

39967-38

10/03/2008

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



United States
Environmental Protection
Agency

Office of Pesticide Programs

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

OCT 3 2008

Attention: Deborah A. Vercek
Regulatory Affairs Specialist

Subject: Biochek 430
EPA Registration No. 39967-38
Notification Dated September 10, 2008

This will acknowledge receipt of your notification to update the label as requested in the EPA letter of August 22, 2008 to remove statements referring to equipment no longer used and other minor labeling changes, 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 not in compliance with PR Notice 98-10 and is not acceptable. Since you are updating the percentages of two (2) active ingredients on your product label, these requests must be handled under the amendment process.

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

Sincerely

A handwritten signature in black ink, appearing to read "M. Swindell".

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

| | | | |
|---|--|---|-----------------------|
| United States Environmental Protection Agency Washington, DC 20460 | | <input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other | OPP Identifier Number |
| Application for Pesticide - Section I | | | |
| 1. Company / Product Number <u>39967-38</u> | | 2. EPA Product Manager <u>Swindell</u> | |
| 4. Company / Product (Name) <u>Biochek 430</u> | | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted | |
| 5. Name and Address of Applicant (include ZIP Code) <u>LANXESS Corporation</u> <u>111 RIDC Park West Drive</u> <u>Pittsburgh, PA 15275-1112</u> <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 update the label as requested in the EPA letter of August 22, 2008 (D353325) and to remove statements referring to equipment no longer used.

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.

| | | | | | |
|---|--|---|--|--|--|
| Section - III | | | | | |
| 1. Material This Product Will Be Packaged In: | | | | | |
| Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | | Water Soluble Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | |
| * Certification must be submitted | | If "Yes" Unit Packaging wgt. | | No. per container | |
| | | If "Yes" Package Wgt | | No. per container | |
| 2. Type of Container <input checked="" 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 checked="" type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) retail Container <u>55 gal drum</u> | | 5. Location of Label Directions <u>On labeling accompanying product</u> | |
| 6. Manner in Which Label is affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glues <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 <u>Deborah A. Vercek</u> | | Title <u>Regulatory Affairs Specialist</u> | |
| | | Telephone No. (Include Area Code) <u>412-809-3709</u> | |
| 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. | | | |
| 2. Signature | | 3. Title <u>Regulatory Affairs Specialist</u> | |
| 4. Typed Name <u>Deborah A. Vercek</u> | | 5. Date <u>9-10-08</u> | |
| 6. Date Application Received (Stamped) <div style="border: 1px solid black; padding: 5px; text-align: center;"> RECEIVED (Stamped) </div> | | | |

LANXESS

Energizing Chemistry

Deborah Vercsek
Material Protection Products
Regulatory Affairs
111 RIDC Park West Drive
Pittsburgh, PA 15275-1112

Phone 412-809-3709
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deborah.vercek@lanxess.com
www.US.LANXESS.com

September 10, 2008

VIA COURIER

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

RE: Products: Biochek 430
Registration #: 39967-38
Label Change Notification

Dear Mr. Swindell:

Enclosed is a notification regarding the Biochek 420 label. This notification is to update the label as EPA requested in the August 22, 2008 EPA letter (D353325). The EPA letter requested 4 changes to the label. Updating the percentages of 2 actives and adding spill instructions under the Pesticide Storage area have been completed. The fourth request to replace any references to Bayer Chemical Corporation with LANXESS Corp. could not be completed because I could not locate any such references on the label or label supplement.

Also I removed the statements on the label referring to a temperature indicator button because this equipment is no longer used.

Specifically enclosed are:

1. Application form (EPA Form 8570-1) for Biochek 430
2. One (1) label highlighting the proposed additions
3. Five (5) copies of the proposed label
4. One (1) copy of the previously approved label dated 5/2/2007 highlighting the statements removed.

Please provide me with a stamped label at the completion of your review for my records.

Please contact me at 412-809-3709 with any questions.

Sincerely,



Deborah A Vercsek
Regulatory Affairs Specialist

BIOCHEK[®] 430

TO INHIBIT THE GROWTH OF MICROORGANISMS IN LATEX EMULSIONS, WAXES, POLISHES, INKS, PAINTS, PIGMENT SLURRIES, COATINGS, AND METAL WORKING FLUIDS AND ADHESIVES (Not for use in metalworking fluids in California)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. CORROSIVE. Causes irreversible eye damage. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not breathe vapor or spray mist. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Remove contaminated clothing and wash before reuse. Handlers must wear: Long-sleeved shirt and long pants; Socks and shoes; Goggles or face shield and Chemical resistant gloves (such as rubber or any waterproof material); and Either a respirator with an organic vapor (OV) cartridge, or a canister with any N, P, R or HE prefilter or a dust/mist filtering respirator (MSHA/NIOSH) approval number prefix TC-21 or a NIOSH approved respirator with any N, P, R or HE prefilter. Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENVIRONMENTAL HAZARDS

This product is toxic to fish and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public 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 sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

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

The amount necessary for desired protection varies, depending on exposure conditions. Do not apply in a way that will contact workers or other persons.

See Label Supplement for additional use instructions.

IN CASE OF EMERGENCY, CALL: CHEMTREC 800-424-9300

EPA Reg. No.: 39967-38

EPA Est. No.:

LANXESS

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

ACTIVE INGREDIENTS:

| | |
|--|----------|
| 1,2-Dibromo-2,4-dicyanobutane | 23.725% |
| 5-Chloro-2-methyl-4-isothiazolin-3-one | 0.057% |
| 2-Methyl-4-isothiazolin-3-one | 0.020% |
| INERT INGREDIENTS: | 76.198% |
| TOTAL | 100.000% |

KEEP OUT OF REACH OF CHILDREN DANGER PELIGRO

FIRST AID

IF IN EYES: Hold eyes 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. 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 by a poison control center or doctor.

IF ON SKIN: 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.

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. Have the product Material Safety Data Sheet (MSDS) with you when calling a poison control center or when going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

The LANXESS Pittsburgh Emergency Response Telephone Number is 800-410-3063.

[®] Biochek is a registered trademark of LANXESS Corp.

Mix well before using this product.

INTERNATIONAL 703-527-3887

Net Contents:

Lot No.:

STORAGE AND DISPOSAL

Do not contaminate water, food, or feeds by storage or disposal.

PESTICIDE STORAGE: Keep container closed when not in use. Ship and store Biochek 430 at temperatures between 0-42 °C (32-108 °F). Freezing the product may cause a temporary water separation, which can be corrected by mechanical agitation. Store away from heat. At temperatures above 42 °C (108 °F), the active ingredients in the dispersion may separate out. Handle and open container in a manner as to prevent spillage. If the container is leaking, invert to prevent leakage and carefully dam up spilled material to prevent runoff. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Absorb spilled material with absorbing type compounds and dispose of as directed below.

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 environmental control agency, or the hazardous waste representative at the nearest regional office for guidance.

CONTAINER DISPOSAL: Disposal of Drums: Do not reuse empty container. Triple rinse (or equivalent). Reseal container then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, by incineration or, if allowed by State and Local authorities, by burning. If burned, stay out of smoke.

LABEL TEXT DATE: drafted 9/09/2008

b/h

LANXESS

Energizing Chemistry

Product Information

BIOCHEK 430

EPA Registration Number 39967-38

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BIOCHEK® 430

BIOCHEK 430 is a preservative which effectively inhibits the growth of microorganisms in latex emulsions, metalworking fluids, adhesives, waxes, polishes, inks, cooling water, paper manufacture, paints, coatings, and pigment slurries. **BIOCHEK 430** is a dispersion of 1, 2-dibromo-2, 4-dicyanobutane, 4-dicyanobutane, 5-chloro-2-methyl-4-isothiazolin 3-one and 2-methyl-4-isothiazolin-3-one. For a general description of the typical chemical and physical properties, see the **BIOCHECK 430** Material Safety Data Sheet.

APPLICATION

The growth of microorganisms in aqueous systems during shipment, storage and handling can be detrimental to effectiveness. Such growth can affect such properties as odor, color viscosity and introduce microbial growth into production equipment and processes. **BIOCHEK 430** is effective in controlling such contamination and can improve the effectiveness and extend the life of materials treated if used according to the instructions given below.

TYPICAL PROPERTIES

| | |
|---|--------------------|
| Color..... | White to off-white |
| Viscosity (Brookfield RVF, #5 Spindle @ 50 rpm @ 25°C)..... | 1300-3100 cps |
| Freezing Point, °C..... | 0°C |
| Specific Gravity, @ 20°C..... | 1.1 |

TYPICAL LEVELS OF USE

Laboratory testing and customer use show **BIOCHEK 430** is typically effective when applied at concentrations shown below. The exact amount necessary for the preservation of any given formulation will depend on the components, storage time and temperature, etc., and can be determined by actual testing. All concentrations are based on the total formulation weight.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. The amount necessary for desired protection varies, depending on exposure conditions.

Do not apply this product in a way that will contact workers or other persons.

BIOCHEK 430 is an in-can preservative intended to protect products during storage from degradation by bacteria, fungi and yeasts. **BIOCHEK 430** does not impart antimicrobial properties to the preserved product.

Aqueous paints and Coatings (including heating and air conditioning systems)

BIOCHEK 430 is formulated to facilitate incorporate by pumping into the makeup water. Biochek 430 can be incorporated by pouring if necessary. **Biochek 430** should be incorporated into the makeup water during the grind.

BIOCHEK 430 is an effective in-can preservative for all type of aqueous paints and coatings when used at levels of 800 – 3000 ppm. The optimum effective concentration can vary with properties of the material being preserved. Testing to determine the appropriate level for your product is highly recommended.

Latex emulsions and High Viscosity Suspensions

BIOCHEK 430 is formulated to facilitate incorporate by pumping into the makeup water. **BIOCHEK 430** can be incorporated by pouring if necessary. Incorporate by pumping or pouring with agitation into the makeup water blend. These products include, but are not limited to, dishwashing liquids, furniture and floor waxes and polishes, cleaners and treatment products and over-the counter inks sold to custom color decorative household projects.

Effective protection is achieved between 500 – 8000 ppm. Optimum effective concentration can vary with properties of the material being preserved. Testing to determine the appropriate level for your product is highly recommended.

BIOCHEK 430 is formulated to facilitate incorporate by pumping into the makeup water. **BIOCHEK 430** can be incorporated by pouring if necessary. Pump or pour using moderate agitation immediately following cool-down of the emulsion, and prior to pumping the emulsion into storage tank facilities. Latex emulsions that are preserved by **BIOCHEK 430** include polyvinyl acetate, acrylic, vinyl acrylic and styrene butadiene. These emulsions are the raw materials used in the formulation of paints, adhesives, joint cements, pigments and household products.

Effective protection is achieved between 500 – 8000 ppm. Optimum effective concentration can vary with properties of the material being preserved. Testing to determine the appropriate level for your product is highly recommended.

Adhesives

BIOCHEK 430 is formulated to facilitate incorporate by pumping into the makeup water. **BIOCHEK 430** can be incorporated by pouring if necessary. Where the adhesive is heated, **BIOCHEK 430** should be added during the cool-down cycle to minimize any evaporative loss. Adhesives for which **BIOCHEK 430** provides effective in-can preservation are starch, epoxy, polyester, polyvinyl acetate, styrene butadiene, methyl cellulose, acrylic, polyvinyl alcohol, hydroxyethyl cellulose, dextrin and casein. Such adhesives include, but are not limited to, those used in manufacturing process, construction projects, packaging materials

Effective protection is achieved between 500 – 8000 ppm. Optimum effective concentration can vary with properties of the material being preserved. Testing to determine the appropriate level for your product is highly recommended.

Joint cements

BIOCHEK 430 is formulated to facilitate incorporate by pumping into the makeup water. **BIOCHEK 430** can be incorporated by pouring if necessary. Incorporate by pumping or pouring with agitation into the makeup water blend. These products include mortar-like sealers that are used to construct walls.

Effective protection is achieved between 2000 – 8000 ppm. Optimum effective concentration can vary with properties of the material being preserved. Testing to determine the appropriate level for your product is highly recommended.

Pigment Slurries and Dispersions

BIOCHEK 430 is formulated to facilitate incorporate by pumping into the makeup water. **BIOCHEK 430** can be incorporated by pouring if necessary. Pump or pour using moderate agitation immediately following cool-down of the dispersed pigment and prior to pumping to the storage tank. **BIOCHEK 430** is an effective in-can preservative to protect the pigment during handling, transportation and storage. Dispersed pigments are used to impart color to many products such as paints and coatings, adhesives and plastics. Such material can be starch, clay, calcium carbonate or titanium dioxide; paper coatings, high viscosity suspensions, e.g., polymers, sizing solutions.

Effective protection is achieved between 400 – 9000 ppm. Optimum effective concentration can vary with properties of the material being preserved. Testing to determine the appropriate level for your product is highly recommended.

Metalworking fluids

BIOCHEK 430 is formulated to facilitate incorporate by pumping, but can be poured. Pump or pour **BIOCHEK 430** into the final diluted fluid either prior to its addition to the system at a level that will provide adequate protection in the diluted system, or after the system has been filled. **BIOCHEK 430** should be thoroughly mixed into the system to assure efficacy. If **BIOCHEK 430** is added to the concentrate, testing should be conducted to assure compatibility.

Effective protection is achieved between 500 – 4000 ppm. Optimum effective concentration can vary with properties of the material being preserved. Testing to determine the appropriate level for your product is highly recommended.

Waxes, polishes, and inks

BIOCHEK 430 is formulated to facilitate incorporate by pumping into the makeup water. **BIOCHEK 430** can be incorporated by pouring if necessary. Incorporate by pumping or pouring with agitation into the makeup water blend. These products include, but are not limited to, dishwashing liquids, furniture and floor waxes and polishes, cleaners and treatment products and over-the counter inks sold to custom color decorative household projects.

Effective protection is achieved between 500 – 4000 ppm. Optimum effective concentration can vary with properties of the material being preserved. Testing to determine the appropriate level for your product is highly recommended.

INDUSTRIAL FIBER PROCESSING FLUIDS

BIOCHEK 430 is an effective preservation for aqueous fluid used to manufacture and process fibers. **BIOCHEK 430** is formulated to facilitate incorporate by pumping into the makeup water. **BIOCHEK 430** can be incorporated by pouring if necessary. These fluids are used at various points in the production of fibers to lubricate, cool and wash. These fibers are typically used in non-apparel application and include all types of canvas materials. Biochek 430 should be added to the to the make-up water of emulsions or to oil with agitation. Effective concentration is 0.2 – 1.2%.

Effective protection is achieved between 2000– 12000 ppm. Optimum effective concentration can vary with properties of the material being preserved. Testing to determine the appropriate level for your product is highly recommended.

INDUSTRIAL RECIRCULATING COOLING WATER

BIOCHEK 430 is formulated to facilitate incorporate by pumping into the makeup water. **BIOCHEK 430** can be incorporated by pouring if necessary. Pump or pour **BIOCHEK 430** to the sump, suction side of the recirculating pump, or any other point of turbulent flow. Badly fouled systems should be cleaned before initial treatment. Optimum performance of **BIOCHEK 430** can be attained by continuous or intermittent feed. Effective concentration is 500-8000 ppm.

PAPER MILLS – SLIME CONTROL

For control of bacterial, fungal and yeast growth in pulp, paper, and paperboard mills, add **BIOCHEK 430** at the rate of 0.08 – 0.4 lbs/ton of finished pulp or paper produced (dry basis). Addition should be made by pumping or pouring at a location that will insure uniform distribution of **BIOCHEK 430** in the mass of fiber and water, such as the beaters, Jordan inlet or discharge, broke chests, furnish chests, save-alls, and white-water chests. It is preferable to clean a fouled machine before slimeicide addition whenever possible. **BIOCHEK 430** is also used for preservation of pigment slurries, adhesives, coatings, emulsions and high viscosity suspensions.

METHOD OF ADDITION

Systems with a tendency to become severely fouled or heavily fouled systems should be thoroughly cleaned and then treated with **BIOCHEK 430** at a range of 0.24 – 0.4 lbs/ton of finished paper produced until control of the problem is achieved. Maintenance levels for systems conducive to slight or moderate fouling should be treated on an intermittent basis with **BIOCHEK 430** at a level of 0.08-0.4 lbs/ton of finished paper product depending upon observed conditions.

METHOD OF ADDITION

For preservation of slurries and high viscosity suspensions, the material should be added at a point in the processing where there will be sufficient time and agitation for good dispersion.

COMPATIBILITY

BIOCHEK 430 is compatible with typical ingredients in end-use formulations. However, it should be added separately from amine-containing and strong nucleophilic agents during product formulations. Mixing **BIOCHEK 430** with these agents may cause a reaction between the ingredients which can deactivate **BIOCHEK 430**.

BIOCHEK 430 is most active over a pH range of 2.0 - 9.5. In some formulations, the product has shown efficacy in higher pH formulations. If the formulation will have a final pH greater than 9.5, laboratory testing is recommended.

CORROSION PROPERTIES

BIOCHEK 430 is compatible with materials such as PVC, polyethylene, polypropylene, Tygon, Teflon and glass. **BIOCHEK 430** is corrosive to mild steel.

Positive displacement pumps are preferred for handling the product. Chemical feed pumps are available.

PACKAGING

BIOCHEK 430 is available in pails, drums, and bins.

REMARKS

If you need assistance or information, please call your nearest LANXESS representative, or our Pittsburgh office at 800-LANXESS.

IN CASE OF EMERGENCY, CALL: CHEMTREC 1-800-424-9300

INTERNATIONAL (703)-527-3887

HAVE THE PRODUCT CONTAINER OF LABEL WITH YOU WHEN CALLING A POISON CONTROL CENTER OR DOCTOR OR GOING FOR TREATMENT.

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

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