

54289-10

09-07-2007

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

NOTICE OF PESTICIDE:

- x Registration
Reregistration

(under FIFRA, as amended)

EPA Reg. Number:

54289-10

Date of Issuance:

SEP - 7 2007

Term of Issuance:

Unconditional

Name of Pesticide Product: Perclean®
Ocean

Name and Address of Registrant (include ZIP Code):

Degussa Corporation
379 Interpace Parkway
Parsippany, NJ 07054

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration 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 is conditionally registered in accordance with FIFRA sec 3(c)(7)(B) 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. Make the labeling changes listed below before you release the product for shipment:

- a. Add the phrase "EPA Registration Number 54289-10."

Signature of Approving Official:

Marshall Swindell
Product Manager-33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Date:

SEP - 7 2007

- b. The levels at which the product can be applied to ballast water must be expressed in units of standard measure (i.e., add 1 gallon of Peraclean to 1000 gallons of ballast water).
- c. Because certain acute toxicity values are <1.0 mg/L, the environmental hazard section of Peraclean® Ocean labels must state:

"This pesticide is toxic to fish, aquatic invertebrates, mussels, and shrimp."

- d. At the beginning of the Use Directions add the statement "Prior to use of this product in ballast water the registrant is required to follow all applicable U.S. Coast Guard regulations."

The Confidential Statement of Formula dated August 8th, 2007, is acceptable.

A storage stability and corrosion characteristics studies must be submitted to the Agency for review. These studies are required for products that contain degradative compounds.

A monitoring study of a harbor must be submitted to the Agency for our review. In order for the monitoring study to be completed, a testing protocol must be submitted, reviewed, and accepted by the Agency. This protocol will be used in order the generate the necessary monitoring study. **This protocol must be submitted to the Agency by December 1, 2007.**

The Agency notes that in Germany's 4/15/05 submission to the International Maritime Organization (IMO) it is stated that field trials with recommended equipment and concentrations of the proposed product (p. 23) and discharge toxicity testing (p. 25) were performed. We require submission of the protocols and raw data from these experiments since they may provide pertinent information relevant to the conduct of any monitoring studies.

When the Agency reviewed your application toxicity values for freshwater and estuarine/marine fish, freshwater and estuarine/marine invertebrates and aquatic plants were compared to the maximum estimated environmental concentration from an modeling scenario. These comparisons yielded risk quotients that were far below the Agency's LOCs for all species (See Table 2 in section V). Therefore, based on the data available, there is not expected to be any significant risk to aquatic species from the use of Peraclean® Ocean as a ballast water treatment. However, the above studies are missing for certain species and must be submitted.

The following studies are required to support the registration of this product and must be **submitted to EPA within 18 months from the date of registration**. This registration is being approved conditionally pending the submittal and acceptance of these studies:

- 1) 850.4400 – Aquatic plant toxicity using *Lemna* spp.
- 2) 850.5400 – Algal toxicity using 4 species (Only *Selenastrum capricornutum* is fulfilled, 3 other species are required.)
- 3) 850.2100 – Avian oral
- 4) 850.1035 – Estuarine/marine shrimp
- 5) Monitoring data from a harbor. Depending on the results of this monitoring data, the following studies may also be required:¹
 - a) 850.1735 – Whole sediment, acute invertebrates, freshwater
 - b) 850.1740 – Whole sediment, acute invertebrates, marine
 - c) 850.1300 – Aquatic invertebrate life cycle
 - d) 850.1400 – Fish early life stage

(1 Laboratory studies using the Technical Grade Active Ingredients (TGAIs) of both hydrogen peroxide and peroxyacetic acid, or the proposed product, Peraclean[®] Ocean, are required.)

When the Agency reviewed your application toxicity values for freshwater and estuarine/marine fish, freshwater and estuarine/marine invertebrates and aquatic plants were compared to the maximum estimated environmental concentration from an modeling scenario. These comparisons yielded risk quotients that were far below the Agency's LOCs for all species (See Table 2 in section V). Therefore, based on the data available, there is not expected to be any significant risk to aquatic species from the use of Peraclean[®] Ocean as a ballast water treatment. However, the above studies are missing for certain species and must be submitted.

3. Submit three (3) copies of the final printed label prior to releasing this product for sale.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,



Marshall Swindell
Product Manager 33
Regulatory Branch I
Antimicrobials Division (7510P)

Enclosure: (Stamped Labeling)

PERACLEAN® Ocean

PERACLEAN® Ocean is a peroxyacetic acid-based biocide developed for the treatment of Ballast Water in shipping vessels to control levels of viable aquatic microorganisms in ballast water discharge.

Active Ingredients:

Hydrogen Peroxide 14.3%

Peroxyacetic Acid 15.0%

Inert Ingredients: 70.7%**Total:** 100%

EPA Reg. No. 54289-?

EPA Estab. No. 74130-DEU-001, 54289-OH-001

Before Using This Product, Please Read This Entire Label Carefully.

KEEP OUT OF REACH OF CHILDREN**DANGER****FIRST AID**

Have the product label or container 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 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 poison control center or doctor for treatment advice.

If swallowed: Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person. Call poison control center or doctor for treatment advice.

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.

For emergency assistance call CHEMTREC (800) 424-9300.

Manufactured by:

Degussa Corporation

379 Interpace Parkway, P.O. Box 677
Parsippany, New Jersey 07054-0677

ACCEPTED
with **COMMENTS**
EPA Letter Dated:

SEP - 7 2007

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 54289-1D

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

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not breathe vapors or spray mist. Do not get in eyes, on skin, or on clothing. Wear goggles and/or face shield and rubber gloves when handling. Do not enter an enclosed area without proper respiratory protection. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

PHYSICAL AND CHEMICAL HAZARDS

STRONG OXIDIZING AGENT. Corrosive. Mix only with water. Product must be diluted in accordance with label directions prior to use. PERACLEAN® Ocean is not combustible; however, at temperatures exceeding 156°F, decomposition occurs releasing oxygen. The oxygen released could initiate combustion.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, fish, and aquatic invertebrates. 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 US Environmental Protection Agency.

DIRECTIONS FOR USE

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

PERACLEAN® Ocean is effective against copepod adults, nauplii, polychaetes, bivalves, rotifers, nematodes, ostracods and protozoans. The best general performance of PERACLEAN® Ocean is obtained when ballast water is treated with 200 ppm for 48 hours.

The best general performance of PERACLEAN® Ocean is when applied to ballast water tanks after pre-separation of solids greater than 50 µm in size. The product can also be applied in a stand alone treatment without prior separation of solids, but the presence of extraneous solids is likely to affect the effective dose. For salt water the concentration of PERACLEAN® Ocean must be 100-300 ppm to be effective without separation with a preferred dose range of 100-150 ppm with separation. For fresh water the dose must be in the range of 50 to 150 ppm.

Apply PERACLEAN® Ocean directly to ballast tank or through the use of a dosing pump that adds a controlled amount of PERACLEAN® Ocean to the incoming ballast water. The dosing pump may add PERACLEAN® Ocean at the discharge end of the ballast water feeding pump to ensure adequate mixing and eliminate the chance of equipment corrosion.

PERACLEAN® Ocean is active up to pH 9 and is particularly effective at pH between 5-7.

PERACLEAN® Ocean is effective at temperatures from 0 to 40°C / 32 - 104 °F.

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Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 54289-10

Release of Ballast Water in Port

Before the release of ballast water into the waters of a port the presence of residual PERACLEAN® Ocean must be determined using a qualitative analytical method such as a test strip that can detect residual oxidizer. If residual oxidant is present to an extent where the release might negatively impact local organisms, the ballast water must be treated to achieve a concentration of 5ppm or less. Satisfactory treatment options include but are not limited to the addition of catalase, sodium bisulfite or sodium thiosulfate.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Train operating personnel in the use and handling of PERACLEAN® Ocean.

Storage: Never return PERACLEAN® Ocean to the original container after it has been removed. Avoid all contaminants, especially dirt, caustic, reducing agents and metals, metal ions, and alkalis. Contamination and impurities will reduce shelf life and can induce decomposition. In case of decomposition, isolate container, douse container with cool water and dilute PERACLEAN® Ocean with large volumes of water. Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight and away from sources of heat such as steam pipes, hot machinery and radiant heaters. To maintain product quality, store at temperatures below 35 °C / 95 °F. Do not store on wooden pallets. The storage room should be located away from living quarters and foodstuffs. Do not store the product in combination with other substances, particularly in combination with combustible materials, lubricating oils, fats, or other organic compounds.

Since only particular grades of stainless steel may be used as storage tank material and special handling equipment must be used to ensure safety, please refer to the PERACLEAN® Ocean Handling and Use manual for complete storage material and equipment information.

Procedures for Leak or Spill: Stop leak if this can be done without risk. Shut off ignition sources; no flames, smoking, flares or spark-producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water.

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. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods of disposal may vary by location, regulatory agencies should be contacted prior to disposal. PERACLEAN® Ocean which is to be discarded should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

Container Disposal: > 5 gallon plastic drums: 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.

Alternate disposal language for >5 gallon plastic tote bin liners

>5 gallons plastic tote bin liners: Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

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