

June 21, 2005

Betsy Heger
Keller and Heckman, LLP
1001 G Street, NW
Suite 500 West
Washington, DC 20001

Subject: Time Limited Label
Ecolab Inc.
Sanova Base 25%
EPA Registration No. 1677-219
Submission Dated: May 27, 2005
Receipt Date: June 1, 2005

Dear Ms. Heger:

The following label submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is accepted with conditions.

This label is accepted on a time-limited basis which expires on August 27, 2006. A new label will be issued when all data have been submitted and accepted by the Agency.

A stamped copy of the labeling is enclosed. Submit a copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please call Wanda Henson at (703) 308-6345.

Sincerely,

Emily H. Mitchell
Product Manager - Team 32
Regulatory Management Branch II
Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL	7510C						
SURNAME	E. Mitchell						
DATE	6-21-05						

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

DANGER. Highly corrosive. May be fatal if swallowed. Do not get in eyes, on skin, or clothing. Do not get on bare hands. Wear goggles or face shield and neoprene gloves and use only thoroughly clean, dry utensils when handling. Irritating to nose and throat. Avoid breathing fumes. Remove and wash contaminated clothing to avoid fire.

ENVIRONMENTAL HAZARDS

This product is toxic to fish. 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 the 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.

CHEMICAL HAZARDS

Dry sodium chlorite is a strong oxidizing agent. This product becomes a fire or explosive hazard if allowed to dry. Mix only into water. Contamination may start a chemical reaction with generation of heat, liberation of hazardous gases (chlorine dioxide is a poisonous, explosive gas), and possible fire and explosion. Do not contaminate with garbage, dirt, organic matter, household products, chemicals, soap products, paint products, solvents, acids, vinegar, beverages, oils, pine oil, dirty rags, or any other foreign matter.

ECOLAB®

Ecolab Inc., Food & Beverage Division
370 Wabasha Street N.
St. Paul, MN 55102

ACCEPTED
with COMMENTS
EPA Letter Dated:

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1677-219

SANOVA® BASE (25%)

ACTIVE INGREDIENT: Wt. %
Sodium Chlorite* 25.0%
INERT INGREDIENTS: 75.0%
Total: 100.00%

*AVAILABLE CHLORINE 39%
Contains 2.58 lbs. of Sodium Chlorite Per Gallon at
70 °F

The mixed solution contains 1200 ppm acidified sodium chlorite when SANOVA® Base and Activator are mixed in the SANOVA® Food Processing Equipment or a similar closed system.

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with plenty of water for at least 15 minutes. Remove contact lenses, if present, after 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 and shoes. Rinse skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for treatment.

IF SWALLOWED: Call poison control center 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 the poison control center or doctor. Do not give anything by mouth to an unconscious person.

DIRECTIONS FOR USE

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

For use in the generation of acidified sodium chlorite in a food processing facility. To be used in conjunction with SANOVA® Activator and the SANOVA® Food Quality System. For maximum efficacy, the mixed solution prepared from SANOVA Base and SANOVA Activator solution should remain in contact with fruits and vegetables for a minimum of 15 to 30 seconds, at a solution temperature of 4 °C to 20 °C (39 °F to 68 °F). Consult the product technical bulletin for specific application instructions. Your Ecolab representative can guide you in the installation and operation of the SANOVA® Food Quality System.

For Control of Human Pathogens:

This product effectively reduces populations of *E. coli* 0157:H7, *Listeria monocytogenes*, *Salmonella typhimurium* and *Shigella dysenteriae* on raw fruits and vegetables intended for commercial food processing. Product must be applied using the immersion process for control of human pathogenic microorganisms.

For Control of Fruit and Vegetable Spoilage Microorganisms:

This product effectively reduces the growth of microorganisms that cause spoilage or decay of fruits and vegetables. The SANOVA mixed solution may be applied using the spray or immersion processes when controlling bacteria or fungi causing decay of fruits or vegetables.

Acidified sodium chlorite, generated from sodium chlorite and citric acid, is cleared for either spray or immersion use on pre-process raw agricultural commodities by the U.S. Food and Drug Administration under 21 C.F.R., Part 173. This regulation permits the use of acidified sodium chlorite in the preparation, packing, or holding of raw agricultural commodities for commercial purposes and when followed by a potable water rinse or by blanching or cooking.

EPA Reg No. 1677-219
EPA Est. No.

_____ Gals. Net (_____)

n/e

STORAGE AND DISPOSAL

STORAGE: Do not contaminate water, food or feed by storage or disposal. Keep product in tightly closed container when not in use. Do not drop, roll or skid drum. Keep upright. Always replace cover. Store in a cool, dry well-ventilated area away from heat or open flame.

In case of contamination or decomposition, do not reseal container. If possible, isolate container in open and well ventilated area. Flood with large volumes of water. If fire occurs, extinguish fire by applying large quantities of water. Any unopened drums near the fire should be cooled by spraying with water.

PESTICIDE DISPOSAL: Pesticide wastes are 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.

Triple rinse container. Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or incinerate if allowed to do so by State and Local Authorities. If burning, stay out of smoke.

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Technical Data Sheet**SANOVA® for use on Pre-Process Raw Agricultural Commodities****Application Description**

Raw Agricultural Commodities (fruits and vegetables) may harbor a wide variety of microbiological contaminants on their surfaces as a result of harvesting and shipping practices commonly used in the industry today. SANOVA® (acidified sodium chlorite) is an antimicrobial that effectively reduces populations of *E. coli* 0157:H7, *Listeria monocytogenes*, *Salmonella typhimurium*, and *Shigella dysenteriae*, as well as microorganisms that cause decay of raw fruits and vegetables intended for commercial food processing.

Acidified sodium chlorite, generated from sodium chlorite and citric acid, is cleared for use on pre-process Raw Agricultural Commodities by the U.S. Food and Drug Administration under 21 CFR, Part 173. This regulation permits the use of acidified sodium chlorite in the preparation, packing, or holding of raw agricultural commodities for commercial purposes and when followed by a potable water rinse or by blanching or cooking.

Feed Requirements

The required dosage of acidified sodium chlorite will vary according to the process conditions and the degree of contamination present on the materials to be treated. Acidification of the sodium chlorite occurs inside the SANOVA® Food Quality System after which, the acidified sodium chlorite should be applied to the raw agricultural commodity through a purpose designed applicator. Acidified sodium chlorite concentrations are effective in reducing spoilage and pathogenic microorganisms at 1200 ppm.

Method of Feed

Sodium chlorite is converted to acidified sodium chlorite through the SANOVA® Food Quality System. The latter is a PLC-regulated proportioning, diluting and mixing system which is designed to ensure the accurate mixing of sodium chlorite, citric acid and potable water to

produce the final use dilution material. Mixed product may be in the pH range from 2.3 to 2.9. Following mixing, the acidified sodium chlorite solution is delivered via closed piping to the application unit.

For control of human pathogenic microorganisms: Apply the mixed solution to the raw agricultural commodities by immersion, which should remain in contact with fresh produce for a minimum of 15 – 30 seconds for effective control of pathogenic microorganisms. The mixed solution temperature should be between 4 and 20 °C (39 – 68 °F) for greatest efficacy.

For control of spoilage and decay-causing bacteria and fungi: The mixed solution may be applied by immersion or by spray. Mixed solution should remain in contact with fresh produce for a minimum of 15 – 30 seconds for effective control.

For immersion of fresh produce; replenish or replace the mixed solution at the same rate of depletion of solution volume. This rate is dependent on the surface irregularity of the vegetables washed. Tanks should be completely emptied at the end of the day, or if in continuous operation, at the end of each 8-hour shift. Refer to the SANOVA Food Processing System set-up calibration data for replacement intervals specific to your operation.

For more information on SANOVA® or the SANOVA® Food Quality System, contact Ecolab Inc., Food & Beverage Division, 370 Wabasha Street N., St. Paul, MN 55102.

Acidified Sodium Chlorite Analysis.

The final concentrations of acidified sodium chlorite used on Raw Agricultural Commodities must be determined by the Iodometric Titration Methodology specified, in 21 CFR, Part 173.

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Ecolab Inc. believes the information contained herein is accurate however, Ecolab Inc. makes no guarantees with respect to such accuracy and assumes no liability in connection with the use of the information contained herein by any party. The provision of the information contained herein and the provision of information by or reliance on Ecolab Inc.'s technical personnel is not intended to be and should not be construed as legal advice or as ensuring compliance with any federal, state or local laws and regulations. Any party using Sanova should review all such laws, rules or regulations prior to using Sanova or the Sanova Food Quality System.