87708-1

01/07/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

JAN - 7 2011

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Catherine M. Byrd Agent for ZappaTec, LLC Wagner Regulatory Associates, Inc. 7460 Lancaster Pike Suite 9 Hockessin, DE 19707

FILE COPY

Subject: Zap-Out EPA Reg. No. 87708-1 Application Dated: December 16, 2010 Receipt Date: December 17, 2010

Dear Ms. Byrd:

The following notification submitted in connection with registration under the provisions of PR Notice 98-10, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9 is acceptable.

Proposed Notification:

 Labeling revision to update Storage and Disposal Statement per PR Notice 2007-4

Comments:

Based on a review of the material submitted, the following comments apply:

This application for notification to revise the label, as referenced above, is acceptable.

Should you have any questions concerning this letter, please contact me at <u>Henson.Wanda@epa.gov</u> or call (703) 308-6345.

Sincerely,

Wanda Henson Acting Product Manager (32) Regulatory Management Branch II Antimicrobials Division (7510P)

Please read instructions on revers	e before completing form	n.		For	m Appro	oved. O	MB No. 20	070-006	50. Approval	2 expires 05-31-98
United States Environmental Protec Washington, DC 2			ction Agency			Registration Amendment Other			OPP Identi	fier Number
<u>`</u>	Annli	cation for	r Pesti	cide - S	X]		
1. Company/Product Number				A Product				3. P	roposed Cla	ssification
87708-1		Wanda Henson								
4. Company/Product (Name)		PM#						None	Restricted	
Zappa-Tec LLC/Zap-Out			32						NOTE	Resilicieu
 Name and Address of Appl Zappa-Tec LLC c/o Wagner Regulatory As P.O. Box 640 Hockessin, DE 19707 Check i 			(b)(l), to: EPA F						IFRA Sectio	
	· · · · · · · ·	Se	ction	-			·			
Amendment - Explain be Resubmission in respons Notification - Explain below Explanation: Use additional (notification is consistent with the g and 156.156. No other changes his 18 U.S.C. Sec. 1001 to willfully mis CFR §§ 156.10, 156.140, 156.144	se to Agency letter dated ow. page(s) if necessary. juidance in PR Notice 20 ave been made to the lat ake any false statement	(For Section)07-4 and the ro beling or the Co to EPA. I furthe	equiremer onfidential er understa	ts of EPA's Statement of and that if th	tter date Applica plain be regulation of Form e amen	ed tion. elow. n of lab ions at 4 ula for t ided lab	el change 40 CFR §§ his produc el is not c	156.10 ct. 1 und onsiste	0, 156.140, 15 lerstand that i nt with the rec	6.144, 156.146, t is a violation of uirements of 40
penalties under sections 12 and 1	4 of FIFRA.	-	ction							
1. Material This Product Wil Child-Resistant Packaging Yes* X No	X Yes If "Yes" No		X	luble Pack Yes No	aging o. per	2.	X	ontain Metal Plastic Glass		
* Certification must be submitted	Unit Packaging wgt. 96 oz	container I 24	Package v	vgt co	ntainer			Paper Other ((Specify) HD	PE lined bags
3. Location of Net Contents Ir X Label Con	I Iformation tainer	4. Size(s) F 4.2 oz (122.		ntainer	5	5. Loca	ation of L On Lab On Lab	el	irections accompanyir	ng product
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Catherine M. Byrd I certify that the statements I hav I acknowledge that any knowing both under applicable law.	ve made on this form and	Agent for 2 cation d all attachmen tement may be	its thereto	are true, ac	curate a imprisc	ind com	plete.	5. Dat	e Application ceived	
2. Signature	_	3. Title Agent for 2	Zappa-Te	ec LLC					(Stamp	- 41
4. Typed Name		5. Date	0							
Catherine M. Byrd		12/16/201	U							



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Wagner Regulatory Associates, Inc. P.O. Box 640 7460 Lancaster Pike, Suite 9 Hockessin, Delaware 19707

December 16, 2010

Document Processing Desk (NOTIF) ATTN: Ms. Wanda Henson, PM 32 Antimicrobial Division (7510P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, Virginia 22202-4501

Re: Zap-Out EPA Reg. No. 87708-1 Revised Storage and Disposal Language Notification per PR Notice 2007-4

Dear Ms. Henson,

On behalf of ZappaTec, LLC, I am submitting this notification of revised storage and disposal language per PR Notice 2007-4 for the above referenced product. Container handling directions for a water soluble packet were added to the Storage and Disposal section of the label. No additional changes were made to the label.

In support of this notification I have enclosed the following documents:

- Letter from ZappaTec, LLC authorizing Wagner Regulatory to serve as Agent;
- Application for Pesticide Registration (EPA Form 8570-1);
- Certification with Respect to Label Integrity; and
- One copy of the revised label with changes clearly marked and CD.

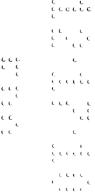
If you have any questions concerning this submission please contact the undersigned.

Sincerely,

Catherine M. Byrd

Catherine M. Byrd Agent for ZappaTec, LLC

enclosures



Zappa-Tec, LLC -- Zap-Out

WSP Storage and Disturbulan Language added (16DEC10)

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-triazinetrione dihydrate	10.2%
OTHER INGREDIENTS	89.8%
TOTAL	100.0%
(Available Chlorine 5.6%)	

EPA Reg. No. 87708-1 Net Weight: 4.2 oz (122 g) EPA Est. No._____

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID

Have the product container or label with you when you call a poison control center or doctor, or when 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 five 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 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.	1 er 1 -						
 Do not induce vomiting unless told to by poison control center or doctor 	•						
• Do not give anything by mouth to an unconscious person.							
IF INHALED:Move person to fresh air.	A	, ,					
• If person is not breathing, call 911 or ambulance, then give artificial respiration, preferable mouth to mouth.							
• Call poison control center or doctor for further treatment advice.							
In case of accidental exposure, call CHEMTREC at 1-800-4	24-9300						

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

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 OR CHEMICAL HAZARDS: This product is an oxidizer. Do not mix with acids. Avoid breathing dust from powder.

DIRECTIONS FOR USE

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

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

This product treats 3000cc of fluid.

This product is intended for use with suction canisters.

	t t t t t t
Always wear hand and eye protection when handling infectious waste.	(
For Zap-Out Bottle	ς τ. τ. τ. τ. τ. τ. τ.
• Shake well to thoroughly mix the Zap-Out powder.	í.
• Turn off suction and remove patient tubing.	1 3 1 1 1 1 1 1 1
• Remove the top of the access port.	
• Remove the top from the Zap-Out bottle.	યું ક દાવ
• Allow the contents to pour into the canister. Be sure all Zap-Out powder is po	oured into the
suction canister.	
 Remove the Zap-Out bottle and cap the open access port. 	4 I
• Allow sufficient time for solidification.	· · · ·
 Dispose of encapsulated material according to institutional procedures and Fe and Local regulations. 	ederal, State

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.

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See side panel for additional precautionary statements.

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 prepare for emergencies.

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 (Plastic Bottle). 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.

Nonrefillable container (Water Soluble Packet). Do not reuse or refill this container. Offer for recycling, if available or dispose of the empty outer plastic or foil pouch in the trash as long as the water soluble packet is unbroken.

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

Manufactured by: Zappa-Tec, LLC 828 Knox Road McLeansville, NC 27301

Made in the U.S.A.

Batch code:

REORDER NO. ZAPOUT 3000