

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Brian Brosdahl
Ecolab, Inc.
370 N. Wabasha Street
St. Paul, MN 55102-1390

**RE: Oxy-15
EPA Reg. No 1677-164, and
KX-6078
EPA Reg. No. 1677-184
Your Amendment Covering Both Products, Dated 5/9/2000**

The Amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to add new product description/limitation labeling as required in the EPA letter dated 4/12/2000, and to add "alfalfa" and "sweet corn" and minor changes to the crop and seed section of the label, and to delete the sentence about biofilm control, and to delete the requirement to use a potable water rinse due to the Section 409 clearance by FDA published in the Federal Register dated 7/19/99, are acceptable **providing** you make the following label change, and submit a revised label within 90 days of the date of this letter, reflecting this change.

The product descriptor phrase, "Water Additive for Microbial Growth Control on Fresh Cut, Post Harvest, and Further Processed Fruits and Vegetables in transport, storage and processing" is unacceptable because it does not convey internally that "Microbial Growth Control" applies only to microorganisms which cause decay and/or spoilage, and does not apply to any public health microorganisms.

You must rephrase the descriptor to convey application to microorganisms that may cause spoilage and/or decay, and non-application to any public health microorganisms. For example, we recommend that you use the following or similar statement:

"Water Additive for Controlling the Growth of Non-Public Health Microorganisms (or "Bacteria") that May Cause Decay and/or Spoilage on Fresh Cut, Post Harvest, and Further Processed Fruits and Vegetables in Transport, Storage and Processing".

CONCURRENCES							
SYMBOL							
SURNAME							

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Stamped copies of the accepted (with comment) label for each product are attached for your records.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

Sincerely,

M Swindell

Marshall Swindell,
Product Manager Team 33,
Regulatory Management Branch I
Antimicrobials Division (7510C)

CONCURRENCES							
SYMBOL							
SURNAME							

ECOLAB

KX-6078

ACCEPTED

with COMMENTS

in EPA Letter Dated:

Water Additive for Microbial Growth Control on Fresh Cut, Post Harvest, and Further Processed Fruits and Vegetables in transport, storage and processing

AUG 02 2000

ACTIVE INGREDIENTS:

Peroxyacetic acid.....	14.9%
Hydrogen peroxide.....	11.4%
INERT INGREDIENTS:.....	73.7%
TOTAL	100.0%

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

1677-184

KEEP OUT OF REACH OF CHILDREN DANGER

PRECAUTIONARY STATEMENTS - HAZARDS TO HUMAN AND DOMESTIC ANIMALS

CORROSIVE: Causes severe eye damage and skin burns. Harmful or fatal if swallowed. Do not get in eyes, on skin, or on clothing. Wear chemical goggles, rubber gloves, and protective clothing if handling concentrate. Wash thoroughly with soap and water after handling. Remove any contaminated clothing and wash before re-use.

STATEMENT OF PRACTICAL TREATMENT

IF ON SKIN: Immediately wash with plenty of soap and water. Get medical attention.
IF IN EYES: Flush immediately with cold water. Remove contact lenses. Hold eyelids open and flush with water for 15 minutes. Get medical attention immediately.
IF SWALLOWED: DO NOT induce vomiting. Immediately drink large quantities of water. Avoid alcohol. Never give anything by mouth to an unconscious person. CALL A POISON CONTROL CENTER OR PHYSICIAN IMMEDIATELY.

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

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

PHYSICAL AND CHEMICAL HAZARDS:

Strong oxidizing agent. Corrosive. Do not use in concentrated form. Mix only with water according to the label instructions. Never bring concentrate in contact with other sanitizers, cleaners, or organic substances.

ENVIRONMENTAL HAZARDS: This product is toxic to birds, 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.

FOR COMMERCIAL OR INSTITUTIONAL USE ONLY

STRONG OXIDIZING AGENT

Manufactured by:

ECOLAB

FOOD & BEVERAGE DIVISION
Ecolab Inc.
370 Wabasha Street
St. Paul, MN 55102

U.S. Patent No. 5,409,713 Other Patents Pending

KX-6078 is intended for use in the control of microorganisms (or bacteria) which cause decay (and/or spoilage) and that may be present in the process water and on the surface of fresh-cut and post-harvest fruits and vegetables, as well as processed fruits and vegetables. Examples of process water are flumes, chill tanks and wash water systems. This product is not intended for control of any public health organisms.

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

FOR TREATMENT OF PROCESS WATER STREAMS:

- A. Batch systems with no makeup water added:
1. Fill vessel containing fruits or vegetables with known amount of water.
 2. Ensure that water is recirculating in vessel.
 3. Add KX-6078 to no more than 533 ppm (wt/wt) total product (80 ppm residual peroxyacetic acid) in use solution. This can be accomplished by initially adding 53.3 grams (47.8 mls) KX-6078 per 100 liters of water, or 1.0 fluid ounces KX-6078 per 16.4 gallons of water.
 4. Contact time of 45 seconds minimum is recommended.

- B. Continuous systems with constant addition of makeup water:

Initial dose: (this brings the recirculating process water up to an initial properly dosed level of KX-6078).

1. Ensure that system is recirculating with known amount of water in vessels and piping.
2. Add initial dose of KX-6078 to no more 533 ppm (wt/wt) total product (80 ppm residual peroxyacetic acid) in use solution. This can be accomplished by adding 53.3 grams (47.8 mls) KX-6078 per 100 liters of water, or 1.0 fluid ounces KX-6078 per 16.4 gallons of water.
3. Contact time of 45 seconds minimum is recommended.

Continuous dose: (ensures steady state dosing of KX-6078 is maintained). Meter no more than 533 ppm (wt/wt) KX-6078 total product (80 ppm residual peroxyacetic acid) in proportion to the fresh makeup water added to the system. For example, makeup water flow rates of 16.4 gallons per minute would require a maximum of 1 fluid ounce (29.6 mls) per minute of KX-6078. Makeup water flow rates of 100 liters per minute would require a maximum of 53.3 grams (47.8 mls) per minute of KX-6078. Contact time of 45 seconds minimum is recommended.

FOR TREATMENT OF FRUIT AND VEGETABLE SURFACES:

Mix KX-6078 with water either batchwise or continuously to no more than 533 ppm (wt/wt) total product (80 ppm residual peroxyacetic acid) in use solution. This can be accomplished by initially adding 53.3 grams (47.8 mls) KX-6078 per 100 liters of water, or 1.0 fluid ounces KX-6078 per 16.4 gallons of water. The fruits and vegetables can be sprayed or submerged in the resulting solution for a minimum contact time of 45 seconds, followed by adequate draining.

STORAGE AND DISPOSAL: DO NOT CONTAMINATE WATER OR FOOD BY STORAGE OR DISPOSAL

STORAGE: Product should be kept cool and in vented container to avoid any explosion hazard.

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.

CONTAINER DISPOSAL: (50 gallon drum) Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke. (300 gallon tote) Verify that the tote is empty. Do not rinse or clean. Seal tote and contact Ecolab for return.

NET CONTENTS: 50 U.S. Gals. (189 liters)

KX-6078 and fun
Vegetal
• Root
sweet p
• Leavi
beet
• Bulb
• Leafy
escarolo
• Brass
cauliflow
• Legum
navy, pi
field, ed
• Fruit
tomatillo
• Cucur
honeyde
melon, v
Fruits
• Citrus
tangerin
• Pome
• Stone
• Small
raspberr
Sprouts
label inc
vegetabl
cucurbits
berries,
Tree nut
English)
Cereal g
sweet co
Herbs an
marjoran
Miscella
fig, grap
pineappl