



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

EPA Reg. Number:

91452-6

Date of Issuance:

6/28/21

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

LEXX RTU Liquid Contact Surface
Disinfectant & Cleaner

Name and Address of Registrant (include ZIP Code):

Frank R. Terranova
ProNatural Brands, LLC
1600 Moseley Road, Suite 600
Victor NY, 14564

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 unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
2. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.

Signature of Approving Official:

Demson Fuller, Product Manager 32
Regulatory Management Branch I
Antimicrobials Division (7510P)

Date:

6/28/21

3. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 91452-6.”
4. The alternate brands Lexx® and ProNatural Brands® are acceptable.
5. Submit one copy of the revised 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.

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 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 subgroup is (large non-enveloped, 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.
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.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. 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 10/06/20
- Alternate CSF 1 dated 03/03/21

Page 4 of 4
EPA Reg. No. 91452-6
Action Case Number/Decision No. 00217482

If you have any questions, you may contact Emilia Oiguenblik at via email at Oiguenblik.emilia@epa.gov or Demson Fuller at Fuller.demson@epa.gov

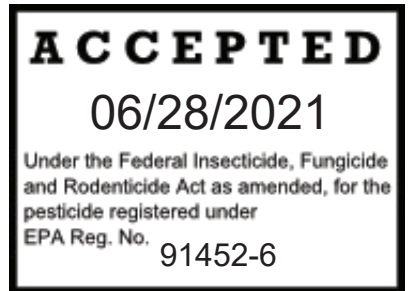
Sincerely,

A handwritten signature in black ink, appearing to read 'DF', with a long horizontal stroke extending to the right.

Demson Fuller, Product Manager 32
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

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

LEXX[®] RTU Liquid Contact Surface Disinfectant & Cleaner



**KEEP OUT OF REACH OF CHILDREN
CAUTION**

For Household, Institutional and Commercial Use

ACTIVE INGREDIENT

Citric acid 0.90%

OTHER INGREDIENTS 99.10%

TOTAL 100.0%

EPA Reg. No. 91452-xx

EPA Est. No. 74348-FL-001

(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: (4.0 ounces) (5.0 ounces) (22 ounces) (24 ounces) (28 ounces) (32 ounces)
(33.8 ounces) (48 ounces)(1/2 gallon (64 ounces)) (67.6 ounces) (1 gallon (128 ounces)

[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 1.844.836.3856 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: Can causes eye and 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

Do not use in combinations with soaps, other detergents or chemicals. Do not use on electrical equipment.

[Optional Marketing Statements]

(Kills tested bacteria on hard non-porous surfaces within 10 minute) (specifically Escherichia coli, Staphylococcus aureus, Listeria monocytogenes, Salmonella enterica, and Campylobacter jejuni) (No harsh fumes)(-and/or- bleach)
(Bactericide)(Bactericidal)(Antimicrobial)(Antibacterial)
(Suitable for walls and floors 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])
(Bactericide -or- Bactericidal)
(Broad spectrum disinfectant [cleaner])
(Cleaner and disinfectant)
(Cleans, disinfects and deodorizes)
(Designed for healthcare)
(For healthcare use)
(Disinfecting formula)
Kills tested bacteria on hard non-porous surfaces
(For hospital use)
(For terminal cleaning)
(Kills and cleans)
(Use -or- cleans and disinfects on hard non-porous surfaces)
(Cleaner)
(Detergent)
(Virucide) against Feline calicivirus, Strain F-9 (which is a norovirus surrogate)
(Deodorizer)
(For Household, Hospital, Medical, Institutional, and Industrial Use) (Disinfectant and Cleaner)
(Liquid Disinfectant, and Cleaner)
Cleans with the power of Citric Acid
Kills 99.99% of bacteria on hard non-porous surfaces within 10 minute

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



[AND/OR]

[Directions for LEXX® RTU Liquid Contact Surface Disinfectant & Cleaner]

Cleaning Non-Food Contact Surfaces

1. Use this container of LEXX® RTU Liquid Contact Surface Disinfectant & Cleaner.
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. Thoroughly preclean all hard, non-porous surfaces prior to disinfection
2. Use this bottle of LEXX® RTU Liquid Contact hard non-porous surfaces Surface Disinfectant & Cleaner solution to disinfect Non-Food contact surfaces.
3. Disinfect surfaces by applying solution to surface via various means such as low-pressure spray, wiping, brushing, or dipping.
4. Allow disinfectant to completely wet surfaces.
5. Surfaces must remain wet for at least ten minutes.
6. Drain, wipe, or remove any excess product and allow disinfected surfaces to air dry. DO NOT RINSE.

[Use Sites: may be listed on product label]

- | | |
|-------------------------|---------------------------------------|
| (Airplanes) | (Laundromat) |
| (Bathroom) | (Laundry rooms) |
| (Blood bank) | (Locker rooms) |
| (Boats) | (Nursing home) |
| (Buses and automobiles) | (Office building) |
| (Clinic) | (Patient room) |
| (Day care center) | (Pharmacy) |
| (Dental office) | (Physician's office) |
| (Doctor's office) | (Public eating places) |
| (Gymnasium) | (Public facility) |
| (Health care facility) | (Recreational center) |
| (Health club) | (Restrooms) |
| (Hospital) | (School bus/vehicle) |
| (Hotel/motel) | (Schools) |
| (Kennel) | (Shelters) |
| (Laboratories) | (Sports care and athletic facilities) |

(Trains)	(Veterinary office)
(Trucks)	(Waiting room)
(Vehicles)	(Weight room)

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

(Bathroom surfaces)	(Plastic)
(Bathtub)	(Polypropylene)
(Bidet)	(Portable pet carriers)
(Brass)	(Portable toilet)
(Cabinets)	(Prostheses and orthotics)
(Car, boat, airplane, and train surfaces and cavities)	(PVC)
(Ceramic floor)	(Recycling bins)
(Chairs)	(Sealed granite)
(Chrome)	(Sealed marble)
(Desk)	(Sealed quartz)
(Door knob)	(Sealed stone)
(Examination tables)	(Shower curtain [plastic])
(Fiberglass)	(Sinks)
(Fixtures)	(Sports equipment)
(Floors)	(Stainless steel)
(Furniture)	(Stretchers)
(Garbage [cans] [pails] [bins])	(Table tops)
(Glass)	(Telephones)
(Glazed ceramic [tile])	(Toilet seats)
(Glazed porcelain [tile])	(Tools)
(Laminate [surfaces])	(Urinals)
(Linoleum)	(Veterinary care surfaces) (Vinyl)
(Metal)	(Vinyl [tile])
(Mirror)	(Walls)
(Outdoor [patio] furniture)	(Washable walls)
(Parquet)	(Wheelchairs)
(Patient chairs)	(Whirlpool interiors)
(Pens)	

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

(LEXX® RTU Liquid Contact Surface Disinfectant & Cleaner 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 LEXX® RTU Liquid Contact Surface Disinfectant & Cleaner solution 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. Pour this complete bottle of LEXX® RTU Liquid Contact Surface Disinfectant & Cleaner into a container and Immerse pre-rinsed instruments in the solution. 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® RTU Liquid Contact Surface Disinfectant & Cleaner. Spray all surfaces of instruments with a fresh solution of LEXX® RTU Liquid Contact Surface Disinfectant & Cleaner 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® RTU Liquid Contact Surface Disinfectant & Cleaner cleans, disinfects and deodorizes hard, nonporous (hospital) (-and/or- medical) surfaces. When used as directed, this LEXX® RTU Liquid Contact Surface Disinfectant & Cleaner is effective as a disinfectant on hard, nonporous surfaces. It (also) eliminates odors leaving surfaces smelling clean and fresh. Use where odors are a problem.

LEXX® RTU Liquid Contact Surface Disinfectant & Cleaner is a (broad spectrum) (disinfectant) cleaner and deodorizer designed for general cleaning (and) disinfecting (deodorizing) (of) hard, nonporous surfaces.

Surface list of microorganisms for disinfectant applications	ATCC #	Contact Time
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 surrogate)	VR-782	10 minutes

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

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

LEXX® RTU Liquid Contact Surface Disinfectant & Cleaner has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, LEXX Liquid Disinfectant & Cleaner 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® RTU Liquid Contact Surface Disinfectant & Cleaner 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.

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.