



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 4, 2014

Tamera McKeehan
Regulatory Specialist
NA Biocides
Ecolab, Inc.
370 N. Wabash Street
St. Paul, MN 55102

Subject: Label Amendment – Add 2 cucurbits, label organization, and CDPR request
Product Name: Antimicrobial Fruit & Vegetable Treatment
EPA Registration Number: 1677-234
Application Date: August 8, 2014
Decision Number: 495671

Dear Ms. McKeehan:

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. If you have any questions, please contact Tom Luminello by phone at (703) 308-8075, or via email at Luminello.Tom@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Julie Chao". The signature is fluid and cursive, with the first name "Julie" being more prominent than the last name "Chao".

Julie Chao, Acting Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

Antimicrobial Fruit & Vegetable Treatment

Water Additive for Pathogen Reduction in Fruit and Vegetable Wash or Process Waters

Controls Spoilage and Decay Causing Bacteria in Fruit and Vegetable Wash or Process Waters

Reduces Bacterial Pathogens on *Processed* Fruit and Vegetable Surfaces[†]

[†]This(These) antimicrobial claim(s) not approved in the state of California

Antimicrobial Fruit and Vegetable Wash

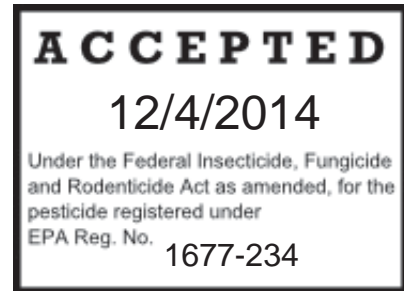
Active Ingredients:

Dodecylbenzenesulfonic acid, sodium salt 1.23%

Lactic Acid..... 17.29%

Other Ingredients:..... 81.48%

Total:..... 100.00%



KEEP OUT OF REACH OF CHILDREN

WARNING

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye injury. Harmful if absorbed through skin. Do not get in eyes, on skin or on clothing. Wear goggles, face shield, or safety glasses. 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. After the product is diluted, safety goggles are not required. Prolonged or frequently repeated skin contact with the concentrate may cause allergic reactions in some individuals.

FIRST AID

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 eyes.
- 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.

**FOR EMERGENCY MEDICAL INFORMATION CALL TOLL-FREE:
1-800-328-0026**

Areas of use: Food retail establishments such as restaurants, cafeterias, food service operations, commissaries, and kitchens.

[NOTE TO REVIEWER: language in parenthesis is interchangeable]

[Optional Marketing Language]

- See side/back panel for first aid
- See (outer container) (package insert) for (first aid) (precautionary statements) (additional directions for use)
- One 4 oz. packet makes 4 – 5.3 gallons of use solution

DIRECTIONS FOR USE:

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

When used as directed, Antimicrobial Fruit & Vegetable Treatment will:

1. Reduce (Kill) 99.9% of the pathogens *Escherichia coli* O157:H7 (ATCC 43895, 35150, 43890), *Listeria monocytogenes* (ATCC 49594, 19114, 19116) and *Salmonella enterica* (ATCC 10721, 6962, 13311) in wash or process water for fruit and vegetable raw agricultural commodities (RACs).
2. Controls (Kill) spoilage and decay causing non-public health microorganisms present in the wash or process water for fruit and vegetable raw agricultural commodities (RACs).

To treat the surface of processed fruits and vegetables subject to FDA regulations[†]:

This product may be used in wash waters to reduce the pathogens *Escherichia coli* O157:H7, *Listeria monocytogenes* and *Salmonella enterica* on the surface of processed fruits and vegetables introduced during handling or processing. This antimicrobial claim not approved in the state of California.

This use must comply with all applicable FDA regulations, including, but not limited to 21 CFR §173.405(a)(b), 21 CFR §184.1061 and 21 CFR §170.3(o)(2).

Cleans (removes) waxes and residue from produce (introduced during handling or processing)

Add Antimicrobial Fruit & Vegetable Treatment into the fruit and vegetable washing/processing vessel (sink) according to the table below, submerge and agitate fruits and vegetables for a minimum of 90 seconds. Drain fruit and vegetables thoroughly and allow to air dry. No rinse required.

If desired just before immediate use, rinse treated produce thoroughly with potable water. Place produce on a pre-cleaned and sanitized surface or in a pre-cleaned and sanitized container.

Minimum Contact Time	Ounces of concentrate per gallon of water	Dilution ratio (parts concentrate : parts water)	Active ingredients	
			ppm SDBS*	ppm Lactic Acid
90 seconds	0.75 – 1.00	1:170 – 1:128	76 –111	1061 – 1391

* Sodium dodecylbenzenesulfonate

Refer to the Antimicrobial Fruit & Vegetable Treatment package insert for the recommended list of fruits and vegetables.

STORAGE AND DISPOSAL:

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL

PESTICIDE STORAGE: Store in a cool, dark, dry place in the original container. Always replace covers.

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. Waste resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL:

(Packet) Non-refillable container. Do not reuse packet. Wrap and put in trash.

Non-refillable container. Do not reuse this container to hold materials other than pesticides or diluted pesticide rinsate. Offer for recycling if available or puncture and dispose in a sanitary landfill, or by other procedures approved by state and local authorities.

RESIDUE REMOVAL INSTRUCTIONS: For containers less than 5 gallons. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Fill container ¼ full with water and recap. Shake 10 seconds. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times.

RESIDUAL REMOVAL INSTRUCTIONS: For containers greater than 5 gallons. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Fill container ¼ full with water. Tip container on its side and roll back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip back and forth several times. Turn the container over

its other end and tip back and forth several times. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times.

FOR COMMERCIAL USE

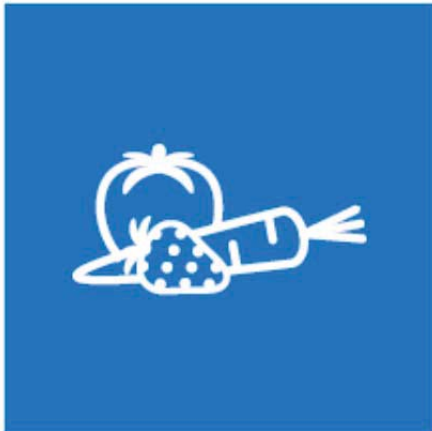
Net Contents:
4 oz.
96 oz.
1 U.S. Gal. (3.78 L)
2.5 U.S. Gal. (9.46 L)
4 U.S. Gal. (15.14 L)
30 U.S. Gal. (113.56 L)

Manufactured by:
Ecolab Inc.
370 Wabasha Street N.
St. Paul, MN 55102

EPA Reg. No. 1677-234

EPA Est. No.: 1677-MN-1 (P), 60156-IL-1 (SI),
1677- CA-2 (R), 1677-TX-1 (D), 1677-IL-2 (J),
1677-GA-1 (M), 1677-WV-1 (V), 89566-IL-1 (C)
Superscript refers to first letter of date code

[Optional Marketing Graphics]



[NOTE TO REVIEWER: language in parenthesis is interchangeable]

PACKAGE INSERT

Water Additive for Pathogen Reduction in Fruit and Vegetable Wash or Process Waters

Controls Spoilage and Decay Causing Bacteria in Fruit and Vegetable Wash or Process Waters

Reduces Bacterial Pathogens on *Processed* Fruit and Vegetable Surfaces[†]

[†]This(These) antimicrobial claim(s) not approved in the state of California

When used as directed for the treatment of raw agricultural commodities and process water, Antimicrobial Fruit & Vegetable Treatment will:

1. Reduce (Kills) 99.9% of the pathogens *Escherichia coli* O157:H7 (ATCC 43895, 35150, 43890), *Listeria monocytogenes* (ATCC 49594, 19114, 19116) and *Salmonella enterica* (ATCC 10721, 6962, 13311) in wash or process water for fruit and vegetable raw agricultural commodities (RACs).
2. Control (Kills) spoilage and decay causing non-public health microorganisms present in the wash or process water for fruit and vegetable raw agricultural commodities (RACs).

Antimicrobial Fruit & Vegetable Treatment can be applied to the following types of fresh fruit, post harvest.

Vegetables

- Root and tuber vegetables such as carrot, potato, radish, rutabaga, sweet potato, yam and sugar beets.
- Leaves of root and tuber vegetables such as turnip greens and sugar beet
- Bulb vegetables such as onions, leeks, garlic and shallots.
- Leafy vegetables such as lettuce (head and leaf), celery, fennel, endive, escarole, parsley, radicchio, rhubarb, spinach
- *Brassica* leafy vegetables such as broccoli, brussel sprouts, cabbage, cauliflower, collards, kale, kohlrabi, mustard greens, mustard spinach and turnips.
- Legumes (succulent) such as beans, peas and alfalfa.
- Fruiting vegetables such as pepper (bell, pimento, hot, sweet), tomato, tomatillo and eggplant.
- Cucurbits such as cucumber, melon (crenshaw, honeydew, honey ball, mango, pineapple, watermelon, cantaloupe, muskmelon), summer squash, pumpkins and winter squash.

Fruits

- Citrus fruits such as sweet orange, sour orange, lemon, lime, tangelo, tangerine, mandarin, citrus citron, kumquats and grapefruit.
- Pome fruits such as apples and pears.
- Stone fruits such as sour and sweet cherry, peach, nectarine and plum.
- Small fruits and berries such as blackberries, blueberries, boysenberries, red and black raspberries and strawberries.

Herbs and Spices

- Basil, chives, dill, oregano, rosemary, sage, savory and thyme.

Other

- Apricots, artichoke, cranberry, dates, figs, grapes, guava, kiwi, mango, mushrooms, okra, olives, persimmons, pomegranate, watercress, coffee fruit (coffee cherry), and coffee bean.

When used as directed for the treatment of *processed* fruits and vegetables under FDA regulations, Antimicrobial Fruit and Vegetable Treatment will[†]:

Reduce the pathogens *Escherichia coli* O157:H7, *Listeria monocytogenes* and *Salmonella enterica* on the surface of processed fruits and vegetables introduced during handling or processing.

This use must comply with all applicable FDA regulations, including but not limited to 21 CFR §173.405(a)(b), 21 CFR §184.1061 and 21 CFR §170.3(o)(2).

[†]This(These) antimicrobial claim(s) not approved in the state of California.

Cleans (Removes) waxes and residue from produce (introduced during handling or processing).

SECONDARY/USE DILUTION CONTAINER LABEL

[Note to reviewer: This secondary/use dilution container label will be used when the product is diluted at 0.75 - 1 oz per gallon of water. Use dilution is to be prepared by end user. This secondary/use dilution label will only be used by the end user and will not be sold or distributed.]

Antimicrobial Fruit & Vegetable Treatment

Concentrate Ingredient Statement

Active Ingredients:

Dodecylbenzenesulfonic acid, sodium salt	1.23%
Lactic Acid.....	17.29%

Other Ingredients:	<u>81.48%</u>
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Total:	100.00%
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Diluted product in this container is 0.75 - 1 oz per gallon water.

When diluted, the active ingredients are:

Active Ingredients:

Dodecylbenzenesulfonic acid, sodium salt	76-111 ppm
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Lactic Acid.....	1061-1391 ppm
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KEEP OUT OF REACH OF CHILDREN

After product has been diluted according to label directions, goggles, face shield, or safety glasses are not required.

The product in this container is diluted as directed on the concentrate product label. Follow the directions for use on the concentrate label when applying this product.

Use solution prepared by end user. **NOT TO BE SOLD OR DISTRIBUTED.**