

87708-1

11/9/2010

1044



ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510-P)
1200 Pennsylvania Avenue N.W.
Washington, D.C. 20460

EPA Reg. Number:
87708-1

Date of Issuance:
Nov. 9, 2010

Term of Issuance:
Conditional

Name of Pesticide Product:
Zap-Out

NOTICE OF PESTICIDE:
[x] Registration
[ ] Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Zappa Tec, LLC
828 Knox Road
McLeansville, NC. 27301

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials 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 (OPP Decision No. 435812) is conditionally registered in accordance with FIFRA sec 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 requires all registrants of similar products to submit such data; and, submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Change EPA File Symbol 87708-R to EPA Registration Number 87708-1.
3. Add "eye" to the end of the eye treatment instructions in the First Aid statement.
4. Change "Physical Hazards" to "Physical or Chemical Hazards" and add "The product contains an Oxidizer. Do not mix with acids."
5. Under Directions for Use change "3000cc's" to "3000cc".
6. Under Directions for Use revise the sixth sentence to read: This product is intended for use with suction canisters.
7. Add "Maintaining a spill kit and fire extinguisher on hand and having emergency phone numbers posted will allow you to be prepared for emergencies" to the Storage instructions.
8. Add the correct postal zip code to the manufactured by address.
9. Delete all Optional Marketing Claims.
10. Within 60 days of this Registration Notice you must submit a protocol to the Agency based on one of two options below. When the protocol is submitted you must provide an anticipated due date for submission of the completed confirmatory study.

Option 1: For suction canisters/encapsulation, registrants would conduct a modified non-food contact sanitizer test which requires a 3 log reduction in the level of Pseudomonas aeruginosa, Staphylococcus aureus, and Samonella choleraesuis in a minimum of 20% blood serum (any animal). In regard to blood serum, the label would state the efficacy of this product has been

(continues on page 2)

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Signature of Approving Official:
Wanda Y. Henson
Acting Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510-P)

Date:
November 9, 2010

2014

Zappa-Tec, LLC - Zap-O

Draft Master Label rev. 6/4/10

Zappa-Tec, LLC  
www.zappa-tec.com

**ZAP-OUT**

**THE EFFICACY OF THIS PRODUCT HAS BEEN DEMONSTRATED IN THE PRESENCE OF 20% BLOOD SERUM**

**ACTIVE INGREDIENT:**

Sodium Dichloro-s-triazinetriene dihydrate ..... 10.2%

**OTHER INGREDIENTS** ..... 89.8%

**TOTAL** ..... 100.0%

(Available Chlorine 5.6%)

EPA Reg. No. \_\_\_\_\_

EPA Est. No. \_\_\_\_\_

Net Weight: 4.2 oz (122 g)

KEEP OUT OF REACH OF CHILDREN

**DANGER**

<b>FIRST AID</b>	
Have the product container or label with you when you call a poison control center or doctor, or when going for treatment.	
<b>IF IN EYES:</b>	
<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first five minutes, then continue rinsing. <i>eye.</i></li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>	
<b>IF ON SKIN OR CLOTHING:</b>	
<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> </ul> Call a poison control center or doctor for treatment advice.	
<b>IF SWALLOWED:</b>	
<ul style="list-style-type: none"> <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 by poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>	
<b>IF INHALED:</b>	
<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or ambulance, then give artificial respiration, preferable mouth to mouth.</li> <li>• Call poison control center or doctor for further treatment advice.</li> </ul>	
<b>In case of accidental exposure, call CHEMTREC at 1-800-424-9300</b>	
<b>NOTE TO PHYSICIAN:</b> Probable mucosal damage may contraindicate the use of gastric lavage.	

ACCEPTED  
with COMMENTS  
in LFP Better Data:

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**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER.** Corrosive. Causes irreversible eye damage. Causes skin irritation. Harmful if swallowed, inhaled, or absorbed through skin. Do not get in eyes, on skin or on clothing. Wear goggles, face shield or safety glasses and rubber gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

**ENVIRONMENTAL HAZARDS**

This product is toxic to fish and aquatic organisms. Do not discharge into lakes, streams, ponds, or other waters unless in accordance with requirements of a National Pollutant Discharge Elimination System (NPDES) permit. 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 U.S. Environmental Protection Agency.

**PHYSICAL HAZARDS:** Avoid breathing dust from powder. *or Chemical*  
*This product contains an oxidizer. Do not mix with acids.*

**DIRECTIONS FOR USE**

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

ACCEPTED

with GORE GENTS  
in EPA Health Dept.  
NOV 09 2010

Liquid Medical Waste  
Encapsulation and Treatment  
For Use Only in Health Care and Veterinary Facilities

*delete*  
This product treats 3000cc~~x~~ of fluid.

This product is intended for use with ~~collection vessels~~ ~~suction canisters~~.

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Always wear hand and eye protection when handling infectious waste.

**For Zap-Out Bottle**

- Shake well to thoroughly mix the Zap-Out powder.
- Turn off suction and remove patient tubing.
- Remove the top of the access port.
- Remove the top from the Zap-Out bottle.
- Allow the contents to pour into the canister. Be sure all Zap-Out powder is poured into the suction canister.
- Remove the Zap-Out bottle and cap the open access port.
- Allow sufficient time for solidification.
- Dispose of encapsulated material according to institutional procedures and Federal, State and Local regulations.

**For Zap-Out Pak (dissolvable pack)**

- Prior to beginning the procedure drop the Zap-Out Pak into the vessel.
- As fluid is introduced into the vessel the Zap-Out Pak powder is released.
- Allow sufficient time for solidification.
- Dispose of encapsulated material according to institutional procedures and Federal, State and Local regulations.

**See side panel for additional precautionary statements.**

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**STORAGE AND DISPOSAL**

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

**STORAGE:** Keep in a cool, dry place. Keep container tightly closed. *Maintaining a spill kit and fire extinguisher on hand and having emergency phone numbers posted will allow you to be prepared for emergency.*  
**PESTICIDE DISPOSAL:** Pesticide wastes are toxic. Improper disposal of excess pesticide is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your state pesticide or environmental control agency, or hazardous waste representative of the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows. Empty the remaining contents into suction canister. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into suction canister or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling, if available 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.

Zap-Out is a trademark of Zappa-Tec, LLC

**Manufactured by:  
Zappa-Tec, LLC  
828 Knox Road  
McLeansville, NC USA**

*Add zip code*

**Made in the U.S.A.**

Batch code: \_\_\_\_\_

**REORDER NO. ZAPOUT 3000**

~~Optional Marketing Claims~~

- ~~• Sanitizer~~
- ~~• Disinfectant~~

} *delete*

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

NOV 09 2010

... pesticide,  
... as  
...  
... No.

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