, porous surfaces that may be present in the typical residential, I&I, and healthcare use sites in addition to the porcelain penicylinder. All carriers should be inert, commercially available, sterilizable and readily immersible in the eluent. Potential materials should include wood (pine).	

Bacterial Sporeformers Summary

Emerging Pathogen is...	PROPOSED Qualifying Claim Options	Final Draft Recommendations
SOFT POROUS SURFACE CLAIMS: Pre-cleaning required for all surfaces		
Bacterial Sporeformer	Protozoa (No 810 guide/method)	We do not recommend this as a prerequisite for an EP policy as there are currently no registration guidelines or registered products for soft porous surfaces.
	Prions (810.2700)	We do not recommend this as a prerequisite for an EP policy as there are currently no registration guidelines or registered products for soft porous surfaces.
	Sterilant (810.2100): B. subtilis + C. sporogenes Porcelain penicylinders + suture loops	Recommend use to support a bacterial sporeforming EP claim for Clostridia spores only based on suture loop testing.
	Sporicidal (810.2100): B. subtilis + C. sporogenes Porcelain pen., SS pen., OR suture loops	Recommend use to support a bacterial sporeforming EP claim for Clostridia spores only based on suture loop testing.
	C. difficile Spore Disinfectant (810.2100), C. difficile; Brushed SS disc	We do not recommend this as a prerequisite for an EP policy as there are currently no registration guidelines or registered products for soft porous surfaces. EPA may consider this for support for Clostridia EPs on a case-by-case basis due to the brushed steel disc surface as needed due to supply chain.
	B. anthracis Decontaminant (810.2100); B. anthracis; porcelain peni + sutures ./SS discs	Recommend use as a prerequisite to support a bacterial sporeforming EP claim based on suture loop testing in the AOAC method; no/few registrations available currently. EPA may consider on a case-by-case basis relying on the brushed steel discs surface in the ASTM method as needed to respond to supply chain issues.
	B. thuringiensis Al Hakam, B. thuringiensis kurstaki HD-1 cry-, B. anthracis Sterne, or B. anthracis ΔSterne: <small>Testing of any one species (spore form) in the AOAC Sporocidal Activity Test 966.04, ASTM E2197, or ASTM E2839 + ASTM E3218</small>	Recommend any of these individual spore tests to be used as the prerequisite to support a bacterial sporeforming EP claim when suture loops and AOAC test method are used for testing; no registrations available currently; A new PRIA Protocol review may be necessary for this. EPA may consider on a case-by-case basis relying on the brushed steel discs surface in the ASTM method as needed to respond to supply chain issues.
Spore Suspension Testing	We do not recommend this as a prerequisite for an EP policy as it is not sufficiently stringent. In a public health crisis, EPA may elect to rely on this information on a case-by-case basis.	
General Recommendation	The EPA Emerging Pathogens working group recommends that the EPA fund a technical assessment of various soft, porous materials in order to establish a stronger justification for selecting a specific type(s) of soft, porous material for anti-microbial testing. Natural and synthetic materials, and materials that range in water-absorbing capabilities from high water absorption to low water absorption should be selected for screening. Cotton, silk, nylon, and polyester are common examples.	

Mycobacteria Summary

Emerging Pathogen is...	PROPOSED Qualifying Claim Options	Final Draft Recommendations
HARD NON-POROUS SURFACE CLAIMS:		
Mycobacteria	Sterilant (810.2100): B. subtilis + C. sporogenes Porcelain penicylinders + suture loops	Recommend use to support a Mycobacteria EP claim.
	Sporicidal (810.2100): B. subtilis + C. sporogenes Porcelain pen., SS pen., OR suture loops	Recommend use to support a Mycobacteria EP claim.
	C. difficile Spore Disinfectant (810.2100), C. difficile; SS penicylinders	Recommend use to support a Mycobacteria EP claim.
	B. anthracis Decontaminant (810.2100); B. anthracis; ; porcelain peni + sutures./SS discs	Recommend use to support a Mycobacteria EP claim.
	B. thuringiensis Al Hakam, B. thuringiensis kurstaki HD-1 cry-, B. anthracis Sterne, or B. anthracis ΔSterne: Testing of any one species (spore form) in the AOAC Sporicidal Activity Test 966.04, ASTM E2197, or ASTM E2839 + ASTM E3218	Recommend any of these individual spore tests to be used as the prerequisite to support a Mycobacteria EP claim; no registrations available currently; A new PRIA Protocol review may be necessary for this.
	Spore Suspension Testing	We do not recommend this as a prerequisite for an EP policy as it is not sufficiently stringent. In a public health crisis, EPA may elect to rely on this information on a case-by-case basis.

Mycobacteria Summary

Emerging Pathogen is...	PROPOSED Qualifying Claim Options	Final Draft Recommendations
HARD POROUS SURFACE CLAIMS:		
Mycobacteria	Sterilant (810.2100): B. subtilis + C. sporogenes Porcelain penicylinders + suture loops	Recommend use to support a Mycobacteria EP claim based on porcelain penicylinders.
	Sporicidal (810.2100): B. subtilis + C. sporogenes Porcelain pen., SS pen., OR suture loops	Recommend use to support a Mycobacteria EP claim based on porcelain penicylinders.
	C. difficile Spore Disinfectant (810.2100), C. difficile; Brush SS disc	We do not recommend this as a prerequisite for a Mycobacteria EP policy on porous surfaces. EPA may consider this for support for Mycobacteria EPs on a case-by-case basis due to the brushed steel disk surface as needed due to supply chain.
	B. anthracis Decontaminant (810.2100); B. anthracis; ; porcelain peni + sutures./SS discs	Recommend use to support a Mycobacteria EP claim based on porcelain penicylinders.
	B. thuringiensis Al Hakam, B. thuringiensis kurstaki HD-1 cry-, B. anthracis Sterne, or B. anthracis ΔSterne: Testing of any one species (spore form) in the AOAC Sporocidal Activity Test 966.04, ASTM E2197, or ASTM E2839 + ASTM E3218	Recommend any of these individual spore tests to be used as the prerequisite to support a Mycobacteria EP claim; no registrations available currently; A new PRIA Protocol review may be necessary for this.
	Spore Suspension Testing	We do not recommend this as a prerequisite for an EP policy as it is not sufficiently stringent. In a public health crisis, EPA may elect to rely on this information on a case-by-case basis.

Mycobacteria Summary

Emerging Pathogen is...	PROPOSED Qualifying Claim Options	Final Draft Recommendations
SOFT POROUS SURFACE CLAIMS:		
Mycobacteria	Sterilant (810.2100): B. subtilis + C. sporogenes Porcelain penicylinders + suture loops	Recommend use to support a Mycobacteria EP claim based on suture loops.
	Sporicidal (810.2100): B. subtilis + C. sporogenes Porcelain pen., SS pen., OR suture loops	Recommend use to support a Mycobacteria EP claim based on suture loops.
	C. difficile Spore Disinfectant (810.2100), C. difficile; Brushed SS disc	We do not recommend this as a prerequisite for an Mycobacteria EP policy on soft porous surfaces. EPA may consider this for support for Mycobacteria EPs on a case-by-case basis due to the brushed steel disc surface as needed due to supply chain.
	B. anthracis Decontaminant (810.2100); B. anthracis; ; porcelain peni + sutures./SS discs	Recommend use to support a Mycobacteria EP claim based on suture loops.
	B. thuringiensis Al Hakam, B. thuringiensis kurstaki HD-1 cry-, B. anthracis Sterne, or B. anthracis ΔSterne: Testing of any one species (spore form) in the AOAC Sporicidal Activity Test 966.04, ASTM E2197, or ASTM E2839 + ASTM E3218	Recommend any of these individual spore tests to be used as the prerequisite to support a Mycobacteria EP claim where testing is conducted in AOAC method on suture loops; no registrations available currently; A new PRIA Protocol review may be necessary for this.
	Spore Suspension Testing	We do not recommend this as a prerequisite for an EP policy as it is not sufficiently stringent. In a public health crisis, EPA may elect to rely on this information on a case-by-case basis.

Mycobacteria Summary

Emerging Pathogen is...	PROPOSED Qualifying Claim Options	Final Draft Recommendations
HARD NON-POROUS & POROUS SURFACE CLAIMS:		
Mycobacteria	Tuberculocide (810.2200): M. bovis (ATCC 35743)	
	AOACTB (965.12) Porcelain penicylinders	PROPOSED: Recommend use to support a Mycobacteria EP claim for both hard porous and non-porous claims.
	Modified AOAC GST (961.02) for spray/towels & M. bovis; Glass carrier	PROPOSED: Recommend use to support a Mycobacteria EP claim for hard, non-porous surfaces only.
	For Glutaraldehyde only: Quantitative Suspension Test (BEAD SOP M-16)	We do not recommend this as a prerequisite for an EP policy as it is not sufficiently stringent. In a public health crisis, EPA may elect to rely on this information on a case-by-case basis. NOTE: The work group requests EPA revisit the use of a suspension test to support tuberculocidal claims as its stringency is not on par with the dried carrier tests and the outcome may not simulate real world conditions.
General Recommendations	PROPOSED: The Work Group recommends EPA research a replacement strain for M. bovis (ATCC 35743) that is easier to work with in the lab and has shorter growth/incubation time (e.g., M. terrae). EPA should consider the value of using resistant strains.	

Mycobacteria Summary

Emerging Pathogen is...	PROPOSED Qualifying Claim Options	Final Draft Recommendations
HARD NON-POROUS SURFACE CLAIMS:		
Mycobacteria	Candida auris (AR Bank #0385) ^{BEAD} <small>MB35/37 (https://www.epa.gov/pesticide-registration/guidance-efficacy-evaluation-products-claims-against-drug-resistant-candida)</small> brushed ss disc	PROPOSED: Recommend use to support a Mycobacteria EP claim.
	Small Non-enveloped Virus - Virucidal Disinfection (810.2200 - E1053) glass carrier What strains? Parvo, HAV, ???? How many?	PROPOSED: Recommend use to support a Mycobacteria EP claims.