

1677-209

10-26-2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OCT 26 2009

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

Attention: Theodore Head
Regulatory Manager

Subject: KX-6178
EPA Reg. No. 1677-209
Amendment Application Date: September 13, 2009

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable provided the following label revisions are followed:

- The proposed section "**TO SANITIZE FLOOR DRAINS IN FOOD PROCESSING AREAS**" is unacceptable and must be removed. A test method to support the proposed use has not been established. Therefore, a protocol must be submitted that discusses methodology on conducting the testing. Accordingly, an action of this type must be accompanied by the appropriate fee per the Pesticide Registration Improvement Renewal Act (PRIA).

The Agency has no objection to include labeling changes to the Storage and Disposal sections. A stamped copy of the label has been included for your records.

If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,

Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510C)

KX-6178

SANITIZER AND DISINFECTANT

Acid Liquid Sanitizer for Food Processing Equipment in Dairies, Dairy Farms, Breweries, Wineries, Beverage and Food Processing Plants

Disinfectant for Farms, Livestock Quarters, Poultry Premises, Poultry Hatcheries, Veterinary Clinics, Animal Life Science Laboratories, Animal Care Facilities and Industrial Facilities

Active Ingredients:

Hydrogen Peroxide.....	7.52%
Peroxyoctanoic Acid.....	1.00%
Octanoic Acid.....	2.85%

Other Ingredients: 88.63%

Total: 100.00%

ACCEPTED
with COMMENTS
EPA Letter 10/16/09

OCT 26 2009

KEEP OUT OF REACH OF CHILDREN
DANGER

Registered with the Federal Insecticide, Fungicide, and Herbicide Act as a sanitizer for the purpose of registered under EPA reg. 40.

1677-209

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: CORROSIVE. Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield or safety glasses), coveralls worn over long-sleeved shirt and long pants, socks, chemical resistant gloves, and chemical resistant footwear. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove contaminated clothing and wash clothing before reuse. Prolonged or frequently repeated skin contact may cause an allergic reaction 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 eye. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor 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.

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

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

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 label instructions. Never bring concentrate in contact with other sanitizers, cleaners or organic substances. This product is not to be used around electrical equipment.

ENVIRONMENTAL HAZARDS (containers 5 gallons or greater): This pesticide 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 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.

DIRECTIONS FOR USE

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

SANITIZATION

KX-6178 acid sanitizer is recommended for use on pre-cleaned surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in dairies, dairy farms, breweries, wineries, beverage and food processing plants. This product is effective as a sanitizer when solution is prepared in water of up to 500 ppm hardness as CaCO₃.

NOTE: FOR MECHANICAL OPERATIONS, prepared used solution may not be reused for sanitizing but may be reused for other purposes such as cleaning.

FOR MANUAL OPERATIONS, fresh sanitizing solution should be prepared at least daily or more often if the solution becomes diluted or soiled.

SANITIZING FOOD CONTACT SURFACES

Prior to sanitizing, remove gross food particles, and then wash with a detergent solution, followed by a potable water rinse. Sanitize with a concentration of 1 oz **KX-6178** concentrate per 6 to 8 gallons of water (0.1% - 0.13% v/v concentration). At this dilution **KX-6178** is an effective food contact surface sanitizer against the following organisms: *Staphylococcus aureus*, *Escherichia coli*, *Escherichia coli* O157:H7, *Pseudomonas aeruginosa*, *Listeria monocytogenes*, *Salmonella typhimurium*, *Enterobacter sakazakii*, *Campylobacter jejuni* and *Candida albicans*. At the same dilution, **KX-6178** is also effective for sanitization against the common spoilage organisms *Pediococcus damnosus*, *Lactobacillus malefermentans* and *Geotrichum candidum*. Use immersion, coarse spray or circulation techniques as appropriate to the equipment. All surfaces should be exposed to the sanitizing solution for a period of not less than one minute unless a longer time is specified by the governing sanitary code. Drain thoroughly and allow to air dry. Do not rinse.

FOAM SANITIZING FOOD CONTACT SURFACES

KX-6178 is an effective foam sanitizer of pre-cleaned food contact surfaces. Foam sanitize with a concentration of 1 oz **KX-6178** concentrate per 6 to 8 gallons of water (0.1% - 0.13% v/v concentration). At this dilution **KX-6178** is an effective foaming food contact surface sanitizer against the following organisms: *Staphylococcus aureus* and *Escherichia coli*, *Escherichia coli* O157:H7, *Listeria monocytogenes*, *Salmonella typhimurium*, *Enterobacter sakazakii*. At the same dilution, **KX-6178** is also effective for foam sanitization against the common spoilage organisms *Pediococcus damnosus* and *Lactobacillus malefermentans*. Use an appropriate device to generate foam intended to cover the food contact surfaces. Contact your Ecolab representative for information on a recommended foamer. All surfaces should be exposed to the sanitizing solution for a period of not less than one minute unless a longer time is specified by the governing sanitary code. Drain thoroughly and allow to air dry. Do not rinse.

CONTINUOUS TREATMENT OF CONVEYORS

Wash, rinse and sanitize conveyor equipment. During processing, apply solution containing 1 oz **KX-6178** concentrate per 6 to 8 gallons of water (0.1% - 0.13% v/v concentration) to a conveyor with Mikro Master or other suitable dispensing equipment. At this dilution **KX-6178** is effective against *Staphylococcus aureus*, *Escherichia coli*, *Escherichia coli* O157:H7, *Pseudomonas aeruginosa*, *Listeria monocytogenes*, *Salmonella typhimurium*, *Enterobacter sakazakii*, *Campylobacter jejuni* and *Candida albicans*. At the same dilution **KX-6178** is effective at reducing the common spoilage microorganisms *Pediococcus damnosus*, *Lactobacillus malefermentans* and *Geotrichum candidum*. Controlled volumes of **KX-6178** are applied to return portion of conveyor through nozzles so located as to permit maximum drainage of **KX-6178** from equipment and to prevent puddles on top of belt. During interruptions in operations, coarse spray the processing equipment with **KX-6178** solution at not more than 0.13% v/v concentration. Conveyor equipment must be free of product when applying coarse spray. Conveyor surface should be exposed to the sanitizing solution for a period of not less than one minute.

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7~~TO SANITIZE FLOOR DRAINS IN FOOD PROCESSING AREAS:~~

~~Use on accessible floor drain openings, removable caps and rings, catch baskets and exposed surfaces that are regularly cleaned. Before sanitizing, pre-clean and scrub all surfaces, rinse thoroughly and apply minimum concentration of 1 oz KX-6178 concentrate per 8 gallons of water (0.1% concentration) by sprayer or immersion to thoroughly wet all surfaces. For sprayer applications, cover or remove all food products. Use a coarse (foam) spray device and apply 6-8 inches from surface. Do not breathe spray. Treated surfaces must remain wet for 1 minute prior to reuse. Prepare fresh solution daily or more often if solution becomes visibly diluted, cloudy, or soiled.~~

SANITIZING NON-FOOD CONTACT SURFACES

Pre-clean surfaces as directed above. Sanitize non-food contact surfaces such as floors, walls, tables, chairs, benches, troughs, and drip pans with 1 to 5 oz **KX-6178** concentrate per 8 gallons of water (0.1% - 0.5% v/v concentration). At this concentration the product is effective as a non-food contact surface sanitizer against the following organisms: *Staphylococcus aureus*, *Enterobacter aerogenes*, *Listeria monocytogenes*, *Salmonella typhimurium*, *Pseudomonas aeruginosa*, *Enterobacter sakazakii* and *Geotrichum candidum*. All surfaces should be exposed to the sanitizing solution for a period of not less than 5 minutes. Drain thoroughly and allow to air dry. No rinse necessary.

FOAM SANITIZING NON-FOOD CONTACT SURFACES

KX-6178 is an effective foam sanitizer of pre-cleaned non-food contact surfaces, such as boots, floors, walls and associated equipment. To foam sanitize, prepare a solution of 1 to 5 oz **KX-6178** concentrate per 8 gallons of water (0.1% - 0.5% v/v concentration) and 1.4 oz **Liquid K** per 8 gallons (0.13% v/v concentration). **Liquid K** is the only approved foam generator. At this concentration the product is effective as a non-food contact surface sanitizer against *Staphylococcus aureus*, *Enterobacter aerogenes*, *Listeria monocytogenes*, *Salmonella typhimurium*, *Enterobacter sakazakii* and *Campylobacter jejuni*. Use an appropriate device to generate foam intended to cover non-food contact surfaces. Wet surfaces thoroughly. Surfaces should be exposed to the sanitizing foam for a period of not less than 5 minutes. No rinse is necessary. Contact your Ecolab representative for information on a recommended foamer.

ENTRYWAY FOAM SANITIZING SYSTEMS:

To prevent cross contamination from area to area, set the system to deliver sanitizing solution at 1 oz **KX-6178** per 1 to 8 gallons of water (0.1% - 0.78% v/v).

Alternately, **KX-6178** can be used along with **Liquid K** to apply the foam by setting the system to deliver 1 oz **KX-6178** per 1 to 8 gallons of water (0.1% - 0.78% v/v) and 1.4 oz **Liquid K** per 8 gallons of water (0.13% v/v concentration).

The foam (or spray) should cover the entire path of the doorway. Set the system so that a continuous wet blanket of sanitizer solution is delivered to the floor.

SHOE BATH SANITIZER DIRECTIONS:

To prevent tracking (into animal areas)(and the packaging and storage areas of food plants), shoe baths containing one inch of freshly made solution should be placed at all entrances to buildings and hatcheries. Scrape waterproof work boots (shoes) and place in solution of 1 oz **KX-6178** per 6 to 8 gallons of water (0.1% - 0.13% v/v) for one minute prior to entering area. (If there is a heavy soil load or excessive traffic place work (boots) (shoes) in a use-solution of 1 oz per 1 to 8 gallons of water (0.1 - 0.78% v/v) (or equivalent dilution) for one minute prior to entering area). Change the solution in the bath daily or more often if solution appears diluted or soiled.

SHOE FOAM SANITIZER DIRECTIONS:

KX-6178 can be used to prevent tracking into processing, packaging and storage areas of food and beverage plants. Apply a foam layer approximately 0.5 to 2 inches thick made from a solution of 1 oz per 1 to 8 gallons of water (0.1% - 0.78% v/v) at all entrances to buildings, hatcheries, production and packaging rooms by using a foam generating machine or aerator to apply foam layer. Follow the foaming directions as specified by the manufacturer of the foam generator/aerator. Scrape water from shoes. Stand and/or walk through foamed area for one minute prior to entering area. Foam area should be washed and replaced daily or when it appears dirty.

OCT 26 2009
Under the Federal Insect
Plant, and Rodent
Control Act the pro
duct is registered under E-1177-709

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DISINFECTION

KX-6178 disinfects as it cleans in one operation. **KX-6178** can be used to disinfect floors, walls and other hard nonporous surfaces such as tables, chairs, countertops, bathroom fixtures, sinks, shelves, racks, carts, exterior surfaces of refrigerators and coolers, tile, linoleum, vinyl, glazed porcelain, plastic (such as polypropylene and polyethylene), stainless steel, or glass. Areas of use include dairies, dairy farms, breweries, wineries, beverage and food processing plants, poultry farms, veterinary facilities, animal care facilities and industrial facilities.

Before use in federally inspected meat and poultry food processing plants and dairies, food products and packaging material must be removed from the room or carefully protected.

COMBINATION DISINFECTION AND CLEANING

KX-6178 is effective as a disinfectant at a concentration of 1 – 2 oz **KX-6178** concentrate per 2 gallons (0.39% - 0.78% v/v concentration) of hard water (500 ppm as CaCO₃), in the presence of 5% blood serum. At this dilution, **KX-6178** is effective against *Staphylococcus aureus*, *Salmonella enterica*, *Pseudomonas aeruginosa* and *Candida albicans*. For heavily soiled areas a pre-cleaning step is required. Prepare a disinfecting and cleaning solution by diluting 1 – 2 oz **KX-6178** concentrate per 2 gallons of water (0.39% - 0.78% v/v concentration). Apply use solution with mop, cloth, sponge, brush, scrubber, or coarse spray device or by soaking or foaming so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, and then remove solution and entrapped soil with a clean wet mop, cloth, or wet vacuum pickup. Prepare a fresh solution daily or when it becomes soiled or diluted.

FOAM DISINFECTION

KX-6178 is an effective foam disinfectant and cleaner on hard, non-porous surfaces, such as boots, floors, walls, drains, and associated equipment. For this application, prepare a solution of 1 – 2 oz **KX-6178** concentrate per 2 gallons of water (0.39% - 0.78% v/v concentration). Apply solution as a foam using recommended equipment. Wet surfaces thoroughly. At this concentration, the product is effective against the following: *Staphylococcus aureus*, *Salmonella enterica*, *Pseudomonas aeruginosa*. Surfaces should be exposed to the disinfecting foam for a period of not less than 10 minutes. No rinse is necessary. Contact your Ecolab representative for information on a recommended foamer.

VIRUCIDAL

KX-6178 is an effective virucide at a concentration of 1 - 2 oz per 2 gallons (0.39%-0.78% v/v concentration) of hard water (500 ppm as CaCO₃), in the presence of 5% blood serum. At this dilution, **KX-6178** is effective against Influenza A (H1N1), Influenza A (H3N2), Influenza B, Reovirus, Influenza A, Norovirus, Feline calicivirus and Avian Influenza when used at 20°C with a 10 minute contact time. Apply as directed under Disinfection.

DIRECTIONS FOR FOGGING

To sanitize hard surfaces as an adjunct to acceptable manual cleaning and disinfecting of room surfaces: Prior to fogging, food products and packaging materials must be removed from the room or carefully protected. Fog desired areas using one quart of a 0.39% - 0.78% v/v (3900 – 7800 ppm product) **KX-6178** solution (1 - 2 oz. per 2 gallons of water) per 1000 cu. ft. of room volume. Vacate the area of all personnel during fogging and until the hydrogen peroxide air concentration is below 0.5 ppm. Allow surfaces to drain thoroughly before operations are resumed. Solutions above 0.5% may be corrosive and are not to be used on all surfaces. Test solutions on surfaces prior to use. All hard non-porous food contact surfaces treated with the fog must be rinsed thoroughly with a potable water rinse.

DISINFECTION OF POULTRY PREMISES, TRUCKS, COOPS AND CRATES

1. Remove all poultry and feed from premises, trucks, coops and crates.
2. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
3. Empty all troughs, racks and other feeding and watering appliances.
4. Thoroughly clean all surfaces with a detergent and rinse with water.

ACCEPTED
 WITH COMMENTS
 OCT 26 2009
 Ecolab Inc. Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No.
 1677-209

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- 5. Saturate surfaces with a 1 - 2 oz per 2 gallons (0.39%-0.78% v/v concentration) solution of **KX-6178** for a period of 10 minutes.
 - 6. Ventilate buildings, coops and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set or dried.
 - 7. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with a detergent and rinse with potable water before reuse.
- See your Ecolab Representative for specific recommendations for all cleaning and rinsing requirements.

POULTRY HATCHERY DISINFECTION

Clean out any remaining eggs and chicks. Remove gross soils, such as litter, down, shell fragments or other hatching related debris. Empty all racks and other equipment. Thoroughly wash all surfaces, including floors, walls, conveyors, trays and water systems with a recommended detergent. Rinse thoroughly with water. Apply a 1 - 2 oz per 2 gallons (0.39%-0.78% v/v concentration) solution of **KX-6178** with a mop, cloth, brush, foam or coarse spray. Wet all surfaces and allow to remain wet for 10 minutes. Ventilate buildings and other closed spaces. Allow to dry before reintroducing eggs.

DISINFECTION AND DEODORIZING OF ANIMAL HOUSING FACILITIES (BARNs, KENNELS, HUTCHES)

Remove animals and feed from facilities. Remove litter, waste matter and gross soils from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all troughs, rack and other feeding and watering equipment. Wash surfaces with a recommended alkaline detergent, by manual, foam, or spray application. Rinse with water. Apply a 1 - 2 oz per 2 gallons (0.39%-0.78% v/v concentration) solution of **KX-6178** with a mop, cloth, brush, foam or coarse spray. Wet all surfaces and allow to remain wet for 10 minutes. Ventilate buildings and other closed spaces. Allow to air dry before reintroducing animals.

(VETERINARY PRACTICE / ANIMAL CARE / ANIMAL LABORATORY / ZOOS / PET SHOP / KENNELS DISINFECTION DIRECTIONS:)

For disinfection and deodorizing of hard nonporous surfaces of equipment used in animal housing facilities including food or water containers, utensils, instruments, cages, crates kennels, stables and catteries.

OR

(FARM PREMISE DISINFECTION DIRECTIONS:)

- 1. Remove all animals and feed from premises, vehicles, and enclosures.
- 2. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals.
- 3. [For "Veterinary Practice...": Empty all feeding and watering appliances.] [For "Farm Premise Use" Empty all troughs, racks and other feeding and watering appliances.]
- 4. Thoroughly clean surfaces with soap or detergent by manual, foam, or spray application and rinse with water.
- 5. Saturate surfaces with a use-solution of 1 – 2 oz **KX-6178** per 2 gallons of water (0.39% - 0.78% v/v concentration or 3900 – 7800 ppm product). (or equivalent dilution) and allow to remain wet for a period of 10 minutes.
- 6. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure. Wipe or allow to air dry.
- 7. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.
- 8. [For "Veterinary Practice..." Thoroughly scrub all treated feeding and watering appliances with soap or detergent, and rinse with potable water before reuse. [For "Farm Premise Use"; Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.]

ACCEPTED
with COMMENTS
in IFA Letter dated
OCT 26 2009

Under the Federal Insecticide, Fungicide, and Rodenticide Act, this product is registered, for the purpose of... registered under EPA Reg. 1677-2009

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STORAGE & DISPOSAL

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

PESTICIDE STORAGE: Product should be kept cool and in a 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:

(1 gallon) Nonrefillable container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available.

(4, 15, 30, 50 gallons plastic) Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. To clean the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Offer for recycling, if available, or puncture and dispose of in a sanitary landfill or by incineration.

(2.5 gal bladder in box) Do not reuse or refill bladder. Triple rinse bladder (or equivalent) promptly after emptying. To clean the bladder before final disposal, empty the remaining contents from bladder into application equipment or a mix tank. Fill the bladder about 10 percent full with water. Agitate vigorously for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Offer bladder and box for recycling, if available, or puncture and dispose of in a sanitary landfill or by incineration.

(Totes) Refillable Container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Verify that the tote is empty. Seal tote and contact Ecolab for return. Cleaning the container before disposal is the responsibility of the person disposing the container. Cleaning before refilling is the responsibility of the refiller. To clean the container empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.

**FOR COMMERCIAL USE ONLY
STRONG OXIDIZING AGENT**

EPA Reg. No. 1677-209
EPA Est. 1677-MN-1 (P), 60156-IL-1 (SI), 1677-CA-2(R),
1677-TX-1(D), 1677-OH-1(H), 1677-IL-1(J), 1677-GA-1(M),
1677-PR-1(B), 1677-CA-1(S), 1677-WV-1(V)
Superscript refers to first letter of date code

Net Contents:	1 U.S. Gal. (3.78 L)
	5 U.S. Gals. (18.9 L)
	15 U.S. Gals. (56.8 L)
	50 U.S. Gals. (189 L)
	300 U.S. Gals. (tote)

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

ACCEPTED
with COMMENTS
in EPA Letter Dated
OCT 26 2009
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
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