

Antimicrobial Products Used to Inactivate *Bacillus anthracis* Spores

Joint Service Scientific Conference

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Environmental Protection Agency

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OVERVIEW

- **LEGAL AUTHORITY**
- **CRISIS EXEMPTIONS**
- **LIQUID, GAS & VAPORIZED DECON CHEMICALS**
- **INTERAGENCY EXPERT PANEL**
- **COLLABORATIVE EFFICACY STUDY**
- **“COMING EVENTS”**

LEGAL AUTHORITY

- **The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires pesticides either to be:**
 - **Registered prior to sale or distribution (Section 3)**
 - **OR**
 - **Exempted for emergency purposes (Section 18)**

FIFRA DEFINITIONS

- ***Pesticide*** = any substance intended to prevent, destroy, repel or mitigate any *pest*.
- ***Pest*** = any form of plant or animal life or virus, bacteria, or other microorganisms, except on or in living man or animals.

DECON CHEMICALS ARE SUBJECT TO FIFRA

- Anthrax spores are “pests”
- Chemicals intended to inactivate anthrax spores are “pesticides”
- Thus, anthrax decon chemicals must either be registered or exempted from FIFRA

CRISIS EXEMPTION PROCESS

- Expedited process was set up for issuing crisis exemptions for anthrax decon chemicals
- Requests came from federal agencies and private companies
- Site-specific requests for fumigations had to include a Remediation Action Plan, Sampling and Analysis Plan, and Ambient Air Monitoring Plan

CRISIS EXEMPTION DECISIONS

- 58 requests received
- 25 crisis exemptions issued
- 32 requests rejected
- 1 request pending
- 2 exemptions withdrawn
- See www.epatechbit.org for copies

STANDARD FOR EPA APPROVAL

- **Registered or exempted pesticides may not cause “unreasonable adverse effects on the environment”**
- **Crisis exemption decisions are based on best available data on safety & efficacy**
- **Registration decisions are based on a complete set of required data**

SAFETY ISSUES

- **Fumigant toxicity/exposure**
- **Building/area containment**
- **Fumigant generation**
- **Negative air & scrubbing systems**
- **Ambient air monitoring**
- **Emergency response plan**
- **Post-treatment aeration**

EFFICACY ISSUES

- **Characterization sampling**
- **Building/area containment**
- **Source reduction and cleaning**
- **Fumigate building once or in sections**
- **Efficacy characteristics of fumigant**
- **Set & monitor treatment parameters**
- **Biological indicators**
- **Clearance sampling**

LIQUID CHEMICALS*

- Aqueous chlorine dioxide
- Hydrogen peroxide/peracetic acid
- Sodium hypochlorite
- Hydrogen peroxide/quaternary ammonium compound (decon foams)

[*Hard, non-porous surfaces only]

LIQUID AGENTS

Sporicidal Chemical	Initial Active Ingredient	Product Trade Name	EPA Registered?	Company	Sites of Use
Aqueous chlorine dioxide	Sodium chlorite	V Charge 1L-3000	Unregistered	Vulcan Chemical	Hart Senate Office Building
Hydrogen peroxide and peracetic acid	Hydrogen peroxide and peracetic acid	Oxonia Active	EPA Reg. No. 1677-129	Ecolab Products	Any gov't. agency
Hydrogen peroxide and peracetic acid	Hydrogen peroxide and peracetic acid	KX-6049	EPA Reg. No. 1677-158	Ecolab Products	Any gov't. agency
Hydrogen peroxide and peracetic acid	Hydrogen peroxide and peracetic acid	Actril Cold Sterilant	EPA Reg. No. 52252-7	Minntech Corporation	Any gov't. agency
Hydrogen peroxide and peracetic acid	Hydrogen peroxide and peracetic acid	Spor-Klenz Ready to Use	EPA Reg. No. 52252-7-1043	STERIS Corporation	Dept. of State, NBC (NY)
Hydrogen peroxide	Hydrogen peroxide	Virex STF	Unregistered	Johnson Wax Professional	Any gov't. agency
Sodium hypochlorite	Sodium hypochlorite	400 registered products available	400 registered products available	(Long list)	Capitol Hill; post offices; NBC; AMf.

GASES/VAPORS (FUMIGANTS)

- Gaseous chlorine dioxide (building)
- Paraformaldehyde (mail bags & equipment)
- Vaporized hydrogen peroxide (building)
- Methyl bromide (tested in trailer)
- Ethylene oxide (chamber sterilization of items)

GAS/VAPOR AGENTS

Sporicidal Chemical	Initial Active Ingredient	Product Trade Name	EPA Registered?	Company	Sites of Use
ClO ₂ (gas)	Sodium chlorite	Drewchlor 4107	EPA Reg. No. 1757-96	Ashland Chemical Co.	Hart Bldg., Cap. Hill mail, Brentwood, Trenton
ClO ₂ (gas)	Sodium chlorate	Akta Klor 25	EPA Reg. No. 21164-6	Vulcan Performance Co.	Hart Senate Office Bldg.
Formaldehyde (gas)	Paraformaldehyde	Paraformaldehyde prills	Unregistered	Hoechst-Celanese	DOJ Mailroom & DOS mail bags
Hydrogen Peroxide (vapor)	Hydrogen peroxide	Vaprox™ Hydrogen Peroxide Sterilant	EPA Reg. No. 58779-4	STERIS Corporation	GSA Bldg. 410, DOJ SA-32, NBC (NY)
Methyl bromide (gas)	Methyl bromide	Meth-O-Gas	EPA Reg. No. 5785-11	Great Lakes Chemical Co.	Trailer tests at Univ. of Florida

GAS/VAPOR AGENTS

Sporicidal Chemical	Initial Active Ingredient	Product Trade Name	EPA Registered?	Company	Sites of Use
Ethylene oxide (gas)	Ethylene oxide	Ethylene oxide	EPA Reg. No. 36376-2	ARC Specialty Products Balchem Corp.	Items from Capitol Hill, DOS and NBC
Ethylene oxide (gas)	Ethylene oxide	Ethylene oxide	EPA Reg. No. 36376-9	ARC Specialty Products Balchem Corp.	Test on mock mail in AZ & PA
Ethylene oxide (gas)	Ethylene oxide	Envirosystems Ethylene Oxide Sterilant	EPA Reg. No. 58779-5	STERIS Corp.	Test on mock mail in AZ & PA
Ethylene oxide (gas)	Ethylene oxide	Oxyfume 2002	EPA Reg. No. 67470-2	STERIS Corp.	Test on mock mail in AZ & PA
Ethylene oxide (gas)	Ethylene oxide	EOGas™	EPA Reg. No. 69340-4	Andersen Products, Inc.	U.S. Agency and N.C.

INTERAGENCY EXPERT PANEL ON ANTHRAX EFFICACY TEST METHODS AND SURROGATES

- **Oct. 9-10, 2002, Working Meeting**
- **Expert Panel formed; first meeting Jan., 2003 (10 agencies)**
- **Five meetings to date**
- **Three sub-groups (methods, gases/vapors, surrogates)**

INTERAGENCY EXPERT PANEL—MISSION

- **Gather data & evaluate sporicidal test methods and surrogates**
- **Identify/perform pre-collaborative studies**
- **Develop/conduct collaborative studies, including validation**
- **Share/leverage data**

INTERAGENCY COLLABORATIVE STUDY

- **Phase 1: Compare three sporicidal test methods on liquid antimicrobial agents:**

- **AOAC Sporicidal Activity Test (ASTM)**
- **QCT-1 (Univ. of Ottawa)**
- **Three-step method (ECBC)**

Three primary labs:

- **EPA, Ft. Meade, MD**
- **ECBC, Aberdeen Proving Ground, MD**
- **FDA, Denver**

Two labs for pre-collaborative work:

FDA, Winchester, MA

Air Force Research Lab

COLLABORATIVE STUDY, Phases 2-4

- **Phase 2—Select/test surrogates on liquids**
- **Phase 3—Select/test gaseous or vaporized agents**
- **Phase 4 (not yet funded)—“Field study” of building decontamination**

DECON CHEMICAL TEST PLANS EXAMINED BY PANEL

- EPA Environmental Testing and Verification (ETV)
- EPA Systematic Decon Program
- ECBC VHP Testing Program
- EPA Dugway Study on ClO_2
- TSWG Study on methyl bromide

ANTHRAX-RELATED “COMING EVENTS”

- EPA “Evaluating Contaminated Sites with Fumigation Responses”
- DHS/LLNL Decon Research Projects: SFIO Response Protocol and “How Clean is Safe”
- DARPA—Efficacy of chlorine dioxide in buildings (CDG Technologies)

PAYOFFS FROM COLLABORATION

- Increased sharing of expertise and experience
- Harmonization of test methods
- Leveraging & efficient use of resources
- “Peer review” enhances value of studies
- Test results serve many “customers”