

49403-14

9/1/2005

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 1 2005

Clariant Corporation
4000 Monroe Road
Charlotte, N. C. 28205

AGENT: Lewis and Harrison
122 C Street, N.W., Suite 740
Washington, D. C. 20001

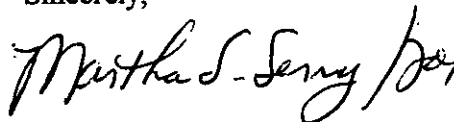
Subject: Nipacide X
EPA Registration No. 49403-14
Your Notification Dated August 9, 2004

This will acknowledge receipt of your notification to add additional indoor, nonfood use sites to the Nipacide X label, 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
Antimicrobial Division (7510C)

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

OFFICIAL FILE COPY

**EPA**

United States
Environmental Protection Agency
Washington, DC 20460

- ☐ Registration
☐ Amendment
☒ Other: Notification

OPP Identifier Number
296847

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# Team 33	
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

<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 of Adding an Indoor, Nonfood Site for an Antimicrobial Product 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 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 EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 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.

Signature: Christina M. SwickDate: 8/9/05**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
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		<input type="checkbox"/> Metal	
	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Plastic
*Certification must be submitted					<input type="checkbox"/> Glass
					<input type="checkbox"/> Paper
					<input type="checkbox"/> Other:
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 Christina M. Swick, Lewis & Harrison 122 C Street NW #740, Washington DC 20001	Title Agent for Clariant Corporation	Telephone No. (Include Area Code) 202-393-3903 (ext. 16)
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 <u>Christina M. Swick</u>	3. Title Agent for Clariant Corporation	
4. Typed Name Christina M. Swick, Lewis & Harrison	5. Date August 9, 2005	

LEWIS & HARRISON

Consultants In Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001

telephone 202.393.3903
fax 202.393.3906

3 8 4

August 9, 2005

HAND DELIVERED

Office of Pesticide Programs
Antimicrobial Division
Document Processing Desk (NOTIF)
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, Virginia 22202

**ATTENTION: Marshall Swindell
Product Manager, Team 33**

**SUBJECT: Clariant Corporation
Nipacide X (EPA Reg. No. 49403-14)
Notification in Accordance With PR Notice 98-10**

Dear Mr. Swindell:

As agent for Clariant Corporation, I am submitting a notification to add additional indoor, nonfood use sites to the Nipacide X label. Please note that the addition of these sites are in accordance with PR Notice 98-10

The following documents are enclosed to support this notification:

1. Application for Pesticide Notification (OPP ID No. 296847);
2. One (1) copy of the proposed product label with changes highlighted; and,
3. Two (2) copies of the proposed product label.

If you have any questions and/or comments, please feel free to contact me at 202-393-3903 x16 or cswick@lewisharrison.com.

Sincerely yours,

Christina M. Swick

Christina M. Swick
Agent for Clariant Corporation

Enclosures

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, floorpolishes, Synthetichubber latices	0.04-0.09
Oil-in-water emulsions: "Spin finish" solutions for use in the textile industry. Cuttingtrotting 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.	
Adhesives: 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
Car care products: Car washes, waxes, silicone emulsions	0.075-0.15
Home cleaning Products: floor cleaners, floor waxes, floor polishes, Surface cleaners	0.05-0.15
Laundry Additives: Liquid laundry detergents, fabric softeners, Stain removers	0.02-0.09
Mineral Slurries and Dispersions	0.02-0.09
Tape Joint Compound	0.06-0.25

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 slimicides 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.

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, mineral slurries, titanium dioxide slurries, tape joint compound.

Active Ingredient:
1,2 benzisothiazolin-3-one
Inert Ingredients

18%
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

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.

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 (d) (180.920, 180.950)
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	Slimicides (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 Meador Road
Charlotte, NC 28205 (704) 241-2100

Net Weight:
Batch No.: