

875-183

11/19/2002

1/6

November 19, 2002

Terry Sabatelli
DiversyLever
3630 E. Kemper Rd.
Cincinnati, OH 45241

Subject: Divosan MH
EPA Registration Number 875-183
Amendment Dated: 8/21/02
Receipt Date: 8/29/02

Dear Mr. Sabetelli:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions listed below.

- Update First Aid Statement Per PR Notice 2001-1
- Update Precautionary Statements
- Update Storage and Disposal Statement

Condition

1. The Shell Egg Sanitizing directions for use must appear as one complete paragraph.
2. Remove the phrase "CONTAC TIME" from the bottom of the label. There was no actual contact time allocated with the provided information, therefore, this phrase could be considered misleading.
3. Remove the VTII from the label. These letters were added without an explanation as to their purpose. A correlation between these letters and this product must be addressed before further consideration can be given to allowing them on this pesticide label.

CONCURRENCES

SYMBOL	7510C						
SURNAME	Mitchell						
DATE	11-19-02						

A stamped copy of the labeling accepted with the condition is enclosed. Submit a 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 Wanda Mitchell at (703) 308-6345.

Sincerely,



*Robert S. Brennis
Product Manager - Team 32
Regulatory Management Branch II
Antimicrobials Division (7510C)*

3/6

Divosan MH

VTII

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Halogenated Acid Sanitizer

U.S. Patent Number: 4,822,513

For Industry and Dairy Use

ACTIVE INGREDIENTS:

Iodine* 2.9%

OTHER INGREDIENTS: 97.1%

TOTAL: 100.0%

ACCEPTED
with COMMENTS
EPA Letter Dated:
NOV 19 2002

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 875-183

* Calculated as available iodine from iodine and iodine monochloride.

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

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

CORROSIVE. CAUSES EYE AND SKIN DAMAGE. HARMFUL OR FATAL IF SWALLOWED.

Causes eye damage and skin irritation. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of 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.

CHEMICAL AND PHYSICAL HAZARDS: Acidic product. Do not use, pour, spill or store near heat or open flame. Do not mix with other cleaners or chemicals or hazardous gasses may be generated. Dilute only with water.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store in original container in a well ventilated area.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of all excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Plastic containers – 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.

DIRECTIONS FOR USE

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

SANITIZING OF MANUALLY CLEANED EQUIPMENT – Dairy, Beverage, Meat, Poultry, Food Processing and Pharmaceutical Plants.

MANUAL CLEANING

1. Rinse tanks, vat, pipelines and equipment with warm water.
2. Disassemble equipment and wash with a recommended DiverseyLever cleaner.
3. Rinse surfaces with potable water and drain.
4. Sanitize by thoroughly wetting all surfaces by flood, coarse spray, mop, or immersion methods in a solution of 1 ounce of DIVOSAN MH in 18 gallons of water providing 12.5 ppm of available iodine. Expose surfaces to sanitizer for 2 minutes.
5. Allow surfaces to drain and air dry on a clean rack or support. Protect from dust and dirt.

Prepare a fresh solution daily or when it becomes soiled or diluted.

If DIVOSAN MH is used in alkaline waters, test to be sure that sanitizer solution pH is less than 3. If high pH is present, use 1 ounce of DIVOSAN MH in 9 gallons of water (25 ppm titratable iodine) for increased acidity. Test sanitizer solution with a DIVOSAN MH Test Kit to ensure that sanitizer solution is not less than 12.5 ppm titratable iodine after sanitizing. If solution is less than 12.5 ppm titratable iodine, repeat sanitizing process. Do not reuse circulated sanitizer for additional sanitizing. Drain system completely before restarting process.

SPRAY SANITIZING – FOOD SERVICE AND PROCESSING EQUIPMENT. Wash equipment with a recommended DiverseyLever product. Rinse with potable water. Apply a solution containing 1 fl. ounce

DIVOSAN MH in 9 gallons of water (providing 25 ppm available iodine) by coarse spray method thoroughly wetting all surfaces. Test spray solution daily with a DIVOSAN MH Test Kit to ensure adequate sanitizer is being supplied by dilution equipment. Allow surfaces to drain and air dry.

Shell Egg Sanitizing – To sanitize previously cleaned food-grade eggs in shell egg and egg product plants, spray with a solution of 1 fl. ounce DIVOSAN MH in 9 gallons of warm water (providing 25 ppm available iodine). The solution should be warmer than the eggs, but not to exceed 130° F. Wet eggs thoroughly and allow to drain. Eggs sanitized with this product shall be subject to POTABLE WATER RINSE ONLY IF THEY

ARE BROKEN IMMEDIATELY for use in the manufacture of egg products. Eggs should be dry before casing or breaking. The solution should not be reused for sanitizing eggs.

CIRCULATION SANITIZING – FOOD PROCESSING EQUIPMENT FLOW/PRESSURE METHOD.

Disassemble equipment and thoroughly clean after use. Assemble equipment into operational position prior to sanitizing. Prepare a sanitizing solution equal to 110% of the volume capacity of the equipment by diluting 1 ounce of DIVOSAN MH in 18 gallons of water (12.5 ppm available iodine). Pump the solution through the system until full flow is obtained at all extremities and the system is completely filled with sanitizer and all air is removed.

CLEANING-IN-PLACE (CIP) METHOD FOR DAIRY AND SMALL PROCESSING FACILITIES –

Thoroughly flush, clean and potable water rinse the system. Prepare a required volume of sanitizer solution needed to sanitize the system by diluting 1 fl. Ounce of DIVOSAN MH in 18 gallons of water (providing 12.5 ppm available iodine).

To sanitize all system by circulation methods, run pumps for at least 2 minutes to thoroughly wet and sanitize all parts of system.

DIVOSAN MH is listed under 21 CFR 178.1010 as a no rinse sanitizer on food processing equipment when used in accordance with label directions.

CONTACT TIME: DIVOSAN MH fulfills the criteria of the Grade “A” Pasteurized Milk Ordinance 1985 Recommendations of the United States Public Health Service in waters up to 500 ppm hardness calculated as CaCO₃ when tested by the method outlined by A.O.A.C. Germicidal Detergent and Sanitizer Test method (15th Ed.)

EPA Reg. No. 875-183

EPA Est. No. 875-OH-1[50]; 875-PA-1[80]; 875-CA-4[MD]; 875-WI-1[10]

Bracketed numbers/letters are the first numbers/letters of the batch number

6/6

Net Contents:

208 L (55 US gal)

18.9 L (5 US gal)

1040 L (275 gal)

Bulk Tanker

DiverseyLever

3630 E. Kemper Rd.

Cincinnati, OH 45241

800 233 1000

24 Hr EMERGENCY TELEPHONE:

Medical: (Call Collect) 303 592 1024

Transportation: (CHEMTREC) 800 424 9300