

39967-55

10/23/2008

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

OCT 23 2008

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Ms. Deborah Vercek
Agent for,
LANXESS Corporation
111RIDC Park West Drive
Pittsburgh, PA 15275-1112

Subject: Biochek BIT 20
EPA Registration Number 39967-55
Your Notification Dated October 13th, 2008
EPA Received Date October 15th, 2008

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to add seed coatings, update the exemption from tolerance statement and technical bulletin as per PR Notice 98-10, is acceptable.

The notification has been made part of the file.

If you have questions concerning this letter, please contact Karen M. Leavy at (703)-308-6237.

Sincerely,

A handwritten signature in cursive script that reads "M Swindell".

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

United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Notification

OPP Identifier Number

Application for Pesticide - Section I

1. Company / Product (Name) 39967-55	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company / Product (Name) BIOCHEK BIT 20	PM# 33	
5. Name and Address of Applicant (include ZIP Code) LANXESS Corporation 111 RIDC Park West Drive Pittsburgh, PA 15275-1112 <input type="checkbox"/> Check of 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 Seed Coating, update the exemption from tolerance statement, and update Technical Information Bulletin per 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.

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
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package Wgt	No. per 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
6. Manner in Which Label is affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other <input type="checkbox"/> Paper glues <input type="checkbox"/> Stenciled					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary. To process this application)		
Name Heather F. Collins	Title Senior Regulatory Affairs Specialist	Telephone No. (Include Area Code) 412-809-3595
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
2. Signature <i>Heather F. Collins</i>	3. Title Senior Regulatory Affairs Specialist	
4. Typed Name Heather F. Collins	5. Date 10/13/08	



VIA COURIER

October 13, 2008

Document Processing Desk (NOTIF)
Attn: Mr. Marshall Swindell (33) Antimicrobial Division
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Heather F. Collins
Material Protection Products
Regulatory Affairs
111 RIDC Park West Drive
Pittsburgh, PA 15275-1112

Phone 412-809-3595
Fax 412-809-1068
heather.collins@lanxess.com
www.US.LANXESS.com

RE: Products: Biochek BIT 20
Registration #: 39967-55
Label Notification

Dear Mr. Swindell:

This is a notification to update the label for our Biochek BIT 20. We would like to add the use for "in-can preservation of seed coating material" to the label. We also are updating the statement regarding exemption from tolerance. The current statement references 40 CFR 180.1001(d) which was withdrawn as per 40 CFR dated January 1, 2004-July 1, 2004 and replaced by 40 CFR 180.920. This product contains the active ingredient, 1,2-benzisothiazolin-3-one (BIT) which is exempted from tolerance.

I have also made changes to the Technical Information Bulletin by removing the duplicative uses listing on page 2 as the uses with dosage recommendations are provided later in the bulletin, removed Regulatory Clearances regarding 21 CFR, removed Physical/ Chemical properties, removed Precautionary statements, removed First Aid, removed Environmental Hazards, and removed Storage and Disposal. I also updated the Technical Information Bulletin listing to "Building and construction compositions" to be consistent with the container label and added "or textile" with Paper coatings to be consistent with the container label.

Specifically enclosed is:

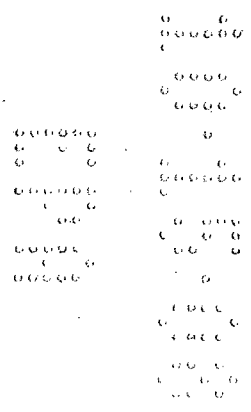
- Application form (EPA Form 8570-1)
- One (1) label highlighting the proposed addition
- Five (5) copies of the proposed label

Please feel free to contact me at 412-809-3595 with any questions.

Sincerely,

Handwritten signature of Heather F. Collins

Heather F. Collins
Senior Regulatory Affairs Specialist



BIOCHEK[®] BIT 20

FOR INDUSTRIAL USE ONLY AS AN ANTIMICROBIAL TO PROTECT AQUEOUS COMPOSITIONS SUCH AS LATICES, OIL-IN-WATER EMULSIONS, PAINTS AND COATINGS, INKS AND FONT SOLUTIONS, WATER-BASED ADHESIVES, AQUEOUS PIGMENT OR MINERAL SLURRIES, BUILDING AND CONSTRUCTION COMPOSITIONS, PESTICIDE FORMULATIONS, HOME CLEANING PRODUCTS, LIQUID LAUNDRY ADDITIVES, CAR CARE PRODUCTS, OIL RECOVERY MATERIALS, SECONDARY OIL RECOVERY FLUIDS, PAPER OR TEXTILE COATING COMPOSITIONS, PULP AND PAPER MILL SYSTEMS, LEATHER PROCESSING SOLUTIONS, INTENDED TO PROTECT FRESH ANIMAL HIDES OR SKINS, OR SEED COATING

**KEEP OUT OF REACH OF CHILDREN
DANGER**

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. CORROSIVE. Causes skin burns and irreversible eye damage. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin, or on clothing. Do not breathe vapor or spray mist. Wear goggles or face shield, chemical resistant gloves, long pants and long sleeved shirt. Wear a mask or pesticide respirator approved by the National Institute for Occupational Safety and Health. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

ENVIRONMENTAL HAZARDS

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 EPA. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not apply in marine or estuarine oil fields.

DIRECTIONS FOR USE

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

For Detailed Directions For Use, Please Refer To The LANXESS Corporation Technical Information Bulletin. Read these entire directions before using BIOCHEK BIT 20.

IN CASE OF EMERGENCY, CALL: CHEMTREC 800-424-9300
EPA REGISTRATION NUMBER: 39967-55
EPA ESTABLISHMENT NUMBER:

LANXESS

LANXESS Corporation
111 RIDC Park West Drive - Pittsburgh, PA 15275-1112

LABEL TEXT DATE: 10/6/2008

ACTIVE INGREDIENTS:

1,2-benzisothiazolin-3-one 19.0%

INERT INGREDIENT: 81.0%

Total 100.0%

FIRST AID

Call a poison control center or doctor immediately for treatment advice. Have the product container or label with you when calling a poison control center or when going for treatment.

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 SKIN IRRITATION OR DERMAL EXPOSURE: Take off contaminated clothes. 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 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 so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

Poison Control Center: Call 1-800-222-1222

[®] Biochek is a registered trademark of LANXESS Corporation

INTERNATIONAL 703-527-3887
Net Contents:
Lot No.:

STORAGE AND DISPOSAL

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

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

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: 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.

Emergencies: In emergency situations, such as spills, fire, or exposure: call 1-800-424-9300

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BIOCHEK® BIT 20

FOR INDUSTRIAL USE ONLY AS AN ANTIMICROBIAL TO PROTECT AQUEOUS COMPOSITIONS SUCH AS LATICES, OIL-IN-WATER EMULSIONS, PAINTS AND COATINGS, INKS AND FONT SOLUTIONS, WATER-BASED ADHESIVES, AQUEOUS PIGMENT OR MINERAL SLURRIES, BUILDING AND CONSTRUCTION COMPOSITIONS, PESTICIDE FORMULATIONS, HOME CLEANING PRODUCTS, LIQUID LAUNDRY ADDITIVES, CAR CARE PRODUCTS, OIL RECOVERY MATERIALS, SECONDARY OIL RECOVERY FLUIDS, PAPER OR TEXTILE COATING COMPOSITIONS, PULP AND PAPER MILL SYSTEMS, LEATHER PROCESSING SOLUTIONS, INTENDED TO PROTECT FRESH ANIMAL HIDES OR SKINS, OR SEED COATING

General

Many aqueous dispersions and emulsions can be spoiled during storage and use due to the growth in them of bacteria, fungi, molds, or other microorganisms. BIOCHEK BIT 20, an aqueous solution of 1,2-benziso-thiazolin-3-one (BIT), is an efficient microbial preservative for many aqueous systems, and exhibits:

- Effective control of a wide range of organisms at cost-effective concentrations.
- Long-term storage stability.
- Ease of use due to its liquid form and good compatibility in most aqueous compositions.
- A clear light color, with attendant advantages.

Properties of BIOCHEK® BIT 20

Composition: A solution of 1,2-Benzisothiazolin-3-one at 19% average in dipropylene glycol & water

DIRECTIONS FOR USE

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

BIOCHEK BIT 20 is an effective preservative in most aqueous compositions. The concentration required to give protection depends on several factors. These include the susceptibility of the system to microbiological degradation, the extent to which micro-organisms can gain access, the species involved, pH, temperature, and length of time for which protection is required.

For protection against bacterial attack, a concentration within the range 0.02 - 0.25% BIOCHEK BIT 20 is almost invariably sufficient. In dilute fluid systems, spoilage is usually controlled with dosages not greater than 0.09%. Control of mold growth, particularly on paste products of high solids content, may occasionally require demand dosages above 0.25%. Do not use concentrations greater than 0.50%.

Trials at different concentrations are recommended. Typical applications, and the suggested range of concentrations on which trials can be based, are:

Type of material to be protected	Lbs BIOCHEK [®] BIT 20 to use per 1000 Lb of material to be protected
Latices , such as: polymer latices based on monomers such as acrylate, butadiene, PVA or styrene; synthetic rubber/latex	0.5 to 1.5 lb (0.05 - 0.15%)
Oil-in-water emulsions , such as textile spin-finish solutions, cutting/rolling oils, soluble oils (metal and engineering industries), and photographic emulsions. Note: limit amount of BIOCHEK BIT 20 in metalworking fluid concentrate (to be diluted before use) to 3.0 % to reduce the possibility of dermal sensitization.	0.5 to 1.8 lb (0.05 - 0.18%)
Paints and coatings , such as aqueous coatings, water-based paints, and emulsion paints	0.5 to 2.5 lb (0.05 - 0.25%)
Inks and font solutions	0.5 to 2.5 lb (0.05 - 0.25%)
Water-based adhesives , including animal glues, adhesives based on carboxymethylcellulose (CMC) and derivatives, gelatin and/or latex	0.5 to 2.5 lb (0.05 - 0.25%)
Aqueous slurries of pigments such as titanium dioxide slurries or of minerals such as kaolin, calcium carbonate, calcium sulfate, or magnesium sulfate	0.4 to 1.25 lb (0.04 - 0.125%)
Building and Construction compositions , such as caulks, sealants, grouts, spackling, ready-mixed cement and wallboard compounds, and tape joint compounds	0.8 to 2.5 lb (0.08 - 0.25%)
Pesticide formulations , including in-can protection and protection of use dilutions	0.5 to 2.5 lb (0.05 - 0.25%)
Home cleaning products , including floor waxes and polishes, surface cleaners, window cleaners, and dish detergents	0.5 to 1.5 lb (0.05 - 0.15%)
Liquid laundry additives , including laundry detergents, fabric softeners, and stain removers	0.5 to 1.5 lb (0.05 - 0.15%)
Car care products , including car washing products, car waxes, and silicone emulsions	0.75 to 1.5 lb (0.075 - 0.15%)
Oil recovery materials , such as drill muds, packer fluids, and completion fluids, containing polysaccharide fluid loss control agents and/or thickeners such as starch, guar, or xanthan gum	0.5 to 1.5 lb (0.05 - 0.15%) of total weight of the fluid , or 15 to 45 lb per 1000 lb of dry polysaccharide added
Secondary oil recovery injection water containing additives, such as polymer or micellar/polymer waterfloods using thickeners such as xanthan gum and/or polyacrylamides	0.15 to 1.5 lb (0.015 - 0.15%) of total weight of fluid
Leather processing solutions , to preserve the solutions	0.25 to 2 lb (0.025 - 0.20%)
Fresh animal skins and hides , to preserve the integrity of the hides and skins before or during processing. Add the appropriate quantity of BIOCHEK BIT 20 to the brine solution during the curing operation or treat hides or skins with an appropriately diluted aqueous solution during other portions of the processing operation. The specific use rate and contact time needed to control microbial attack will depend on the degree of decomposition of the hides or skins prior to treatment.	1 to 24 pounds (13 fluid ounces to 2.5 gallons) of BIOCHEK BIT 20 per 1000 pounds of hides or skins
Paper or textile coatings to be used in papermaking, including rosin dispersions, starch and casein based products	0.5 to 1.5 lb (0.05 - 0.15%)

Type of material to be protected	Lbs BIOCHEK® BIT 20 to use per 1000 Lb of material to be protected
<p>Seed Coating BIOCHEK BIT 20 is effective for the protection of in-can preservation of Seed Coatings Materials which includes, but is not limited to, colorants, dyes, seed coatings, and pesticide formulations up to 500 ppm of BIOCHEK BIT 20.</p> <p>BIOCHEK BIT 20 is exempt from tolerance under 40 CFR 180.920: Materials exempted from the requirements of a tolerance, when used in accordance with good agricultural practice as an inert (or occasionally active) ingredients in pesticide formulations applied to growing crops only.</p>	<p>0.5 to 5 lb (0.05 – 0.50%)</p>
<p>Pulp & paper mill system slime control The preferred method of addition is by shock dosing because this ensures that a high concentration of BIOCHEK BIT 20 is present in the system for several hours. If a slime control agent is added by continuous methods over periods of several hours, its concentration in the system at all times is low. This can lead to the development of resistant organisms, which is less likely to occur when the shock dosing method is used.</p> <p>It is not possible to give precise recommendations as to the quantity of BIOCHEK BIT 20 to add to control slime formation, because 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.</p> <p>The following quantities of BIOCHEK BIT 20 are suggested for trial: Shock dosing: If this preferred method is adopted, add 2.5 to 9 ounces of BIOCHEK BIT 20 for each ton of paper produced per day as a single shock dose, the actual quantity to be 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.</p> <p>Continuous addition: If this method is adopted, add BIOCHEK BIT 20 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. Meter BIOCHEK BIT 20 into the recirculated backwater at a rate of 7 to 8.5 ounces for each ton of paper produced during the dosing period.</p>	

LANXESS Corporation
 111 RIDC Park West Drive
 Pittsburgh, PA 15275
 412-809-1000

The conditions of your use and application of our products, technical assistance and information (whether verbal, written or by way of production evaluations), including any suggested formulations and recommendations, are beyond our control. Therefore, it is imperative that you test our products, technical assistance and information to determine to your own satisfaction whether they are suitable for your intended uses and applications. This application-specific analysis at least must include testing to determine suitability from a technical as well as health, safety and environmental standpoint. Such testing has not necessarily been done by LANXESS Corporation. All information is given without warranty or guarantee. It is expressly understood and agreed that the customer assumes and hereby expressly releases LANXESS from all liability, in tort, contract or otherwise, incurred in connection with the use of our products, technical assistance and information. Any statement or recommendation not contained herein is unauthorized and shall not bind LANXESS. Nothing herein shall be construed as a recommendation to use any product in conflict with patents covering any material or its use. No license is implied or in fact granted under the claims of any patent.

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