

49403 -26

6-5-2008

1/4

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



United States
Environmental Protection
Agency

Office of Pesticide Programs

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

JUN - 5 2008

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

Attention: Wendy A. McCombie

Subject: Nipacide BIT 10

EPA Registration No. 49403-26
Notification Dated May 9, 2008

This will acknowledge receipt of your notification for the following additional brand name, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

ADDITIONAL BRAND NAME

"Nipacide BIT 10W"

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been made a part of your file.

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

Sincerely

A handwritten signature in cursive script, appearing to read "Martha Terry" or "Marshall Swindell".

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

7

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

2/4

direct 202.393.3903 ext. 11
wmccombie@lewisharrison.com

May 9, 2008

HAND DELIVERED

Antimicrobials Division (Mail Code 7504P)
Office of Pesticide Programs
Document Processing Desk [NOTIFY]
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

ATTENTION: Marshall Swindell
Product Manager, Team 33
Antimicrobials Division

SUBJECT: Clariant Corporation
Nipacide® BIT 10 (EPA Reg. No. 49403-26)
Notification of an Alternate Brand Name

Dear Mr. Swindell:

On behalf of Clariant Corporation ("Clariant"), we are notifying the Agency of an alternate brand name for Nipacide® BIT 10.

The proposed alternate brand name is:

Nipacide® BIT 10W

Please find enclosed the following documents to support the notification for Nipacide® BIT 10:

- 1) Pesticide Application Form; and,
- 2) Three (3) copies of the product label bearing the alternate brand name.

Insofar as I am the authorized "Contact Point" and "Company Agent" for Clariant, please relay all correspondence directly to me at 122 C Street NW, Suite 740, Washington DC 20001. If you have any questions, please contact me by telephone at 202-393-3903 ext. 11 or by e-mail at wmccombie@lewisharrison.com.

Thank you very much for your cooperation.

Sincerely,



Wendy A. McCombie
for,
Clariant Corporation

Enclosures

**EPA**
 United States
Environmental Protection Agency
 Washington, DC 20460

☐ **Registration**
☐ **Amendment**
☒ **Other - Notification**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 49403-26	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Nipacide® BIT 10	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 type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)**APPLICATION FOR NOTIFICATION: ALTERNATE BRAND NAME****Notification of Alternate Brand Name 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 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: Wendy A. McCombleDate: MAY 9, 2008**THIS SUBMISSION IS NOT SUBJECT TO PRIA FEES****Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
	If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
*Certification must be submitted				<input type="checkbox"/> Other (Specify)	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container No Retail Containers		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input checked="" 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: Wendy A. McComble, Lewis and Harrison, LLC 122 C St., NW Suite 740 Washington, DC 20001 wmccomble@lewisharrison.com	Title Agent for Clariant Corporation	Telephone No. (Include Area Code) 202-393-3903 ext. 11
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>Wendy A. McComble</u>	3. Title Agent for Clariant Corporation	
4. Typed Name Wendy A. McComble, Lewis & Harrison, LLC	5. Date May 9, 2008	

NIPACIDE® BIT 10W

INDUSTRIAL MICROBIOSTAT

DIRECTIONS FOR USE

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

Nipacide BIT 10 is an aqueous solution of 1,2-benzisothiazolin-3-one which was developed as a water soluble, nonformaldehyde, halogen-free organic preservative to control the growth of slime forming bacteria in water based systems. When used at suggested application levels, **Nipacide BIT 10** is cost effective, offers ease of incorporation, maintains stability over a wide pH range and is thermally stable.

APPLICATION

Aqueous compositions during production and storage are susceptible to the growth of slime forming bacteria. This microbial contamination can be introduced into synthetic and natural based systems by the raw materials used, contaminated equipment, the production or storage environment and worker contact. The growth of microbial organisms can be detrimental to the integrity of the system, resulting in changes in viscosity, discoloration and staining, mal odors and gas generation. The use of **Nipacide BIT 10** to control biodeterioration in these systems will help maintain product functionality and improve the storage life of the treated material.

USE

At use levels of 0.04 - 0.5% based on the total weight of the formulation, **Nipacide BIT 10** has been shown to be effective under laboratory and field use conditions. It is suggested that the preservative be added with sufficient agitation and allowing enough time for uniform dispersion. **Nipacide BIT 10** may be added at anytime during the production process. The level of **Nipacide BIT 10** required for optimum effectiveness is dependent on the anticipated storage/protection time, susceptibility of the system to microbial degradation, pH, temperature and other factors. Clariant recommends that all formulation components be evaluated for efficacy, stability and compatibility prior to commercialization in the final formulation/product.

The following applications and suggested dose levels are typical for aqueous based systems:

Application	% Nipacide Bit 10 (Based On Total Formulation Weight)
Aqueous Polymer Emulsion And Latex Systems	0.08 - 0.18
Water Based Paint And Coatings Systems	0.08 - 0.50
Aqueous Adhesive And Sealant Systems	0.04 - 0.18
Mineral Slurries And Dispersions	0.04 - 0.18
Metal Working Fluids (Rolling, Cutting And Grinding Fluids)	0.08 - 0.36*
Paper And Textile Coatings	0.04 - 0.18
Pesticide Formulations (For Product Preservation)	0.09 - 0.45

*Should not exceed 0.45% (Max.) based on the weight of the working dilution

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

Active Ingredient:

1,2 benzisothiazolin-3-one	9%
Inert Ingredients	91%
	100%

KEEP OUT OF REACH OF CHILDREN DANGER

FIRST AID	
IF IN EYES:	<ul style="list-style-type: none">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:	<ul style="list-style-type: none">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:	<ul style="list-style-type: none">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. 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. 49403-26

EPA Est. No. 49403-NC-01

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® BIT 10 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: 49403-26

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

Net Weight:
Batch No.: