



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

SEP 27 2010

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Janine Gydus
Staff Scientist for Purdy Products Company
Carter Ledyard & Milburn LLP
701 8th Street, NW
Suite 410
Washington, DC 20001

FILE COPY

Subject: Sani-Kleen
EPA Registration No. 178-15
Application Date: August 13, 2010
EPA Receipt Date: August 13, 2010

Dear Ms. Gydus:

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

Proposed Amendment:

- Label Amendment

Conditions:

Revise the label as follows:

1. On page 1:
 - a. Add the word 'Kitchen' before the word 'Utensils'.
 - b. Add the word 'Sealed' before the words 'Floors' and 'Countertops'.
 - c. Delete the word 'Only' from the heading 'For Institutional Use Only'.
2. On page 2:

Revise the statement "... chewing gum, or using tobacco." to read "...chewing gum, using tobacco, or using the toilet."
3. On page 3:

Revise the statements "Clean and sanitize by soaking for at least one minute..." to read "Clean by soaking for at least one minute..." and "Brush clean and sanitize all..." to read "Brush clean all...".
4. On page 4:

Revise the statement "Wash, rinse and sanitize by soaking..." to read "Wash and rinse by soaking..."

5. On page 5:

- a. Revise the subheading beginning "Utensils, dishes..." to read "Kitchen utensils, dishes..."
- b. Revise the phrase "...warm water to yield 100 ppm chlorine." to read "...warm water to yield 100 ppm available chlorine."
- c. Revise the phrase "Immerse into sanitizing solution..." to read "Immerse equipment components, kitchen utensils, dishes, glasses, or miscellaneous food-contact machine parts into sanitizing solution..."
- d. Revise the heading beginning "Floors, Countertops..." to read "Sealed Floors, Sealed Countertops..."

6. On page 6:

- a. Revise the phrase "Drain unit and rinse with fresh water." to read "Drain unit and rinse with potable water."
- b. Revise the statement "Drain solution, but do not rinse." to read "Drain solution and allow to air dry. Do not rinse. Follow local health codes."
- c. Revise the statement "Do not rinse." to read "Drain solution and allow to air dry. Do not rinse. Follow local health codes."

7. On page 7:

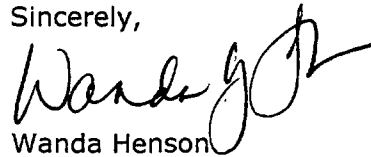
- a. Add the word 'Kitchen' before the word 'Utensils'.
- b. Add the word 'Sealed' before the words 'Floors' and 'Countertops'.
- c. Delete the word 'Only' from the heading 'For Institutional Use Only'.

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 at Henson.Wanda@epa.gov or call (703) 308-6345.

Sincerely,



Wanda Henson
Acting Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

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[FRONT PANEL]

Sani-Kleen

[Optional Marketing Statements]

- (Cleans and Sanitizes Frozen Dessert Machines and Other Food Contact Surfaces)
- (Sanitizer and Cleaner)
- (Chlorinated Cleaner/Sanitizer)
- (Sanitizer)
- (Sanitizer for Frozen Dessert Machines)
- (Sanitizer/Cleaner/Milkstone Remover)
- (Sanitizer/Cleaner/Milkstone Remover for Frozen Dessert Machines)
- (Sanitizer and Cleaner for Frozen Dessert Machines)
- (Cleaner and Sanitizer for Frozen Dessert and Beverage Machines)
- (General Purpose Cleaner and Sanitizer for Utensils, Dishes, Glasses, Food-Contact Machine Parts, Floors, Countertops & Stationary Equipment Surfaces)
- (Detergent/Sanitizer/Milkstone Remover)
- (Detergent/Sanitizer/Milkstone Remover for Frosty™ Machines)
- (Milkstone Remover)
- (Chlorinating sanitizer for kitchen utensils and other food-contact surfaces)
- (Cleaner and Sanitizer for Ice Machine Bins and Evaporators)
- (Tea Brewer Cleaner & Sanitizer)
- (Tea Brewer/Dispenser Cleanser and Sanitizer)

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 27 2010

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 178-15

For Institutional Use Only

ACTIVE INGREDIENT

Sodium Dichloro-S-Triazinetrione Dihydrate* 2.4%

OTHER INGREDIENTS 97.6%

TOTAL 100.0%

*Available chlorine 1.34%

KEEP OUT OF REACH OF CHILDREN WARNING

[When necessary, the following will be added to final printed label, depending on container type/size]

(Read Additional Precautionary Statements on (side) (back) (panel(s)) (outer carton)

(Read outer carton label for additional Precautionary Statements and complete Directions for Use)

[For Outer Carton] (Read precautionary statements on side panel.)

[For Jar] (Read additional Precautionary Statements on side panel.)

MANUFACTURED BY
PURDY PRODUCTS CO.
P.O. BOX 456, WAUCONDA, IL 60084

EPA Reg. No. 178-15
EPA Est. No.
Net Weight:

(Batch Code:) [to appear on front or back panel of label or immediate container, depending on container type/size]

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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 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 poison control center or doctor for treatment advice.

If swallowed:

- Call 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 to do so by poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

FOR MEDICAL EMERGENCY INFORMATION CALL 1-800-222-1222

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

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Warning: Causes eye and skin irritation. Do not get in eyes, on skin or on clothing. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

PHYSICAL AND CHEMICAL HAZARDS

Do not use in combination with soaps, other detergents or chemicals.

DIRECTIONS FOR USE

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

SANI-KLEEN required use dilution

[for 2 oz. packet or jar with 2 oz. scoop] 2 oz. to 2 gal. water = 100 ppm. Available Chlorine
pH between 9 and 10

(PLEASE REFER TO YOUR OPERATOR'S MANUAL FOR DETAILED INSTRUCTIONS.)

(When used as directed, Sani-Kleen is used for cleaning and sanitizing frozen dessert and beverage machines) (and to clean and sanitize surfaces such as:)

(Acrylic;) (Aluminum;) (Brass;) (Copper;) (Chrome;) (Corian®;) (Glass;) (Glazed ceramic, enameled, and porcelain surfaces;) (Iron;) (Laminated surfaces;) (Linoleum;) (Metal;) (Plastics (such as nylon, polystyrene or polypropylene);) (Porcelain;) (Rubber (such as EPDM or Viton);) (Sealed granite;) (Sealed limestone;) (Sealed marble;) (Sealed slate;) (Sealed stone;) (Sealed terracotta;) (Sealed terrazzo;) (Stainless steel;) (Vinyl;) (and) (Vinyl graphics)

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[Directions for 2 oz. packet, and 2 oz. scoop]

CLEANING AND SANITIZING FROZEN DESSERT AND BEVERAGE MACHINES

(Soft-serve ice cream & shake freezers, batch freezers, frozen yogurt, frozen custard, frozen carbonated beverages, smoothie and granita machines, iced cappuccino machines, shaved iced machines, slush machines, and other frozen dessert and beverage machines)

CLEANING AND DISASSEMBLY INSTRUCTIONS

1. Follow manufacturer's directions to drain and rinse freezing hopper (or dispenser) and freezing cylinder. Rinse until water is clear.
2. Dissolve one (2 oz. packet) [OR] (2 oz. scoop) into 2 gallons of warm water. Pour into hopper/dispenser.
3. Agitate solution per manufacturer's suggested wash cycle. Or, manually brush clean making sure solution makes contact with all surfaces.
4. Drain solution completely.
5. Following manufacturer's directions, take all removable parts to sink. Clean and sanitize by soaking for at least one minute using one (2 oz. packet) [OR] (2 oz. scoop) per 2 gallons of warm water. Allow to air dry. Follow local health ordinances.
6. Repeat procedures for each freezing cylinder or dispenser. To insure adequate cleaning, do not reuse solution.

ASSEMBLY AND SANITIZING INSTRUCTIONS

1. Assemble machine and lubricate all parts according to manufacturer's specifications.
2. Dissolve one (2 oz. packet) [OR] (2 oz. scoop) in 2 gallons of warm water. Pour into hopper (or dispenser).
3. Agitate sanitizing solution per manufacturer's suggested wash cycle, but for no less than one minute.
4. Drain solution completely. Repeat procedures for each machine freezing cylinder or dispenser. DO NOT REUSE SOLUTION. Do not rinse. Follow local health codes.

[OR]

[Directions for 2 oz. packet, and 2 oz. scoop]

CLEANING AND SANITIZING FROZEN DESSERT AND BEVERAGE MACHINES

(Soft-serve ice cream & shake freezers, batch freezers, frozen yogurt, frozen custard, frozen carbonated beverages, smoothie and granita machines, iced cappuccino machines, shaved iced machines, slush machines, and other frozen dessert and beverage machines)

CLEANING AND DISASSEMBLY INSTRUCTIONS

1. Take hopper cover, gasket and mix feed device to sink for cleaning.
2. Place control switch in "Wash" position.
3. Drain all product into sanitized rerun container if local health codes permit.
4. Pour 2 gallons of cool rinse water into hopper. Brush clean hopper and inlet hole.
5. Place control switch in "Wash" position and agitate for two minutes. Drain rinse water. Switch to "Off positions". Repeat rinsing procedure until water is clear.
6. Dissolve one (2 oz. packet) [OR] (2 oz. scoop) in 2 gallons of warm water. Pour into hopper.
7. Place control switch in "Wash" position to agitate for five minutes. Drain solution completely. Switch to "Off" position.
8. Remove all freezing cylinder parts and door. Brush clean and sanitize all disassembled parts by soaking in sanitizing solution for at least one minute. Allow to air dry. Follow local health codes.
9. Repeat procedures for each freezing cylinder. To insure cleaning, do not reuse solution.

ASSEMBLY, SANITIZING AND OPERATING INSTRUCTIONS

1. Assemble machine and lubricate all parts according to manufacturer's specifications.

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2. Dissolve one (2 oz. packet) [OR] (2 oz. scoop) in 2 gallons of warm water. Pour into hopper (or dispenser).
3. Place control switch in "Wash" position to agitate for five minutes. Drain solution completely. Switch to "Off" position. DO NOT RINSE. Follow local health codes.
4. Repeat procedures for each freezing cylinder. DO NOT REUSE SOLUTION.

[AND/OR]

[Directions for 2 oz. packet, and 2 oz. scoop]

CLEANING AND SANITIZING FROSTY™ * MACHINES

CLEANING AND DISASSEMBLY INSTRUCTIONS

1. Place control switch in "Wash" position.
2. Take hopper cover, gasket and mix feed device to 3-compartment sink for cleaning.
3. Drain all product into sanitized stainless steel pail, cover and place in walk-in for reuse if local health codes permit. NOTE: Never leave machine in "Wash" position for more than 5 minutes.
4. Pour 2 gallons of cool rinse water into hopper. Brush clean hopper inlet hole and sensing probe.
5. Place control switch in "Wash" position and agitate for two minutes. Drain rinse water. Repeat rinsing procedure until water is clear. Switch to "Off" position.
6. Dissolve one (2 oz. packet) [OR] (2 oz. scoop) in 2 gallons of warm water in stainless steel bucket.
7. Pour sanitizing solution into hopper. Brush clean hopper, inlet hole and sensing probe.
8. Place control switch in "Wash" position, to agitate for five minutes. Drain all solution. Switch to "Off" position.
9. Unplug Frosty™ machine.
10. Remove all freezing cylinder parts and door. Brush clean all disassembled parts at the 3-compartment sink. Wash, rinse and sanitize by soaking with this product for at least one minute and allow to air dry.
11. Repeat procedures for units with two freezing cylinders. Do not reuse solution.

ASSEMBLY, SANITIZING AND OPERATION INSTRUCTIONS

NOTE: Make sure Frosty™ Machine is unplugged.

1. Assemble and lubricate all disassembled parts according to manufacturer's specifications.
2. Plug in Frosty™ Machine.
3. Dissolve one (2 oz. packet) [OR] (2 oz. scoop) in 2 gallons of warm water in a stainless steel bucket.
4. Pour 2 gallons of sanitizing solution into hopper. As it enters the freezing cylinder, brush-clean hopper, inlet hole and sensing probe.
5. Place control in "WASH" position, to agitate for five minutes. Drain all sanitizing solution. Switch to "Off" position.
6. Pour specified amount of fresh mix into hopper. Raise draw arm to force remaining sanitizer from freezing cylinder. NOTE: Prime machine no sooner than 30 minutes before using. DO NOT RINSE. Follow local health codes. DO NOT REUSE SOLUTION.

*Frosty™ is a trademark of Wendy's/Arby's Group, Inc.

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[AND/OR]
[Directions for 2 oz. packet, and 2 oz. scoop]

(DAILY MAINTENANCE PROCEDURES FOR ALL ICED TEA BREWERS/DISPENSERS)
[OR THE FOLLOWING HEADING]

(For China Mist Iced Tea Brewers/Dispensers)
DAILY Maintenance Procedures For All Manufacturers and Models)

1. Drain tea from dispenser. DO NOT KEEP TEA OVERNIGHT.
2. Fill tea dispenser with warm water.
3. Mix one (2 oz. packet) [OR] (2 oz. scoop) for every 2 gallons of warm water to yield 100 ppm available chlorine.
4. Stir solution until dissolved. Put brew funnel into solution. Allow solution to soak for 1 – 2 minutes.
5. Drain small amount of solution into a container to soak spigot later.
6. Drain approximately three-quarters of solution through spigot. To drain the remainder, take dispenser to sink, swish solution and pour out from top of dispenser. Be sure to pour out any particulate matter.
7. Allow dispenser & brew funnel to air dry. DO NOT RINSE. Follow local health codes.
8. Dismantle spigot and soak in solution for at least 60 seconds. Remove spigot & allow to air dry. Follow local health codes.
9. Before brewing tea, reassemble and attach spigot. Replace lid before brewing tea.

[AND/OR]
[Directions for 2 oz. packet, and 2 oz. scoop]

GENERAL PURPOSE CLEANING AND SANITIZING
(Utensils, dishes, glasses, miscellaneous food-contact machine parts)

1. Rinse and remove all loose food soil substances.
2. Dissolve one (2 oz. packet) [OR] (2 oz. scoop) in 2 gallons of warm water.
3. Wipe or brush clean surface.
4. Rinse with potable water.
5. Sanitize using one (2 oz. packet) [OR] (2 oz. scoop) in 2 gallons of warm water to yield 100 ppm chlorine.
6. Immerse into sanitizing solution for at least one minute.
7. Remove and allow to air dry. Do not rinse. Follow local health codes.

[AND/OR]
[Directions for 2.0 oz. packet, and 2 oz. scoop]

FLOORS, COUNTERTOPS & STATIONARY EQUIPMENT SURFACES

1. For previously cleaned surfaces, mix the appropriate amount of sanitizing solution by mixing one (2 oz. packet) [OR] (2 oz. scoop) for every 2 gallons of warm water to yield 100 ppm available chlorine.
2. Apply with a clean cloth, sponge, spray, or completely flood surface making sure the solution completely covers the whole surface for at least 60 seconds. Let air dry. Do not rinse. Follow local health codes.

[AND/OR]
[Directions for 2.0 oz. packet, and 2 oz. scoop]

CLEANING AND SANITIZING ICE MACHINES

To Clean Ice Machine Evaporator

1. Turn off refrigeration. Leave machine pump on.
2. Drain unit.
3. Dissolve one (2 oz. packet) [OR] (2 oz. scoop) for every 2 gallons of warm water needed.
4. Pour into unit per manufacturer's instructions. Allow to circulate for 30 minutes.
5. Brush clean any areas where solution does not contact surfaces needed to be cleaned.
6. Ice machine drums can be cleaned by soaking in solution prepared by mixing one (2 oz. packet) [OR] (2 oz. scoop) in 2 gallons of warm water.
7. Drain unit and rinse with fresh water.

To Sanitize Ice Machine Evaporator

1. Follow steps 1 – 4 above, making sure the sanitizing solution completely covers the whole surface for at least 60 seconds.
2. Drain solution, but do not rinse.
3. Discard first batch of ice.

To Clean Ice Machine Bin

1. Turn off refrigeration and water supply.
2. Remove ice from bin.
3. Mix one (2 oz. packet) [OR] (2 oz. scoop) in 2 gallons of warm water in bucket.
4. Pour into ice bin.
5. Brush clean as necessary.
6. Take any removable parts that require cleaning and soak in solution prepared by mixing one (2 oz. packet) [OR] (2 oz. scoop) for every 2 gallons of warm water needed.

To Sanitize Ice Machine Bin

1. Follow steps 1 – 6 above, making sure the sanitizing solution completely covers the whole surface for at least 60 seconds.
2. Do not rinse.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Keep product dry in tightly closed container when not in use. Store in cool, dry, well-ventilated area away from heat or open flame.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL:

[2 oz. plastic packet] (Packet:) Container is destroyed by removing product. Discard completely empty packet in trash.

[Outside carton] (Carton:) Offer for recycling, if available, or discard in trash.

[4 lb. Plastic jar] (Jar:) Non-refillable container. Do not reuse or refill container. Triple rinse (or equivalent). Offer for recycling, if available, or discard in trash.

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[Proposed Packet Design:
When complete label is not printed on packet, the following packet design will be used:]

[FRONT PANEL]

Sani-Kleen

[Optional Marketing Statements]

- (Cleans and Sanitizes Frozen Dessert Machines and Other Food Contact Surfaces)
- (Sanitizer and Cleaner)
- (Chlorinated Cleaner/Sanitizer)
- (Sanitizer)
- (Sanitizer for Frozen Dessert Machines)
- (Sanitizer/Cleaner/Milkstone Remover)
- (Sanitizer/Cleaner/Milkstone Remover for Frozen Dessert Machines)
- (Sanitizer and Cleaner for Frozen Dessert Machines)
- (Cleaner and Sanitizer for Frozen Dessert and Beverage Machines)
- (General Purpose Cleaner and Sanitizer for Utensils, Dishes, Glasses, Food-Contact Machine Parts, Floors, Countertops & Stationary Equipment Surfaces)
- (Detergent/Sanitizer/Milkstone Remover)
- (Detergent/Sanitizer/Milkstone Remover for Frosty™ Machines)
- (Milkstone Remover)
- (Chlorinating sanitizer for kitchen utensils and other food-contact surfaces)
- (Cleaner and Sanitizer for Ice Machine Bins and Evaporators)
- (Tea Brewer Cleaner & Sanitizer)
- (Tea Brewer/Dispenser Cleanser and Sanitizer)

For Institutional Use Only

ACTIVE INGREDIENT

Sodium Dichloro-S-Triazinetrione Dihydrate* 2.4%

OTHER INGREDIENTS 97.6%

TOTAL 100.0%

*Available chlorine 1.34%

KEEP OUT OF REACH OF CHILDREN
WARNING

Read outer carton label for additional Precautionary Statements and complete Directions for Use

MANUFACTURED BY
PURDY PRODUCTS CO.
P.O. BOX 456, WAUCONDA, IL 60084

EPA Reg. No. 178-15
EPA Est. No. 178-IL-1
Net Weight: 2 oz.

(Batch Code: __) [Reviewer: Batch Code will be placed on front or back of packet with or without the heading "Batch Code"]

10/10

[Proposed Packet Design

When complete label is not printed on packet, the following packet design will be used:]

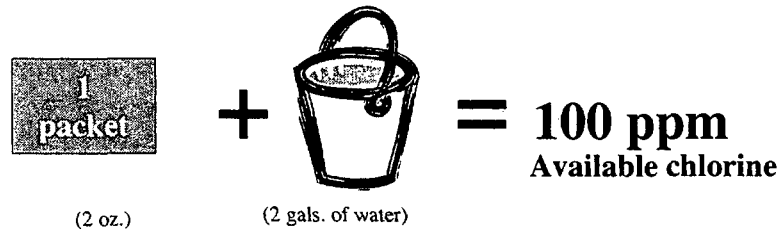
[BACK PANEL]

DIRECTIONS FOR USE

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

SANI-KLEEN required use dilution:

[Reviewer: This label will include a picture similar to the picture below, depicting mixing directions required for 100 ppm available chlorine]



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 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 poison control center or doctor for treatment advice.

If swallowed:

- Call 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 to do so by poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

FOR MEDICAL EMERGENCY INFORMATION CALL 1-800-222-1222

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

(Batch Code: __) [Reviewer: Batch Code will be placed on front or back of packet with or without the heading "Batch Code"]

(*Frosty™ is a trademark of Wendy's/Arby's Group, Inc.)