

72372-1

115/2011

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

FMC Corporation, Peroxygens Division
1735 Market Street
Philadelphia, PA 19103

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

JAN 05 2011

Attention: John Dubeck
Regulatory Counsel/Agent

Subject: B-Cap 35 Antimicrobial Agent – Label Amendment to Add an Additional New
Use: Aseptic Food Processing on Food packaging Materials
EPA Reg. No. 72372-1
Amendment Letter Dated August 25, 2010

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. The Agency approves the following Amendments to the label:

- Addition of language supporting Aseptic Food Processing Operations.

The submitted efficacy data support the use of the product as a Sterilant against *Bacillus subtilis* and *Clostridium sporogenes* following a 20 second exposure time.

Variations in the concentration, time, and temperature to commercial sterility are not permitted unless testing for each variation has been approved by EPA. As such, the following language changes must be made to the label prior to printing:

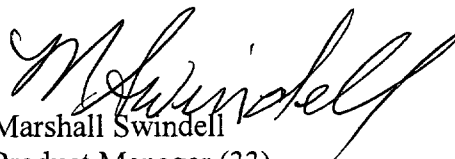
- On page 3 under the heading "Aseptic Food Processing Operations" remove the proposed phrase, "Validated food processing systems that have control over the contaminant load on food packaging prior to fill and appropriate food processing equipment surfaces may vary concentrations, temperatures, and contact time to achieve commercial sterility. Such use must comply with all applicable FDA regulations, including but not limited to 21 CFR parts 108, 110, 113, and 114."
- Under the same heading remove the phrase "; longer contact times may be required in certain aseptic food processing lines."

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A stamped copy of the accepted labeling is enclosed. Submit three copies of your final printed labeling to the Agency before distributing or selling the product bearing the revised labeling.

If you have any questions concerning this letter, please contact Abigail Downs at (703) 305-5259.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Swindell", written in a cursive style.

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

MASTER LABEL

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-TX-001

60156-IL-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

B-Cap™ 35 is for use in aseptic food processing operations to achieve commercial sterility of food packaging and equipment.

Active Ingredients: Hydrogen Peroxide 35%

Inert Ingredients: 65%

Total 100%

**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.

Net Contents: _____

ACCEPTED
with COMMENTS
in EPA Pesticide Data Book

JAN 05 2011

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

72372-1

MASTER LABEL**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 B-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

Nonrefillable containers less than 5 gallons. Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Nonrefillable containers greater than or equal to 5 gallons. Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over into its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Empty drums are not returnable to FMC unless special arrangements have been made. Dispose of drums in accordance with local, state, and Federal regulations.

All Refillable containers. Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Return to FMC for 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, use a 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 Microorganisms 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.

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

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MASTER LABEL

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 HPV generating equipment. The hydrogen peroxide vapor is intended for use as a sterilant in treating enclosures up to 3500 cubic feet (validated) or greater (non-validated). Use this product for sterilization as instructed in the BIOQUELL Use Manual. This product may not be used on food-contact surfaces unless followed by a potable water rinse.

For Enclosures up to 35 cubic feet

1. Ensure that all porous and non-porous surfaces are visibly clean and free from gross organic contamination.
2. Connect the BIOQUELL HPV generator and add B-Cap® 35 Antimicrobial Agent according to the Use Manual instructions. Seal the enclosure to be sterilized.
3. Apply B-Cap® 35 Antimicrobial Agent at an injection rate of 3.1 g/minute for 55 minutes.
4. Allow vapor to remain for a minimum of 3 hours.
5. Aerate the chamber using the BIOQUELL HPV generator until hydrogen peroxide vapor is at or below 1.0 ppm. See the BIOQUELL Use Manual for complete instructions for aeration and recommended methods of measuring hydrogen peroxide vapor.

For Enclosures Greater than 35 Cubic Feet to a Maximum of 3500 Cubic Feet

(Multiple 500 mL containers required for volumes greater than 35 cubic feet – refer to the table in item 3 below)

1. Ensure that all porous and non-porous surfaces are visibly clean and free from gross organic contamination.
2. Connect the BIOQUELL HPV generator and add B-Cap® 35 Antimicrobial Agent according to the Use Manual instructions. Seal the enclosure to be sterilized.
3. Apply B-Cap® 35 Antimicrobial Agent at an injection rate of 10 g/minute for 2.5 hours.

Volume to be treated	B-Cap® 35 Antimicrobial Agent Required	Number of 500 mL Packages Required
Up to 35 cubic feet	170.5 g	1
36 – 3500 cubic feet	1500 g	3

4. Allow vapor to remain for a minimum of 15 minutes.
5. Aerate the chamber using the BIOQUELL HPV generator until hydrogen peroxide vapor is at or below 1.0 ppm. See the BIOQUELL Use Manual for complete instructions for aeration and recommended methods of measuring hydrogen peroxide vapor.

Aseptic Food Processing Operations

B-Cap™ 35 Antimicrobial Agent is a ready to use solution. It may be used to achieve commercial sterility of food packaging materials and food processing equipment.

Apply B-Cap™ 35 Antimicrobial Agent on the exterior and interior of food containers and closure systems (caps, seals, etc.), or appropriate food processing equipment surfaces. Use techniques such as, but not limited to, immersion, coarse spray, or circulation to sterilize the equipment. Apply B-Cap 35 Antimicrobial Agent at a minimum temperature of 75°C. The product must remain in contact with the packaging surface for a minimum of 20 seconds; ~~longer contact times may be required in certain aseptic food processing lines.~~

~~Validated food processing systems that have control over the contaminant load on food packaging prior to fill and appropriate food processing equipment surfaces may vary concentrations, temperatures, and contact time to achieve commercial sterility. Such use must comply with all applicable FDA regulations, including but not limited to 21 CFR parts 108, 140, 145 and 144. Use in an aseptic food processing operation includes testing required for the process validation. Food subject to these FDA regulations may not be sold in a treated package until after the scheduled process for the food processing operation has been accepted by the FDA.~~

This product may not be used to sterilize medical devices.

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

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

UN 2014

Ver. 08-24-2010

ACCEPTED
 with COMMENTS
 in EPA Letter D-00-00-00

JAN 0 5 2011

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

72372-1