

49403-14

06/30/2004
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1/4

JUN 30 2004

Clariant Corporation
P.O. Box 866
625 East Catawba Avenue
Mount Holly, N. C. 28120

Attention: Michelle M. Ford
Product Safety Chemist

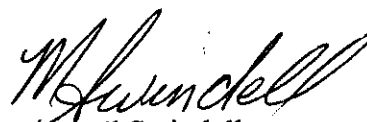
Subject: Nipacide X
EPA Registration No. 49403-14
Your Notification Dated May 26, 2004

This will acknowledge receipt of your notification to add a new indoor, non food use site, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

The notification is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely



Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510C)

| CONCURRENCES | | | | | | | |
|--------------|--|--|--|--|--|--|--|
| SYMBOL | | | | | | | |
| SURNAME | | | | | | | |
| DATE | | | | | | | |

33
Clariant Corporation

P.O. Box 866
625 East Catawba Avenue
Mount Holly, NC 28120
800.255.6189

 **Clariant** ^{2/4}

May 26, 2004

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

ATTENTION: Marshall Swindell
Product Manager, Team 33

SUBJECT: Clariant Corporation
Nipacide X (EPA Reg. No. 49403-14)
Application for Pesticide Notification

Dear Mr. Swindell:

Clariant Corporation is submitting an application to add a new use via notification to the registration of the product, Nipacide X (EPA Reg. No. 49403-14). The purpose of the notification is to add a new indoor, non food use site in accordance with PR Notice 98-10. In addition, a CFR reference has been added to show that this product is approved for use under 40 CFR 180.1001 (d). As of April 1, 2004 these are now approved under 40 CFR 180.950 and 180.920.

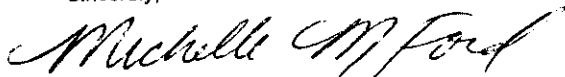
Enclosed please find the following documents in support of this notification:

- 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

**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 49403-14 | 2. EPA Product Manager Marshall Swindell | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) Nipacide® X | PM# 33 | |
| 5. Name and Address of Applicant (Include ZIP Code) Clariant Corporation 4000 Monroe Road Charlotte, NC 28205 <u>PLEASE SEND ALL CORRESPONDENCE TO "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

| | |
|--|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application |
| <input checked="" type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below |

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)**NOTIFICATION TO ADD NEW INDOOR NON FOOD USE SITE****Notification of REVISIONS OF ALTERNATE SOURCES OF ACTIVE INGREDIENT in Accordance with PR Notice 98-10.**

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement or formula of this product. I understand that it is a violation of 18 U.S.C. Sec 1001 to willfully make any false statements to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be the subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Signature: *Michelle M Ford*Date: *5/27/04***Section - III**

| | | | |
|--|---|---|--|
| 1. Material This Product Will Be Packaged In: | | | |
| Child-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 | 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) |
| *Certification must be submitted | | If "Yes" Unit Packaging wgt. No. per container | If "Yes" Package wgt. No. per container |
| 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 _____ | | | |

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): 704-822-2617 |
| 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. | | C. Date Application Received (Stamped) |
| 2. Signature <i>Michelle M Ford</i> | 3. Title Product Safety Chemist | |
| 4. Typed Name Michelle M. Ford | 5. Date <i>5/27/04</i> | |

NIPACIDE® X

INDUSTRIAL MICROBIOSTAT

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Nipacide® X is an effective preservative in most aqueous compositions. Typical applications and the suggested range of concentrations on which trials can be based, are:

| Product | % Nipacide® X (based on total wt. of product) |
|---|---|
| Pesticide Formulations: For Product preservation | 0.1-0.5 |
| Latices: Polymer latices based on acrylate, butadiene, PVA, styrene for various applications, e.g., wax, floor polishes. Synthetic rubber latices | 0.04-0.09 |
| Oil-in-water emulsions: "Spin finish" solutions for use in the textile industry. Cutting/rolling oils. Soluble oils* (metal and engineering industries). | 0.04-0.18 |
| *We suggest formulator limit the addition of Nipacide® X to 0.9% maximum in metal-working fluid concentrates. This will give a maximum recommended use level of 0.09% Nipacide® X in a 10:1 dilution of the concentrate and reduce the possibility of skin sensitization. | |
| Emulsion paint: For preservation in the can. | 0.04-0.25 |
| Adhesives: Carboxy methyl cellulose (CMC) and derivatives, animal glues, adhesives based on gelatin and latex. Latex based sealants. | 0.02-0.09 |
| **Paper coating compositions: Rosin dispersions. Starch and casein based products | 0.02-0.09 |

The concentration required to give protection depends on several factors. These include the susceptibility of the system to microbiological degradation, the extent to which microorganisms can gain access, the species involved, pH, temperature, and length of time for which protection is required.

**For use as a component of paper and paperboard in contact with aqueous and fatty foods. The active ingredient 1,2 Benzisothiazolin-3-one may be used in paper coating compositions at a level not to exceed 0.01 mg/in² (0.00016 mg/cm²) of finished paper and paperboard. For use as a component of paper and paperboard in contact with dry foods, the level of active ingredient in the paper coating must not exceed 0.02 mg/in² (0.0031 mg/cm²) of finished paper and paperboard.

For protection against bacterial attack, a concentration within the range 0.02-0.35 Nipacide® X is almost invariably sufficient.

The control of mold growth, particularly on paste product of high solids content, may occasionally demand dosages above 0.35%.

In dilute fluid systems, spoilage is usually controlled with dosages not greater than 0.09%.

A simple method of determining the effective dosage rate is to prepare samples of the product containing varying concentrations of Nipacide® X, e.g., 0.02, 0.04, 0.06, and 0.15%. These can then be stored at approx. 25°C for a period of time and compared with a control sample of product containing no preservative stored under similar conditions.

SLIME CONTROL

There are two methods of adding slimeicides to paper mill systems: shock dosing and continuous dosing.

The preferred method of addition is by shock dosing since this ensures that a high concentration of Nipacide® X is present in the system for several hours. When a slime control agent is added by continuous methods over periods of several hours, its concentration in the system at any time is low. This can lead to the development of resistant organisms, an effect that is less likely to occur when the shock dosing method is used.

It is not possible to give precise recommendations as to the quantity of Nipacide® X to add to control slime formation, since the magnitude of the problem varies greatly from mill to mill, depending on the furnish employed, the cleanliness of the mill system, and the additional nutrients (for example, starch) that may be added to the stock.

Directions for Use Continued on Side Panel

For industrial use only as a microbiostat preservative for aqueous compositions such as oil in water emulsions, latices, emulsion paints, water based adhesives, pesticide formulations, detergents and cleaning solutions, casein/rosin dispersions, and textile spin-finish solutions and for control of slime producing bacteria in paper making processes.

| | |
|----------------------------|------|
| Active Ingredient: | |
| 1,2 benzisothiazolin-3-one | 18% |
| Inert Ingredients | 82% |
| | 100% |

KEEP OUT OF REACH OF CHILDREN

DANGER
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 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 a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

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.

HOTLINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-424-9300 in case of emergency.

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. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. 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 and before eating or smoking. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARD: 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.

EPA Reg. No. 49403-14
EPA Est. No. 49403-NC-01

The following quantities of Nipacide® X are suggested for trial:

(a) Shock dosing: Between 80 and 300 g (2.8 - 11 oz. av.) of Nipacide® X for each ton of paper produced per day should be added as a single daily shock dose, the actual quantity used depending on the severity of the slime problem.

This addition may be made to any part of the stock preparation or backwater system. Alternatively, the addition may be made to those parts of the system where it is known that slime deposits accumulate.

(b) Continuous Addition: If this method is adopted, Nipacide® X should be added continuously for either the single period of 8 hours during every 24 hours or for two separate periods of 4 hours during every 24 hours.

Nipacide® X should be metered at the rate of 125-150g (4.5 - 5.3 oz. av.) for each ton of paper produced during the dosing period. preferably, this addition should be made to the recirculated backwater.

STORAGE AND DISPOSAL

STORAGE: Protect from frost. If frozen, allow to thaw and stir well before reuse.

PESTICIDE DISPOSAL: Do not contaminate water, food, or feed by storage or 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. Open dumping is prohibited.

CONTAINER DISPOSAL: 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.

REGULATORY CLEARANCES

All components of Nipacide® X are cleared for use under the following U.S. Environmental Protection Agency and U.S. Food and Drug Administration registrations and clearances:

US EPA Registration Number: 49403-14
US EPA 40 CFR 180.1001 (a) (180.520, 180.510)
US FDA:

| | |
|-----------------|---|
| 21 CFR 175.105 | Components of adhesives |
| 21 CFR 176.170 | Components of paper and paperboard in contact with aqueous and fatty foods |
| 21 CFR 176.180 | Components of paper and paperboard in contact with dry food. |
| 21 CFR 176.300 | Slimeicides (in the manufacture of paper and paperboard that contact food). |
| 21 CFR 177.2600 | Rubber Articles Intended for Repeated Use |

FOR YOUR PROTECTION

The information and recommendations in this publication are, to the best of our knowledge, reliable. Suggestions made concerning uses or applications are only the opinion of Clariant Corporation and users should make their own tests to determine the suitability of these products for their own particular purposes. However, because of numerous factors affecting results, Clariant Corporation MAKES NO WARRANTY OF ANY KIND, EXPRESSED OR IMPLIED, INCLUDING THOSE OF MERCHANTABILITY AND FITNESS FOR PURPOSE, other than that the material conforms to its applicable current Standard Specifications. Statements herein, therefore, should not be construed as representations or warranties. The responsibility of Clariant Corporation for claims arising out of breach of warranty, negligence, strict liability, or otherwise is limited to the purchase price of the material. Statements concerning the use of the products or formulations described herein are not to be construed as recommending the infringement of any patent and no liability for infringement arising out of any such use is assumed.

Manufactured by:

Clariant Corporation

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

Net Weight:
Batch No.:

Revised 5/2004

4/4