JUL 1 6 2002

T. Jeffrey Jones, Agent for Multisorb Technologies c/o Delta Analytical Corporation 7910 Woodmont Avenue, Suite 1000 Bethesda, MD 20814

Subject: Sanisorb X EPA Reg. No. 72675-1

Your Submission Dated 1/18/02

The submission referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to provide confirmatory sanitizing efficacy data (MRID 45585501) using the current product formula, and a revised label, is acceptable with the following comment.

- 1. As per the EPA letter dated 1/4/02, these time limited confirmatory efficacy data were required to be submitted and found acceptable by 8/31/2002 in order to support your amendment dated 8/30/2001. The time limited restriction on the amendment is hereby lifted and satisfied.
- 2. We note that the original conditional Registration Notice for this product, dated 1/4/01, was time limited until 6/5/02 based on submission and acceptance of the composition of the water soluble ink used on the packaging. You submitted this information and the Agency is in the final stages of its review. Upon an acceptable review finding, an updated Registration Notice will be issued without a time limited condition. If the information is not found acceptable, another time limited Registration Notice will be issued with specific requirements for the water soluble inks.

A copy of the accepted revised label (version 1/17/02) is attached.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

Marshall Swindell,

Product Manager Team 33,

Regulatory Management Branch I

			CONCURRENCES	Antimier	obials Division	r <del>(7510C)</del>	
SYMBOL							
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EPA Form 1320-1A (1/90) Printed on F		Printed on Recycled Pa	Recycled Paper			OFFICIAL FILE COPY	

ACCEPTED with COMMENTS in EPA Letter Dated:

SaniSorbX

JUL 1 6 2002

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. Dissolvable Pouch Sanitizer/Solidifier

72675-1

Sanitizes and Solidifies Liquid Medical Waste

Antibacterial. Controls odor formation by destroying odor-causing bacteria.

Active Ingredient

Glutaraldehyde.....9.6%

Other Ingredients......90.4%

Total: 100.0%

# 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	<ul> <li>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.</li> <li>Call a poison control center or doctor for treatment advice</li> </ul>				
If on Skin or Clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a Poison Control Center or doctor for further treatment advice.</li> </ul>				
If Inhaled	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.</li> <li>Call a Poison Control Center or doctor for further treatment advice.</li> </ul>				
If Swallowed	<ul> <li>Call Poison Control Center or doctor immediately for treatment advice.</li> <li>Have Person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by the poison control center or doctor</li> <li>Do not give anything by mouth to an unconscious person</li> </ul>				

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

#### **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.
- 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.

ACCEPTED with COMMENTS in EPA Letter Dated:

JUL 1 6 2002

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 7 2 6 25 - 1 Right Panel

#### **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.
- If pouch opening and solidification does not occur, handle as untreated medical waste following 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

ACCEPTED with COMMENTS in EPA Letter Dated:

JUL 1 6 2002

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

72675-1

## Pouch Label

Front Side

#### SaniSorbX

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

**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

ACCEPTED with COMMENTS in EPA Letter Dated:

JUL 1 6 2002

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

72675-1