

6836-338

3/22/2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 22, 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Joanna Holcombe
Lonza
90 Boroline Rd
Allendale, NJ 07401

Subject: Dantobrom Granular
EPA Registration Number: 6836-338
Amendment Date: December 22, 2011
EPA Receipt Date: December 23, 2011

Dear Ms. Holcombe:

The proposed amendment submitted under the connection of registration under FIFRA, as amended, is acceptable with conditons.

Proposed Amendment:

- Response to Agency letter dated March 28, 2011

Conditions

Revise the label as follows:

- 1.) Revise the statement under the signal word by deleting the phrase, "and First Aid."
- 2.) According to 40 CFR 156.68(d), "First Aid" statement must appear on the front panel of the label for all products assigned to Toxicity Category I by any route of exposure. Therefore, the First Aid Statements must be moved from page 2 to page 1.
- 3.) The 2nd statement, "For use formulating disinfectants, algacides, fungicides, bactericides, and slimicides" in the "Directions for Use" is too broad. The MUP should indicate what use patterns the active ingredient(s) are approved for formulation into end-use products. Also, the above example implies that the product is already approved for certain levels of antimicrobial activity (i.e disinfectant, sanitizer). However, it is the end-users responsibility to generate the appropriate data to prove that the end-use product is efficacious as a disinfectant, sanitizer, and/or fungicide. Therefore, revise it to read:

For use in formulating antimicrobial pesticides for use in/on commercial, industrial, residential premises and equipment, recirculating water systems, pulp and paper, and secondary oil recovery.

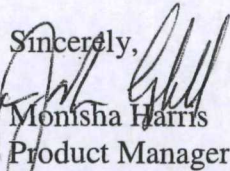
CONCURRENCES

SYMBOL							
SURNAME							
DATE							

General Comments

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

If you have questions concerning this letter, then please contact David Liem by email at liem.david@epa.gov or by calling at (703) 305-1284.

Sincerely,

Monisha Harris
Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510P)

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

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DANTOBROM[®] GRANULAR

FOR REFORMULATING AND / OR REPACKAGING USE

Contents: GRANULAR

Active Ingredients:

1-bromo-3-chloro-5,5-dimethylhydantoin	54.2 %
1,3-dichloro-5,5-dimethylhydantoin	28.9 %
1,3-dichloro-5-ethyl-5-methylhydantoin	15.9 %
Other Ingredients	1.0 %
Total:	100.0 %

ACCEPTED
with COMMENTS
EPA Letter Dated:

MAR 22 2012

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

6836-338

Total Available Halogen as Bromine: 141%
(and/or)
Total Available Halogen as Chlorine: 62.8%

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID ←

See side / back / right / left panel for Precautionary Statements and First Aid ~~delete~~

EPA Reg. No. 6836-338
EPA Est. No. 6836-PA-01
NET WEIGHT: *(as indicated on container)*
[Country of origin (insert country)]
[Manufactured in (insert country)]
[Barcode]

Lonza Inc.
90 Boroline Road, Allendale, NJ 07401

Emergency Contact Number: (_____)

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

DANGER: HIGHLY CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if swallowed. Do not take internally. Irritating to nose and throat. Avoid breathing dust. Use with adequate ventilation. Do not get into eyes, on skin or on clothing. Wear protective clothing, chemical resistant gloves and protective eyewear (goggles, face shield or safety glasses). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

move to front page after DANGER.

FIRST AID

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

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.

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 do so by the poison control center or doctor. Do not give anything by mouth 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 by mouth-to-mouth, if possible.

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

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. 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 EPA.

PHYSICAL AND CHEMICAL HAZARDS

CHEMICAL HAZARD: STRONG OXIDIZING AGENT. Mix only with water. Use clean dry utensils. Do not add this product to any dispensing device containing remnants of any other product. Such use may cause a violent reaction leading to fire or explosion. Contamination with moisture, organic matter, or other chemicals may start a chemical reaction with generation of heat, liberation of hazardous gases, and possible generation of fire and explosion. In case of contamination or decomposition, do not reseal container. If possible, isolate container in open air or well-ventilated area. Flood with large volumes of water if necessary.

FOR REFORMULATING AND / OR REPACKAGING USE

DIRECTIONS FOR USE:

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

For use in formulating disinfectants, algaecides, fungicides, bactericides and / or slimicides for recirculating water systems, antimicrobials for pulp and for manufacture of food and non-food grades of paper and paperboard, and in enhanced oil recovery in non-estuarine waters.

Reformulated or repackaged products must be registered with EPA. The registrant must supply data required for their own registration.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE:

- Do not store in direct sunlight.
- Do not store at temperatures above 100°F.
- Store in a well ventilated area away from heat or open flame.
- In case of decomposition, isolate container, if possible, and flood with large amounts of water to dissolve all material before discarding.

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 the label instructions, contact your State Pesticide or Environmental Control Agent or the hazardous waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL:

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying.

(Metal and plastic containers): Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Follow pesticide disposal instructions for rinsate. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

(Fiber drums and liners): Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Then dispose of liner and drum in a sanitary landfill or incinerate if allowed by state and local authorities. Do not reuse empty drum or liner.