

72372-1

09/18/2008

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

SEP 18 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Matthew E. Talley
Regulatory Specialist for,
FMC Corporation
Peroxygens Division
1735 Market Street
Philadelphia, PA 19103

Mail to: LuAnn Maloney
FMC Corporation
Peroxygens Division
1735 Market Street
Philadelphia, PA 19103

Subject: B-Cap 35 Antimicrobial Agent
EPA Registration Number 72372-1
Your Amendment Dated June 9th, 2008
EPA Received Date June 9th, 2008

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to add directions for use for B-Cap 35 Antimicrobial Agent as a non-food contact sterilant, is acceptable.

The submitted efficacy data (MRID Nos. 474394-01 and 474249-01) in conjunction with previously submitted efficacy data support the use of the product, when used in conjunction with the Clarus Hydrogen Peroxide Vapour Generator, as a sterilant against *Bacillus subtilis* and *Clostridium sporogenes*.

The proposed label claims that the product is effective sterilant, when used in conjunction with Clarus Hydrogen Peroxide Vapour Generator, for treating enclosure up to 35 ft³. A product injection rate of 3.1 g/minute for 55 minutes and exposure time of 3 hours are specified. Data provided supports these claims.

LABELING:

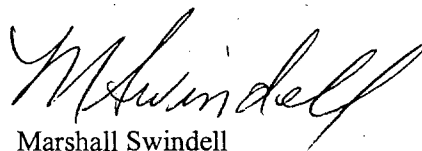
- Under the "Storage and Disposal" section of the proposed label, change "Cap 35 Antimicrobial Agent" to read "B-cap 35 Antimicrobial Agent."
- Under the "Air Washers...." Section of the proposed label, change "Once control is achieved continuous feed of" to read "Once control is achieved **use a** continuous feed of."
- In the "Control of Slime....." heading of the proposed label, change "other Microorganism" to read "Other Microorganisms."
- On page 2 of the product label under the directions for using the product as a sterilant, change (in numerous locations) "**Operating Manual**" to read "**Use Manual.**"
- On page 2 of the product label under the directions for using the product as a sterilant, **identify the types of surfaces/objects that may be sterilized.**
- On page of the label revise the sentence, "This product may not be used on food contact surfaces unless followed by a potable water rinse" by deleting all words following "surfaces". Place a period after the word "surfaces".

A stamped copy of the labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3 (c)(5) when the Agency requires all registrants of similar products to submit such data.

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

Sincerely,



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

B-Cap™ 35 Antimicrobial Agent

For Industrial Use Only –
Not for human consumption or household use

EPA Registration No. 72372-1
 EPA Est. No. 65402-WV-001
 65402-TX-001

B-Cap™ 35 Antimicrobial Agent is for use as a sterilant in conjunction with BIOQUELL Clarus™ hydrogen peroxide vapor generating equipment.

B-Cap™ 35 Antimicrobial Agent is for biofouling and slime control in:

- Pulp and paper mill systems
- Recirculating and once through cooling water systems
- Pasteurizer cooling water systems
- Process Waters
- Biocidal control in packaging and storage vessels

Active Ingredients: Hydrogen Peroxide.....35%

Inert Ingredients:65%

Total100%

KEEP OUT OF REACH OF CHILDREN
DANGER

FMC and B-Cap™ are trademarks of FMC Corporation

FMC

FMC Corporation
Peroxygens Division
1735 Market Street
Philadelphia Pennsylvania 19103

Precautionary Statements

Hazards to Humans and Domestic Animals

DANGER

Corrosive, causes eye and skin damage. Harmful 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. Do not breathe vapor or spray mist. Do not enter an enclosed area without proper respiratory protection.

Physical or Chemical Hazards

Strong oxidizing agent. Mix only with water. B-Cap™ 35 Antimicrobial Agent is not combustible; however, at temperatures exceeding 156°F, decomposition occurs releasing oxygen. The oxygen released could initiate or promote combustion of other materials.

Environmental Hazards

This pesticide is toxic to birds, mammals, fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with 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.

Any solution released from the system should be diluted with water and tested for residuals to ensure that there is less than 3 ppm peroxygen remaining.

First Aid

Have the product container or label with you when calling a poison control center or doctor, or 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 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.

If inhaled

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

If swallowed

- Call 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.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

ACCEPTED
with COMMENTS
in EPA Label Doc#:

SEP 18 2008

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended by the FIFRA Act of 1990,
 registered under EPA Reg. No.

72372-1

Storage and Disposal

Storage

NEVER RETURN B-CAP™ 35 ANTIMICROBIAL AGENT TO THE ORIGINAL CONTAINER AFTER IT HAS BEEN REMOVED. Avoid all contaminants, especially dirt, caustic, reducing agents, and metals. Contamination and impurities will reduce shelf life and can induce decomposition. In case of a decomposition, isolate container, douse container with cool water and dilute Cap™ 35 Antimicrobial Agent with large volumes of water.

Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at temperatures below 86°F. Do not store on wooden pallets.

Procedure for Leak or Spill

Stop leak if this can be done without risk. Shut off ignition sources; no flames, smoking, flares, or spark producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water. Undiluted material should not enter confined spaces.

Disposal

Pesticide Disposal

If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods of disposal may vary by location, regulatory agencies should be contacted prior to disposal.

B-Cap™ 35 Antimicrobial Agent, which is to be discarded, should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

Container Disposal

Empty drums are not returnable to FMC unless special arrangements have been made. Triple rinse drums with water. Dispose of drums in accordance with local, state, and Federal regulations. **DO NOT REUSE.**

Directions for Use

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

B-Cap™ 35 Antimicrobial Agent

A microbiocide for use in controlling slime and sulfate forming bacteria in process waters, air washing systems, recirculating and once through water cooling towers and systems, including pasteurizer cooling water systems and industrial closed recirculating process water systems, and packaging and storage vessels.

Air Washers and Recirculating and Once Through Cooling Water Systems, (cooling towers, evaporative condensers).

1. Severely fouled systems should be cleaned prior to treatment.
2. This product may be used in all types of cooling water systems that have mist-eliminating components. B-Cap™ 35 Antimicrobial Agent should be added at a point where uniform mixing can be achieved, for example the basin area. Addition may be intermittent or continuous. Hydrogen peroxide should not be mixed with other chemicals or additives without first checking for compatibility. Contamination with other chemicals could cause product decomposition.
 - Intermittent (Slug Dose) – For severely fouled systems add 3 to 163 fl oz of B-Cap™ 35 Antimicrobial Agent per 1000 gallons of water in the system, (10 to 500 ppm). Repeat until control is achieved. When control is evident add 1 to 31 fl oz of B-Cap™ 35 Antimicrobial Agent per 1000 gallons of water in system (3 to 100 ppm H₂O₂) as needed to maintain control.
 - Continuous Feed – Initial Dose: If the system is noticeably fouled use slug dose procedure for the initial treatment. Once control is achieved, continuous feed of 0.3 to 16 fl oz B-Cap™ 35 Antimicrobial Agent per 1000 gallons of water per day in the system (1 to 50 ppm H₂O₂). Dosage rates should be increased or decreased depending on the extent of biofouling and control achieved.

Pasteurizer Cooling Water Systems

The product can be used at the same application rates and in the same manner as described above. The solution should be added to the

closed recirculating system at a point where uniform mixing can be achieved, e.g., basin, sump, or collection areas.

Biofouling Control in Pulp and Paper Mill Systems

For use in the manufacture of paper and paperboard intended for non-food contact only. Not for use in the manufacture of paper and paperboard intended for food contact.

The product can be used to control bacterial, fungal and yeast growth in pulp, paper and papeboard mills.

1. Severely fouled systems should be cleaned prior to treatment with B-Cap™ 35 Antimicrobial Agent. Add B-Cap™ 35 Antimicrobial Agent directly to the system, don't mix with other chemicals or additives without first testing for compatibility. Contamination with other chemicals could result in product decomposition.
2. Add B-Cap™ 35 Antimicrobial Agent at a point in the system where it can be mixed uniformly with the pulp, e.g., the beater, hydropulper, fan pump, broke pump, etc.
3. Apply 1 to 40 fl oz of B-Cap™ 35 Antimicrobial Agent per ton of (dry basis) pulp or paper produced, (10 to 500 ppm H₂O₂). Addition may be continuous or intermittent depending on the type of system and severity of the biofouling.

Process Water

B-Cap™ 35 Antimicrobial Agent may be used to aid in minimizing slime formation in process waters intended for use in precleaning hard non-porous surfaces, e.g., metals, glass or plastics prior to being painted, plated, or coated; cleaning pipes, equipment or other process equipment.

1. Add B-Cap™ 35 Antimicrobial Agent at a point in the system where it can be mixed uniformly. The quantity of product required will depend upon the severity of the fouling.
2. Apply 0.3 to 163 fl oz per 1000 gallons of water in the system (1 to 500 ppm). Once control is achieved, reduce application rate accordingly.

Control of Slime, Bacteria, Fungi, and other Microorganism in packaging and storage vessels such as railcars, trucks, ships, totes, IBCs tanks, etc. used to contain clays, calcium carbonate, titanium dioxide, barium sulfate, and other filler materials.

1. If treating the container or vessel in the field, place the vessel or container on an area with an impervious surface with controlled runoff. Ensure that the antimicrobial treatment solution will not be released to the environment.
2. Remove gross contamination with a cleaner or other suitable detergent and rinse with water.
3. Prepare a dilute solution of the product by adding 1 to 4 volumes of B-Cap™ 35 Antimicrobial Agent to 11 volumes of potable water. This will provide solutions containing 3% to 10% hydrogen peroxide. Apply the diluted solution, at ambient or elevated temperatures, to the surface as a coarse spray, wipe/mop or flood to reduce bacterial and fungal contamination.
4. Allow antimicrobial agent to contact the surface for a period of time sufficient to ensure adequate cleaning. Depending on the microbial load, contact times can range from 5 to 30 minutes or longer.
5. Drain dry. Do not rinse.

B-Cap™ 35 Antimicrobial Agent is a sterilant for use in conjunction with BIOQUELL Clarus™ hydrogen peroxide vapor generating equipment. The hydrogen peroxide vapor is intended for use as a sterilant in enclosures up to 35 cubic feet. Use this product for sterilization as instructed in the Clarus™ Operating Manual. This product may not be used on food-contact surfaces unless followed by a potable water rinse.

1. Ensure that all surfaces are visibly clean and free from gross organic contamination.
2. Connect the Clarus™ generator and add B-Cap® 35 Antimicrobial Agent according to the operating manual instructions. Seal the enclosure to be sterilized.
3. Apply B-Cap® 35 Antimicrobial Agent at an injection rate of 3.1 gal/1000 ft³ of air.
4. Allow the hydrogen peroxide vapor to remain for a minimum of 3 hours.
5. After the chamber is empty, the chamber should be ventilated until hydrogen peroxide vapor is at or below 1.0 ppm. See the Clarus™ Operating Manual for complete instructions for application and recommended methods of measuring hydrogen peroxide vapor.

SEP 10 2008

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended by the pesticide, registered under EPA Reg. No. 72372-1

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In all applications, always prepare a new solution daily to ensure effectiveness. Do not reuse solutions. Dispose of any unused solution.

EMERGENCY TELEPHONE NUMBERS (24 HOURS)

MEDICAL: COLLECT 303-595-9048

TRANSPORTATION: 800-424-9300

OTHER: 609-924-6677

For more information see Material Safety Data Sheet

Label Effective Date: July 2006

Proper Shipping Name:

Hydrogen peroxide,
aqueous solution with not
less than 20 percent but
not more than 40 percent
hydrogen peroxide.

UN 2014

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 18 2008

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.

72372-1