

84545-9

4/2/2010

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

Reg. Number:

84545-9

Date of Issuance:

4/2/10

Term of Issuance:

Conditional

Name of Pesticide Product:

Steriplex Ultra Solution Part A

NOTICE OF PESTICIDE:

Registration
 registration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

sBioMed, LLC
1272 South 1380 West
Orem, Utah 84058

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA Section 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA Sec. 3(c)(5) when the Agency request all registrants of similar product to submit such data; and submit such data; and acceptable response required for re-registration of your product under FIFRA Section 4.
2. Make the labeling changes listed below before you release the product to shipment:
 - a. Add the phase "EPA Registration Number 84545-9."

Signature of Approving Official:

Dennis H Edwards for

Marshall Swindell,
Product Manager, Team 33
Regulatory Management Branch I, Antimicrobials Division

Date:

April 2, 2010

EPA Reg. No. 84545-9

3. The confidential Statement of Formula dated August 24, 2009, is acceptable.

4. The following additional Terms and Conditions of Registration apply:

a. Sale and Distribution Limitations

The registrant commits not to sell or distribute the product except to:

- Federal On-Scene Coordinators (FOSC), and contractors and other trained Federal/state/local response personnel under the FOSC's supervision;
- Trained U.S. Military personnel and contractors under their supervision;
- Person who, within the preceding 24 months, have been trained and determined to be competent by the registrant (or its contractor) in each of the topics described under item 2 below.

The registrant commits to verify, prior to sale or distribution, that the recipient falls within one of the above user categories. For the first two user categories listed above (i.e., FOSCs, U.S. Military personnel, their contractors, and other persons under their supervision),, such verification may be accomplished through a critical review of documents, such as a letter on government letterhead, a government purchase order, or a government-issued identification badge.

b. Training and determination of Competency of Applicators

Where a registrant proposes to sell or distribute anthrax-related products to persons other than FOSCs, trained U.S. Military personnel, and contractors and other response personnel under the supervision of FOSC's or trained U.S. Military personnel, the registrant commits to providing training for such persons and to determining their competency through written examination. The registrant may itself perform the training and competency determination, or enter into a contract with a qualified third party to conduct the training and competency determination on the registrant's behalf. The registrant further commits that the training curriculum will provide for refresher training and competency determination at least every two years and, at a minimum, include instruction concerning:

- Characteristics of and human health hazards posed by *B. anthracis* spores;
- Personal Protective Equipment (PPE) appropriate for protection against *B. anthracis* spores and while using the pesticide product;
- Detailed instructions for safe and effective use of the registered pesticide product and any associated equipment;
- Detailed review of the steps involved in the remediation and restoration process as provided in guidance from federal agencies (e.g., National Response Team Technical Assistance for Anthrax Response, Interim Final Draft, July 2005) as well as review of

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For use only by:

- Federal On-Scene Coordinators and contractors and other trained federal/state/local response personnel under the FOSC's supervision;
- Trained U.S. Military personnel and contractors under their supervision;
- Persons who, within the preceding 24 months, have been trained and determined to be competent by the registrant (or its contractor) following completion of the required training.

Under the terms and conditions of this product's registration, this product may only be sold or distributed by the registrant directly to the persons identified above.

**STERIPLEX Ultra™ Activator
(Part B)**

SPORICIDAL DECONTAMINANT for INACTIVATION of *Bacillus anthracis* SPORES on DRY, PRECLEANED, HARD NON-POROUS SURFACES

STERIPLEX Ultra™ Activator is a sporicidal decontaminant that inactivates *Bacillus anthracis* spores on dry, precleaned, hard nonporous surfaces at certain sites when used in accordance with all precautions and directions specified on this label and in the attached Training Manual.

STERIPLEX Ultra™ Activator (Part B) is to be used only in the mixture with STERIPLEX Ultra™ (Part A) as a sporicidal decontaminant

Active Ingredients:	Hydrogen Peroxide	22.0%
	Peroxyacetic Acid	15.0%
Inert Ingredients:		63.0%
	Total:	100.0%

**KEEP OUT OF REACH OF CHILDREN
DANGER**

**SEE (SIDE) (BACK) PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS AND DIRECTIONS FOR USE**

EPA Reg. No. 84545-9

EPA Est. No. 84545-UT-001

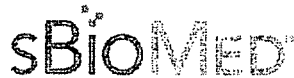
Net Contents: 1 quart

1 gallon

5 gallons

55 gallons

**ACCEPTED
with COMMENTS
EPA Letter Dated:**



1272 South 1380 West

Orem, Utah 84058 TEL: 801-922-1111 FAX: 801-922-1100

APR - 2 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 84545-9

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FIRST AID FOR STERIPLEX Ultra™ Activator (Part B)	
IF IN EYES	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing. Call a poison control center or physician for treatment advice.
IF ON SKIN OR CLOTHING	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or physician for treatment advice.
IF SWALLOWED	Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person. Call a poison control center or doctor immediately for treatment advice.
IF INHALED	Move person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.	
Have the product container or label with you when calling a poison control center or going for treatment.	
FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-222-1222	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not breathe vapors or spray mist. Do not get in eyes on skin or on clothing. Wear goggles and/or face shield and rubber gloves when handling. Do not enter an enclosed area without proper respiratory protection. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE) WHEN MIXING THIS PRODUCT:

Eyes and Face: Use cup type chemical goggles and a full-face shield when mixing and applying this product to the intended surfaces.

Protective Clothing: Use rubber or neoprene footwear and a rubber or neoprene apron or full-body protective clothing. Completely submerge into water any clothing or other materials contaminated with hydrogen peroxide from contact with the concentrated or mixed products, and then allow clothing to dry. Residual hydrogen peroxide, if allowed to dry on fabrics, cotton, leather, wood, paper or other combustibles, can cause the material to ignite and result in a fire.

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EPA Letter Date:

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Gloves: Rubber or neoprene gloves are required when mixing and applying product. Thoroughly wash the outside of gloves with soap and water prior to removal. Inspect regularly for leaks.

Respiratory: Wear an approved full-face acid/gas cartridge or canister respirator. If concentrations are unknown (e.g., significant spill or other emergencies), or if they are anticipated to be above 5 ppm for hydrogen peroxide or 50 ppm for acetic acid, use a self-contained breathing apparatus (SCBA).

Follow manufacturer's instruction for cleaning/maintaining protective eyewear and respirator users:

The respirator user must be fit tested and fit checked using a program that conforms to OSHA's requirements (29 CFR 1910.134)

The respirator user must be trained using a program that conforms to OSHA's requirements (29 CFR 1910.134)

A qualified medical practitioner to ensure the physical ability of the user to safely wear the type of respirator to be worn must examine the respirator user.

The respirator equipment must be maintained according to a program that conforms to OSHA's requirements (29 CFR 1910.134).

PPE REQUIRED FOR PROTECTION FROM *BACILLUS ANTHRACIS* SPORES:

When applying the product to areas contaminated with *Bacillus anthracis* spores, wear the personal protective equipment (PPE) described in the Training Manual.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, fish, and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the US Environmental Protection Agency.

PHYSICAL AND CHEMICAL HAZARDS

STRONG OXIDIZING AGENT. Corrosive. Mix only with STERIPLEX Ultra™ (Part A) disinfectant solutions. Product must be diluted in accordance with label directions prior to use. STERIPLEX Ultra™ Activator (Part B) is not combustible; however, at temperatures exceeding 156°F, decomposition occurs releasing oxygen. The oxygen released could initiate combustion.

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EPA Letter Dated:

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STERIPLEX Ultra™ Activator (Part B)

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 84545-9

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DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT
IN A MANNER INCONSISTENT WITH ITS LABELING.

STERIPLEX Ultra™ is a two part sporicidal decontaminant that inactivates *Bacillus anthracis* spores on dry, precleaned, hard, nonporous surfaces, and may be used on sites listed below. This product is for use only by persons listed in the enclosed box above the product name. Read and follow all safety precautions and use directions on the label and in the Training Manual.

For use as a sporicidal decontaminant in Industrial, Commercial, and Institutional settings, including the following sites: Offices, Government and Residential buildings; Educational buildings, Public and Private buildings; Commercial, Government and Private vehicles; Personal Protective Equipment; Hospitals/Healthcare facilities; Military institutions and equipment; Manufacturing facilities; Hotels; Cruise ships; Airports.

Do not use this product on food contact surfaces.

PREPARATION – STERIPLEX Ultra™ is a two-part sporicidal decontaminant system consisting of:

STERIPLEX Ultra™ (Part A) (EPA Reg. No. 84545-): a one gallon container of 0.03% silver, and

STERIPLEX Ultra™ Activator (Part B) (EPA Reg No. 84545-): a smaller bottle containing 15.0% peracetic acid and 22.0% hydrogen peroxide

1. Wearing specified personal protective equipment (PPE) as described under the PRECAUTIONARY STATEMENTS on this label, find the STERIPLEX Ultra™ Activator (Part B) bottle. Remove the cap from the bottle.
2. On the "Part A" container, remove the cap. Pour the entire contents of the STERIPLEX Ultra™ Activator (Part B) into the opening of the "Part A" container.
3. Discard the spent STERIPLEX Ultra™ Activator (Part B) container in an approved waste disposal receptacle as directed on the STERIPLEX Ultra™ Activator (Part B) label. Replace cap back onto the "Part A" container.
4. Mix the two-part solution by agitating the contents for approximately 15 seconds.
5. Pour the mixed solution into applicator equipment for usage.
6. Mix fresh batch daily. Dispose of unused solution within 24 hours after mixing.

Application Methods – For use on Hard, Non-Porous, Non-Food Contact Surfaces

STERIPLEX Ultra™ can be applied to surfaces by conventional (spray) (mopping) (cloth) or (sponge) method.

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To Fill or (refill) empty spray bottle:

1. Remove trigger sprayer (or cap) from empty bottle. ~~APP~~ - 2 2010

STERIPLEX Ultra™ Activator (Part B)

Under the Federal Insecticide,
Fungicide, and Rodenticide Act March 24, 2010
amended, for the pesticide,
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2. Unscrew cap (or open spigot) and pour contents into empty bottle.
3. Replace trigger sprayer (or cap) and use as instructed.

Refill sprayer only with STERIPLEX Ultra™ mixture.

IMPORTANT: Once activated, the mixed STERIPLEX Ultra™ solution can only be used as a sporicide for 10 days. Dispose of any solution that has exceeded this timeframe after activation. Mark the date the solution was mixed on the container with a permanent marker in the space provided.

For Use on Dry, Precleaned, Hard Non-Porous Surfaces

For heavily soiled areas, a precleaning step is required. Wash soiled surfaces with a compatible detergent using a cloth, sponge or cleaning device to ensure visible soils are removed. Rinse with potable water and allow to dry. Spray or wipe on the mixed STERIPLEX Ultra™ solution by the following means: mop, cloth, sponge, spray bottle or commercial sprayer.

1. Thoroughly apply the solution to the surface using a prescribed method covering the surface with a thin film of product at room temperature.
2. Allow the product to remain on the surface for a minimum of 30 minutes.
3. Rinse the surfaces with a clean cloth or sponge several times with running water.
4. Larger areas may be treated by applying the product with a spray bottle or commercial sprayer. Allow the product to remain on the contact surface for a minimum of 30 minutes, and then rinse surfaces as prescribed above.
5. Dispose of cleaning utensils as directed in the instructions.

DECONTAMINATION OF EQUIPMENT – For heavily soiled areas, a precleaning step is required. To the extent possible, dismantle equipment and tools. Wash soiled surfaces with a compatible detergent using a cloth, sponge or cleaning device to ensure visible soils are removed. Rinse with potable water and allow to dry. All surfaces to be treated must be dry (i.e, not visibly wet) prior to application. Apply the STERIPLEX Ultra™ mixed solution in the following manner:

1. Pour desired amount of solution into a tray or receptacle that will hold the tools and allow for complete immersion in solution.
2. Immerse equipment or tools for a minimum of 30 minutes.
3. Transfer equipment or tools to a rinse bath to remove the solution. Dipping the equipment or tools a couple of times into the rinse bath will thoroughly remove any solution.
4. Allow equipment or tools to air dry prior to reuse.

See Training Manual for additional, detailed instruction on product applications.

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with **COMMENTS**
EPA Letter Dated:

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STERIPLEX Ultra™ Activator (Part B)

Under the Federal Insecticide,
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STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Never return STERIPLEX Ultra™ Activator (Part B) to the original container after it has been removed. Avoid all contaminants, especially dirt, caustic reducing agents, and metals. Contamination and impurities will reduce shelf life and can induce decomposition. In case of decomposition, isolate container, douse container with cool water and dilute STERIPLEX Ultra™ Activator (Part B) with large volumes of water. Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at temperatures below 86 °F. Do not store on wooden pallets.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods of disposal may vary by location, regulatory agencies should be contacted prior to disposal. STERIPLEX Ultra™ Activator (Part B), which is to be discarded, should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

CONTAINER DISPOSAL:

Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap and shake for 10 seconds, then uncap and discard rinsate. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times, and then discard container and cap.

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EPA Letter Dated:
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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 84545-9

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TRAINING MANUAL

USE OF STERIPLEX Ultra™ (Part A) and (Part B) FOR THE DECONTAMINATION AND INACTIVATION OF ANTHRAX SPORES

(EPA Reg. Nos. 84545-8 and 84545-9)

STUDENT MANUAL

JUNE 2009

(Revised 2-25-2010)

sBioMed

1272 So. 1380 West
Orem, Utah 84058

Program Administrator:

Contact Stanley Trout

801-847-3301

stan.trout@sbiomed.com

ACCEPTED
with COMMENTS
EPA Letter Dated:

APR - 2 2010

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

PURPOSE

This course provides information on the virulent *Bacillus anthracis* (Anthrax), the National Response Framework for future incidents, and the decontamination process to inactivate anthrax spores.

Course Objective

- The course objective is to enable participants to demonstrate basic knowledge to:
 - The characteristics of Anthrax and related health issues
 - The National Response Framework for future incidents
 - The incident response/decontamination process to inactivate Anthrax and other biological agents listed on the label

Training Content

The training is comprised of the following units:

1. Unit 1: Course Overview
2. Unit 2: Anthrax Overview
3. Unit 3: NRF Overview
4. Unit 4: Incident Response/Decontamination Process Overview
5. Unit 5: sBiomed's STERIPLEX Ultra™

Unit 1: Course Overview

Topic Unit Introduction

Unit 1:

Course Overview

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Key Points

This course will introduce you to the :

- * Characteristics of Anthrax and related health issues,
- * The National Response Framework,
- * The Incident Response Decontamination process to inactivate Anthrax,
- * and, sBioMed's Product overview.

Topic Course Objectives

Course Objectives (1 of 2)

Describe:

- The characteristics of the virulent *B. Anthracis* (Anthrax) spore
- Related human health issues
- Provide key information on the National Response Framework to future incidents



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Key Points

The objective of this course is for you to demonstrate basic knowledge of Anthrax and its related issues, understand the role of government agencies and the National Response Framework established to respond to future incidents and have a basic understanding of the decontamination process and how STERIPLEX Ultra™ inactivates Anthrax and other biological agents listed on the label.

By the end of this course, you should be able to describe:

- * The characteristics of Anthrax.
- * The health and safety issues relating to Anthrax
- * The nations response to future incidents

See the next page for the rest of the course objectives

Topic Course Objectives**Course Objectives (2 of 2)****Describe:**

- Key federal agencies and plans to address future incidents
- Decontamination activities to inactivate anthrax or other biological agent
- Regulatory compliance to an EPA registration for a Product to inactivate the anthrax spore


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31.01.1**Key Points**

Continuation of course objectives:

- * Key federal agencies and plans developed to manage future incidents
- * Incident Response activities in the event of a biological release
- * Decontamination activities to inactivate Anthrax or other biological agents listed on the label

Topic Participant Introductions

Class Introductions



- Name, Job title, and organization
- Overall experience with emergency or incident response
- Any chemical or biological related hazmat training

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Key Points


Introduce yourself by providing:

- * Your name, job title and organization
- * Overall experience with emergency or incident response
- * Any previous chemical or biological hazmat training

Topic Course Logistics

Course Logistics

- Course Agenda
- Sign-in sheet
- Housekeeping
 - Breaks
 - Message and telephone location
 - Cell phone policy
 - Facilities
 - Other concerns



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Key Points

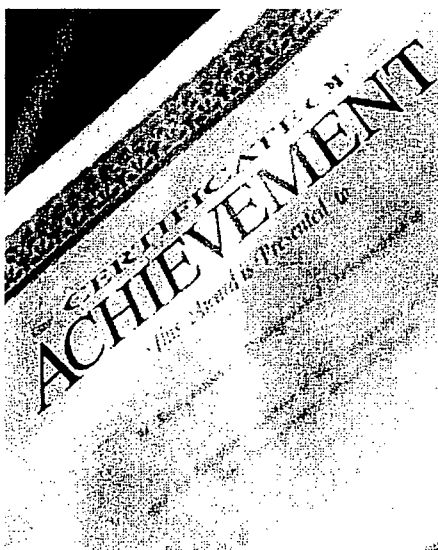
Be mindful of the following course logistics in order to benefit fully from course instruction:

- * Course Agenda
- * Sign-in sheet
- * Housekeeping
 - * Breaks
 - * Message and telephone location
 - * Cell phone policy
 - * Facilities
 - * other concerns

Topic Successful Course Completion

Successful Course Completion

- Participate in unit activities and exercises.
- Achieve 70% or higher on the final exam.
- Complete the end-of-course evaluation



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Course Overview

Key Points


Successful course completion requires you to:

- * Participate in Unit activities
- * Achieve 70% or higher on final exam
- * Complete the end-of-course evaluation

Next Unit will provide the overview of Anthrax

Topic Unit Introduction

Unit 2: Anthrax Overview



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Anthrax Overview

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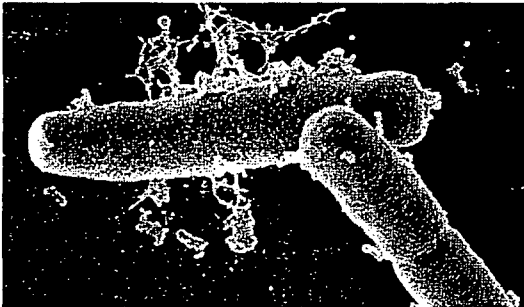
Key Points

Unit 2 provides a general understanding of the Anthrax disease.

Topic Unit Objectives

Unit 2 Objectives

- To describe characteristics of Anthrax
- Where it's found
- How it's transmitted
- Symptoms of the disease
- Treatment



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Anthrax Overview

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Key Points


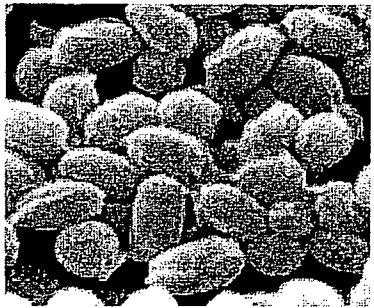
By the end of this unit, you should be able to describe:

- * The characteristics of Anthrax,
- * Where it is found,
- * How it is transmitted,
- * The symptoms of the disease,
- * and Treatments once it has been contracted.

Topic Characteristics of Anthrax

What is Anthrax? (1 of 2)

Anthrax is an acute infectious disease caused by the spore-forming bacterium *Bacillus anthracis*.



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ANTHRAX © 1999 SBI

Key Points

Anthrax is an acute infectious disease caused by the spore-forming bacterium *Bacillus anthracis*. Like many other members of the genus *Bacillus*, *Bacillus anthracis* can form dormant spores that are able to survive in harsh conditions for extremely long periods of time—even decades or centuries.^[1] Such spores can be found on all continents, even Antarctica. When spores are inhaled, ingested, or come into contact with a skin lesion on a host they may reactivate and multiply rapidly.

Topic Characteristics of Anthrax**What is Anthrax? (2 of 2)**

- Anthrax most commonly occurs in wild and domestic lower vertebrates such as:
 - Cattle
 - Sheep
 - Goats
- Humans may contract anthrax from blood or tissue of diseased animals, or from contaminated animal by-products (e.g., untreated hides)



Anthrax Overview

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Slide 11**Key Points**

Anthrax commonly infects wild and domesticated herbivorous mammals which ingest or inhale the spores while browsing—in fact, ingestion is thought to be the most common route by which herbivores contract anthrax. Carnivores living in the same environment may become infected by consuming infected animals. Diseased animals can spread anthrax to humans, either by direct contact (e.g. inoculation of infected blood to broken skin) or consumption of diseased animals' flesh.

Topic Transmitting Anthrax**How is it transmitted?**

- Anthrax infection can occur in three forms: cutaneous (skin), inhalation, and gastrointestinal.
- Anthrax spores can survive in the soil for many years, and humans can become infected with anthrax by handling products from infected animals or by inhaling anthrax spores from contaminated animal products.
- Anthrax can also be contracted by eating undercooked meat from infected animals.
- Incidence of anthrax in humans in the U.S. is rare.

Anthrax Overview

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Anthrax can enter the human body through the intestines (ingestion), lungs (inhalation), or skin (cutaneous).

Infection of humans can result from contact with infected animal products such as fur or wool or by inhaling the spores from contaminated animal products.

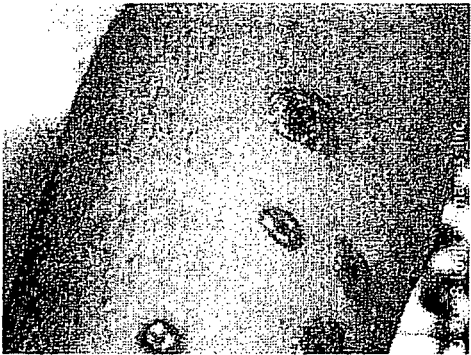
Anthrax can also be contracted by eating undercooked meat from infected animals.

Topic Symptoms of the Disease

What are the symptoms? (1 of 3)

Symptoms of disease vary depending on how the disease was contracted, but symptoms usually occur within 7 days.

- **Cutaneous:** Most (about 95%) anthrax infections occur when the bacterial spore enters a cut or abrasion on the skin. About 20% of untreated cases of cutaneous anthrax will result in death. Deaths are rare with appropriate antimicrobial therapy.



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Anthrax Overview

Key Points

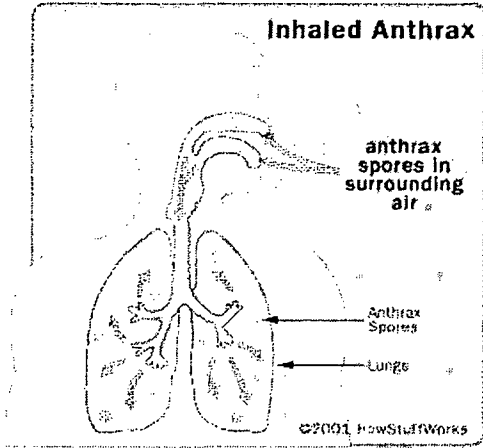
Cutaneous (on the skin) anthrax infection in humans shows up as a boil-like skin lesion that eventually forms an ulcer with a black center (eschar). The black eschar often shows up as a large, painless necrotic ulcer (beginning as an irritating and itchy skin lesion or blister that is dark and usually concentrated as a black dot, somewhat resembling bread mold) at the site of infection. Cutaneous infections generally form within the site of spore penetration between 2 and 5 days after exposure. Unlike bruises or most other lesions, cutaneous anthrax infections normally do not cause pain.

Cutaneous anthrax is rarely fatal if treated, but without treatment about 20% of cutaneous skin infection cases progress to toxemia and death.

Topic Symptoms of the Disease

What are the symptoms? (2 of 3)

- Inhalation:** Initial symptoms may resemble a common cold. After several days, the symptoms may progress to severe breathing problems and shock. Inhalation of anthrax is usually fatal, and even with aggressive antibiotic and supportive therapy 45% of inhalation anthrax cases were fatal in the bio-terrorist attack in the fall of 2001.



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Anthrax Overview

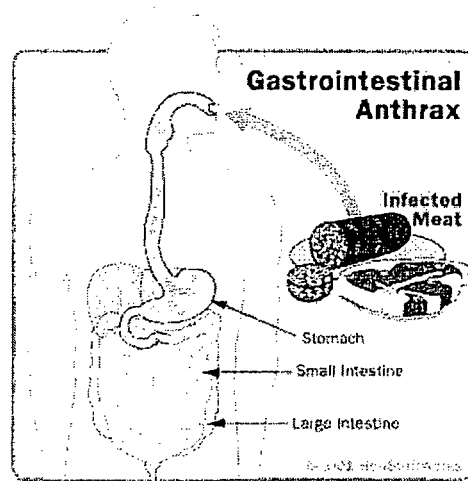
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Key Points

Respiratory infection in humans initially presents with cold or flu-like symptoms for several days, followed by severe (and often fatal) respiratory collapse. Historical mortality was 92%, but when treated early (seen in the 2001 anthrax attacks) observed mortality was 45%. Illness progressing to the fulminate phase has a 97% mortality regardless of treatment.

Topic Symptoms of the Disease**What are the symptoms? (3 of 3)**

- **Intestinal:** The intestinal disease form of anthrax may follow the consumption of contaminated meat and is characterized by an acute inflammation of the intestinal tract. Initial signs include nausea, loss of appetite, vomiting, fever are followed by abdominal pain, vomiting of blood, and severe diarrhea. Intestinal anthrax results in death in 25% to 60% of cases.



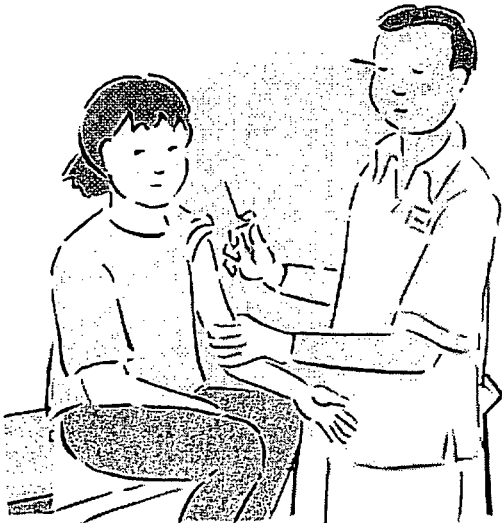
Anthrax 5/10/10

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Slide 13**Key Points**

Gastrointestinal infection in humans is most often caused by eating anthrax-infected meat and is characterized by serious gastrointestinal difficulty, vomiting of blood, severe diarrhea, acute inflammation of the intestinal tract, and loss of appetite. Some lesions have been found in the intestines and in the mouth and throat. After the bacteria invades the bowel system, it spreads through the bloodstream throughout the body, making even more toxins on the way. Gastrointestinal infections can be treated but usually result in fatality rates of 25% to 60%, depending upon how soon treatment commences.

Topic Prevention

Is There a Way to Prevent Infection?



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- In countries where anthrax is common and vaccination levels of animal herds are low, humans should avoid contact with livestock and animal products and avoid eating meat that has not been properly slaughtered and cooked.
- Also, an anthrax vaccine has been licensed for use in humans. The vaccine is reported to be 93% effective in protecting against anthrax.

Anthrax Overview

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Slide 16

Key Points

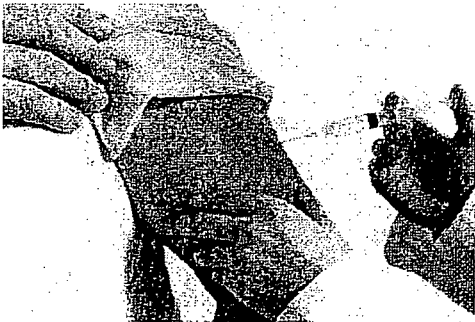
To prevent the infection in the first place:

- * Avoid contact with livestock or animal products if you are in an area that has a high incident level of contracted disease. Avoid eating meat if it has not been slaughtered and cook properly.
- * If you in a high incident area, the anthrax vaccine is available.

Topic Treatment

Is There a Treatment for Anthrax?

- Doctors can prescribe effective antibiotics.
- To be effective, treatment should be initiated early.
- If left untreated, the disease is most likely fatal.



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Anthrax (The) 11

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Slide 20

Key Points


Early detection of sources of anthrax infection can allow preventive measures to be taken.

Delays of only a few days may make the disease untreatable and treatment should be started even without symptoms if possible contamination or exposure is suspected.

The most effective form of prevention is vaccination against infection but this must be done well in advance of exposure to the bacterium, and does not protect indefinitely.

Topic Unit Introduction

Unit 3: National Response Overview



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Site 32

Key Points

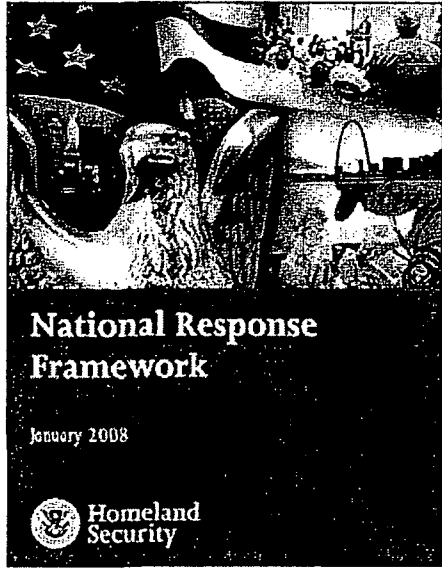
This unit provides an overview of the National Response to future incidents involving hazardous biological agents or other acts of terrorism in the United States.

Topic Unit Objectives

Unit 3 Objectives

Describe:

- The nation's response to the anthrax incidents in 2001
- The purpose of the National Response Framework (NRF)
- The key federal agencies, the structure, laws and guidelines in place to manage future incidents



Anthrax Overview

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Key Points

By the end of this Unit you should be able to describe :

- * The nations response to future incidents
- * The purpose of the National Response Framework (NRF)
- * Key federal agencies, structure and laws that will manage future incidents

Topic A Nations Response

National Response

As a result of the documented anthrax incidents, the National Response Team (NRT) formed a working group chaired by the EPA and made up of technical experts from:

- U.S. Department of Health and Human Services (HHS)
- Centers for Disease Control and Prevention (CDC)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- National Institute of Occupational Safety and Health (NIOSH)
- Occupational Health and Safety Administration (OSHA)
- U.S. Coast Guard (USCG)

To create the technical assistance and guidelines that would be critical in responding effectively, timely and safely to further releases of Anthrax or any other biological agent.

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Key Points


- * The National Response Team was set up to create technical assistance and guidelines that would be effective, timely and safe in the event of a future release of Anthrax or other biological agent
- * Expert from various agencies made up the NRT including: HHS, CDC, ATSDR, NIOSH, OSHA and USCG

Topic Introduction to the NRF (Video)

National Response Guidance

In January 2008, the Department of Homeland Security (DHS) issued a National Response Framework (NRF) which describes how federal agencies/departments will conduct all-hazards response to domestic incidents such as natural disasters or terrorist attacks. ([View Facts about NRF](#))

[Click to view Video](#)



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Key Points

This video provides an introduction to the NRF:

Video Transcript:

In recent years, our Nation has faced an unprecedented series of disasters and emergencies. As a result, our national response structures have evolved and improved to meet these threats.

The National Response Framework is the next step in this evolution, and as such defines how we respond as a Nation. Based on best practices and stakeholder input, the Framework presents the guiding principles that enable all response partners to prepare for and provide a unified national response to disasters and emergencies – from the smallest incident to the largest catastrophe.

Topic Introduction to the NRF (Video)

Video Transcript continued:

Building on the National Incident Management System, the Framework's coordinating structures align key roles and responsibilities fostering response partnerships at all levels of government, and with nongovernmental organizations and the private sector. Given its flexibility and scalability, the National Response Framework is always in effect and elements can be implemented at any level and at any time.

The Framework establishes a response vision through five key principles. Let's take a closer look at these principles, starting with engaged partnership.

Engaged partnership means that leaders at all levels develop shared response goals and align capabilities so that no one is overwhelmed in times of crisis.

The next principle is tiered response. Incidents must be managed at the lowest possible jurisdictional level and supported by additional capabilities when needed.

The third principle is scalable, flexible, and adaptable operational capabilities. As incidents change in size, scope, and complexity, the response must adapt to meet requirements.

The fourth principle is unity of effort through unified command. Unity of effort respects the chain of command of each participating organization while harnessing seamless coordination across jurisdictions in support of common objectives.

The last principle is readiness to act. It is our collective duty to provide the best response possible. From individuals, households, and communities to local, tribal, State, and Federal governments, national response depends on our readiness to act.

The National Response Framework strives to improve coordination among all response partners. And through these partnerships, we can work together to help save lives and protect America's communities.

[end of transcript]

The purpose of the National Response Framework is to ensure that all response partners across the Nation understand domestic incident response roles, responsibilities, and relationships in order to respond more effectively to any type of incident.

The framework is written especially for government executives, private-sector and nongovernmental organization leaders, and emergency management practitioners.

Topic Federal Agencies and Plans

Key Federal Agencies and Plans

As the release and detection of anthrax is mostly associated with a criminal or terrorist act, a response will be carried out under the frame work of one, two or all of the following plans.

- The U.S. Government Interagency Domestic Terrorism Concept of Operations Plan (CONPLAN) when the threatened or actual release is suspected to be or is the result of a criminal or terrorist act. Under the CONPLAN, the DOJ and FBI are the lead agencies that coordinate the overall federal response and leads crisis management activities.
- The Federal Response Plan (FRP), which is usually activated by a Presidential Disaster Declaration. Under the FRP, FEMA should be the lead agency coordinating activities.
- The National Oil and Hazardous Substance Pollution Contingency Plan (NCP), under which EPA, the USCG or other federal agency would lead incident activities depending on location and seriousness of incident.

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Slide 66

Key Points

- * The CONPLAN is the primary mechanism for federal response to a suspected act of terrorism in the United States. The CONPLAN provides overall guidance on how the government would act to a threat or incident, particularly one involving WMD.
- * The FRP outlines how the federal government implements the Robert T. Stafford Disaster Relief and Emergency Assistance Act to assist state and local governments when a major disaster overwhelms their ability to respond.
- * The NCP, 40 CFR Part 300, implements the response authorities of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, or "SuperFund") and the Clean Water Act. The NCP provides policy and protocols for cleaning up releases of oil and hazardous substances, including terrorist-related releases of chemical and biological contamination.

Topic Applicable Laws

Applicable Laws and Regulations

- Several federal laws apply to bio-contaminated sites such as, but not limited to:
 - Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the Superfund Amendments and Reauthorization Act (SARA), which authorizes EPA to conduct "removal actions" for pollutants or contaminants
 - Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which requires bio-decontamination products to be registered or exempted.
 - Occupational Health and Safety Act, which has requirements concerning HASP

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Slide 37**Key Points**

The enactment of several laws identify guidelines on how contaminated sites are to be managed

- * The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the Superfund Amendments and Reauthorization Act (SARA),
- * The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),
- * and the Occupational Health and Safety Act.

Topic Applicable State Laws

Applicable State and Local Laws and Regulations

- State and local governments may also have laws or regulations that apply to bio-contaminated sites
- Decontamination product users must comply with all applicable federal, state and local requirements.

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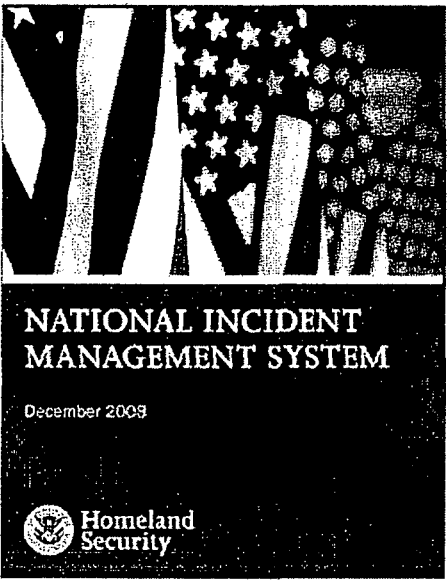
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Key Points

State and local regulations are required to be understood and followed in addition to federal regulations

Topic Unit Introduction

Unit 4:
Incident Response Overview



Homeland National Overview

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Site 26

Key Points

The Department of Home Land Security (DHS) has issued a National Incident Management System (NIMS) that provides a Standard Incident Command System (ICS) for use by federal, state and local agencies when responding to a domestic incident.

This unit will help you to become familiar with :

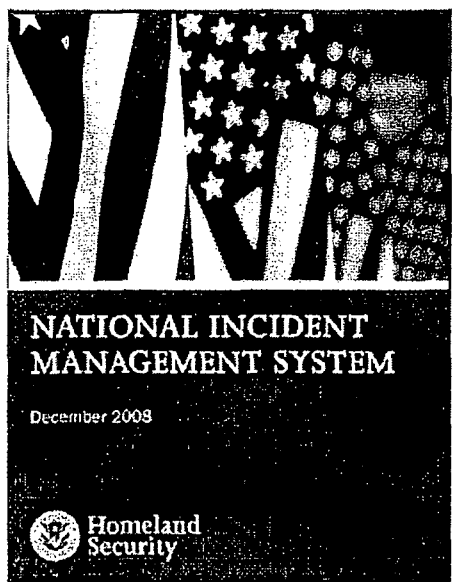
- * The incident response steps to an incident,
- * The key activities in the decontamination process
- * and the key elements of the Health and Safety Plan (HASP)

Topic Unit Objectives

Unit 4 Objectives

Describe:

- The incident response activities
- The decontamination response activities
- The key elements of the Remediation Action Plan
- The key elements of the Health and Safety Plan (HASP)
- Proper Personal Protective Equipment (PPE)



Agilent Overview

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Slide 46

Key Points

By the end of this Unit you should be able to describe:

- * The incident response activities in the event of a release of Anthrax or other biological agent
- * The decontamination steps that have been identified to inactivate a suspected release of Anthrax or other biological agents listed on the label
- * The key elements of a Remediation Action Plan
- * The key elements of a Health and Safety Plan (HASP)
- * The proper personal protective equipment (PPE) that is required in a contaminated environment

Topic Introduction to incidence response

Incidence Response Overview

In the event of national incident that involves the release of a biological substance, key responses are triggered to quickly identify, assess, decontaminate and restore the environment to a safe condition.

Each response is well defined in the various agency plans that have been created to manage any crisis.

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Slide 41

Key Points

- * A future incident involving the release of a biological substance will trigger key responses that have been created to quickly identify, assess, decontaminate and restore the environment to its original state

Topic Incident Response Activities

Response and Recovery					
Crisis Management		Consequence Management			
Notification	First Response	Remediation/Cleanup			Restoration/Reoccupancy
		Characterization	Decontamination	Clearance	
Receive information on biological incident Identification of suspect release sites Notification of appropriate agencies	Initial threat assessment HAZMAT and emergency activities Forensic investigation Public health actions Screening sampling Determination of agent type, concentration, and stability Risk communication	Characterization of biological agent Characterization of affected site Site containment Continue risk communication Characterization environmental sampling and analysis Initial risk assessment Clearance goals	Decontamination strategy Remediation Action Plan Worker health and safety Site preparation Source reduction Waste disposal Decontamination of sites or items Decontamination verification	Clearance environmental sampling and analysis Clearance decision	Renovation Reoccupation decision Long-term environmental and public health monitoring

Key Points

There are six phases to a response of a biological incident:

- * Crisis Management
 - * Notification - Notification of appropriate agencies, identification of release sites
 - * First response - Initial assessment, Forensic investigation, sampling, etc,
- * Consequence Management
 - * Characterization - of biological agent, site., environmental sampling, clearance goals
 - * Decontamination - Strategy, Remediation Action Plan, site preparation, decontamination activities, verification
 - * Clearance - environmental sampling, clearance decision
 - * Restoration - Renovation, Reoccupation decision, monitoring

Topic Decontamination Activities

Decontamination Response Activities

- **Characterization of the Agent and Site**—Environmental sampling and lab analyses are performed to identify the agent, its characteristics, and the locations and levels of contamination.
- **Decontamination Strategy**—The nature and extent of agent contamination, site characteristics, and other factors are considered in determining the optimal strategy for decontamination.
- **Remediation Action Plan (RAP)**—A comprehensive remediation plan is developed and approved by the IC/UC that will guide the remediation/cleanup.
- **Decontamination of Sites or Items**—As specified in the RAP, one or more decontamination methods are applied to inactivate, reduce or remove the target spores.
- **Clearance Environmental Sampling**—Environmental sampling of treated surfaces is performed to determine whether the clearance goals have been met. If so, the decontamination is deemed successful and unprotected reentry into the site is allowed.

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Key Points

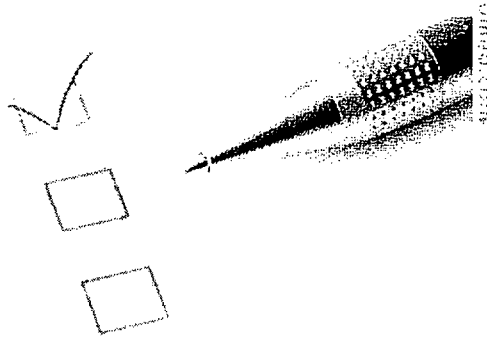
Key decontamination activities include, but not limited to the following :

- * Characterization of the Agent and site - samplings are performed to identify the agent, its characteristics and the location and level of contamination.
- * Decontamination Strategy - a detailed strategy is developed after characterizing the nature, and extent of the contamination.
- * Remediation Action Plan (RAP) - a comprehensive remediation plan is developed.
- * Decontamination of Sites or items - As specified by the RAP, decontamination methods are applied to inactivate, reduce or remove the suspected biological agent.
- * Clearance Environmental Sampling - sampling of treated surfaced is performed to determine the effectiveness of the process and determine if the clearance goals have been met.

Topic Introduction to the Remediation Action Plan

Remediation Action Plan Characteristics

- A Remediation Action Plan (RAP) or equivalent plan describes the procedures and steps that are necessary for ensuring a legal and effective remediation of the contaminated area
- The person(s) applying an antimicrobial pesticide will likely be responsible for assisting the property owner and/or responsible government agency in developing a RAP or equivalent plan.
- The contents of a RAP or equivalent plan will vary from site-to-site.
- The applicator must follow the RAP as well as the labeling for each product.



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Key Points

- * The Remediation Action Plan (RAP) describes the procedures and steps required to effectively remediate the contaminated sites.
- * The entities assigned to apply the antimicrobial pesticide will assist in developing the RAP.
- * The contents of the RAP are site specific.
- * Those entities responsible for applying the antimicrobial product are required to follow the RAP as well as the label and use-directions of the product.

Topic Contents of the Remediation Action Plan

Remediation Action Plan Contents (1 of 2)

- A brief summary of the site characterization report.
- Worker health and safety plans and quality assurance/quality control procedures.
- A list of required Federal, State and local permits or approvals to conduct the remedial action.
- A discussion of how the remedial action will attain the selected remediation standard for the site.
- Design and construction details for the remedial action, including expected effectiveness.

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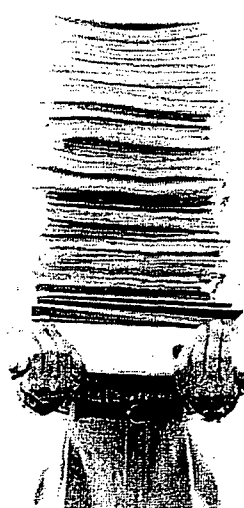
Key Points

- * A brief summary of the site characterization report
- * Worker health and safety plans and quality assurance quality control procedures
- * List of permits required by Federal, State and local governments to conduct remedial action
- * Discussion on how the remedial action will be successful
- * Details of the plan including expected effectiveness

Topic Contents of the Remediation Action Plan

Remediation Action Plan Contents (2 of 2)

- Operation and maintenance details for the remedial action.
- A site map showing the location of buildings, roads, property boundaries, remedial equipment locations and other information pertinent to the remedial action.
- A description of the media and parameters to be monitored or sampled during the remedial action.
- A description of the analytical methods to be utilized and an appropriate reference for each.
- A description of the methodology that will be utilized to demonstrate attainment of the selected remediation standard.



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Slide 45

Key Points

- * Operation and maintenance details for the remedial action
- * Site map showing the location buildings, roads, etc pertinent to the remedial action
- * Description of the media and parameters to be monitored or sampled during the remedial action
- * Description of the analytical methods to be used
- * Description of the methodology that will be used to verify remediation standard

Topic Introduction to HASP

Health and Safety Considerations

The safety and well being of workers and other individuals potentially exposed to anthrax is the primary focus of the Health and Safety Plan (HASP).

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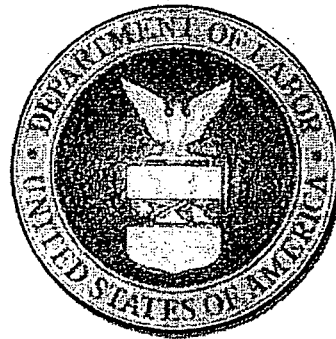
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Key Points

* In the event of a future incident involving the release of a biological substance, health and care of workers in and around the site are of primary concern and is one of the subjects addressed in the Health and Safety Plan (HASP)

Topic What is HASP**What is HASP?**

- It is part of OSHA's *Hazardous Waste Operations and Emergency Response* (HAZWOPER) standard (29 CFR 1910.120)
- It is a written health and safety plan that identifies site hazards and appropriate controls to protect employee health and safety for cleanup operations

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Since 1977**Key Points**

What is HASP

- * It is a written plan that identifies the site hazard and the appropriate controls to protect employee and worker health while proceeding with cleanup operations.
- * It is part of OSHA's Hazardous Waste Operations and Emergency Response (HAZWOPER) standard

Topic Key elements of HASP

Key Elements of HASP

- The recommended elements identified below meet or exceed the intent of a site-specific HASP as described in the standard, 1910.120(b)(4):
 - Organizational Structure
 - Site Characterization and Job Hazards Analysis
 - Site Control
 - Training
 - Medical Surveillance
 - **Personal Protective Equipment**
 - Exposure Monitoring
 - Temperature Extremes
 - Spill Containment
 - Decontamination
 - Emergency Response
 - Standard Operating Procedures

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Key Points

- * These are key elements of the HASP plan
- * HASP describes how PPE is selected and used to protect workers from exposure to hazardous substances and hazardous conditions on the site. Exposure hazards from anthrax spores, as well as those from the decontamination process, are considered.

Topic Introduction to Worker Health and Safety

Worker Health and Safety

- Workers entering an area contaminated with the anthrax spores must follow the procedures described in an approved Health and Safety Plan (HASP).
- The HASP describes all site hazards (including physical, biological, and chemical hazards) and appropriate protective measures such as Personal Protective Equipment (PPE) and vaccinations and/or medications.
- Workers must also be HAZWOPER trained, as required by OSHA (29 CFR 1910.120 and 29 CFR 1926.65).
- Workers who enter the Hot Zone must wear appropriate PPE and when they exit the Hot Zone, doff PPE and decontaminate self and equipment per the HASP.

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Key Points

- * All workers must be HAZWOPER trained. Employees receive general training regarding proper selection, use and inspection of PPE during initial HAZWOPER training (or equivalent) and subsequent refresher training.
- * An initial level of PPE is assigned to each task to provide an adequate barrier to exposure hazards. Initial PPE ensembles are selected based on the anticipated route(s) of entry of biological and chemical hazards and their concentration.

Topic Personal Protective Equipment (PPE)

Personal Protective Equipment (PPE)

Workers should know when PPE is necessary, what type to use, how it should be worn, what its limitations are, and how long it is likely to last. (ref 29 CFR 1910.134)

Skin Protection - Tyvek or equivalent coveralls should be used as a minimum level of protection. Unpowdered disposable gloves made of lightweight nitrile or vinyl for the hands with a thin cotton glove inside for prolonged exposure is recommended.



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Key Points

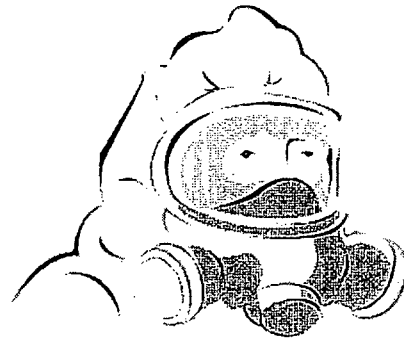
- * Skin Protection is provided by specially designed lightweight materials that protect the worker from the hazardous microorganisms being treated.

Topic Personal Protective Equipment (PPE)**Personal Protective Equipment (PPE)**

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Respiratory Protection -

Respiratory protection is a required component of the PPE program. Powered air-purifying respirators (PAPRs) with P100 filters or full-face negative pressure air purifying respirators (APRs) with N95 filters provide adequate protection in most cases.

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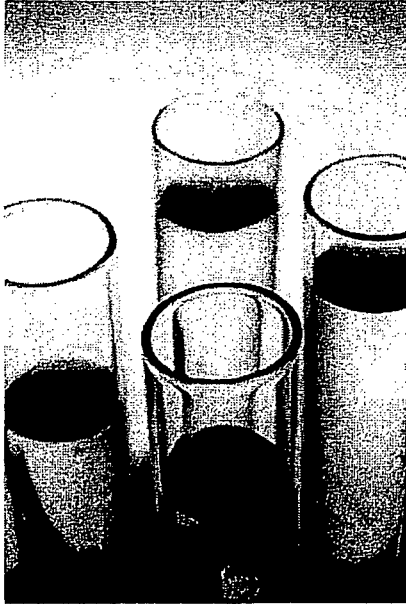
Key Points

- * Respiratory protection is selected, fitted, used, stored and maintained in accordance with the Respiratory Protection Program.
- * Powered air-purifying respirators (PAPRs) with P100 filters or full face negative pressure air purifying respirators (APRs) with N95 filters provide adequate protection in most cases.

Topic Unit Introduction

Unit 5

**sBioMed
STERIPLEX Ultra™
Overview**



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Key Points

This unit will help you to become familiar with :

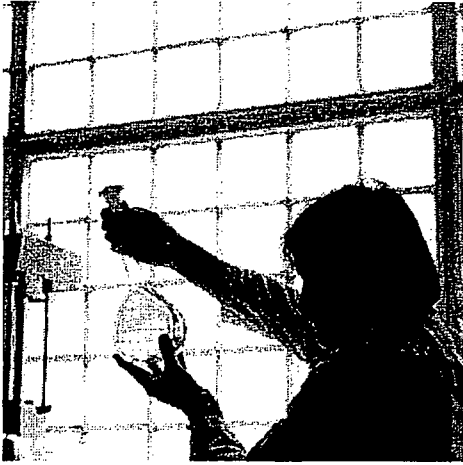
- * The properties of the STERIPLEX Ultra™ family of products,
- * How to prepare STERIPLEX Ultra™ for application
- * Use-directions on how to apply STERIPLEX Ultra™ in the inactivation process

Topic Unit Objectives

Unit 5 Objectives

Describe:

- The characteristics of STERIPLEX Ultra™
- The activation process of the two part product
- The methods to apply STERIPLEX Ultra™ to affected areas
- Other Label instructions
- Post-decontamination activities



AgriMed Chemicals

SBIO MED
Slide 22

Key Points


By the end of this unit, you should be able to describe:

- * Characteristics and properties of STERIPLEX Ultra™ ,
- * The process to activate the STERIPLEX Ultra™ product,
- * The methods of applying the STERIPLEX Ultra™ product to contaminated surfaces.
- * and, Post-decontamination activities

Topic Product Characteristics

Efficacy of Steriplex Ultra™

- Steriplex Ultra has been tested and proven to destroy the anthrax spore.
- EPA approved protocols have demonstrated that Steriplex can penetrate bio-burden and kill anthrax in 30 minutes.
- Independent laboratories using suspension tests recorded killing rates greater than 7 log in 30 seconds



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Slide 78

Key Points

- * STERIPLEX Ultra™ is extremely effective against *Bacillus anthracis*.
- * Endospores is the toughest class to kill, anthrax is part of this group.
- * Efficacy data has been developed that demonstrate high rates of kill. (99.99999%)

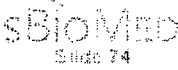
Topic Product Characteristics

STERIPLEX Ultra™ (Part A) Toxicity

Steriplex Ultra™ is a two-part system requiring the activation of the product prior to use.

Acute Oral Toxicity	No Mortalities or side effects. No LD ₅₀
Acute Dermal Irritation	Non Irritating to Skin.
Acute Dermal Toxicity	No Mortalities or side effects.
Dermal Sensitization	No Contact Sensitization.
Acute Eye Irritation	Moderate Temporary Irritation.
Acute Inhalation Toxicity	No Mortalities or side effects.

Part A, comprising of solution in the main container has a signal word of "CAUTION".



Slide 74

Key Points

* STERIPLEX Ultra™ is a two-part system that must be activated prior to use. The main component has a signal word of "CAUTION" applied to the label. The data that was generated with respect to the toxicity shows low toxic effects of Part A.

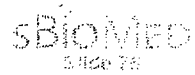
Topic Product Characteristics

STERIPLEX Ultra™ (Part B) Toxicity

Steriplex Ultra™ is a two-part system requiring the activation of the product prior to use.

Acute Oral Toxicity	1015 mg/kg LD ₅₀
Acute Dermal Irritation	Non Irritating to Skin.
Acute Dermal Toxicity	1912 mg/kg LD ₅₀
Dermal Sensitization	Strongly Corrosive
Acute Eye Irritation	Corrosive
Acute Inhalation Toxicity	0.49 mg/l

Part B, comprising of solution in the 10oz container has a signal word of "DANGER".



Since 78

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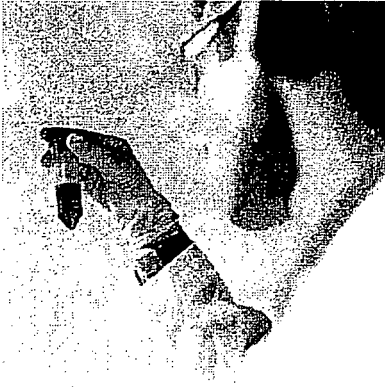
Key Points

- * STERIPLEX Ultra™ is a two-part system that must be activated prior to use. The activator component (part B) has a signal word of "DANGER". The data that was generated shows a HIGH degree of toxicity. Care is required when preparing STERIPLEX Ultra™ for use.
- * Once the product has been activated with Part B, the mixed product has a toxicity profile similar to the Part A solution.

Topic Product Applications

STERIPLEX Ultra™ applications:

- For use as a sporicidal decontaminant in industrial, commercial, and institutional settings including the following sites:
 - Offices
 - Government and residential buildings
 - Educational buildings
 - Public and private buildings
 - Commercial, government and private vehicles
 - Personal Protective Equipment
 - Hospitals/Health care facilities
 - Military institutions and equipment
 - Manufacturing facilities
 - Hotels, Cruise ships and Airports



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Slide 10

Key Points

- * Numerous applications will benefit from the use of STERIPLEX Ultra™
- * Industrial and commercial applications will enjoy the effectiveness of STERIPLEX Ultra™
- * Government and Military will benefit from the efficacy properties as well

Topic Product Packaging, Labeling and Use-directions

sBioMed™ Packaging Labeling and Use-directions

For use only by:

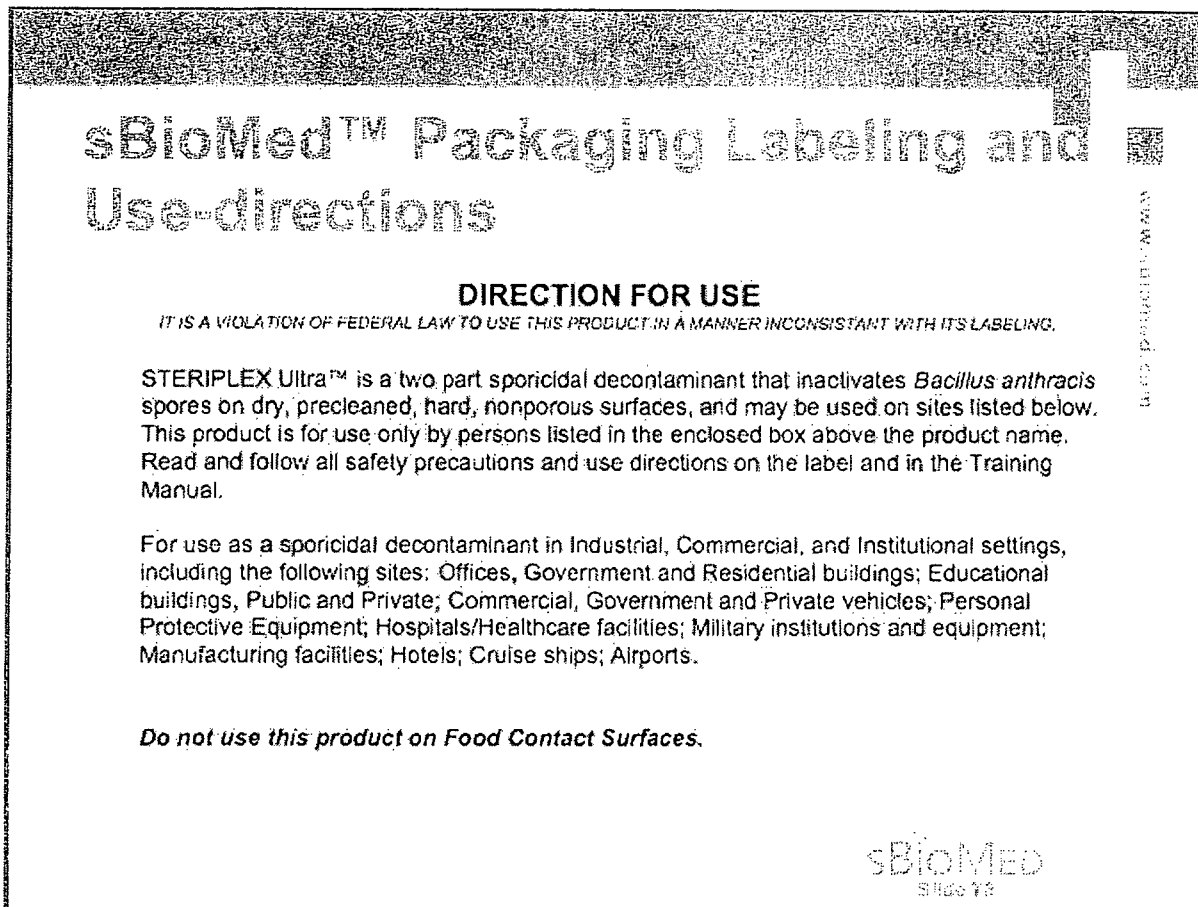
- Federal On-Scene Coordinators and contractors and other trained federal/state/local response personnel under the FOOSC's supervision;
- Trained U.S. Military personnel and contractors under their supervision;
- Persons who, within the preceding 24 months, have been trained and determined to be competent by the registrant (or its contractor) following completion of the required training.

Under the terms and conditions of this product's registration, this product may only be sold or distributed by the registrant directly to the persons identified above.

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Key Points

- * STERIPLEX Ultra™, will be strictly regulated through the EPA.
- * Only designated agencies and personnel will be able to purchase and use the STERIPLEX Ultra™ product
- * Special training is required, under law, in order to use this product for the inactivation of an anthrax spores.

Topic Product Packaging, Labeling and Use-directions

sBioMed™ Packaging Labeling and Use-directions

DIRECTION FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTANT WITH ITS LABELING.

STERIPLEX Ultra™ is a two part sporicidal decontaminant that inactivates *Bacillus anthracis* spores on dry, pre-cleaned, hard, nonporous surfaces, and may be used on sites listed below. This product is for use only by persons listed in the enclosed box above the product name. Read and follow all safety precautions and use directions on the label and in the Training Manual.

For use as a sporicidal decontaminant in Industrial, Commercial, and Institutional settings, including the following sites: Offices, Government and Residential buildings; Educational buildings, Public and Private; Commercial, Government and Private vehicles; Personal Protective Equipment; Hospitals/Healthcare facilities; Military institutions and equipment; Manufacturing facilities; Hotels; Cruise ships; Airports.

Do not use this product on Food Contact Surfaces.

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Key Points

- * It is a violation of Federal Law to misuse the product as labeled.
- * STERIPLEX Ultra™ can be used in many different settings
- * Product is not intended for use on food contact surfaces.

Topic Product Packaging, Labeling and Use-directions

sBioMed™ Packaging Labeling and Use-directions

DIRECTION FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTANT WITH ITS LABELING.

PREPARATION— STERIPLEX Ultra™ is a two-part sporicidal decontaminant system consisting of: STERIPLEX Ultra™ (Part A) (EPA Reg. No. 84545-); a one gallon container of 0.03% silver, and STERIPLEX Ultra™ Activator (Part B) (EPA Reg. No. 84545-); a smaller bottle containing 15% peracetic acid and 22% hydrogen peroxide .

1. Wearing specified personal protective equipment (PPE) as described under the PRECAUTIONARY STATEMENTS on this label, find the STERIPLEX Ultra™ Activator (Part B) bottle. Remove the cap from the bottle.
2. On the "Part A" container, remove the cap. Pour the entire contents of the STERIPLEX Ultra™ Activator (part B) into the opening of the "Part A" container.
3. Discard the spent STERIPLEX Ultra™ Activator (Part B) container in an approved waste disposal receptacle as directed on the STERIPLEX Ultra™ Activator (Part B) label. Replace cap back onto the "Part A" container.
4. Mix the two-part solution by agitating the contents for approximately 15 seconds.
5. Pour the mixed solution into applicator equipment for usage.
6. Mix fresh batch daily. Dispose of unused solution within 24 hours of mixing.

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Key Points

- * STERIPLEX Ultra™ is a two part disinfection system.
- * STERIPLEX Ultra™ part A is found in the main container, usually a one gallon container.
- * Part B is a bottle of activator that will be supplied with the main container.

Topic Product Packaging, Labeling and Use-directions

STERIPLEX Ultra™ (Part A)
FIRST AID Statements

**FIRST AID FOR
 STERIPLEX Ultra™ (Part A)**

IF IN EYES	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing. Call a poison control center or physician for treatment advice.
IF ON SKIN OR CLOTHING	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or physician for treatment advice.
IF SWALLOWED	Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person. Call a poison control center or doctor immediately for treatment advice.

Have the product container or label with you when calling a poison control center or going for treatment.
 FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-222-1222

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Key Points

- * STERIPLEX™ Ultra is a two part disinfection system.
- * STERIPLEX™ Ultra part A First Aid instruction are also applicable to Part A only.

Topic Product Packaging, Labeling and Use-directions

STERIPLEX Ultra™ Activator (Part B)

FIRST AID Statements

FIRST AID FOR STERIPLEX Ultra™ Activator (Part B)	
IF IN THE EYES	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after 5 minutes, and then continue rinsing. Call a poison control center or physician for treatment advice.
IF ON SKIN OR CLOTHING	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or physician for treatment advice.
IF SWALLOWED	Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person. Call a poison control center or doctor immediately for treatment advice.
IF INHALED	Move person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.	
Have the product container or label with you when calling a poison control center or going for treatment.	
FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-222-1222	

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Key Points

- * STERIPLEX™ Ultra is a two part disinfection system.
- * STERIPLEX™ Ultra First Aid statements applicable only to Part B.

Topic Product Application Methods

STERIPLEX Ultra™ Application Methods

Application Methods - For use on Hard, Non-porous, Non-Food Contact Surfaces

STERIPLEX Ultra™ can be applied to surfaces by conventional (spray), (mopping), (cloth) or (sponge) method.

To Fill or (refill) empty spray bottle:

1. Remove trigger sprayer (or cap) from empty bottle.
2. Unscrew cap (or open spigot) and pour contents into empty bottle.
3. Replace trigger sprayer (or cap) and use as instructed.

Refill sprayer on with STERIPLEX Ultra™ mixture.

IMPORTANT: Once activated, the mixed STERIPLEX Ultra™ solution can only be used as a sporicide for 10 days. Dispose of any solution that has exceeded this timeframe after activation. Mark the date the solution was mixed on the container with a permanent marker in the space provided.

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Key Points

- * STERIPLEX™ Ultra is intended to be used on Dry, Pre-cleaned, Hard, Non-porous, Non-Food contact surfaces
- * Product can be applied using conventional methods such as spray, mopping, cloth or sponge
- * Follow the appropriate instructions for using these methods
- * Once the solution is mixed it is active as a sporicide for 10 days. Any product remaining after these timeframes must be disposed of. Marking the date of activation on the container will aid in tracking the period of activation

Topic Product Use-Directions

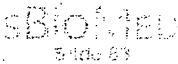
STERIPLEX Ultra™ Application Methods

For Use on Dry, Precleaned, Hard Non-Porous Surfaces

For heavily soiled areas, a precleaning step is required. Wash soiled surfaces with a compatible detergent using a cloth, sponge or cleaning device to ensure visible soils are removed. Rinse with potable water and allow to dry. Spray or wipe on the mixed STERIPLEX Ultra™ solution by the following means: mop, cloth, sponge, spray bottle or commercial sprayer.

1. Thoroughly apply the solution to the surface using a prescribed method covering the surface with a thin film of product at room temperature.
2. Allow the product to remain on the surface for a minimum of 30 minutes.
3. For clean up, rinse the surfaces with a clean cloth or sponge several times with running water.
4. Larger areas may be treated by applying the product with a spray bottle or commercial sprayer. Allow the product to remain on the contact surface for a minimum of 30 minutes, and then rinse surfaces as prescribed above.
5. Dispose of cleaning utensils as directed in the directions.

See Training Manual for additional, detailed instruction on product applications.


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Key Points

- * Surfaces must be cleaned before treating with STERIPLEX Ultra™
- * Surfaces must remain in contact with the solution for 30 minutes before rinsing and removing the solution.

Topic Product Use-Directions**STERIPLEX Ultra™ Application
Methods**

DECONTAMINATION OF EQUIPMENT – For heavily soiled areas, a precleaning step is required. To the extent possible, dismantle equipment and tools. Wash soiled surfaces with a compatible detergent using a cloth, sponge or cleaning device to ensure visible soils are removed. Rinse with potable water and allow to dry. All surfaces to be treated must be dry (i.e., not visibly wet) prior to application. Apply the STERIPLEX Ultra™ mixed solution in the following manner:

1. Pour desired amount of solution into a tray or receptacle that will hold the tools and allow for complete immersion in solution.
2. Immerse equipment or tools for a minimum of 30 minutes.
3. Transfer equipment or tools to a rinse bath to remove the solution. Dipping the equipment or tools a couple of times into the rinse bath will thoroughly remove any solution.
4. Allow equipment or tools to air dry prior to reuse.

See Training Manual for additional, detailed instruction on product applications.

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Key Points

- * Equipment must be cleaned and/or dismantled before treating with STERIPLEX Ultra™
- * Equipment must remain in contact with the solution for 30 minutes before rinsing and removing the solution.

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Topic Product Precautionary Statements**STERIPLEX Ultra™ Precautionary Statement****PERSONAL PROTECTIVE EQUIPMENT (PPE) WHEN MIXING THIS PRODUCT**

Eyes and Face: Use cup type chemical goggles and a full-face shield when mixing and applying this product to the intended surfaces.

Protective Clothing: Use rubber or neoprene footwear and a rubber or neoprene apron or full-body protective clothing. Completely submerge into water any clothing or other materials contaminated with hydrogen peroxide from contact with the concentrated or mixed products, and then allow clothing to dry. Residual hydrogen peroxide, if allowed to dry on materials such as fabrics, cotton, leather, wood, paper, or other combustibles can cause the material to ignite and result in a fire.

Gloves: Rubber or neoprene gloves are required when mixing and applying product. Thoroughly wash the outside of gloves with soap and water prior to removal. Inspect regularly for leaks.

Respiratory: Wear an approved full-face acid/gas cartridge or canister respirator. If concentrations are unknown (e.g., significant spill or other emergencies), or if they are anticipated to be above 5 ppm for hydrogen peroxide or 50 ppm for acetic acid, use of a self-contained breathing apparatus (SCBA).

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Slide 25**Key Points**

- * When using this product, personal protective equipment must protect the eyes and skin (mainly the hands) and must protect against inhalation of the product.

Topic Product Precautionary Statements for Part A

STERIPLEX Ultra™ (Part A)
Precautionary Statements (1 of 3)

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION - Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Harmful if absorbed through skin. Remove and wash contaminated clothing before reuse.

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Key Points

- * It is important for user to understand hazards of the product to themselves and the environment
- * Use care in protecting eyes and skin when product (Part A) is in contact with the user.

Topic Product Cautionary Statements for Part A**STERIPLEX Ultra™ (Part A)
Precautionary Statements (2 of 3)****Environmental Hazards**

This pesticide is toxic to birds, fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact you State Water Board or Regional Office at the EPA.

SBIOMED
Slide 95**Key Points**

- * Protect estuaries and other water sources by discarding the product properly.
- * Contact local Water Board or Regional EPA offices for proper disposal methods.

Topic Product Precautionary Statements for Part A**STERIPLEX Ultra™ (Part A)
Precautionary Statements (3 of 3)****Physical and Chemical Hazards**

The mixed product (STERIPLEX Ultra™ (Part A) and STERIPLEX Ultra™ Activator (Part B) contains hydrogen peroxide and peroxyacetic acid, which are strong oxidants and pose a **fire, explosion or container rupture hazard**. Avoid excessive heat, contamination, or contact with combustible materials. In case of fire use water only. Contain spills and dilute with at least 20 parts of water. After diluting the spill, sodium sulfite may be used to destroy the peroxide. Minimal corrosion effects may occur with natural rubber and soft iron products. Stainless steels, plastics and polymers exhibit no corrosive effects. Never bring mixture in contact with other sanitizers, cleaners or organic substances.

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Key Points

- * Product should not be exposed to elements such as heat or other combustible materials.
- * The product contains elements which are strong oxidants and pose a fire, explosion or container rupture hazard if not treated properly.
- * USE WATER only in the case of fire.

Topic Product Storage and Disposal for Part A

STERIPLEX Ultra™ (Part A) Storage and Disposal (1 of 2)

STORAGE AND DISPOSAL
Do not contaminate water, food, or feed by storage or disposal

PESTICIDE STORAGE: Store in original containers in a cool, well-vented area, away from direct sunlight. Do not allow product to become overheated in storage. This may cause increased degradation of the product, which will decrease product effectiveness. In case of spill, flood area with large quantities of water.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or environmental control agency, or the hazardous waste representative at the nearest EPA Regional Office for guidance.

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Key Points

* It is a violation of federal law to dispose of unused product in a manner not identified in the product label.

Topic Product Storage and Disposal for Part A

**STERIPLEX Ultra™ (Part A) Storage
and Disposal (2 of 2)**

STORAGE AND DISPOSAL (Continued)

CONTAINER DISPOSAL:

Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available.

[Container sizes of 1 gal. – 5 gal.] – Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

[Containers with capacities greater than 5 gallons or 50lbs] – Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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Key Points

* Disposal of containers is detailed on the label instructions.

Topic Product Precautionary Statements for Part B

STERIPLEX Ultra™ (Part B)
Precautionary Statements (1 of 3)

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not breathe vapors or spray mist. Do not get in eyes on skin or on clothing. Wear goggles and/or face shield and rubber gloves when handling. Do not enter an enclosed area without proper respiratory protection. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse.

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Key Points

- * It is important for user to understand hazards of the product to themselves and the environment
- * Use care in protecting eyes and skin when product (Part B) is in contact with the user. User must use and follow all of the precautionary guides as identified on the label to protect themselves.

Topic Product Precautionary Statements**STERIPLEX Ultra™ (Part B)
Precautionary Statements (2 of 3)****Environmental Hazards**

This pesticide is toxic to birds, fish, and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the US Environmental Protection Agency.

SBIOMED
Slide 103**Key Points**

- * Protect estuaries and other water sources by discarding the product properly.
- * Contact local Water Board or Regional EPA offices for proper disposal methods.

Topic Product Precautionary Statements**STERIPLEX Ultra™ (Part B)
Precautionary Statements (3 of 3)****Physical and Chemical Hazards**

STRONG OXIDIZING AGENT. Corrosive. Mix only with STERIPLEX Ultra™ (Part A) disinfectant solutions. Product must be diluted in accordance with label directions prior to use. STERIPLEX Ultra™ (Part B) Activator is not combustible; however, at temperatures exceeding 156°F, decomposition occurs releasing oxygen. The oxygen released could initiate combustion.

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Key Points

- * Product should not be exposed to elements such as heat or other combustible materials.
- * The product contains elements which are strong oxidants and pose a fire, explosion or container rupture hazard if not stored properly.
- * **USE WATER** only in the case of fire.

Topic Product Storage and Disposal Statements

STERIPLEX Ultra™ (Part B) Storage and Disposal (1 of 3)

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE:
 Never return STERIPLEX Ultra™ Activator (Part B) to the original container after it has been removed. Avoid all contaminants, especially dirt, caustic reducing agents, and metals. Contamination and impurities will reduce shelf life and can induce decomposition. In case of decomposition, isolate container, douse container with cool water and dilute STERIPLEX Ultra™ Activator (Part B) with large volumes of water. Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at temperatures below 86° F. Do not store on wooden pallets.

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Key Points

* Appropriate storage of the STERIPLEX Ultra Activator™ (Part B) in approved conditions is necessary to achieve top performance.

Topic Product Storage and Disposal Statements**STERIPLEX Ultra™ (Part B) Storage
and Disposal (2 of 3)****STORAGE AND DISPOSAL (Continued)****PESTICIDE DISPOSAL:**

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods of disposal may vary by location, regulatory agencies should be contacted prior to disposal. STERIPLEX Ultra™ (Part B) Activator, which is to be discarded, should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

SBIOMED
Side 103**Key Points**

- * It is a violation of federal law to dispose of unused product in a manner not identified on the product label.

Topic Product Storage and Disposal Statements

STERIPLEX Ultra™ (Part B) Storage and Disposal (3 of 3)

STORAGE AND DISPOSAL (Continued)

CONTAINER DISPOSAL:
 Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available.
 Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap and shake for 10 seconds, then uncap and discard rinsate. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times, and then discard container and cap.

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Key Points

- * Disposal of containers is detailed on the label instructions.
- * All containers are non-refillable. Offer for recycling if available
- * To clean containers before disposal, follow the triple rinse instructions

Topic Post Decontamination Activities

Post Decontamination Activities

Decontamination of Personal Protective Equipment (PPE)

A Personnel Decontamination Program should be implemented to prevent secondary contamination from the PPE. A multi-station personal decontamination line must be established for personnel and tools leaving the contamination areas. The Remediation Action Plan will address the specific methods and procedures.

Post-Decontamination Equipment Procedures

The Remediation Action Plan (RAP) will address the appropriate procedures to decontaminate equipment and apparatus that are used in the cleanup process. Sufficient detail will identify the proper cleaning and disposal techniques that will be required for specific equipment, tools or other items that are used during the decontamination process.

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Key Points

Post Decontamination Activities :

- * Decontamination of Personal Protective Equipment,
 - * Multi-station line to decontaminate personnel and tools, as personnel exit the contamination site
- * Decontamination of equipment used in the cleanup process

Topic Post-Decontamination Activities**Additional Post-Decontamination Activities**

- Collection, Treatment and Disposal of Wastes
- Clearance sampling and analysis
- Renovation
- Reoccupation
- Long term Monitoring

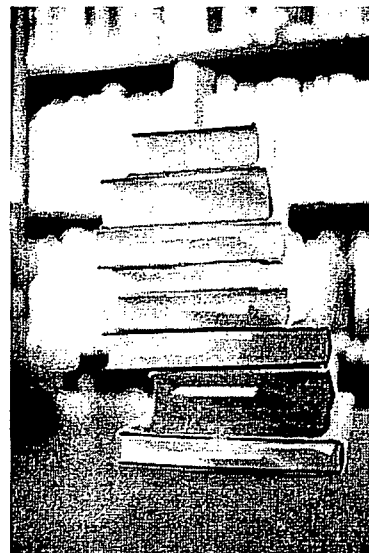
SBIOMED
since 1985**Key Points**

Post Decontamination activities include:

- * Collection, Treatment and disposal of wastes,
- * Clearance sampling and analysis,
- * Renovation
- * Reoccupation
- * Long term monitoring

Topic Review Activities**Review - What we have learned**

- The characteristics of the virulent *B. anthracis* (Anthrax) spore and related health issues
- The National Response Framework, agencies and plans to address future incidents
- Decontamination activities to inactivate anthrax or other biological agent.
- The use of Steriplex Ultra™ as a registered EPA product to inactivate the anthrax spore



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Key Points

- * We have learned what Anthrax is, where it occurs and the implications on human health
- * We have learned what the framework is that has been developed on the National level to address future incidents of biological releases
- * We have learned about the many activities and plans that have been created to decontaminate an area or equipment that has been exposed to anthrax or other biological agents
- * We have learned about the STERIPLEX Ultra™ product that is used to decontaminate anthrax spores