JAN 04 2002

Multisorb Technologies, Inc. c/o Delta Analytical Corporation 7910 Woodmont Ave, Suite 1000 OF EMPERCHMENTAL PROTECTION AGENCY Bethesda, MD 20814

Attn.:

Jeff Jones, Agent

Subject:

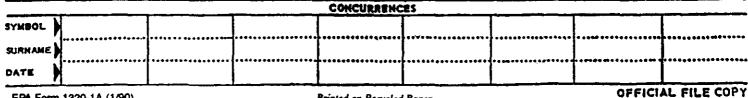
SanisorbX

EPA Registration No. 72675-1

Amendment Dated August 30, 2001 and

The amendment referred to above submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act as amended to make modifications to your product formulation and label use directions is acceptable on a time limited basis. The approval of this amendment request will automatically expire on August 31, 2002 unless you comply with the conditions outlined below:

- 1. Because of the change in formulation you must submit Confirmatory Efficacy Data (see the DIS/TSS-5 Enclosure) by May 1, 2002. The Confirmatory Data must be generated on the new formulation and according to the new use directions (i.e., 30% blood serum), reviewed by the Agency and found acceptable by August 31, 2002.
- 2. Delete the phrase "Solidifies and Sanitizes Liquid Laboratory, Human and Animal Wastes." Your product labeling and use directions do not adequately describe such uses.
- 3. You may wish to change "Sanitizes Liquid Medical Waste" to "Sanitizes and Solidifies Liquid Medical Waste."
- 4. Provide specific instructions which indicate how the medical waste should be handled if the soluble pouch does not break under conditions of use.
- 5. Submit five (5) copies of draft labeling revised in accordance with the labeling changes above within thirty days of the date of this letter.



The new basic Confidential Statement of Formula form dated October 26, 2001 has been reviewed and is acceptable. A stamped copy of the label is enclosed for your records.

Please note that the Agency is reviewing its policy regarding medical waste treatment products and may require additional data and labeling changes in the future. Once the Agency has finalized a labeling and testing policy for these types of products all affected manufacturers will be notified in writing.

If you have any questions concerning this letter please contact Tony Kish at 703-308-9443.

Sincerely yours,

Marshall Swindell Product Manager 33

Regulatory Management Branch 1 Antimicrobials Division (7510C) SaniSorbX

ACCEPTED

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JAN 0 4 2002

Dissolvable Pouch Sanitizer/Solidifier

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Sanitizes Liquid Medical Waste

Solidifies and Sanitizes Liquid Laboratory, Human and Animal Wastes. Antibacterial. Controls odor formation by destroying odor-causing bacteria.

Keep Out of Reach of Children **DANGER**

First Aid Have the product container or label with you when calling a poison control center or doctor, or going for treatment.		
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, then continue rinsing eye. Call a poison control center or doctor 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 doctor for further treatment advice. 	
If Inhaled	 Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a Poison Control Center or doctor for further treatment advice. 	
If Swallowed	 Call Poison Control Center or doctor immediately for treatment advice. Have Person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor Do not give anything by mouth to an unconscious person 	

See side panel for additional precautionary statements

EPA Reg. No. 72675-1 EPA Est. No. 72675-NY-1

Manufactured by Multisorb Technologies Inc., 325 Harlem Road, Buffalo, NY 14224-1893

Net Contents: 75 Pouches (15 grams each; 1.1 kg total)

Left Panel

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with COMMENTS
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Precautionary Statements

Hazards to Humans and Domestic Animals

DANGER. Corrosive. Cause irreversible eye damage. Causes skin irritation. Harmful if inhaled. Harmful if swallowed. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Causes asthmatic signs and symptoms in hyper-reactive individuals.

- Do not get in eyes, on skin or on clothing.
- Avoid breathing vapor.
- Do not swallow.

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- Wear protective goggles, protective clothing, and rubber gloves. As long as the water soluble packaging remains intact, goggles are not required.
- Wash thoroughly with soap and water after handling
- Remove contaminated clothing and wash before reuse.

Storage and Disposal

Storage: Store in a cool, dry, well ventilated area.

Pesticide Disposal: Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Pesticide wastes are toxic. Improper disposal of excess pesticides is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or you Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Empty bags and boxes in which the product is shipped may be offered for recycling or disposed of in a sanitary landfill. If allowed by State and local authorities, they may be disposed of by burning. If burned, stay out of smoke.

Right Panel

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with COMMENTS
in EPA batter Dated:

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Under the Federal Insociotica, Fungicies, and Rodendelde Act as amor deal for the pesticide, registered under EPA Reg. No.

72675-1

Directions for Use

It is a violation of Federal Law to use this pesticide in a manner inconsistent with its labeling.

- Wear gloves and eye protection when handling infectious waste.
- SaniSorbX is a dissolvable pouch.
- Insert the SanisorbX pouches through the port of the suction canister. See table below for applicable number of pouches depending on size of suction canister
- SanisorbX is effective for suction canister contents up to 30% blood serum.
- Recap port and allow 30 minutes for solidification before handling.
- Dispose of treated medical waste in compliance with local, state, and federal regulations.

Canister Size [cubic centimers (cc)]	No. of Pouches
500	1
1000	2
1500	3
2000	4
2500	5
3000	6

Pouch Label

Front Side

SaniSorbX

Dissolvable Pouch
Sanitizer/Solidifier
Active Ingredient:
Glutaraldehyde 9.6%
Keep Out of Reach of Children
DANGER

ACCEPTED with COMMENTS in EPA Letter Dated:

JAN 0 4 2002

Under the Federal Insecticide, Pungicide, and Rodendoide Act as amended, for the pesticide, registered under EPA Reg. No. 72675–1

Back Side

See box for
Precautionary Statements
and Directions For Use.
EPA Reg. No. 72675-1
[Patent Information]
Multisorb Technologies Inc.
1 800 445-9890