



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 22, 2016

Kevin R. Kutcel
Agent for ProNatural Brands, LLC
c/o KRK Consulting, LLC
5807 Churchill Way
Medina, OH 44256

Subject: PRIA Label Amendment – Adding organisms for food contact surfaces
Product Name: Lexx Liquid Sanitizer & Cleaner Concentrate
EPA Registration Number: 91452-1
Application Date: July 15, 2016
Decision Number: 519944

Dear Mr. Kutcel:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Tom Luminello by phone at (703) 308-8075, or via email at luminello.tom@epa.gov.

Sincerely,



Jacqueline Hardy, Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure Stamped Label

Notes to reviewer are bracketed []
Statements in parenthesis are optional or alternate text ()

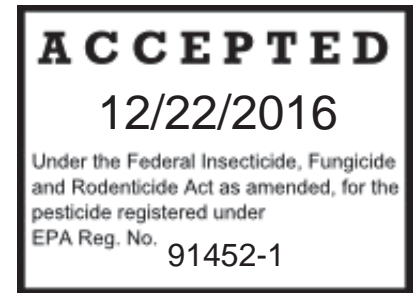
LEXX™ Liquid Sanitizer & Cleaner Concentrate

[The following company logo will be optionally included on the label]
(ProNatural Brands)



[Optional Marketing Statements]

(Detergent/Sanitizer)
(Milkstone Remover)
(Milkstone Preventer)
(Prevents and Removes Milkstone)
(Tea Brewer Cleaner & Sanitizer)
(Tea Brewer/Dispenser Cleanser and Sanitizer)
(Sanitizer)
(Sanitizer for Frozen Dessert Machines)
(Sanitizer for Frozen and Non-Frozen Dessert Machines)
(Sanitizer/Cleaner)
(Sanitizer/Cleaner for Frozen Dessert Machines)
(Sanitizer/Cleaner for Frozen and Non-Frozen Dessert Machines)
(Sanitizer and Cleaner for Frozen Dessert Machines)
(Sanitizer and Cleaner for Frozen and Non-Frozen Dessert Machines)
(Cleaner and Sanitizer for Frozen Dessert and Beverage Machines)
(Cleaner and Sanitizer for Frozen and Non-Frozen Dessert and Beverage Machines)
(General Purpose Cleaner and Sanitizer for Utensils, Dishes, Glasses, Food-Contact Machine
Parts, Floors, Countertops & Stationary Equipment Surfaces)
(General Purpose Cleaner and Sanitizer for Hard, Non-Porous Surfaces)
(Cleaner and Sanitizer for Ice Machine Bins and Evaporators)
(Sanitizer and Cleaner)
(Works exclusively with Hydra Rinse™)
(Hydra Rinse™)
(- Hydra Rinse™)
(For Hydra Rinse™)
(Kills 99.999% of bacteria on food contact surfaces within 1 minute)(,specifically, Escherichia coli, Staphylococcus aureus, Listeria monocytogenes, Salmonella enterica, and Campylobacter jejuni)



(One-step cleaner and sanitizer for hard, non-porous surfaces)
(Cleans and sanitizes without bleach)
(Cleans and sanitizes with no)(harsh fumes)(-and/or- bleach)
(Bactericide)(Bactericidal)(Antimicrobial)(Antibacterial)
(Suitable for use in (homes,)(schools,)(offices,)(hotels,)(food preparation facilities,)(restaurants,)(kitchens,)(cafeterias,)(food storage areas)(-and/or- fitness gyms)
(Kills odor causing bacteria)

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

For Institutional Use

ACTIVE INGREDIENT

Citric acid 25.0%

OTHER INGREDIENTS 75.0%

TOTAL 100.0%

EPA Reg. No. 91452-1

EPA Est. No. 74348-FL-1

(U.S. Patent xxxxx)

MAUFACTURED BY
PRONATURAL BRANDS, LLC
7870 LEHIGH CROSSING
VICTOR, NY 14564

(SDS) (and) (ingredients) (is) (are) (available at pronaturalbrands.com)

(Made in the USA)

(For general information and questions call: 1.585.433.2787)

(For emergency information contact a poison control center or 1.585.433.2787 and have the product container or label on hand)

Net Contents: (1.0 ounce) (2.0 ounces) (4.0 ounces) (5.0 ounces)
(1/2 gallon (64 ounces)) (1 gallon (128 ounces))

[For smaller package sizes the following wording may be included on the primary package]
(Not for individual sale)

[When necessary, the following will be added to the 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)

(See carton for more info)

[For Outer Carton] (Read precautionary statements on side panel.) [For Bottle] (Read additional Precautionary Statements on side panel.)

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

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.
FOR MEDICAL EMERGENCY INFORMATION CALL A POISON CONTROL CENTER OR 1.585.433.2787 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

Caution: Causes moderate eye and moderate skin irritation. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

PHYSICAL AND CHEMICALS HAZARDS

Combustible. Do not use or store near heat or open flame. Do not use in combinations with soaps, other detergents or chemicals. Do not use on electrical equipment.

[The NSF listed logo will be optionally included on the label on the back or side panel]



DIRECTIONS FOR USE

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

[Directions for Concentrates that are Manually Diluted]

**Lexx Liquid Sanitizer & Cleaner Concentrate required use dilution
[for concentrated liquid]**

(Food Contact Surface Sanitizing: 1 fluid oz. to 1 gal. water (1:128 dilution))

(Non-Food Contact Surface One-Step Cleaning and Sanitizing: 2 fluid oz. to 1 gal. water (1:64 dilution))

[Directions for 64 fl oz “EZ-Mix” (also called Pro Mix or Pro Mixx) Container that Automatically Dilutes Concentrate]

**Lexx Liquid Sanitizer & Cleaner Concentrate required use dilution
[for concentrated liquid]** (1 fluid oz. to 1 gal. water (1:128 dilution)).

- 1) Hook up the (EZ-Mix) (Pro Mix) (Pro Mixx) container to a water source.
- 2) Select either bottle or bucket dispensing using the selectable button
- 3) Squeeze the bottle trigger to dispense the diluted solution (1:128 dilution) into a bottle, bucket, or other suitable container

(REFER TO YOUR MACHINE OPERATOR’S MANUAL FOR DETAILED INSTRUCTIONS ON HOW TO CLEAN AND SANITIZE WITH LEXX)

(LEXX Liquid Sanitizer & Cleaner is used (for cleaning and sanitizing frozen and non-frozen dessert and beverage machines) (and) (for cleaning and sanitizing hard, non-porous surfaces) (such as:)

(Glass;) (Glazed ceramic and porcelain surfaces;) (Laminates;) (Metals;), (Plastics;) (Sealed natural and stone surfaces;) (Sealed cement surfaces;) (and) (Sealed tile))

[Directions for liquid concentrate]

MANUAL CLEANING AND SANITIZING FROZEN AND NON-FROZEN DESSERT AND BEVERAGE MACHINES

(Soft-serve ice cream & shake freezers,) (batch freezers,) (frozen yogurt,) (frozen custard,) (frozen carbonated beverages,) (smoothie machines,) (shaved iced machines,) (slush machines,) (Fruit and vegetable juice squeezers and dispensers,) (and/or) (Other frozen and non-frozen dessert and beverage machines)

MANUAL MACHINE CLEANING AND DISASSEMBLY INSTRUCTIONS

1. Refer to the machine manufacturer’s directions for detailed cleaning and sanitizing instructions.
2. Drain food product from hopper or (dispenser) and freezing or cooling cylinder.
3. Rinse with water until water is clear.
4. Dilute 1 to 2 fluid oz. of LEXX liquid concentrate into 1 gallon of warm water and pour into hopper/dispenser.
5. Follow the manufacturer’s wash instructions to circulate the LEXX sanitizing and cleaning solution to clean the machine. Alternatively, following the manufacturer’s instructions, manually brush clean the machine using the LEXX sanitizing and cleaning solution. Ensure that the sanitizing and cleaning solution is applied to all surfaces and stays wet for at least one minute.
6. Drain the LEXX sanitizing and cleaning solution completely.
7. Following the manufacturer’s directions, place all removable parts in a sink. Clean and sanitize by soaking for at least one minute using LEXX sanitizing and cleaning solution (1 fluid oz. of LEXX liquid concentrate into 1 gallon of warm water). Allow removable parts to dry. Follow local health codes.
8. Repeat procedures for each hopper or dispenser and freezing or cooling cylinder, but **DO NOT REUSE SOLUTION.**

MACHINE ASSEMBLY AND SANITIZING INSTRUCTIONS

1. Following the operator’s manual, assemble the machine and lubricate all required parts
2. Dilute 1 fluid oz. of LEXX liquid concentrate into 1 gallon of warm water to prepare a sanitizing solution. Pour into hopper (or dispenser).
3. Follow the manufacturer’s wash instructions to circulate the LEXX sanitizing solution and sanitize the machine for at least one minute.
4. Drain solution completely. **DO NOT RINSE.** Follow local health codes.
5. Repeat procedures for each hopper or dispenser and freezing or cooling cylinder, but **DO NOT REUSE SOLUTION.**

[AND/OR]

[Directions for liquid concentrate]

SEMI-AUTOMATED CLEANING AND SANITIZING FROZEN AND NON-FROZEN DESSERT AND BEVERAGE MACHINES USING THE HYDRA-RINSE CLEANING SYSTEM

(Soft-serve ice cream & shake freezers,) (batch freezers,) (frozen yogurt,) (frozen custard,) (frozen carbonated beverages,) (smoothie machines,) (shaved iced machines,) (slush machines,) (fruit and vegetable juice squeezers and dispensers,) (and/or) (Other frozen and non-frozen dessert and beverage machines)

SEMI-AUTOMATED CLEANING, DISASSEMBLY, AND SANITIZING INSTRUCTIONS

1. Follow manufacturer's directions to remove food product from machine.
2. For cleaning removable parts, mix 1 fluid oz. of LEXX liquid concentrate into 1 gallon of warm water.
3. Follow the Hydra Rinse Operator's Manual to remove any identified parts from the machine. Place the removed parts into the cleaning solution and thoroughly clean parts.
4. Follow Hydra Rinse Operator's Manual for installation on the machine and usage. Ensure that the LEXX liquid concentrate container is properly placed into the Hydra Rinse holder and present during operation and a water source is attached to the Hydra Rinse.
5. Following the Operator's Manual, start the Hydra Rinse and allow it to complete the washing and sanitizing cycles. During this process, the Hydra Rinse will automatically clean the machine with LEXX liquid concentrate diluted in a 1:128 ratio with tap water and then rinse the cleaned machine with water. The Hydra Rinse will then dilute the LEXX liquid concentrate in a 1:128 ratio with tap water to produce the sanitizing solution. The Hydra Rinse will circulate the sanitizing solution throughout the machine for a minimum of 2 minutes to ensure complete sanitization.
6. For the removed parts, mix another 1 fluid oz. of LEXX liquid concentrate into 1 gallon of warm water to prepare a sanitizing solution. Place the previously-cleaned parts into the sanitizing solution for at least 1 minute. Follow manufacturer's directions to reassemble the machine.
7. Remove the Hydra Rinse from the machine and drain any remaining solution from the machine. **DO NOT RINSE. DO NOT REUSE SOLUTION.** Follow local health codes.

[AND/OR]

[Directions for liquid concentrate]

MAINTENANCE PROCEDURES FOR ICED TEA BREWERS/DISPENSERS

1. Drain tea from brewer/dispenser and discard tea.
2. Dilute 1 fluid oz. of LEXX liquid concentrate per 1 gallon of warm water. Pour sanitizing and cleaning solution into brewer/dispenser.
3. Place the brew funnel into the sanitizing and cleaning solution and allow the solution to soak for at least one minute.
4. Remove brew funnel and drain approximately one half of the sanitizing and cleaning solution through the spigot. Drain the remainder by taking the brewer/dispenser to the sink, swirling the solution to suspend any particulates, and pouring the cleaning and sanitizing solution out from the top of the brewer/dispenser. Rinse out any remaining particulates with water, if needed.
5. Prepare a sanitizing solution by diluting 1 fluid oz. of LEXX liquid concentrate per 1 gallon of water and pour into brewer/dispenser.
6. Drain a small amount of sanitizing solution into a container and retain solution for soaking the spigot.
7. Place brew funnel into sanitizing solution for at least 1 minute, remove, and allow to air dry. DO NOT RINSE.
8. Drain sanitizing solution through the spigot and dump any residual solution out from the top of the brewer/dispenser. Allow to air dry. DO NOT RINSE. Follow local health codes. Dismantle spigot and soak in retained sanitizing solution for at least 1 minute. Remove spigot and allow to air dry. DO NOT RINSE.
9. Before brewing tea, reassemble the brewer/dispenser, spigot, brew funnel, and lid.

[AND/OR]

[Directions for liquid concentrate]

MANUAL CLEANING AND SANITIZING ICE MACHINES

Cleaning and Sanitizing the Ice Machine Evaporator

1. Follow the ice machine manufacturer's instructions to clean and sanitize the evaporator.
2. Turn off refrigeration, but leave the machine pump on.
3. Dilute 1 fluid oz. of LEXX liquid concentrate per 1 gallon of warm water to prepare a cleaning solution.
4. Following the ice machine manufacturer's instructions, pour the cleaning solution into the unit per manufacturer's instructions and allow to circulate for at least 30 minutes.
5. For areas that require cleaning but are not contacted by the cleaning solution, manually brush clean those areas using the cleaning solution.
6. Ice machine drums can be cleaned by soaking in solution prepared by diluting 1 fluid oz. of LEXX liquid concentrate per 1 gallon of warm water.
7. Drain the unit and rinse with fresh water.
8. Prepare a sanitizing solution by diluting 1 fluid oz. of LEXX liquid concentrate per 1 gallon of water.
9. Sanitize the ice machine evaporator by pouring the sanitizing solution into the unit per the manufacturer's instructions. Ensure that the sanitizing solution completely contacts all required evaporator surfaces for at least 1 minute.
10. Drain sanitizing solution. **DO NOT RINSE.**

Cleaning and Sanitizing the Ice Machine Bin

1. Follow the ice machine manufacturer's instructions to clean and sanitize the ice bin.
2. Turn off the machine and water supply.
3. Remove ice from bin and discard.
4. Dilute 1 fluid oz. of LEXX liquid concentrate per 1 gallon of warm water to prepare a cleaning solution.
5. Following the ice machine manufacturer's instructions, pour the cleaning solution into the ice bin.
6. Brush clean the ice bin.
7. For any removable parts that require cleaning, soak in a solution prepared by diluting 1 fluid oz. of LEXX liquid concentrate per 1 gallon of warm water.
8. Prepare a sanitizing solution by diluting 1 fluid oz. of LEXX liquid concentrate per 1 gallon of water.
9. Follow steps 5 – 7 above using the prepared sanitizing solution, making sure the solution completely covers the whole surface for at least 1 minute. Drain solution. **DO NOT RINSE.** Follow local health codes.

[AND/OR]

[Directions for liquid concentrate]

COUNTERTOPS & STATIONARY FOOD PROCESSING EQUIPMENT SURFACES

1. Clean surfaces using a solution prepared by mixing 1 to 2 fluid oz. of LEXX liquid concentrate per 1 gallon of warm water.
2. Rinse surfaces with potable water.
3. Mix the appropriate amount of sanitizing solution by diluting 1 fluid oz. of LEXX liquid concentrate per 1 gallon of warm water.
4. Sanitize surfaces by applying solution with a clean cloth, sponge, spray, or completely flood surface making sure the solution completely covers the whole surface for at least 1 minute. Let air dry. **DO NOT RINSE.** Follow local health codes.

[AND/OR]

[Directions for liquid concentrate]

GENERAL PURPOSE CLEANING AND SANITIZING

(Hard, non-porous surfaces, such as sinks, cutting boards, counter tops, salad preparation surfaces, utensils, dishes, glasses, and miscellaneous food-contact machine parts in kitchens, restaurants, other eating establishments, dairies, and food processing plants)

1. Rinse and remove all loose food soil substances.
2. Dilute 1 to 2 fluid oz. of LEXX liquid concentrate per 1 gallon of warm water.
3. Clean surfaces by applying solution to surface via various means such as low-pressure spray, wiping, brushing, or dipping.
4. Rinse with potable water.
5. Make sanitizing solution by diluting 1 fluid oz. of LEXX liquid concentrate per 1 gallon of warm water.
6. Apply sanitizer via various means such as low-pressure spray, wiping, brushing, or dipping.
7. Allow sanitizer to completely wet surfaces for at least one minute or for a contact time specified by local health codes.
8. Drain and allow sanitized surfaces to air dry. **DO NOT RINSE.** Follow local health codes.

[AND/OR]

[Directions for liquid concentrate]

ONE-STEP CLEANING AND SANITIZING OF NON-FOOD CONTACT SURFACES
(Hard, non-porous surfaces, such as (floors,)(walls,)(garbage cans,)(sports equipment,)(prostheses and orthotics,)(car, boat, airplane and train surfaces and cavities,)(finished woodwork,)(laminated surfaces,)(glazed tile,)(metals,)(glass,)(fiberglass,)(plastic,)(-and/or- vinyl and similar polymers) and any other non-porous surface where bacteria or unpleasant odors are a concern.)

1. Dilute 2 fluid oz. of LEXX liquid concentrate per 1 gallon of warm water.
2. For heavily soiled areas, clean excess dirt first.
3. Clean and sanitize surfaces by applying solution to surface via various means such as low-pressure spray, wiping, brushing, or dipping.
4. Allow sanitizer to completely wet surfaces for at least two minutes.
5. Drain, wipe, or remove any excess and allow sanitized surfaces to air dry. No rinsing is required.

Food contact surface list of microorganisms for sanitization applications	ATCC #	Kill Rate
Salmonella enterica	10708	99.999% in 1 minute
Escherichia coli (E. coli)	11229	99.999% in 1 minute
Campylobacter jejuni	29428	99.999% in 1 minute
Listeria Monocytogenes (Listeria)	15313	99.999% in 1 minute
Staphylococcus aureus (Staph)	6538	99.999% in 1 minute

Non-Food contact surface list of microorganisms for sanitization applications	ATCC #	Kill Rate
Enterobacter aerogenes	13048	99.9% in 2 minutes
Staphylococcus aureus (Staph)	6538	99.9% in 2 minutes

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Combustible. Do not use or store near heat or open flame. Store in cool, dry, well-ventilated area. Keep product container closed and tightly capped when not in use.

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

CONTAINER HANDLING: [Outside carton] (Carton:) Offer for recycling, if available, or discard in trash. [1 gal. plastic bottle] (Bottle:) Nonrefillable 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. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this procedure two more times. Offer for recycling, if available, or discard in trash.