

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

May 29, 2003

Brian C. Brosdahl
Manager, North American Registrations
Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102-1390

Subject: XY-12
EPA Registration No. 1677-52
Application Date: March 24, 2003
Receipt Date: March 27, 2003

Dear Mr. Brosdahl:

This application was submitted in response to a January 15, 2003 - Agency deficiency letter.

The amendment submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions listed below:

Conditions

The Agency requested that you cite a substantially similar product in labeling and composition to your 8.4% Sodium Hypochlorite product. The product that you cited did provide the use sites. However, your language is significantly different from the EPA registered product. Therefore, the Agency requests that you remove the following directions for use:

- Algae and Slime Control in Cooling and Process Waters
- Recirculating Cooling Towers and Other Process Waters
- For Use in Federally Inspected Meat and Poultry Plants

These use sites/patterns have been crossed out on the stamped label. You must cite an 8.4%, EPA registered, sodium hypochlorite product with language identical or substantially similar to the proposed use site/patterns. If you wish to deviate from accepted labels, you would to indicate the reasons for labeling differences and provide a justification for that change.

CONCURRENCES

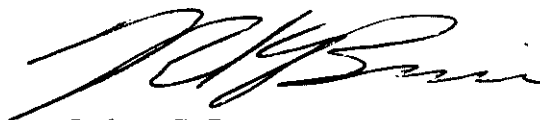
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General Comments

A stamped copy of the labeling accepted with conditions 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 contact Wanda Mitchell at (703) 308-6345.

Sincerely,



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

XY-12
LIQUID SANITIZER
ALGAE AND SLIME CONTROL IN COOLING AND PROCESS WATERS

Active Ingredient:
Sodium Hypochlorite 8.4%
Inert Ingredients: 91.6%
Total: 100.0%

ACCEPTED
with COMMENTS
EPA Letter Dated:
MAY 29 2003

KEEP OUT OF REACH OF CHILDREN
DANGER

FOR INDUSTRIAL USE ONLY

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. *1677-52*

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: CORROSIVE: May cause severe skin and eye irritation or chemical burns to broken skin. Causes eye damage. Wear rubber gloves, chemical goggles and protective clothing. Wash after handling. Avoid breathing vapors. Vacate poorly ventilated areas as soon as possible. Do not return until odors have dissipated.

ENVIRONMENTAL HAZARDS

(only required for containers 5 gallons and larger): This pesticide is toxic to fish and aquatic organisms. 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.

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 eye. 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.

IF SWALLOWED: Call a poison control center or doctor for treatment advice. Have a 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.

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

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

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

PHYSICAL AND CHEMICAL HAZARDS:

Strong oxidizing agent: Mix only with water according to label directions. Mixing this product with chemicals (e.g. ammonia, acids, detergents, etc.) or organic matter (e.g. urine, feces, etc.) will release chlorine gas which is irritating to eyes, lungs and mucous membranes.

4 7 9

DIRECTIONS FOR USE

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

NOTE: This product degrades with age. Use a chlorine test kit and increase dosage, as necessary, to obtain the required level of available chlorine.

SANITIZING NONPOROUS FOOD CONTACT EQUIPMENT RINSE METHOD

A solution of 100 ppm available chlorine may be used in the sanitizing solution if a chlorine test kit is available. Solutions containing an initial concentration of 100 ppm available chlorine must be tested and adjusted periodically to insure that the available chlorine does not drop below 50 ppm. Prepare a 100 ppm sanitizing solution by thoroughly mixing 2 oz. of XY-12 with 13 gallons of water. If no test kit is available prepare a sanitizing solution by mixing 4 oz. of XY-12 with 13 gallons of water to provide approximately 200 ppm available chlorine by weight.

At 100 ppm available chlorine this product is an effective sanitizer against *Vibrio cholerae* and *Escherichia coli* O157:H7. Clean all surfaces with proper detergent and rinse with water. Just prior to use, rinse all surfaces thoroughly with the sanitizing solution maintaining contact with the sanitizer for at least 2 minutes. If solution contains less than 50 ppm available chlorine as determined by a suitable test kit, either discard the solution or add sufficient product to reestablish a 200 ppm residual. Allow equipment to drain thoroughly. Do not rinse and do not soak overnight.

SANITIZING POROUS FOOD CONTACT EQUIPMENT-RINSE METHOD

Prepare a 600 ppm solution by thoroughly mixing 3 oz. of this product in 3 gal. water. Clean surfaces in the normal manner. Rinse all surfaces thoroughly with the 600 ppm solution, maintaining contact for at least 2 minutes. Prior to using equipment, rinse all surfaces with a 200 ppm available chlorine solution (4 oz./13 gallons). Do not rinse and do not soak overnight.

BACTERIOPHAGE CONTROL

XY-12 will significantly reduce the incidence of *Streptococcus cremoris* and *S. diacetilactis* bacteriophage in cheese manufacturing establishments by fogging at concentrations of 600 ppm available chlorine. Fogging should be used as a supplement to acceptable manual cleaning and sanitizing of room surfaces as described above.

Directions for fogging:

Prior to fogging, clean all surfaces and remove or carefully protect all food products and packaging materials. Fog desired areas using one quart per 1000 cu. ft. of room area with an XY-12 solution containing 600 ppm of available chlorine. Vacate the area of all personnel for a minimum of 2 hours after fogging. All food contact surfaces must then be thoroughly rinsed with an XY-12 solution at 200 ppm of available chlorine. Allow surfaces to drain thoroughly before operations are resumed.

For continuous treatment of meat and poultry or fruit and vegetable conveyors: Wash, rinse and sanitize conveyor equipment. During processing, apply XY-12 at a 200 ppm available chlorine level to conveyors with MIKRO MASTER or other suitable feeding equipment. Controlled volumes of sanitizer are applied to the return portion of conveyor through nozzles so located as to permit maximum drainage of sanitizer from equipment and to prevent puddles on top of belt. During interruptions in operations, apply a coarse spray to equipment, peelers, collators, slicers and saws with MIKRO MASTER dispensed XY-12 solution of 200 ppm available chlorine. Conveyor equipment should be free of product when applying this coarse spray.

NOTE: For mechanical operations, prepared use solutions may not be reused for sanitizing but may be re-used for other purposes such as cleaning.

For manual operations, fresh sanitizing solutions should be prepared as soon as they become diluted or soiled.

SANITIZATION OF NONPOROUS NON-FOOD CONTACT SURFACES

Rinse Method: Prepare sanitizing solution by thoroughly mixing 4 oz. of this product with 13 gallons of water to provide approximately 200 ppm available chlorine by weight. Clean surfaces such as floors and walls in the normal manner. Rinse all surfaces thoroughly with the sanitizing solution, maintaining contact with the sanitizer for at least 2 minutes. Do not rinse with water after treatment.

DISINFECTION OF NONPOROUS NON-FOOD CONTACT SURFACES

Rinse Method: If the product is to be used immediately, prepare a disinfecting solution by thoroughly mixing 12 oz. of this product with 13 gallons of water to provide approximately 600 ppm available chlorine by weight. If the product will be stored for an extended period of time, between 1 to 8 hours, prepare a disinfecting solution by mixing 14 oz. of this product with 13 gallons of water to provide approximately 700 ppm available chlorine by weight. Clean surfaces, such as floors and walls, in the normal manner. Rinse all surfaces thoroughly with the disinfecting solution, maintaining contact with the solution for at least 10 minutes. Do not rinse with water after treatment.

**DO NOT MIX WITH ANYTHING BUT WATER
WATER CHLORINATION**

For farm, private or small municipal water chlorination, use 0.2 to 0.6 ppm available chlorine. Use chlorine test kit for the determination of proper concentrations and amount of residual chlorine. The desired range in available chlorine must be maintained throughout the distribution system. For municipal water chlorination bacteriological sampling must be conducted as required in the National Primary Drinking Water Regulations.

ALGAE AND SLIME CONTROL IN COOLING AND PROCESS WATERS

XY-12 is formulated to control algae and slime growth in recirculating cooling water systems and evaporative condensers, as well as cooling tunnels and warmers. It can be used in cooling water for thermal processing and pasteurizing operations in dairies, breweries, soft drink and food canning plants.

To control algae and bacterial slimes, use the following procedure:

Recirculating Cooling Towers and Other Process Waters

Initially, use not more than 55 fluid ounces per 1,000 gallons of water to be treated (up to 20 ppm available chlorine). Increase dosage to 80 fluid ounces per 1,000 gallons of water, if necessary, except in dairy recirculating cooling water (commonly referred to as sweetwater) systems where dose is limited to not more than 20 ppm available chlorine. Repeat initial dose every seven days or increase the frequency, if needed.

For use in federally inspected meat and poultry plants. XY-12 helps prevent staining of meat and poultry product containers, when added to the water used to cook and cool the containers. XY-12 also assists with corrosion control and deposit formation on the surfaces of the processing equipment. XY-12 should be used at the same application rates, and in the same manner as described above for recirculating cooling tower water.

TREATMENT OF POULTRY PROCESSING WATER

Follow guidelines of local water authority for water potability treatment.

Continuous Feed: Using an automatic metering device, continuously feed this product into the water to obtain and/or maintain a level of 5-20 ppm available chlorine (1 oz product per 130 gal. water, to 2 oz product per 65 gallons water). Confirm target chlorine level with either a chlorine test kit or an automatic testing device. When the available chlorine level reaches 20 ppm, notify the USDA plant inspector.

Intermittent Feed: Start up by adding 1.5 ounces of this product per 1,000 gallons of water for each 1 ppm of available chlorine needed. For subsequent doses, check chlorine level with a chlorine test kit. Add enough of this product to maintain the target chlorine level and confirm this level with a chlorine test kit. Do not pour this product directly on poultry product in the water.

AVAILABLE CHLORINE TABLE OF PROPORTIONS

0.5 ppm - 1 oz. in 1300 gal. water

50 ppm - 1 oz. in 13 gal. water
100 ppm - 2 oz. in 13 gal water/1 oz. in 6.5 gal. water
200 ppm - 4 oz. in 13 gal. water/2 oz. in 6.5 gal. water
600 ppm - 12 oz. in 13 gal. Water

XY-12
Technical Data Sheet

Additional Directions for Use:

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

SANITIZING EATING AND DRINKING UTENSILS - IMMERSION METHOD

1. Scrape and preflush utensils to remove excess soil.
2. Wash with good detergent or compatible cleaner (see your Ecolab representative for a recommendation.)
3. Rinse with clear water.
4. Sanitize in a solution of 100 ppm available chlorine if a chlorine test kit is available. Test and adjust solutions periodically to insure that the available chlorine does not drop below 50 ppm. If no test kit is available, prepare sanitizing solution to provide 200 ppm available chlorine. Immerse all utensils for at least one minute. Use 2 minute exposure time if required by governing sanitary code.
5. Drain and air dry.

TABLEWARE SANITIZER AND DESTAINER FOR MECHANICAL SPRAY WAREWASHING MACHINES.

For sanitizing tableware in low-temperature warewashing machines, inject XY-12 into the final rinse water at a concentration of 100 ppm available chlorine. Do not exceed 200 ppm. Air dry.

To insure that available chlorine concentration does not fall below 50 ppm, periodically test the rinse solution with a suitable test kit and adjust the dispensing rate accordingly. Consult your local Ecolab Specialist for technical assistance and further information on sanitizing tableware in warewashing machines.

FORMULATED FOR USE WITH ECOLAB AUTOMATIC DISPENSING SYSTEMS. DO NOT USE ON SILVER AND SILVER PLATE.

For brand name product sold for dispensing through computerized systems the following directions for use will appear on the label: For use only with the (Brand Name) Allocation System.

**LAUNDRY SANITIZATION
HOUSEHOLD LAUNDRY SANITIZING**

In soaking suds - Thoroughly mix 4 oz. XY-12 to 13 gallons of wash water to provide 200 ppm available chlorine. Wait 5 minutes, then add soap or detergent. Immerse laundry for at least 11 minutes prior to starting the wash/rinse cycle.

In Washing Suds - Thoroughly mix 4 oz. XY-12 to 13 gallons of wash water containing clothes to provide 200 ppm available chlorine. Wait 5 minutes, then add soap or detergent and start the wash/rinse cycle.

SWIMMING POOL WATER DISINFECTION

For a new pool or spring start-up, superchlorinate with 75 to 150 oz. of product for each 10,000 gallons of water to yield 5 to 10 ppm available chlorine by weight. Check the level of available chlorine with a test kit. Adjust and maintain pool water pH between 7.2 to 7.6. Adjust and maintain the alkalinity of the pool to between 50 and 100 ppm.

To maintain the pool, add manually or by a feeder device 16 oz. of this product for each 10,000 gallons of water to yield an available chlorine residual between 0.6 to 1.0 ppm by weight. Stabilized pools should maintain a residual of 1.0 to 1.5 ppm available chlorine. Test the pH, available chlorine residual and alkalinity of the water frequently with appropriate test kits. Frequency of water treatment will depend upon temperature and number of swimmers.

Every 7 days, or as necessary, superchlorinate the pool with 75 to 150 oz. of product for each 10,000 gallons of water to yield 5 to 10 ppm available chlorine by weight. Check the level of available chlorine with a test kit. Do not reenter pool until the chlorine residual is between 1.0 to 3.0 ppm.

At the end of the swimming pool season or when water is to be drained from the pool, chlorine must be allowed to dissipate from treated pool water before discharge. Do not chlorinate the pool within 24 hours prior to discharge.

WINTERIZING POOLS - While water is still clear and clean, apply 4 oz. of product per 1000 gallons, while filter is running, to obtain a 3 ppm available chlorine residual as determined by a suitable test kit. Cover pool, prepare heater, filter and heater components for winter by following manufacturer's instructions.

SPAS/HOT-TUBS - Apply 7 oz. of product per 1000 gallons of water to obtain a free available chlorine concentration of 5 ppm, as determined by a suitable chlorine test kit. Adjust and maintain pool water pH between 7.2 and 7.8. Some oils, lotions, fragrances, cleaners, etc. may cause foaming or cloudy water as well as reduce the efficiency of the product.

To maintain the water, apply 7 oz. of product per 1000 gallons of water over the surface to maintain a chlorine concentration of 5 ppm.

After each use, shock treat with 11 oz. of this product per 500 gallons of water to control odor and algae.

During extended periods of disuse, add 4 oz. of product daily per 1000 gallons of water to maintain a 3 ppm chlorine concentration.

COMMERCIAL LAUNDRY SANITIZING

Wet fabrics or clothes should be spun dry prior to sanitization. Thoroughly mix 4 oz. XY-12 to 13 gallons of water to yield 200 ppm, available chlorine. Promptly add the solution into the prewash prior to washing fabrics/clothes in the regular wash cycle with a good detergent. Test the level of available chlorine if solution has been allowed to stand. Add more XY-12 if the available chlorine level has dropped below 200 ppm.

LAUNDRY BLEACH

Add 2 oz. product per 10 gallons of wash water (125 ppm available chlorine).

FOOD EGG SANITIZATION

Thoroughly clean all eggs before proceeding. To sanitize clean shell eggs intended for food or food products, apply solution with a coarse spray 2 oz of product in 6.5 gallons of water (providing 200 ppm available chlorine). The solution must be equal to or warmer than the eggs, but not to exceed 130 deg F. Wet eggs thoroughly and allow to drain. Eggs that have been sanitized with this chlorine compound may be broken for use in the manufacture of eggs product without a prior potable water rinse. Eggs must be thoroughly dry before casing or breaking. The solution must not be reused for sanitizing eggs.

FRUIT AND VEGETABLE WASHING

Thoroughly clean all fruits and vegetables in a wash tank. Thoroughly mix 8 oz of product in 200 gallons of water to make a sanitizing solution of 25 ppm available chlorine. After draining the tank, submerge fruits or vegetables for 2 minutes in a second wash tank containing the recirculating sanitizing solution. Coarse spray rinse vegetables with the sanitizing solution prior to packaging. Rinse fruit with potable water only prior to packaging.

XY-12 ADDITIONAL DIRECTIONS FOR USE

A solution of sodium hypochlorite for control of organisms causing decay of apples, asparagus, cabbage, carrots, cauliflower, celery, cherries, citrus, cucumbers, lettuce, mushrooms, nectarines, onions, peaches, pears, peppers, potatoes, prunes, quinces, and radishes after harvest.

APPLICATION

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For the recommended concentration of available chlorine for various commodities to be treated see the attached table. To obtain a 100 ppm solution of chlorine, add 1.2 gallons XY-12 to 1,000 gallons of water. For other application rates use appropriate dilutions. Rinse treated fruit with potable water.

For citrus canker quarantine:

Use of XY-12 at 200 ppm is achieved by adding 2.4 gallons XY-12 to 1,000 gallons of water. Apply for two minutes using a suitable coarse spray or dip tank treatment.

NOTE: This product degrades with age. Use of monitoring chlorine level and increasing dosage, as necessary, is recommended to obtain the required level of available chlorine. Since chlorine reacts readily with dirt and organic matter in dip tanks, the concentration should be checked at least three to four times each day by use of colorimetric kit or titrimetric kit. Once opened, use the entire contents of the container within 30 days.

Recommended levels of chlorine:

<u>Commodity</u>	<u>ppm of available chlorine to use</u>
Apple	150-200
Artichokes	100-150
Asparagus	125-150
Brussel sprouts	100-150
Carrots	100-200
Cauliflower	300-400
Cherry	75-100
Celery	100-110
Chopped Cabbage ²	80-100
Chopped Lettuce ²	80-100
Cucumbers	300-350
Green Onions	75-120
Lemon and Grapefruit	40-50
Melons ⁵	100-150
Mushrooms ³	100-120
Oranges (in drencher)	20-30
Peaches and Nectarines and Plums	50-100
Pears (without buffer)	200-300
Peppers ^{1,4}	300-400
Potatoes ^{1,4}	65-125
Radishes	100-150
Stonefruit (Hydrocooler)	30-75
Tomatoes	300-350

NOTE:

1. Concentration given for use in a flow through washer system only.
2. After treatment the adhered moisture must be removed by a centrifugation process.
3. After treatment with the chlorinated water, the mushrooms must be treated with 0.2% sodium bisulfite (anti-oxidant) treatment to prevent browning.
4. For treating peppers in a dump tank, use 100-135 ppm Cl₂; for treating potatoes in a pit system, use 100-150 ppm Cl₂; for treating tomatoes in a dump tank system, use 70-120 ppm Cl₂.
5. For hydrocooler, use 10 ppm.

DISINFECTANT FOR PHARMACEUTICAL AND COSMETIC INDUSTRIES

DISINFECTING PHARMACEUTICAL AND COSMETIC SURFACES

XY-12 is recommended for use on pre-cleaned, hard, non-porous, environmental surfaces such as floors, walls and processing equipment in pharmaceutical and cosmetic processing facilities.

9 8 9

Prior to disinfection, clean surfaces in the normal manner. Prepare disinfecting solution by thoroughly mixing 12 ounces of this product with 13 gallons of water to provide approximately 600 ppm available chlorine by weight. Rinse all surfaces with the disinfecting solution, maintaining contact with the solution for at least 10 minutes. Product contact surfaces must be rinsed with sterile water.

For service or additional information, call 1-800-35-CLEAN (352-5326).

STORAGE & DISPOSAL

Pesticide Storage: Store this product in a cool, dry area, away from direct sunlight and heat to avoid deterioration. In case of spill, flood the area with large quantities of water.

Pesticide Disposal: Product or rinsates that cannot be used should be diluted with water before disposal in a sanitary sewer. Do not contaminate water, food or feed by storage, disposal or cleaning of equipment.

Container Disposal:

(1 gal.): Do not reuse empty containers. Wrap container and put in trash.

(5 gal., 55 gal.): 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.

(Tote): Verify that the tote is empty. Do not rinse or clean. Seal tote and contact Ecolab for return.

(sealed container): Dispense product through the appropriate Ecolab equipment until container is empty. Dispose of empty container in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Net Contents:	1 U.S. Gal. (3.78 L)
	5 U.S. Gals. (18.9 L)
	55 U.S. Gals. (207.9 L)
	300 U.S. Gals. (1134 L) - tote

EPA Reg. No. 1677-52

EPA Est.: 1677-IL-2 (J), 1677-NJ-1 (W), 1677-TX-1 (D), 1677-GA-1 (M), 1677-CA-1 (S), 1677-MN-1 (P), 1677-PR-1 (B), 11321-CA-1 (C), 1677-OH-1 (H), 1677-CA-2 (R), 1677-MO-1 (K), 1677-WV-1 (V).

Superscript refers to first letter of date code

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