



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

1677-264

Date of Issuance:

12/30/19

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

XLS-CQC

Name and Address of Registrant (include ZIP Code):

Heidi Popelka
Senior Regulatory Specialist
EcoLab Inc.
1 Ecolab Place
St. Paul, MN 55102

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Eric Miederhoff, Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Date:

12/30/19

2. You are required to comply with the data requirements described in the DCI identified below:
 - a. DDAC GDCI-069149-30869, -0681

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>

3. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 1677-264.”
4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

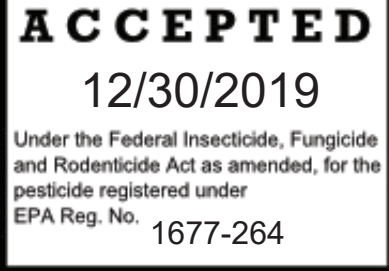
- Basic CSF dated 07/09/2019

These Alternate Brand Names for this product are acceptable:

- Klercide Cleanroom Quat Unit Dose Concentrate
- Klercide Cleanroom Quat Metered Dose Concentrate

If you have any questions, please contact Tara Flint via email at flint.tara@epa.gov or Eric Miederhoff at Miederhoff.eric@epa.gov.

Enclosure



XLS-CQC

[Filtered to 0.2 microns] [0.2 Micron Filtered] [Filtered] [Aseptically Filtered Formula] [Quat blended with WFI] [Quat blended with Water for Injection] [WFI Formula] [Water for Injection] [USP Water] [USP Water Pharma Grade] [DI Water]

[HARD, NON-POROUS SURFACE] [NON-FOOD CONTACT SANITIZER/
HARD, NON-POROUS SURFACE DISINFECTANT /
HARD, NON-POROUS SURFACE FUNGICIDE

[For Use in [Industrial] [and/or] [Institutional] Applications]

[Note to Reviewer. Text appearing in brackets or parenthesis is optional text.]

Active Ingredient:

Didecyl dimethyl ammonium chloride..... 1.84%

Other Ingredients: 98.16%

Total:..... 100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

[See [back], [side], [inside], [other] [fold-out] [product container] [label(s)] [panel(s)] [container] for [complete] [additional] [information] [directions for use] [storage and disposal] [container handling and disposal.]

[PELIGRO: Si no puede leer en inglés, pregunte a su supervisor sobre las instrucciones de uso apropiadas antes de trabajar con este producto.]

[DANGER: If you cannot read English, ask your supervisor for the appropriate instructions before handling this product.]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: CORROSIVE. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear rubber or chemical resistant gloves, long sleeved shirt, long pants, socks, and shoes, and protective eyewear such as safety glasses or goggles. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

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. 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.

**FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-328-0026
OUTSIDE OF NORTH AMERICA, CALL 1-651-222-5342**

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

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

[Note to Reviewer: For containers of 5 gallons or more, the following Environmental Hazards language will appear on the final product label.]

ENVIRONMENTAL HAZARDS: 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.

This product is designed specifically as a [non-food contact sanitizer][non-porous, hard surface non-food contact sanitizer][non-porous, hard surface disinfectant][hard surface fungicide] for use on environmental surfaces in cleanrooms / and non-product contact surfaces in manufacturing locations in areas such as*:

Table 1: Use Sites

Animal Life Science Facilities	Biomedical Facilities	Biotechnology Facilities
Biopharmaceutical Manufacturing Facilities	Cleanrooms	Comparative Medicine Facilities
Compounding Pharmacies	Controlled Areas	Diagnostic Manufacturing Facilities
Healthcare Institutions	Hospitals	Hospital Compounding Pharmacies
Industrial Facilities	Institutional Facilities	Laboratory Facilities
Life Science [Facilities][Laboratories]	Medical Device Manufacturing Facilities	Pharmacies
Pharmaceutical Manufacturing Facilities	Research Facilities	

This product is not to be used as a sterilant/high-level disinfectant on any surface or instrument that: (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

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For use on hard, non-porous surfaces only [in] [or] [on]:

Table 2: Use Surfaces

Aseptic Filling Rooms	[Biosafety Level][BSL] Hoods	Carts
Ceilings	Counters	Countertops
Equipment	Floors	General Manufacturing Areas
Gowning Rooms	Hard, non-porous Surfaces only	Hoods
Isolators	[Laboratory] Benches	Laminar Flow Benches
Laminar Flow Curtains	Machinery	Material Transfer
Production Vessel Exteriors	Shelves	Tables
Transfer Disinfection	Transfer Hatches	Walls

This product is compatible with hard, non-porous materials such as: [the listed materials]. [If the product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.]

Table 3: Material Compatibility

[Anodized] Aluminum	[Cast][Extruded] Acrylic	Laminate
Polycarbonate	Polypropylene	Polyvinyl chloride
PVC	PVC-Coated Mild Steel	Stainless Steel
Vinyl	Zinc Galvanized Mild Steel	

- Use water of suitable quality for the environment [such as] [water for injection] [deionized water] [USP water pharma grade] to make the dilution.
- Mix the diluted solution well before use.
- Apply solution with mop, cloth, [sponge], [brush], [scrubber], disposable wipe[r], or by soaking or flooding, to fully wet all surfaces.
- Allow surfaces to remain wet for a minimum of [insert desired contact time] and then allow to air dry, or if desired, wipe dry with a [sterilized] cloth or wipe[r].

FOR USE AS A SANITIZER:

This product is a sanitizer for pre-cleaned, hard, non-porous, non-food contact surfaces.

[For Unit Dose bottle]: Add [1 bottle] [2.6 fl. oz.] to water of suitable quality for the environment [such as] [water for injection] [deionized water] [USP water pharma grade] to make up 1 gallon (3.79 liters) of diluted sanitizer

[For Metered Dose bottle]: 2.6 fl. oz. (76 mL) should be diluted as a 1:49 dilution with water of suitable quality for the environment [such as] [water for injection] [deionized water] [USP water pharma grade] to make 1 gallon (3.79 liters) of diluted sanitizer.

- Mix the diluted sanitizer well before use.
- Apply solution with mop, cloth, [sponge], [brush], [scrubber], disposable wipe[r], [coarse spray device,] or by soaking or flooding, to fully wet all surfaces.
- Allow surfaces to remain wet for a minimum of 5 minutes and then allow to air dry, or if desired, wipe dry with a [sterilized] cloth or wipe[r] [of a suitable quality].

FOR USE AS A DISINFECTANT ON NON-FOOD CONTACT SURFACES

This product is a disinfectant for pre-cleaned, hard, non-porous surfaces.

[For Unit Dose bottle]: Add 3 bottles (7.68 fl. oz.) with water of suitable quality for the environment [such as] [water for injection] [deionized water] [USP water pharma grade] to make up 1 gallon (3.79 liters) of diluted disinfectant.

[For Metered Dose botte]: 7.68 fl. oz. (227 mL) should be diluted as a 3:47 dilution water of suitable quality for the environment [such as] [water for injection] [deionized water] [USP water pharma grade] to make 1 gallon (3.79 liters) of diluted disinfectant.

- Mix the diluted sanitizer well before use.
- Apply solution with mop, cloth, [sponge], [brush], [scrubber], disposable wipe[r], or by soaking or flooding, to fully wet all surfaces.
- Allow surfaces to remain wet for a minimum of 10 minutes and then allow to air dry, or if desired, wipe dry with a [sterilized] cloth or wipe[r] [of a suitable quality].

FOR USE AS A DISINFECTANT ON FOOD CONTACT SURFACES

This product is a disinfectant for pre-cleaned, hard, non-porous surfaces.

[For Unit Dose bottle]: Add 3 bottles (7.68 fl. oz.) with water of suitable quality for the environment [such as] [water for injection] [deionized water] [USP water pharma grade] to make up 1 gallon (3.79 liters) of diluted disinfectant.

[For Metered Dose botte]: 7.68 fl. oz. (227 mL) should be diluted as a 3:47 dilution water of suitable quality for the environment [such as] [water for injection] [deionized water] [USP water pharma grade] to make 1 gallon (3.79 liters) of diluted disinfectant.

- Mix the diluted sanitizer well before use.
- Apply solution with mop, cloth, [sponge], [brush], [scrubber], disposable wipe[r], or by soaking or flooding, to fully wet all surfaces.
- Allow surfaces to remain wet for a minimum of 10 minutes and then allow to air dry, or if desired, wipe dry with a [sterilized] cloth or wipe[r] [of a suitable quality].
- Follow with a potable water rinse.

FOR USE AS A FUNGICIDE ON NON-FOOD CONTACT SURFACES

This product is a fungicide for pre-cleaned, hard, non-porous surfaces.

[For Unit Dose bottle]: Add 5 bottles (12.8 fl. oz.) to water of suitable quality for the environment [such as] [water for injection] [deionized water] [USP water pharma grade] to make up 1 gallon (3.79 liters) of diluted fungicide.

[For Metered Dose botte]: 12.8 fl. oz. (379 mL) should be diluted as a 1:9 dilution with water of suitable quality for the environment [such as] [water for injection] [deionized water] [USP water pharma grade] to make 1 gallon (3.79 liters) of diluted fungicide.

- Mix the diluted sanitizer well before use.
- Apply solution with mop, cloth, [sponge], [brush], [scrubber], disposable wipe[r], or by soaking or flooding, to fully wet all surfaces.
- Allow surfaces to remain wet for a minimum of 10 minutes and then allow to air dry, or if desired, wipe dry with a [sterilized] cloth or wipe[r] [of a suitable quality].

FOR USE AS A FUNGICIDE ON FOOD CONTACT SURFACES

This product is a fungicide for pre-cleaned, hard, non-porous surfaces.

[For Unit Dose bottle]: Add 5 bottles (12.8 fl. oz.) to water of suitable quality for the environment [such as] [water for injection] [deionized water] [USP water pharma grade] to make up 1 gallon (3.79 liters) of diluted fungicide.

[For Metered Dose botte]: 12.8 fl. oz. (379 mL) should be diluted as a 1:9 dilution with water of suitable quality for the environment [such as] [water for injection] [deionized water] [USP water pharma grade] to make 1 gallon (3.79 liters) of diluted fungicide.

- Mix the diluted sanitizer well before use.
- Apply solution with mop, cloth, [sponge], [brush], [scrubber], disposable wipe[r], or by soaking or flooding, to fully wet all surfaces.
- Allow surfaces to remain wet for a minimum of 10 minutes and then allow to air dry, or if desired, wipe dry with a [sterilized] cloth or wipe[r] [of a suitable quality].
- Follow with a potable water rinse.

Use	Unit Dose	Metered Dose
Sanitizer	Add 1 bottle (2.6 fl. oz.) to make up 1 gallon (3.79) L	Dilute 2.6 fl. oz. (76 mL) at 1:49 dilution to make 1 gallon (3.79 L)
Disinfectant	Add 3 bottles (7.68 fl. oz.) to make up 1 gallon (3.79 L)	Dilute 7.68 fl. oz. (227 mL) at 3:47 dilution to make 1 gallon (3.79 L)
Fungicide	Add 5 bottles (12.8 fl. oz.) to make up 1 gallon (3.79 L)	Dilute 12.8 fl. oz. (379 mL) at 1:9 dilution to make 1 gallon (3.79 L)

Non-Food Contact Sanitizing			
Organism	ATCC Strain	Contact Time	Use Concentration
<i>Burkholderia cepacia</i>	ATCC 25416	5 minutes	2.56 fl. oz/1 gallon
<i>Enterobacter aerogenes</i>	ATCC 13048	5 minutes	2.56 fl. oz/1 gallon
<i>Escherichia coli</i>	ATCC 11229	5 minutes	2.56 fl. oz/1 gallon
<i>Pseudomonas aeruginosa</i>	ATCC 15442	5 minutes	2.56 fl. oz/1 gallon
<i>Staphylococcus aureus</i>	ATCC 6538	5 minutes	2.56 fl. oz/1 gallon
<i>Staphylococcus epidermidis</i>	ATCC 12228	5 minutes	2.56 fl. oz/1 gallon
Disinfection			
Organism	ATCC Strain	Contact Time	Use Concentration
<i>Staphylococcus aureus</i>	ATCC 6538	10 minutes	7.68 fl. oz/1 gallon
<i>Pseudomonas aeruginosa</i>	ATCC 15442	10 minutes	7.68 fl. oz/1 gallon
Fungicidal			
Organism	ATCC Strain	Contact Time	Use Concentration
<i>Candida albicans</i>	ATCC 10231	10 minutes	2.56 fl. oz/1 gallon
<i>Penicillium chrysogenum</i>	ATCC 10003	10 minutes	7.68 fl. oz/1 gallon
<i>Trichophyton interdigitale</i>	ATCC 9533	10 minutes	12.8 fl. oz/1 gallon

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store in the original container in a dry cool place. Absorb spills with inert dry absorbent or sand, then place in a chemical waste container.

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 HANDLING AND DISPOSAL:

[For containers 5 gallons or less]

Non-refillable container. Do not reuse or refill this container. Triple Rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. 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.

[For Use in [Industrial] [and/or] [Institutional] Applications]

[Lot Number / Batch Code XXXXXX]
EXPIRY: Day/Month/Year]

Net Contents: 2.6 US fl. oz. (76 mL) 1 US gal. (3.78 L)
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US EPA Reg. No. 1677-[pending]
US EPA Est. No.: 1677-GBR-001, 5389-NC-1 (G), 303-IN-1 (L)
Superscript refers to the first letter of the date code.

[Manufactured by:] [Distributed by:]
Ecolab Inc.
1 Ecolab Place
St. Paul, MN 55102
USA

[Made in Great Britain]
[Made in USA]

This product may be patented | Ce produit peut être breveté | Este producto puede ser patentado: www.ecolab.com/patents

(All rights reserved) (© insert year) (Ecolab USA Inc)
(Insert label number) (*****/****/****)

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Optional Claims [Marketing Claims]

- Concentrated [non-food contact sanitizer] [disinfectant] [fungicide] for hard, non-porous surfaces for use in cleanrooms and controlled areas, containing a quaternary ammonium compound blended with [WFI] [Water for Injection] [DI] [Deionized Water]
- [Aseptic Processed] [Sterile] [non-food contact sanitizer] [disinfectant] [fungicide]
- [Aseptic Processed] [rotational] [non-food contact sanitizer] [disinfectant] [fungicide] for use on hard, non-porous surfaces
- This [product] [non-food contact sanitizer] [disinfectant] [fungicide] is a blend of quaternary ammonium compound and [WFI] [Water for Injection] [Deionized Water] [USP Purified Water]
- No additional activators are required
- This [product] [non-food contact sanitizer] [disinfectant] [fungicide] is blended with [Water for Injection] [USP Water for Injection] [USP Purified Water] [Deionized Water] [DI Water]
- This [product] [non-food contact sanitizer] [disinfectant] [fungicide] is [single] [double] [triple] bagged [for easy transfer into cleanrooms]
- [Economical] [Cost effective] [Easy to use] [product]
- Total cost of ownership can be reduced by controlling indirect costs such as PPE and downtime
- [Insert product name] [This product] is [0.2 micron] [0.5 micron] filtered [aseptically filled] and [single] [double] [triple] bagged [under unidirectional air flow in cleanrooms using a strictly controlled and validated process]
- [Application Areas:] For use on floors, walls and hard, non-porous surfaces [in cleanrooms and controlled areas.]
- It is suitable for use on hard, non-porous surfaces in cleanrooms and controlled environments, isolators, LAFs (Laminar Air Flows), equipment and production vessel exteriors
- [Insert product name] [This product] can be used as part of a rotation with other Ecolab Contamination Control [products]
- Each bottle makes one gallon of diluted product
- [Efficacious] [Effective] against organisms commonly found in cleanrooms [*] while leaving minimal visible [residues] [streaks] [*e.g. *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Burkholderia cepacia*, *Pseudomonas aeruginosa*, *Candida albicans*, and *Penicillium chrysogenum*]
- When diluted as a sanitizer, it is the same concentration as [RTU] [Ready-to-use] Klercide Cleanroom Quat
- [This product] [insert product name] is a broad-spectrum disinfectant [that controls organisms commonly found in a controlled environment [*]] [*e.g. *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Burkholderia cepacia*, *Pseudomonas aeruginosa*, *Candida albicans*, and *Penicillium chrysogenum*]

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- [This product] [Insert product name] is compatible with other Klercide products for rotational use
- For optimum results, after the appropriate contact time, wipe the surface to physically remove any contaminants
- No rinse required when used on non-food contact surfaces
- This product is a [non-food contact sanitizer] [disinfectant] [fungicide] for use on hard, non-porous surfaces and leaves no visible [residues] [streaks], making it ideal for daily use [in all grades] [high grade] cleanrooms where visual cleanliness [to reduce contamination] is important
- This [product] [non-food contact sanitizer] [disinfectant] [fungicide] with minimal visible [residue] [streaking] is non-corrosive to most surfaces [and can be used in most cleanroom [cleaning] [and] [sanitizing] [disinfecting] [fungicidal] applications]
- [Insert product name] [this product] is formulated to leave [minimal] [low] visible [residues] [streaks] when used as a [non-food contact sanitizer] [disinfectant] [fungicide]
- [Insert product name] [this product] leaves no visible [residues] [streaks] when used as a non-food contact sanitizer, minimizing the need for [rinsing] [cleaning] to achieve visibly clean [non-product contact] surfaces within [cleanrooms] [controlled areas] to reduce contamination

Manufacturing Claims:

- Manufactured by an ISO 9001 facility
- Certificates of analysis [and sterility] with every batch
- [Insert product name] [this product] is [0.2 micron] [0.5 micron] filtered [to remove [particulates][particles] from end use product]
- [Insert product name] [this product] is manufactured in cleanrooms for use in cleanrooms.
- [Insert product name] [this product] is made in accordance to the principles of Good Manufacturing Practices



SECONDARY CONTAINER LABEL [Note to reviewer: This secondary container label will be used only when the product is diluted following the directions for use on the concentrate label.]

XLS-CQC

[Concentrate Ingredient Statement]

Active Ingredient:

Didecyl dimethyl ammonium chloride..... 1.84%

Other Ingredients: 98.16%

Total:..... 100.00%

The product in this container is diluted as directed on the pesticide product label.

Diluted product in this container is _____ oz. per gallon water.

KEEP OUT OF REACH OF CHILDREN

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Causes moderate eye irritation. Do not get in eyes, on skin or on clothing. Remove and wash contaminated clothing before use. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

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. 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.

Follow the directions for use on the concentrate label when applying this product.

Use solution prepared by end user.

Not for sale or distribution.

[DO NOT DRINK]

EPA Reg. No. 1677-[pending]