UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 16 1997

Nipa Hardwicke, Inc.
3411 Silverside Road
Wilmington, DE. 19810

Subject: Nipacide X
EPA Registrant No. 49403-14
Notification Per PR-Notice 95-2

Dear Ms. McCombie:

This will acknowledge receipt of your notification to add "detergents and cleaning solutions" to the middle panel of the product label submitted under the provisions of FIFRA section 3 (c) 9. Based on a review of the submitted material, the following comments apply.

The application is acceptable and the notification has been made a part of the records for this file.

Sincerely,

M Swindell

Marshall Swindell
Notification Coordinator
Antimicrobial Program Branch
Antimicrobial Division (7505W)

CONCURRENCES								
SYMBOL	7505W							
SURNAME	P. Hosty							
DATE	4/16/97							

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
230556

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
49403-14	Marshall Swindell	☒ None ☐ Restricted
4. Company/Product (Name)	PM#	
Nipacide X	PM Team 31	

5. Name and Address of Applicant *(Include ZIP Code)*

Nipa Hardwicke, Inc.
3411 Silverside Road
Wilmington, DE 19810

☐ *Check if this is a new addresss*

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

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

Notification of minor label changes as per PR Notice 95-2 (Certification Statement is attached). Change includes the addition of "detergents and cleaning solutions" to the middle panel of the product label.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ 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	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

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

Name	Title	Telephone No. (Include Area Code)
Wendy A. McCombie, Lewis & Harrison 122 C St. NW Suite 740, Washington DC 20001	Agent for Nipa Hardwicke, Inc.	202-393-3903

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	3. Title	4. Typed Name	5. Date
Wendy A. McCombie	Agent for Nipa Hardwicke, Inc.	Wendy A. McCombie, Lewis & Harrison	03/17/97

HIGHLIGHTED COPY

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)
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.	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/in^2 (0.00016 mg/cm^2) 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/in^2 (0.0031 mg/cm^2) 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.

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, 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

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Call a physician immediately.

IF SWALLOWED: Drink large quantities of water. Do not give anything by mouth to an unconscious person. Call a physician or poison control center immediately.

IF ON SKIN: Wash with plenty of soap and water.

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. 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.

Contents Made in Great Britain
EPA Reg. No. 49403-14
EPA Est. No. 49403-EN-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 (4.4 - 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 cleard for use under the following U.S. Environmental Protection Agency and U.S. Food and Drug Administation registrations and clearances:

US EPA Registration Number: 49403-14
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).

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 NIPA Hardwicke Inc. 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, NIPA Hardwicke Inc. 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 NIPA Hardwicke Inc. for claims arising out of breech 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 for:

NIPA Hardwicke Inc. 3411 Silverside Rd. Wilmington, DE 19810 (302) 478-1522

Net Weight:
Batch No.:

Revised 03/17/97

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)
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.	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/in^2 (0.00016 mg/cm^2) 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/in^2 (0.0031 mg/cm^2) 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 stimicides 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, 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

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Call a physician immediately.

IF SWALLOWED: Drink large quantities of water. Do not give anything by mouth to an unconscious person. Call a physician or poison control center immediately.

IF ON SKIN: Wash with plenty of soap and water.

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. 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.

Contents Made in Great Britain
EPA Reg. No. 49403-14
EPA Est. No. 49403-EN-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 (4.4 - 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 cleard for use under the following U.S. Environmental Protection Agency and U.S. Food and Drug Administation registrations and clearances:

US EPA Registration Number: 49403-14
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).

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 NIPA Hardwicke Inc. 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, NIPA Hardwicke Inc. 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 NIPA Hardwicke Inc. for claims arising out of breech 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 for:

NIPA Hardwicke Inc. 3411 Silverside Rd.
Wilmington, DE 19810 (302) 478-1322

Net Weight:
Batch No.:

Revised 03/17/97