



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

May 15, 2023

Frank R. Terranova  
Registering Agent  
ProNatural Brands Inc.  
7870 Lehigh Crossing, Suite 1  
Victor, NY 14564  
[frtnovab@cs.com](mailto:frtnovab@cs.com)

Subject: PRIA Label Amendment – Adding Efficacy Claims  
Product Name: LEXX RTU Liquid Food Contact Surface Disinfectant & Cleaner  
EPA Registration Number: 91452-6  
Received Date: 06/06/2022  
Action Case Number: 00368993

Dear Mr. Terranova:

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. Pursuant to 40 CFR 156.10(a)(6), 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 FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). 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) lists 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, FIFRA section 12(a)(1)(B). 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 Assurance.

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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 Terria Northern by email at [northern.terria@epa.gov](mailto:northern.terria@epa.gov)

Sincerely,



Marcel Howard, Product Manager, Team 34  
Regulatory Management Branch II  
Antimicrobials Division (7510M)  
Office of Pesticide Programs

Enclosure: Approved label

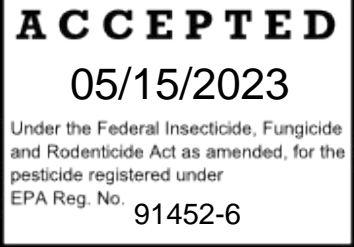
# LEXX<sup>®</sup> RTU Liquid Contact Surface Disinfectant & Cleaner



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

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**

(Store in cool, dry (,) (well-ventilated area) (-or-) (place))  
(Eye and Skin Irritant) (See side (back) panel(s) for additional precautionary statements)



**For Household, Institutional and Commercial Use**

**ACTIVE INGREDIENT**

Citric Acid .....	0.90%
<b>OTHER INGREDIENTS</b> .....	99.10%
TOTAL	100.0%

EPA REG. NO. 91452-6  
EPA EST. NO. (as indicated on container / label)  
(Beginning of) (batch) (lot) code indicates EPA (Est.) (Establishment) (#) (No.) (Number)

(U.S. Patent xxxxx)  
MAUFACTURED BY  
PRONATURAL BRANDS, INC.  
7870 LEHIGH CROSSING  
VICTOR, NY 14564

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

(Made in the USA)

(For general information and questions) (call: (1.844.836.3856) (or) (and)  
(email: ) ( [customercare@pronaturalbrands.com](mailto: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) (16 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) (See (side) (back) (panel(s)) for additional Precautionary Statements)

[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]**

**{Note to reviewer: the following may be used to identify both the producer, supplemental distributor and a specific retailer (who is not the registrant or a supplemental distributor). Brand graphics for the company or retailer may be added to accompany identified parties}**

**(Manufactured by) (Made by) (Produced by) {insert producer only}**

**(Distributed by)(sold by)(Packed for) {insert supplemental distributor only}**

**(Made for) (marketed by) (sold (exclusively) by) {insert supplemental distributor or retailer that is not also a supplemental distributor}**

<b>FIRST AID</b>	
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.
<b>FOR MEDICAL EMERGENCY INFORMATION CALL A POISON CONTROL CENTER OR 1.844 .836.3856</b> <b>Have the product container or label with you when calling a poison control center or doctor, or going for treatment</b>	

## **PRECAUTIONARY STATEMENTS**

### **Hazards to Humans and Domestic Animals**

Caution: Can cause 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 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.

**{Note to reviewer: All areas where Brand Name, Additional Brand Name, Product name is used to refer to the action to be taken, can be replaced throughout label to be referred as (This) (this) (Product) (product)}**

## [ Optional Marketing Statements]

(Kills Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus)<sup>3</sup> in 1(-) minute (60(-) seconds))  
(Kills (SARS-CoV-2) (COVID-19 Virus)<sup>3</sup> in 1(-) minute (60(-) seconds))  
(Kills SARS-CoV-2 which causes COVID-19 on hard non-porous surfaces IN (1(-) MINUTE(!)) (or) (60(-) SECONDS(!))  
(Kills (the) COVID-19 Virus (\*\* refer to back label<sup>1,2,3</sup>) Kills SARS-CoV-2<sup>2</sup> on hard non-porous surfaces)<sup>2</sup>  
(Virucide<sup>2,3</sup>)\*, against Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus)<sup>3</sup>  
Kills (the) COVID-19 Virus<sup>3</sup>,\*\*;"Effective against SARS-CoV-2<sup>3</sup>\*\*;"Kills SARS-CoV-2<sup>3</sup>\*\* (in) (just) (1(-)minute)(60(-)seconds)"  
(Formulated with (natural) ingredients)  
(No Rinse required!) (Multi-purpose cleaner)  
(Botanical Formulation)  
(Contains ingredients listed as full green circle, on the Safer Choice list)  
(Naturally occurring raw ingredients) (naturally derived formulation)  
(Using (Lexx® RTU Disinfectant cleaner) (-or-) (this product) will leave all areas in your home, office, and schools, smelling fresh & clean)  
(No more concerns when using (Lexx® RTU Disinfectant cleaner) (-or-) (this product) in your daily cleaning)  
(Cleans with the power of Citric Acid, naturally)  
(Cleans and Disinfects without (any) (odors) (or) Bleach)  
(Kills 99.99% of bacteria, when used according to directions for disinfection<sup>1</sup>\*\*) (\*\*see back (-or-) (side) panel for more information<sup>1,2,3</sup>)  
(\*\*Kills tested bacteria<sup>1</sup> on hard non-porous surfaces within 10-minutes)  
(Sustainable Cleaning = Sustainable living)  
(Citric Acid! The Power of Clean)  
(Don't Just Rinse...Clean with Lexx®)  
(Citrus Fresh Scent) (New Citrus Fresh Scent) (Now with Citrus Oil Scent)  
(Fresh Lavender Scent) (Fresh Clean Scent) (Fresh Floral Scent) (New Fresh Lavender Scent) (New (Fresh) (Clean) Scent)  
(\*\* See back (-or-) (side) panel for all organisms that Lexx® Kills in its contact time, when used as directed<sup>1,2,3</sup>)  
(Kills tested bacteria on hard non-porous surfaces within 10 minutes<sup>1</sup>) (\*\* specifically Staphylococcus aureus<sup>1</sup>, Pseudomonas aeruginosa<sup>1</sup>,  
Escherichia coli<sup>1</sup>, Klebsiella pneumoniae (CRE)<sup>1</sup>, Acinetobacter baumannii (MDR)<sup>1</sup>, Staphylococcus aureus (MRSA)<sup>1</sup>)  
(No more chemical fumes) (-and/or- bleach odors)  
(Bactericide)(Bactericidal)(Antimicrobial)  
(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<sup>1</sup>)  
(Disinfects non-food contact surfaces in (ten) (-or-) (10-) minutes for the following organisms<sup>1</sup>\*\*)  
(\*\*see back (-or-) (side) panel for more information<sup>1,2,3</sup>)  
(For hospital use)  
(For terminal cleaning)  
(Kills and Cleans)  
(Use -or- cleans and disinfects on hard non-porous surfaces)  
(Cleaner)  
(Detergent)  
(Virucide<sup>2,3</sup>)\*, against Feline calicivirus<sup>2</sup>, 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<sup>1</sup>\*\*) (\*\*when used according to the use direction<sup>1,2,3</sup>)

[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.**

**[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 surfaces with a 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 Surface Disinfectant & Cleaner solution to disinfect Non-Food hard non-porous 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 and stay visibly wet for at least ten minutes.
5. When disinfecting for Coronavirus (SARS-CoV-2) COVID-19 virus<sup>3</sup>, surfaces must remain visibly wet for at least one minute.
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)	(Laundry rooms)
(Bathroom)	(Locker rooms)
(Blood bank)	(Office building)
(Boats)	(Patient room)
(Buses and automobiles)	(Pharmacy)
(Clinic)	(Physician's office)
(Day care center)	(Public eating places)
(Dental office)	(Public facility)
(Doctor's office)	(Recreational center)
(Gymnasium)	(Restrooms)
(Health care facility)	(School bus/vehicle)
(Health club)	(Schools)
(Hospital)	(Shelters)
(Hotel/motel)	(Sports care and athletic facilities)
(Kennel)	(Veterinary office)
(Laboratories)	(Waiting room)
(Trains)	(Weight rooms)
(Trucks)	(Weight rooms)
(Vehicles)	

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

(Bathroom surfaces)	(Linoleum)
(Bathtub)	(Metal)
(Bidet)	(Mirror)
(Brass)	(Outdoor [patio] furniture)
(Cabinets)	(Parquet)
(Car, boat, airplane, and train surfaces and cavities)	(Patient chairs)
(Ceramic floor)	(Pens)
(Chairs)	(Plastic) (Polypropylene)
(Chrome)	(Portable pet carriers)
(Desk)	(Portable toilet)
(Door knob)	(Prostheses and orthotics) (PVC)
(Examination tables)	(Recycling bins) (Sealed granite) (Sealed marble) (Sealed quartz)
(Fiberglass)	(Sealed stone)
(Fixtures)	(Shower curtain [plastic]) (Sinks) (Sports equipment) (Stainless steel)
(Floors)	(Stretchers) (Table tops)
(Furniture)	(Telephones) (Toilet seats)
(Garbage [cans] [pails] [bins])	(Tools)
(Glass)	(External surfaces of Urinals only)
(Glazed ceramic [tile])	(Veterinary care surfaces) (Vinyl) (Vinyl [tile]) (Walls)
(Glazed porcelain [tile])	(Washable walls) (Wheelchairs)
(E61:E81Laminate [surfaces])	(Whirlpool interiors)

**[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 and visibly wet all surfaces and 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 and visibly 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 and a cleaner on hard, nonporous surfaces, when surfaces remain visibly wet during the contact time. 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). All visible soil must be removed prior to disinfection. 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) designed for disinfecting (of) hard, nonporous surfaces, when surfaces remain visibly wet during the contact time. LEXX® RTU Liquid Contact Surface Disinfectant & Cleaner also is designed for general cleaning (and) (deodorizing) (of) hard, nonporous surfaces, keeping your home smelling fresh and clean.

Surface list of microorganisms for disinfectant application	ATCC #	Contact Time
Staphylococcus aureus <sup>1</sup>	6538	10 Minute
Pseudomonas aeruginosa <sup>1</sup>	15442	10 Minute
Escherichia coli <sup>1</sup>	11229	10 Minute
Klebsiella pneumoniae (CRE) <sup>1</sup>	BAA-2146	10 Minute
Acinetobacter baumannii (MDR) <sup>1</sup>	BAA-1605	10 Minute
Staphylococcus aureus (MRSA) <sup>1</sup>	33591	10 Minute
Feline calicivirus <sup>2</sup> , Strain F-9 (norovirus surrogate)	VR-782	10 Minute
Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus) <sup>3</sup>	USA-WA 1/2020	1 minute (60 seconds)

**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 <sup>2</sup> (Norovirus surrogate)
Large, non-enveloped virus	Feline calicivirus <sup>2</sup> (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<sup>2</sup>, 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<sup>2</sup>, Strain F-9 (norovirus surrogate) on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information

**Footnotes**

- <sup>1</sup> Kills tested bacteria killed in 10-minutes on hard non-porous surfaces, when used as directed
- <sup>2</sup> Kills Feline calicivirus (Norovirus surrogate) in 10-minutes on hard non-porous surfaces, when used as directed
- <sup>3</sup> Kills Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus) in 1-minute (60-seconds) on hard non-porous surfaces, when used as directed

## STORAGE AND DISPOSAL

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

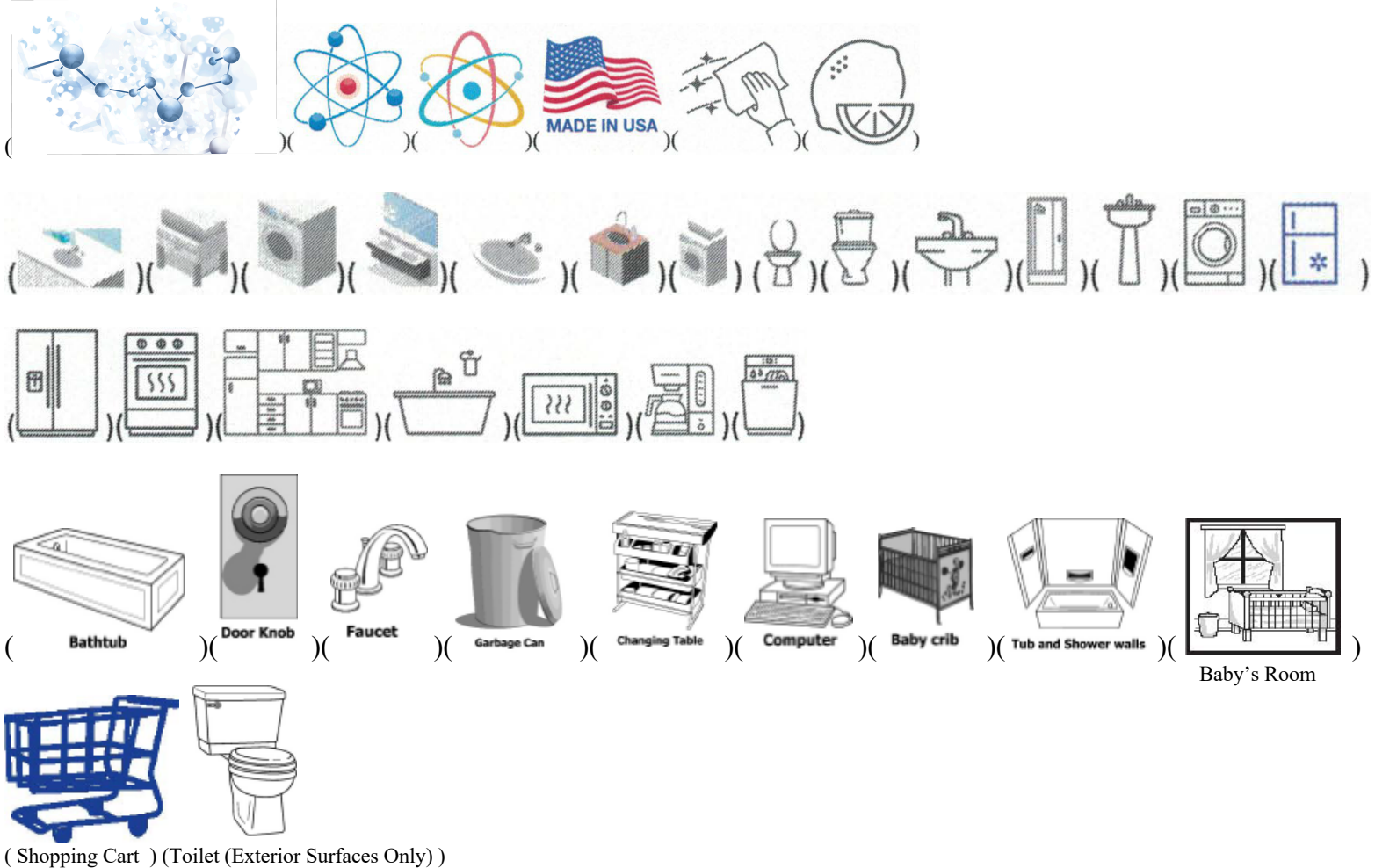
**PESTICIDE STORAGE:** Do not use or store near heat or open flame. Store in cool, dry (,) (well-ventilated area) (-or-) (place). Keep product container closed and tightly capped when not in use.

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

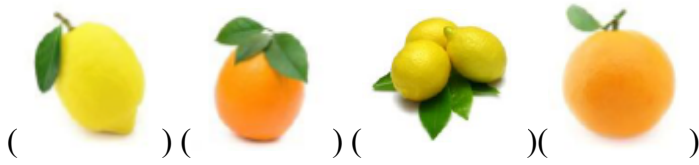
**CONTAINER HANDLING:** [Outside carton] (Carton:) Offer for recycling, if available, or discard in trash. [1 gal. plastic bottle] (Bottle:) Nonrefillable container. Do not reuse or refill this container. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and 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 rinse disposal. Repeat this procedure two more times. Offer for recycling, if available, or discard in trash.

### ADDITIONAL GRAPHICS [Optional Images to be added to label]

{Note to Reviewer: These are representative icons / descriptions for use sites/application methods that may appear on the label listed with the appropriate directions for use, PPE or package type. Toilets and urinal graphics should be qualified with “\*exterior surfaces only” under or near the graphic}



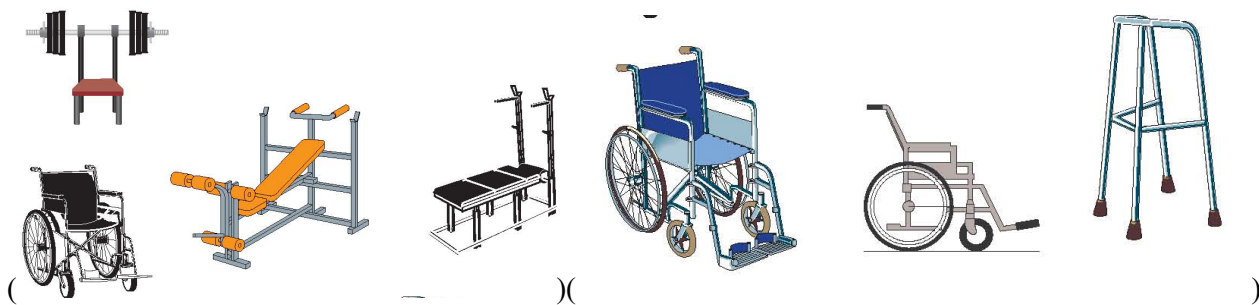
{NOTE TO REVIEWER: The following fruit icons/graphics can only be used with product that is lemon, orange or citrus scented.}

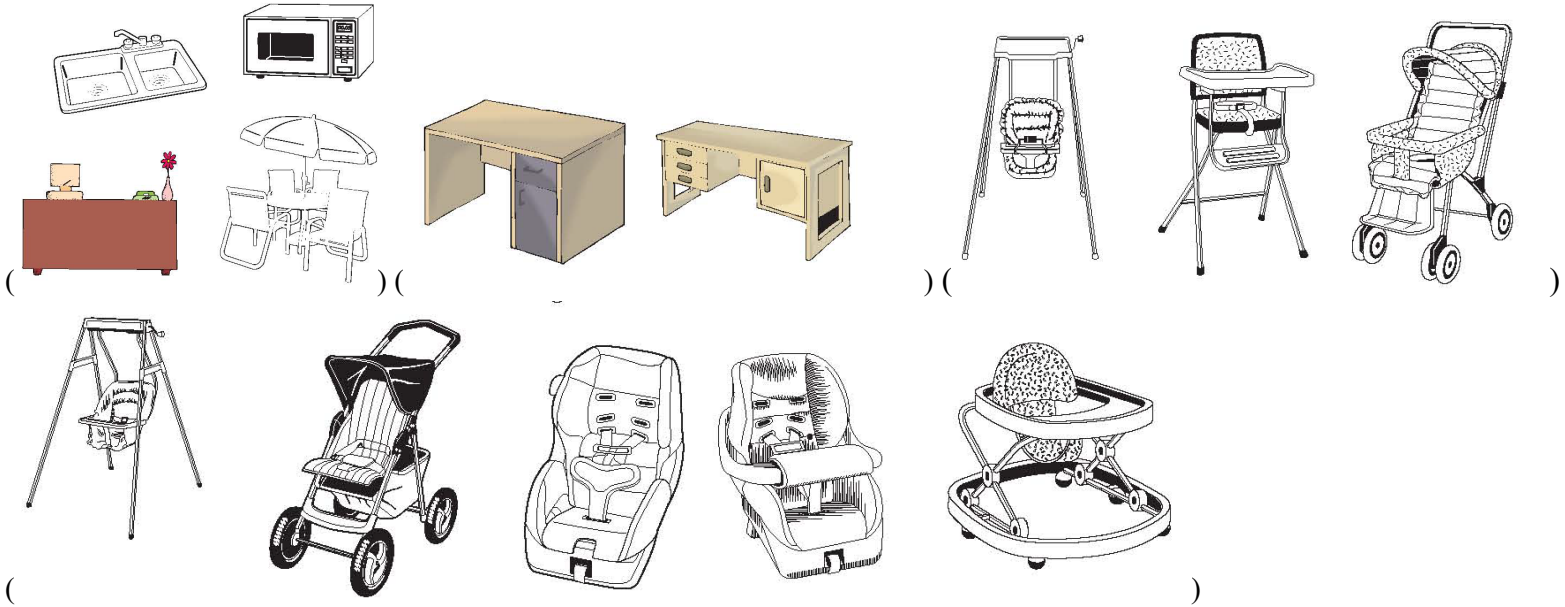


{NOTE TO REVIEWER: The following floral/ lavender icons/graphics can only be used with product that is floral or lavender scented.}



{Note to reviewer the exact virus image below may be used in association with SARS-CoV-2<sup>3\*</sup> marketing claims and applicable directions for use as a stylized graphic including any of the following statements: “Kills (the) COVID-19 Virus<sup>3,\*</sup>”; “Effective against SARS-CoV-2<sup>3\*</sup>”; “Kills SARS-CoV-2<sup>3\*</sup> (in) (just) (1(-)minute) (60(-)seconds)”.





(OR)

(sink with faucet)

(work station tub or sink)

(rubber gloves) (masks) (PPEs)

(table)

(chair)

(bed frame)

(wall)

(cabinet)

(doorknob)

(garbage can)

(non-wooden picnic table)

(outdoor furniture except cushions and wood frames).

(telephone)

(non-food contact counter tops, equipment, shelves, racks and carts)

(shower stalls)

(shower doors and curtains)

(tubs)

(glazed tiles)

(toilets- exterior surfaces only)

(urinals- exterior surfaces only)

(glazed porcelain tile) and (restroom fixtures).

(wheelchair)

(walkers/canes)

(non-porous hard surfaces of workout/gym equipment)

(non-porous hard services of child car seats, highchairs, baby swings, strollers, baby walkers)

(vehicle) (boat) (RV) (trailer)

(recycling logo) {Note to reviewer: Only for containers which may be recycled per storage and disposal directions}

(American flag logo) {Note to reviewer: May only be used on labels which carry "Made in USA" or "Assembled in America" marketing statements.}

(Brand or Company name specific graphics, logos, and stylized fonts including background patterns and fill colors)