

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

November 18, 2002

David R. Joy
Keller and Heckman LLP
1001 G Street, NW
Suite 500 West
Washington, DC 20001

Subject: Alcide Corporation
SANOVA Base (31%)
EPA Registration No. 45631-20
Application Date: August 20, 2002 and November 15, 2002
Receipt Date: August 20, 2002 and November 15, 2002

Dear Mr. Joy:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable on a time-limited basis. This amendment will expire on November 18, 2004. A fully acceptable label (without time limits) will be issued if the following actions are taken and found to be acceptable by the Agency:

1. The efficacy testing protocol has been resubmitted for review. If changes to that protocol are required, you need to submit those changes within 2 months of the date of the letter requesting changes. Once the protocol is accepted, you will need to submit efficacy studies conducted according to the accepted protocol within one year from acceptance. Those data would then need to be accepted by the Agency.
2. The Agency recognizes that this use was essentially accepted by FDA under their authority, and that is the reason we are providing this time-limited acceptance. However, the Agency will need to conduct a risk assessment under FQPA to determine if this use is fully acceptable, before this use can be made permanent.

Please provide any additional data that is not part of the sodium chlorite available data base to assist the Agency in completing its review.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

- 3. *Submit any additional studies completed identifying residue levels (after utilizing a potable wash, cooking or blanching) for representative fruits and vegetables. We may request additional residue data after analyzing these available data.*
- 4. *Please provide additional information regarding the SANOVA food processing equipment to allow the Agency to evaluate whether there are additional worker protection issues that need to be addressed.*

A stamped accepted copy of the label has been enclosed with this letter. If you have any other questions, you may contact me at 703-308-6264.

Sincerely,



*Robert S. Brennis
Product Manager - Team 32
Regulatory Management Branch II
Antimicrobials Division (7510C)*

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, dirt, rags, or any other foreign matter.

User is responsible for compliance with applicable Federal, State, and local laws regarding proper use and disposal of the waste generated.

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 45631-20

SANOVA® BASE (31%)

ACTIVE INGREDIENT:

Sodium Chlorite*31.0%

INERT INGREDIENTS:.....69.0%

Total:.....100.00%

*AVAILABLE CHLORINE.....48.6%

Contains 3.3 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. These components must be 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 chlorous acid in a food processing facility to eliminate the growth of microorganisms that cause spoilage on fruits, vegetables. 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.

To be used in conjunction with the SANOVA® Activator and the SANOVA® Food Quality System. The mixed solution prepared from SANOVA® Base and SANOVA® Activator provides effective control of spoilage microorganisms and listed pathogens when the commodities are in contact with the solution for a minimum of 15 to 30 seconds, and the solution temperature is 4 °C to 20 °C (39 °F to 68 °F).

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 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.

Consult the product technical bulletin for specific application instructions. Your Alcide representative can guide you in the installation and operation of the SANOVA® Food Quality System.

Alcide Corporation

8561 154th Avenue NE
Redmond, WA 98052-3557

EPA Reg. No. 45631-20 EPA Est. No. 5382-KS-16

_____ Gals. Net (_____)

ACCEPTED
with COMMENTS
EPA Letter Dated:
NOV 18 2002

E. Sprues 11/18/04

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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.

**ACCEPTED
with COMMENTS
EPA Letter Dated:**

NOV 18 2002

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

45631-20 Expires on 11/18/04

425

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* on raw fruits and vegetables intended for commercial food processing.

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 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 continuously or intermittently 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. Mixed product is applied to the Raw Agricultural Commodities by either immersion or spray depending upon the final requirements of the user. For either method of application, the mixed solution should remain in contact with fresh produce for a minimum of 15 – 30 seconds for effective control of spoilage and pathogenic microorganisms. The mixed solution temperature should be between 4 and 20 °C (39 – 68 °F) for greatest efficacy.

For continuous spray application, use of the spray application cabinet is recommended. Apply mixed solution evenly on all surfaces.

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 Alcide Corporation, 8561 154th Avenue NE, Redmond, Washington 98040. (Tel: 1-800-543-2133).

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.

Alcide Corporation believes the information contained herein is accurate however, Alcide Corporation makes no guarantee of 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 Alcide Corporation's technical personnel is not intended to 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.

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B. Price 07/11/18/04