

49403-23

2/19/2004

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

February 19, 2004

Michelle M. Ford
Product Safety Chemist
Clariant
625 East Catawba Avenue
Mount Holly, NC 28120

Subject: Super Oxide Hospital Cleaner
EPA Registration No. 49403-23
Application Date: January 9, 2004
EPA Received Date: January 21, 2004

Dear Ms. Ford:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA 3(c)9.

Proposed Notification

- Removal of Physical and Chemical Hazards Statement

General Comments

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

The notification application is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at 703-308-6422.

Sincerely,

[Signature]
Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510 C)

CONCURRENCES

SYMBOL	7510 C						
SURNAME	V. Heyward						
DATE	2-19-04						

34

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 Clariant

Clariant Corporation

P.O. Box 866
625 East Catawba Avenue
Mount Holly, NC 28120

January 9, 2004

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
US Environmental Protection Agency
401 M Street SW
Washington, D.C. 20460-0001NOTIFICATION
Date Reviewed:
Reviewed By:

ATTENTION: Adam Heyward
Product Manager, Team 34

SUBJECT: Clariant Corporation
Super Oxide Hospital Cleaner-Disinfectant (49403-23)
Application for Pesticide Notification

Dear Mr. Heyward:

Clariant Corporation is submitting an application to remove an incorrect phrase from the label of Super Oxide Hospital Cleaner Disinfectant (EPA Reg. No. 49403-23). The purpose of the notification is to remove incorrect phrases as part of the FIFRA language for Physical and Chemical Hazards, in accordance with PR Notice 98-10. It was incorrectly on previous labels.

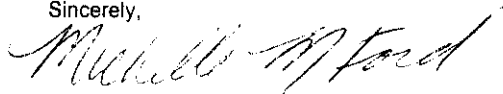
Enclosed please find the following documents in support of this notification:

- 1) Application for Pesticide Notification (OPP ID No. 265394);
- 2) One (1) copy of the revised product label with changes highlighted; and,
- 3) Five (5) copies of the draft proposed product labeling.

If you have any questions, or require additional information, please call me at 704-822-2677 or you may email me at michelle.ford@clariant.com

Thank you for your assistance.

Sincerely,



Michelle M. Ford
Product Safety Chemist

Enclosures

3 7 6

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 05-31-98

**EPA**

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other:

OPP Identifier Number
265394

Application for Pesticide - Section I

1. Company/Product Number 49403-23	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Super Ocide Hospital Cleaner-Disinfectant	PM# Team #34	
5. Name and Address of Applicant (Include ZIP Code) Clariant Corporation 4000 Monroe Road Charlotte, NC 28205 <u>PLEASE SEND ALL CORRESPONDENCE TO</u> <u>"CONTACT POINT" LISTED BELOW</u> <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

- ☐ Amendment - Explain below. ☐ Final printed labels in response to Agency letter dated _____
- ☐ Resubmission in response to Agency letter dated _____ ☐ "Me Too" Application
- ☒ Notification - Explain below. ☐ Other - Explain below

planation: Use additional page(s) if necessary. (For Section I and Section II.)

Application for Notification Under PR Notice 98-10:

Removal of statement of "Physical and Chemical Hazards: Do not contaminate water, food, or feed by storage or disposal." This product does not meet the criteria for the language required by 40 CFR 156.78 and was incorrectly added to the label. **The Storage and Disposal section repeats the words, 'Do not contaminate water, food, or feed by storage or disposal' in correct placement on the label.**

This Notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and not other changes have been made to the labeling or the Confidential Statement of Formula of this product. I understand that it is a violation of 18 U.S. C. Sec. 1001 to willfully make any false statement to the EPA. I further understand that if this notification is not consistent with the terms of PR Notice 90-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

* Material This Product Will Be Packaged In:			
Id-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No
	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.
* Certification must be submitted		2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

NOTIFICATION

Date Reviewed: 2-14-04
Reviewed By: 56-rcy

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Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)

Name Michelle M. Ford	Title Product Safety Chemist	Telephone No. (Include Area Code) 704-822-2677
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Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature
Michelle M Ford

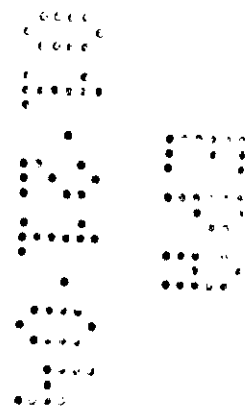
3. Title
Product Safety Chemist

4. Typed Name

Michelle M. Ford

5. Date

1/9/2004



OCIDE

HOSPITAL CLEANER-DISINFECTANT VIRUCIDAL* • FUNGICIDAL • TUBERCULOCIDAL • PSEUDOMONACIDAL

ACTIVE INGREDIENTS:

Ortho-Benzyl-Para-Chlorophenol.....10.10%

Ortho-Phenylphenol.....4.90%

Para-Tertiary-Amylphenol.....2.50%

INERT INGREDIENTS82.50%

TOTAL100.00%

KEEP OUT OF REACH OF CHILDREN DANGER

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

Danger. Corrosive. Causes eye and skin damage or skin irritation. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. Remove and wash contaminated clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- long-sleeved shirt and long pants
- socks and shoes
- goggles or face shield
- chemical resistant gloves (such as barrier laminate, nitrile rubber, neoprene rubber or viton)

Follow manufacturers' instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should:

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

• remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

• remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible wash thoroughly.

EPA REG. NO. 49403-23
EPA EST. NO. 65020-EN-1

NET CONTENTS: 1 U.S. Gallon (3.79 L)

Manufactured by:



Clariant

Clariant Corporation
4000 Monroe Road
Charlotte, NC 28205 USA
(704) 822-2259



NOTIFICATION

Date Reviewed: 01-09-04
Reviewed By: 2-18-04

FIRST AID

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 on 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 inhaled:	•Move person to fresh air. •If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. •Call a poison control center or doctor for further 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.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. In case of emergency call toll free: 1-800-424-9300	
Note to Physician:	Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

DIRECTIONS FOR USE

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

GENERAL PRECAUTIONS AND RESTRICTIONS:

Do not apply this product in a way that will contact other persons. Only protected handlers must be in the area during application.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

This is an extremely effective cleaner and disinfectant, recommended for general hospital use on hard, non-porous surfaces such as floors, walls, woodwork, and equipment in all departments.

For disinfection, use ½ oz. to each gallon of water. This product is effective in controlling *Staphylococcus aureus*,

Ocide (49403-23) Label Revised January 9, 2004

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Pseudomonas aeruginosa, *Salmonella choleraesuis*,
Mycobacterium tuberculosis var. *bovis* (BCG),
Trichophyton mentagrophytes.

Before disinfecting, remove heavy soil and thoroughly pre-clean surfaces. Apply solution; allow to remain wet for at least ten minutes. Mop or wipe up. **For heavy duty cleaning**, first remove loose soil. Use 2 oz. per gallon of water, mop or wipe on; allow to soak several minutes, remove. **For rapid cleaning**, use 4 oz. per gallon of water in automatic scrubbing machines. Always rinse floors before applying polish or wax. **For daily maintenance of waxed floors**, damp mop with solution of 1-½ oz. per gallon of water to remove most soils. Recommended for use in hospitals, clinics, veterinary hospitals, rest homes, athletic departments, industrial plants-where a need exists to clean and disinfect thoroughly.

DIRECTIONS FOR USE AGAINST* HIV-1 (AIDS VIRUS):

Kills HIV-1 (AIDS VIRUS) on precleaned environmental surfaces/objects previously soiled with blood/body fluids in healthcare settings or other settings in which there is an expected likelihood of soiling inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects ly to be soiled with blood or body fluids can be .ociated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

PERSONAL PROTECTION: Disposable latex or vinyl gloves, gowns, face masks or eye coverings as appropriate, must be worn during all cleaning of body fluids, blood and decontamination procedures.

CLEANING PROCEDURES: Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of disinfectant.

CONTACT TIME: Effective against HIV-1 (AIDS Virus) on d, nonporous surfaces in the presence of a moderate .ount of organic soil (5% blood serum) when diluted at 1:256 dilution in 400 ppm CaCO₃ hard water for a contact time of 10 (ten) minutes at room temperature (20 - 25°C).

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to Federal, State and local regulations for infectious waste disposal.

DIRECTIONS FOR USE IN POULTRY HOUSE AND FARM PREMISE:

Do not use in milking stalls, milking parlors or milk houses.

1. Remove all poultry, animals and feed from the premises.
2. Remove all trucks, coops, crates, water troughs and feed racks.
3. Remove all gross soil, litter, manure, droppings from animals and poultry from floors, walls and surfaces of barns, pens, stalls, chutes, hatchers and other facilities and fixtures occupied or traversed by animals and poultry.

4. Empty all troughs, racks, and other feeding and watering appliances.
5. Thoroughly clean and saturate all surfaces with a solution of ½ oz. of product disinfectant per gallon (4 ml/ L) of water. Use high-pressure sprayer or other suitable sprayer.
6. Allow disinfectant to remain in contact for at least ten minutes.
7. Immerse halters, ropes and other types of equipment used in handling and restraining animals, as well as forks, shovels, scrapers used for removing litter and manure, in a solution of ½ oz. of product disinfectant per gallon (4 ml/ L) of water. Allow to remain in contact for ten minutes.
8. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and mangers with a solution of product disinfectant at ½ ounce per gallon of water. Rinse with potable water before reuse.
9. Ventilate buildings, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.

removed

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Store only in original container. Do not reuse empty container. Keep this product under locked storage sufficient to make it inaccessible to children or persons unfamiliar with its proper use. **DO NOT STORE NEAR HEAT OR OPEN FLAME**

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.

CONTAINER DISPOSAL: (*Smaller than 1 gallon*) Do not reuse empty container. Wrap container and put in trash. (*Larger than 1 gallon*) - Triple rinse, then other for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. In addition, plastic containers may be disposed of by incineration, or if allowed by state and local authorities, by burning. If burned stay out of smoke.

ENVIRONMENTAL HAZARDS:

(*Larger than 5 gallons*) This product 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 E.P.A.