

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT - 7 2004

Rachel A. G. Davis
Business Relations Manager
Texas Gulf Industries, Inc.
4240 Shannon Drive, Suite A
Baltimore, Maryland 21213

Subject: **Santimine 150**
EPA Registration Number 9279-3
Application Dated July 7, 2004
EPA Received Date July 13, 2004

Dear Ms. Davis:

The following amendment, submitted in connection with registration the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the following comments:

Proposed Amendment:

- update labeling

Label Comments:

1. In the first paragraph remove this statement " This sanitizing product is registered with the US Environment Protection Agency...adverse affects to humans or the environment." An endorsement is implied by this statement which is unacceptable as per 40 CFR 156.10 A(5) v.
2. In the second statement beginning: "This sanitizing product is authorized..." delete "by USDA" as jurisdiction over these products has been given to the EPA.
3. In the third statement beginning : "Santimine 150 sanitizing solutions..." delete "as specified under Subpart F of the Food Additives Amendment by the US Food and Drug Administration." This use is now regulated under the EPA.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

4. Revise the "Precautionary Statements" to read as follows:

Corrosive: Causes irreversible eye damage and skin burns. May be fatal if inhaled, absorbed through the skin or swallowed. Do not breathe (dust, vapor, or spray mist.) Do not get in eyes, on skin, or on clothing. Wear protective clothing, goggles, and protective gloves. Wash thoroughly with soap and water after handling and before eating, drinking chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

5. Revise the "First Aid Statement" to read: as follows

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.
Call a poison control center or doctor for treatment advice.

IF ON SKIN: Take off contaminated clothing.
Rinse skin immediately with plenty of water for 15-20 minutes.
Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a 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 by a poison control center or doctor.
Do not give anything to an unconscious person.

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.

6. Revise "Storage and Disposal" to read as follows.

Begin this section with the heading: "**Storage and Disposal**" followed by the statement:
"Do not contaminate water, food, or feed by storage or disposal."
Then revise your label to include the following three sections:

Pesticide Storage: Store in original container in a dry area utilizing locked storage to keep product out of the reach of children or others who may be unfamiliar with the use of this product.

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.

Container Disposal: Triple rinse (or equivalent). 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.

7. Under the product name "Santimine 150" delete the claim "Kills HIV-1 AIDS Virus when used as directed for sanitizing." This product supports a sanitizing claim against bacteria. Separate data must be provided to support claims against viruses.

8. Under the "Directions"

Item # 1 - Delete the phrase "whenever possible".

Item # 3 - Delete the word "clean" and replace with "potable".

9. Under "Directions For Spraying"

Change Item # 1 to read "Remove or cover all food items from surfaces to be treated. Scrape all articles and surfaces thoroughly." as per DIS/TISS17

Change current #1 to #2 and rinse to read: "Wash all articles and surfaces thoroughly with a compatible detergent."

Add item #3 as: "Rinse with portable water."

Change current #2 to #4 .

10. Delete the entire statement: "Kills HIV-1 (AIDS virus) when used as directed for sanitizing." as killing a virus is not a sanitizing claim. You must submit data for HIV claims. Such a claim would also require a separate set of directions for use.

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General Comments:

A stamped copy of the labeling accepted with conditions is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland on (703) 308-6224.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

Proposed label

This sanitizing product is registered with the US Environmental Protection Agency as required by federal law to insure that when used as directed, it has proven to be effective as claimed without causing unreasonable adverse effects to humans or the environment.

This sanitizing product is authorized by USDA for use in federally inspected meat and poultry plants. Santimine 150 sanitizing solutions of 200 ppm concentration may be safely used on food processing equipment, utensils, and on other food contact articles as specified under Subpart F of the Food Additives Amendment by the US Food and Drug Administration.

This product fulfills the sanitizing criteria of the US Public Health Service in waters up to 500 ppm of hardness calculated as CaCO₃ when tested by the AOAC Germicidal and Detergent Sanitizers—Official Method

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER — Keep Out of Reach of Children.**

Tablet dust causes eye damage and skin irritation. Do not get dust in eyes, skin, or clothing. Avoid prolonged skin contact. In case of contact, flush with plenty of water. If irritations persists get medical attention. Avoid contamination of food.

STATEMENT OF PRACTICAL TREATMENT

If tablets are swallowed, promptly drink large quantities of water. Avoid alcohol. Get medical attention immediately.

NOTE TO PHYSICIAN: Probable mucosal damage by contraindicate the use of gastric lavage.

DISPOSAL: Do no reuse empty container. Wrap container and put in trash.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT 7 - 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 9279-3

SANTIMINE 150

**FOR SANITIZING FOOD CONTACT SURFACES
USE ONE TABLET PER ONE GALLON OF WATER
Kills HIV-1 AIDS Virus when used as directed for sanitizing.**

EPA REG. NO: 9279-3
EPA EST. 9279-MD-1

ACTIVE INGREDIENT.....50%
n-Allyl (C14 95%, C12 3%, C16 2%) dimethyl benzylammonium chlorides monohydrate
INERT INGREDIENTS.....50%

**DANGER
KEEP OUT OF REACH OF CHILDREN**

See left panel for additional precautionary statements.
For Institutional and Commercial use only.

Manufacturer:
Texas Gulf Industries, Inc.
4240 Shannon Drive, Suite A
Baltimore, Maryland 21213
Phone: (410) 488-5100

150
TABLETS

NET WEIGHT
8 OUNCES

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DIRECTIONS

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

Prepare sanitizing solutions with warm water. Allow several minutes for tablets to dissolve before using.

FOR SANITIZING DISHES, GLASSES, AND UTENSILS IN RESTAURANTS, TAVERNS, ETC.

1. Scrape and prewash utensils and glasses whenever possible.
2. Wash with a good detergent or compatible cleaner in first sink compartment.
3. Rinse with clean water in second sink compartment.
4. Sanitize in a solution of 1 TABLET PER ONE GALLON OF WATER (200 ppm) in third sink compartment. Immerse all utensils for at least one minute or for contact time specified by governing sanitary code.
5. Place sanitized utensils on a rack or drain board to air dry.
6. A fresh sanitizing solution must be prepared at least daily or more often if the solution becomes diluted or soiled.

DIRECTIONS FOR SPRAYING

FOR SANITIZING FOOD PROCESSING EQUIPMENT, DAIRY EQUIPMENT, SINKS, COUNTERTOPS, REFRIGERATED STORAGE AND DISPLAY EQUIPMENT and other hard non-porous food contact articles and surfaces.

1. Wash and rinse all articles and surfaces thoroughly.
2. Apply a solution (SPRAY ON WITH HAND TRIGGER SPRAYER OR WIPE ON) of 200 ppm concentration and allow surface to remain wet for at least one minute followed by adequate draining and air drying.

KILLS HIV-1 (AIDS Virus) when used as directed for sanitizing.

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