

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 20, 2020

Kevin Kutcel Agent ProNatural Brands, LLC 7870 Lehigh Crossing Road, Suite 1 Victor, NY 14564

Subject: Label Amendment: Emerging Viral Pathogens Claim

Product Name: Lexx Liquid Sanitizer & Cleaner Concentrate

EPA Registration Number: 91452-1 Application Date: March 9, 2020

Decision Number: 561022

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.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging viral pathogen program guidance final 8 19 16 001 0.pdf, you are

09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

- 2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
- 3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for "U.S. Based Outbreaks" (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (www.cdc.gov/outbreaks) (also released through the CDC's Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page

(www.oie.int/wahis 2/public/wahid.php/Diseaseinformation/WI).

- A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroups are large non-enveloped and enveloped.
- B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
- 4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE's publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

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5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Feline calicivirus (Norovirus surrogate) is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

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, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,

Steven Snyderman, Acting Product Manager 33

Regulatory Management Branch 1 Antimicrobials Division (7510P) Office of Pesticide Programs

Steven Inyderman

Enclosure: stamped label

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

LEXXTM Liquid Sanitizer & Cleaner Concentrate

Alternate Brand Name LEXXTM

[The following company logos 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)

ACCEPTED

04/20/2020

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 24450

91452-1

(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) (Cleaner and Sanitizer for (Draught)(Draft)(Craft) Beer Lines) (Cleaner and Sanitizer for Wineries) (Cleaner and Sanitizer for Winery Equipment and Wine Lines) (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 RinseTM) (Hydra RinseTM) (- Hydra RinseTM) (For Hydra RinseTM) (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)

(Vanilla Scented)

(Vanilla Scent)

(Now with a Vanilla Scent)

(Scented with Vanillin)

(New Scent)

(Bactericide -or- Bactericidal)

(Broad spectrum disinfectant [cleaner])

(Cleaner and disinfectant)

(Cleans, disinfects and deodorizes)

(Designed for healthcare)

(Disinfecting formula)

(Disinfects -and/or- deodorizes -and/or- kills -and/or- removes bacteria)

(For healthcare use)

(For hospital use)

(For terminal cleaning)

(Hospital disinfectant cleaner)

(Kills and cleans)

(Use in places you are concerned about bacteria -and/or- viruses)

(Use -or- cleans and disinfects on healthcare surfaces)

(Versatile cleaner disinfectant)

(Cleaner)

(Disinfectant)

(Detergent)

(Virucide)

(Deodorizer)

(For Hospital, Medical, Institutional, and Industrial Use)

(Hospital grade broad spectrum disinfectant)

(General Purpose disinfectant)

(Disinfectant, Sanitizer, and Cleaner Concentrate)

(Sanitizer and Cleaner Concentrate)

(Disinfectant and Cleaner Concentrate)

(Disinfectant, Sanitizer, and Cleaner)

(Liquid Disinfectant, Sanitizer, and Cleaner Concentrate)

(Liquid Sanitizer and Cleaner Concentrate)

(Liquid Disinfectant and Cleaner Concentrate)

(Liquid Disinfectant, Sanitizer, and Cleaner)

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: 1.844.836.3856) (or) (customercare@pronaturalbrands.com)

(For emergency information contact a poison control center or 1.844.836.3856 and have the product container or label on hand)

Net Contents: (0.25 ounce) (0.5 ounce) (1.0 ounce) (1.5 ounces) (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.		
CENTER OF Have the pro	CAL EMERGENCY INFORMATION CALL A POISON CONTROL R 1.844.836.3856 oduct container or label with you when calling a poison control center or ing 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))

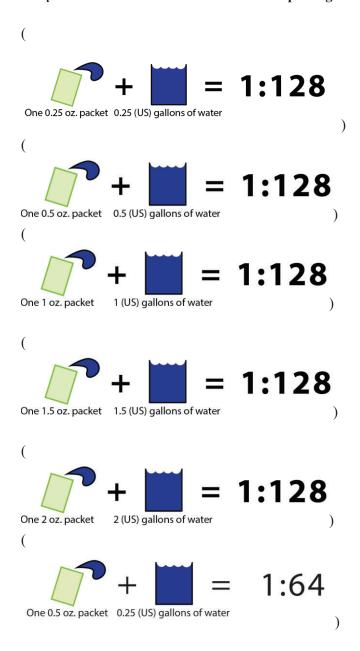
(Non-Food Contact Surface Disinfection: 4 fluid oz. to 1 gal. water (1:32 dilution))

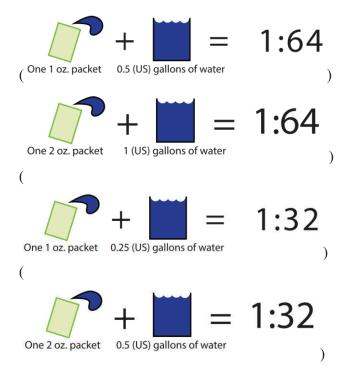
[Directions for 64 fl oz "EZ-Mix" (also called Pro Mix or Pro Mixx) Container that Automatically Dilutes Concentrate]

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

[Icons that will be included on smaller package sizes to aid with LEXX concentrate dilution]





(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 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 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 water to prepare a sanitizing solution. Pour into hopper (or dispenser) of assembled machine that has surfaces to be sanitized at room temperature.
- 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.

[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 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, with the rinsed surfaces at room temperature after the cleaning/rinsing process. 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, which has surfaces to be sanitized at room temperature, 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 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.

[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 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 NOTE 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.

[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 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 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, at room temperature, 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 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 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, at room temperature, for at least 1 minute. Drain solution. DO NOT RINSE. Follow local health codes.

[Directions for liquid concentrate]

MANUAL CLEANING AND SANITIZING BEER AND WINE LINES AND EQUIPMENT

Cleaning Beer and Wine Lines and Equipment

- 1. Follow the beer or wine dispensing equipment manufacturer's directions for dissembling the lines and associated dispensing equipment such as valves.
- 2. Thoroughly drain lines of any fluid.
- 3. Dilute 1 fluid oz. of LEXX liquid concentrate per 1 gallon of water to prepare a cleaning solution.
- 4. Clean removed parts, such as valves, using the diluted LEXX solution.
- 5. Follow the beer or wine dispensing equipment manufacturer's directions for cleaning the lines with diluted LEXX solution.
- 6. After initial cleaning, let the LEXX solution soak the lines for at least 2 minutes.
- 7. Drain the lines of the LEXX solution and remove any parts from the diluted LEXX solution.

Sanitizing Beer and Wine Lines and Equipment

- 1. Prepare a sanitizing solution by diluting 1 fluid oz. of LEXX liquid concentrate per 1 gallon of water.
- 2. Sanitize removed parts by spraying or dipping them with the LEXX sanitizing solution and letting the LEXX solution contact the parts for at least 1 minute. Drain excess liquid but DO NOT RINSE. Follow local health codes.
- 3. Sanitize the lines using the LEXX sanitizing solution and let the LEXX solution sit in the lines for at least 1 minute. Drain excess liquid but DO NOT RINSE. Follow local health codes.
- 4. Reassemble the beer or wine dispensing equipment.
- 5. Run a small amount of beer or wine through the dispensing equipment to flush any excess LEXX sanitizing solution and discard.

[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 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 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.

[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 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 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 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.

[Directions for liquid concentrate]

DISINFECTING NON-FOOD CONTACT SURFACES

Cleaning Non-Food Contact Surfaces

- 1. Make cleaning solution by diluting 1 to 4 fluid oz. of LEXX liquid concentrate per 1 gallon of water.
- 2. Clean surfaces by applying solution to surface via various means such as low-pressure spray, wiping, brushing, or dipping.
- 3. Rinse surface with potable water.

Disinfecting Non-Food Contact Surfaces

- 1. Make disinfecting solution by diluting 4 fluid oz. of LEXX liquid concentrate with water to a total of 1 gallon.
- 2. Disinfect surfaces by applying solution to surface via various means such as low-pressure spray, wiping, brushing, or dipping.
- 3. Allow disinfectant to completely wet surfaces.
- 4. Surfaces must remain wet for at least ten minutes.
- 5. Drain, wipe, or remove any excess and allow disinfected surfaces to air dry. DO NOT RINSE.

[Use Sites: may be listed on product label]

(Airplanes)(Locker rooms)(Bathroom)(Nursing home)(Blood bank)(Office building)(Boats)(Patient room)(Breweries)(Pharmacy)

(Buses and automobiles)
(Clinic)
(Commercial kitchens)
(Day care center)
(Physician's office)
(Public eating places)
(Recreational center)

(Dental office) (Restaurant) (Distilleries) (Restrooms)

(Doctor's office) (School bus/vehicle)

(Food service facilities) (Schools) (Gymnasium) (Shelters)

(Health care facility) (Sports care and athletic facilities)

(Health club)(Trains)(Hospital)(Trucks)(Hotel/motel)(Vehicles)

(Kennel)(Veterinary office)(Laboratories)(Waiting room)(Laundromat)(Weight room)(Laundry rooms)(Wineries)

[Additional hard, non-porous surfaces: may be listed on product label]

(Bathroom surfaces) (Pens) (Bathtub) (Plastic)

(Bidet) (Polypropylene)
(Brass) (Portable pet carriers)
(Cabinets) (Portable toilet)

(Car, boat, airplane, and train surfaces and (Prostheses and orthotics)

cavities) (PVC)

(Ceramic floor) (Recycling bins)

(Chairs) (Refrigerator [exteriors] [interiors at room

(Chrome)temperature])(Countertops)(Sealed granite)(Desk)(Sealed marble)(Door knob)(Sealed quartz)(Drinking fountains)(Sealed stone)

(Examination tables) (Shower curtain [plastic])

(Faucets) (Sinks)

(Fiberglass)
(Fixtures)
(Floors)
(Floors)
(Furniture)
(Garbage [cans] [pails] [bins])
(Glass)
(Class 1 consists [tital)
(Sports equipment)
(Stainless steel)
(Stretchers)
(Table tops)
(Telephones)
(Toilet seats)

(Glass) (Toilet se (Glazed ceramic [tile]) (Tools) (Glazed porcelain [tile]) (Urinals)

(Laminate [surfaces]) (Veterinary care surfaces)

(Linoleum)(Vinyl)(Metal)(Vinyl [tile])(Mirror)(Walls)

(Outdoor [patio] furniture) (Washable walls)
(Parquet) (Wheelchairs)

(Patient chairs) (Whirlpool interiors)

[The following statement only to be used on institutional labels with medical use sites, medical devices and/or bloodborne pathogens]

(This product is not to be used as a terminal 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.)

(To Preclean Instruments Prior to Terminal Sterilization/High Level Disinfection:

As a precleaning spray - Place instruments into a suitable container. Spray diluted LEXX (1:32 dilution) onto instruments to thoroughly wet all surfaces. Let stand for up to 10 minutes. Rinse instruments.

As a manual instrument cleaner - Thoroughly pre-rinse dirty instruments under running water to remove visible, gross debris. Immerse prerinsed instruments into an appropriate size container filled with LEXX (1:32 dilution). Scrub instruments using a stiff bristle brush until visibly clean. Submerge instruments while scrubbing. Rinse instruments thoroughly. Change solution daily. Follow with an appropriate disinfection process. Cleaning of critical and semi-critical devices must be followed by an appropriate terminal sterilization/high-level disinfection process.)

(To Disinfect Non-Critical, Precleaned Instruments:

Instruments must be thoroughly precleaned to remove excess organic debris, rinsed, and rough dried. Clean and rinse lumens of hollow instruments. Spray visible surfaces of lumens with this product. Only clearly visible surfaces of instruments can be pre-cleaned with LEXX. Spray all surfaces of instruments with LEXX (1:32 dilution) until thoroughly wet. Let stand for 10 minutes. Wipe with a clean, damp cloth or paper towel and allow to air dry.)

(Hospitals/Healthcare facilities:

LEXX cleans, disinfects and deodorizes hard, nonporous (hospital) (-and/or- medical) surfaces. When used as directed, LEXX diluted 1:32 is effective as a disinfectant on hard, nonporous surfaces. Removes dirt, grime, fungus, mold, food residue, blood and other organic matter commonly found in hospitals (in -and/or- health care facilities) (on medical surfaces). It (also) eliminates odors leaving surfaces smelling clean and fresh. Use where odors are a problem. LEXX is a concentrated (broad spectrum) (disinfectant) cleaner and deodorizer designed for general cleaning (and) disinfecting (deodorizing) (of) hard, nonporous surfaces. Removes dirt, grime, mold, food residue, blood and other organic matter commonly found in hospitals (in healthcare facilities) (on medical surfaces).)

Food contact surface list of microorganisms	ATCC #	Kill Rate
for sanitization applications	11100	12111
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

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ATCC #	Kill Rate
13048	99.9% in 2 minutes
6538	99.9% in 2 minutes
	13048

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Surface list of microorganisms for disinfectant	ATCC#	Contact Time
applications		
Staphylococcus aureus	6538	10 minutes
Pseudomonas aeruginosa	15442	10 minutes
Escherichia coli	11229	10 minutes
Klebsiella pneumoniae (CRE)	BAA-2146	10 minutes
Acinetobacter baumannii (MDR)	BAA-1605	10 minutes
Staphylococcus aureus (MRSA)	33591	10 minutes
Feline calicivirus, Strain F-9 (norovirus	VR-782	10 minutes
surrogate)		

Emerging Pathogens Statement

[The following statements shall be made only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.]

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- -Enveloped Viruses
- -Large Non-Enveloped Viruses

For an emerging viral pathogen that is a/an	follow the directions for use for the
	following organisms on the label:
Enveloped virus	Feline calicivirus (Norovirus surrogate)
Large, non-enveloped virus	Feline calicivirus (Norovirus surrogate)

LEXX Liquid Sanitizer & Cleaner Concentrate has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, LEXX Liquid Sanitizer & Cleaner Concentrate can be used against [name of emerging virus] when used in accordance with the directions for use against Feline calicivirus, Strain F-9 (norovirus surrogate) on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. LEXX Liquid Sanitizer & Cleaner Concentrate kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against Feline calicivirus, Strain F-9 (norovirus surrogate) on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.)

STORAGE AND DISPOSAL

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

PESTCIDE 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 ½ 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.