

875-185

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8310 16th Street, MS 707
Sturtevant, WI 53177-1964

JUN - 4 2009

Subject: PRO-KLEEN
EPA Registration No. 875-185
Application Date: March 12, 2009
Receipt Date: March 13, 2009

Dear Ms. Lyddon:

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

Proposed Amendment

- Revised labeling per Agency letter dated January 29, 2009
- Addition of toll free number to First Aid Statement

Comments

- On page two (2) of the product label, within the Use Classification section, you must remove the phrase "such as." This phrase implies a larger list of use sites than is specified on the label.
- Revise page two (2) to include mandatory language as per PR Notice 2000-5. Revise #4 of the sanitizing directions to include: "Surfaces *must* remain wet..." Revise the Foam Cleaning and Sanitizing to begin: "This product *is* applied as a foam...", "Foam applications *are* used...", revise #1 to begin: "*Pre*clean surfaces. Prepare a dilution..." and Descaling to begin: "Pro-Kleen *is* foamed at..."
- In the foam cleaning and sanitizing directions on page two (2), item #3 delete the word "impingement" as this terminology is confusing to the user.
- Increase the font size of the signal word "Danger" on the front panel of the label.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

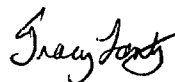
- On page four (4) of the product label within the Environmental Hazards statement, revise the phrase "This pesticide is toxic to fish" to read "This pesticide is toxic to fish and aquatic organisms."
- Revise the small nonrefillable container language on page three (3) to indicate the at the rinsate is to be disposed as follows: "...or store rinsate for disposal. Drain..." Make the same correction to both versions of the Large nonrefillable containers statement on page four (4).

General Comments

A stamped copy of the accepted labeling is enclosed. Submit 1 copy of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6415 or email address at: Lantz.Tracy@epa.gov during the hours of 8:00 am to 3:30 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Tracy Lantz
 Acting Product Manager (34)
 Regulatory Management Branch II
 Antimicrobials Division (7510P)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Note to Agency: Text appearing in parenthesis or brackets is done to show optional text.

JohnsonDiversey



PRO-KLEEN™
Self-Foaming Acidic Cleaner/Descaler/Sanitizer
For (Institutional) (and) (Industry) (Industrial) Use (Only)

ACTIVE INGREDIENTS:	
Phosphoric acid	54.00%
Dodecylbenzene sulfonic acid.....	4.50%
INERT (OTHER) INGREDIENTS:	41.50%
TOTAL:	100.00%

KEEP OUT OF REACH OF CHILDREN
DANGER

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.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

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 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.

IN CASE OF EMERGENCY, CALL A POISON CONTROL CENTER OR DOCTOR FOR TREATMENT ADVICE.

XXX-XXX-XXXX

Have the product container or label with you when calling a Poison Control Center or doctor or going in for treatment.

Note to Physician: Probable mucosal damage may contraindicate gastric lavage.

See additional precautionary statements on back (side) (left) (right) (panel) (of) (label) (below).

ACCEPTED
with COMMENTS
in EPA Letter Dated:
JUN - 4 2009

Net Contents:

(Product of USA)

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. **875-185**

March 12, 2009

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EPA Reg. No. 875-185

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Note to Agency: Text appearing in parenthesis or brackets is done to show optional text.

For use in spray, foam or immersion cleaning and institutional/industrial sanitization of previously cleaned, hard, non-porous food-contact surfaces and equipment, such as food preparation surfaces, pipelines, tanks, vats, fillers, evaporators, pasteurizers, transport tank trucks, pre-mix vending units, food serving equipment such as glasses, dishes, utensils, pots, and pans; belts, cutting tables and other utensils and equipment and aseptic equipment in:

- Dairies, Wineries, Breweries, and Beverage Plants
- Meat and Poultry Processing/Packaging Plants
- Milk and Dairy Products Processing/Packaging Plants
- Seafood and Produce Processing/Packaging Plants
- Food Processing/Packaging Plants
- Egg Processing/Packaging Plants
- Food Service Industry/Eating Establishments
- Final Sanitizing Bottle Rinse

DIRECTIONS FOR USE:

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

USE PROCEDURES FOR SANITIZING:

1. Pre-flush with potable water to remove gross food particles.
2. Clean with recommended alkaline cleaner.
3. Rinse with potable water.
4. To sanitize, apply 1 part Pro-Kleen™ to 200 parts water (2 ½ ounces per 4 gallons of water) by immersion, flooding, foaming or spraying with a coarse droplet spray. Surface should remain wet for at least 1 minute.
5. Drain and air dry. Allow adequate draining before contact with food.

For manual operations, fresh sanitizing solution must be prepared at least daily. Prepare more often if the solution becomes diluted or soiled.

Solution used in spray operations may not be re-used for sanitizing. Only 1 sanitization per solution is allowed. The solution, if not soiled, may be used for cleaning, polishing stainless steel, or descaling.

FOAM CLEANING AND SANITIZING

This product can be applied as a foam for sanitizing previously cleaned hard, non-porous, food-contact surfaces and general environmental (non-food contact) hard non-porous surfaces such as floors, walls, ceilings, drains and boots. Foam applications can be used where penetration and retention of product for required times is difficult to achieve. Examples include operating conveyor belts, and vertical or uneven surfaces.

1. Prepare a dilute solution by mixing Pro-Kleen™ with water at 1:30 to 1:40 dilution and mix until it is in solution. The product is immediately ready to be foamed.
2. Apply the sanitizing solution as a foam using commercially available foam generating equipment. Allow foam to contact surfaces for at least 1 minute. For cleaning, allow the foam to remain on the surface to be cleaned until the soil is loosened.
3. Rinse well with a strong impingement water spray.

DESCALING, REMOVAL OF HARD WATER DEPOSITS AND MILKSTONE:

Pro-Kleen™ should be foamed at 1:30 to 1:40. At this level it is an effective hard water protein scale remover. Lesser concentrations can be used for lighter soil and stronger concentrations for heavier soils.

Note to Agency: Text appearing in parenthesis or brackets is done to show optional text.

MICROBIOLOGICAL DATA:

METHOD: Germicidal and Detergent Sanitizing Action of Disinfectants, A.O.A.C., 15th Ed., 1990.

RESULTS: Pro-Kleen™ at 1:200 (2 ½ ounces per 4 gallons of water) reduces bacterial numbers by 99.999% when tested by this method with a 30 second contact time in 500 ppm hard water. The organisms used in these tests were *Escherichia coli* (ATCC 11229), *Staphylococcus aureus* (ATCC 6538) and *Listeria monocytogenes* (ATCC 15313). Copies of the test data are available on request.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store in original container in areas inaccessible to children.

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 *Note to reviewer – One or more of the following paragraphs for Container Disposal will be selected, depending on packaging type:*

(If not being refilled with this product,) 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.

NONREFILLABLE SEALED CONTAINERS: *Note to EPA: Several of our packaging options (including ACCUMIX Containers™, Solutions Center™, J-Fill™, OUTPOST™, Single Solutions™, Smart Dose, Command Center™, or RTD™) are sealed containers or bottles designed to reduce worker exposure to the concentrate. None of these can be triple rinsed because they are closed, sonically welded, sealed containers. The following text will be used on these sealed container types:*

Nonrefillable container. Do not reuse or refill this container. Wrap empty container and put in trash.

NONREFILLABLE NON-RIGID CONTAINERS: *Note to EPA: Several of our packaging options are Bag-in-Box containers (a plastic bag liner supported inside a box) or are flexible bag-type containers (such as ACCUPACK™ Containers). These flexible containers are exempt from the triple rinsing requirements. The following text will be used on these container types:*

Nonrefillable container. Do not reuse or refill this container. Wrap empty container and put in trash.

SMALL NONREFILLABLE CONTAINERS: *Note to EPA: The following text will be used on rigid, nonrefillable containers small enough to shake (5 gallons or smaller):*

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer container for recycling, if available.

Note to Agency: Text appearing in parenthesis or brackets is done to show optional text.

LARGE NONREFILLABLE CONTAINERS: *Note to EPA: One of the following paragraphs will be used on labels for rigid, nonrefillable containers too large to shake (larger than 5 gallons):*

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water and replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for at least 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Offer container for reconditioning, if appropriate.

OR

Nonrefillable container. Clean container promptly after emptying. Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or a mix tank or collect rinsate for later use or disposal. Insert pressure-rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip. Offer for reconditioning, if appropriate.

REFILLABLE CONTAINERS: *Note to EPA: One of the following paragraphs will be used on labels for refillable containers:*

Refillable container. Refill this container with (this brand or brand name) pesticide only. Do not reuse this container for any other purpose.

Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

OR

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

To clean the container prior to final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.

ENVIRONMENTAL HAZARDS *(for containers of 5 gallons or more)*

This pesticide 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 agency 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.

