

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

June 1, 2018

Michael T. Novak Authorized Agent PeroxyChem, LLC 2005 Market St Suite 3200 Philadelphia, PA 19103

Subject: PRIA Label Amendment – Adding Food Processing Uses Product Name: B-Cap 27 Antimicrobial Agent EPA Registration Number: 72372-4 Application Date: 01/16/2018 Decision Number: 537398

Dear Mr. Novak:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6.

The following alternate brand names have been added to the product record:

- Durox 27
- Durox 27 LRA
- Durox 27 LRD

If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at <u>heffernan.aline@epa.gov</u>.

Sincerely,

Zeno Bain, Product Manager 33 Regulatory Management Branch I Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure: Stamped Label

B-Cap[™] 27 Antimicrobial Agent

ABNs: Durox[™] 27, Durox[™] 27 LRA, Durox[™] 27 LRD

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

EPA Registration No. 72372-4 EPA Est. No. _____

B-Cap[™] 27 Antimicrobial Agent is for use in aseptic food processing operations to achieve commercial sterility of food packaging and equipment.

B-Cap[™] 27 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 27%
Inert Ingredients: Total	

KEEP OUT OF REACH OF CHILDREN DANGER

⁽²⁾ PeroxyChem</sup> and B-Cap™ are trademarks of PeroxyChem, LLC



PeroxyChem, LLC 1735 Market Street Philadelphia Pennsylvania 19103

Net Contents

Gallons

Precautionary Statements Hazards to Humans and Domestic Animals

DANGER

Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through the skin. Do not get in eyes or on skin or clothing. Do not breathe (dust, vapor or spray mist). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Wear coveralls over long sleeved shirt and long pants, socks, chemical resistant footwear and chemical resistant gloves. Wear appropriate protective eyewear. Wear a respirator with an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G.

Physical or Chemical Hazards

Strong oxidizing agent. Mix only with water. At temperatures exceeding 156°F, decomposition of B-Cap[™] 27 Antimicrobial Agent could occur, 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 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. 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 swallowed	 Gall 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	 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 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.
Note to Physic	ian: Probable mucosal damage may contraindicate the
	use of gastric lavage

Storage and Disposal

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

STORAGE:

NEVER RETURN B-CAP™ 27 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 decomposition, isolate container, douse container with cool water and dilute B-Cap[™] 27 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.

Pesticide Disposal

Pesticide wastes may be 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

Nonrefillable containers less than 5 gallons. Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. If recycling is unavailable puncture, dispose of in trash, or in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances. 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 ¹/₄ 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. If recycling is unavailable puncture, dispose of in trash, or in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances. 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 1/4 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 for disposal. Repeat this procedure two more times. Empty drums are not returnable to PeroxyChem, LLC 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 PeroxyChem, LLC for reuse.

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.

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.

Directions for Use

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

B-Cap[™] 27 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 such as holding ponds and lagoons, including pasteurizer cooling water systems and industrial closed recirculating process water systems and packaging and storage vessels.

Aseptic Food Processing Operations

B-Cap[™] 27 Antimicrobial Agent is a ready to use solution. It may be used to achieve commercial sterility of food packaging materials prior to fill and equipment used in aseptic food processing applications.

Food Packaging Materials

Apply B-Cap[™] 27 Antimicrobial Agent on the exterior and interior of food containers and closure systems (caps, seals, etc.). Apply B-Cap[™] 27 Antimicrobial Agent at a minimum temperature of 176°F (80°C). The product must remain in contact with the packaging surface for a minimum of 20 seconds.

This product may be used on food packaging as an aseptic packaging antimicrobial rinse in food packaging processing operation that has a scheduled process accepted by FDA. The aseptic food processing operation must comply with all applicable FDA regulations, including but not limited to 21 CFR parts 108, 110, 113, and/or 114. Use in an aseptic food processing operation includes testing required for the process validation.

Food Processing Equipment

B-Cap[™] 27 Antimicrobial Agent is a ready to use solution. This product may be used to achieve commercial sterility of non-porous food manufacturing, packaging and filling equipment.

B-CapTM 27 Antimicrobial Agent may be used on manufacturing, filling (including rotary fillers) and packaging equipment.

- 1. Remove gross soil particles from equipment surfaces.
- 2. Clean surfaces thoroughly.
- 3. Rinse thoroughly with potable water.
- Apply B-CapTM 27 Antimicrobial Agent at a minimum temperature of 176°F (80°C). Use immersion, coarse spray or circulation techniques to apply B-CapTM 27 Antimicrobial Agent.
- 5. Allow contact time of at least 20 seconds.
- 6. Allow to drain dry.
- 7. A final rinse with sterile water is required.

This product may be used on equipment used in aseptic packaging antimicrobial rinse in food processing operation that has a scheduled process accepted by FDA. The aseptic food processing operation must comply with all applicable FDA regulations, including but not limited to 21 CFR Parts 108, 110, 113, and/or 114. Use in an aseptic food processing operation includes testing required for the process validation.

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[™] 27 Antimicrobial Agent should be added at a point where uniform mixing can be achieved, for example, in 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 4 to 215 fl. oz of B-Cap[™] 27 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-CapTM 27 Antimicrobial Agent per 1000 gallons of water in system (3 to 100 ppm) 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 0.4 to 21.5 fl oz B-Cap[™] 27 Antimicrobial Agent per 1000 gallons of water per day in the system (1 to 50 ppm). Dosage rates should be adjusted depending on the extent of biofouling and control achieved.

Pasteurizer Cooling Water Systems

B-Cap[™] 27 Antimicrobial Agent may be used for control of slime, bacteria, fungi, and other microorganisms in brewery and other pasteurizer systems and warmers 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 nonfood contact only. Not for use in the manufacture of paper and paperboard intended for food contact. This product may be used to control bacterial, fungal and yeast growth in pulp, paper and papeboard mills.

- Severely fouled systems should be cleaned prior to treatment with B-Cap[™] 27 Antimicrobial Agent. Add B-Cap[™] 27 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[™] 27 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.
- Apply 1 to 52 fl oz. of B-Cap[™] 27 Antimicrobial Agent per ton of pulp (dry basis) or paper produced, (10 to 500 ppm). Addition may be continuous or intermittent depending on the type of system and severity of the biofouling.

Process Water

B-Cap[™] 27 Antimicrobial Agent may be used to aid in minimizing slime formation in process waters intended for use in precleaning hard nonporous 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[™] 27 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.
- Apply 0.4 to 215 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, IBC's tanks, etc. used to contain clays, calcium carbonate, titanium dioxide, barium sulfate, and other filler materials.

- 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 treatment solution will not be released to the environment.
- 2. Remove gross contamination with a cleaner or other suitable detergent and rinse with water.
- Prepare a dilute solution of the product by adding 1 to 4 volumes of B-Cap[™] 27 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.
- Allow B-Cap[™] 27 Antimicrobial Agent to contact the surface for a period of time sufficient to ensure adequate cleaning. Depending on microbial load, contact times can range from 5 to 30 minutes or longer.
- 5. Drain dry if needed. Do not rinse.

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 281-474-8750 CHEMTREC: 800-424-9300 OTHER: 609-924-6677

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