



**Safety, Efficacy, and Regulatory Assessment for:**

**LEXX<sup>®</sup>**

**(Liquid Disinfectant, Sanitizer, and Cleaner Concentrate)**

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## Safety, Efficacy, and Regulatory Compliance of LEXX®

### EXECUTIVE SUMMARY

LEXX® (Liquid Disinfectant, Sanitizer, and Cleaner Concentrate and Ready To Use formulations) is a patented US Environmental Protection Agency (EPA)-registered (91452-1; 91452-5; 91452-6), 100% naturally-derived of food additive ingredients, broad spectrum hospital/healthcare grade disinfectant, sanitizer (food and non-food contact surfaces), and general-purpose cleaner. LEXX® is a broad-spectrum hospital/healthcare grade disinfectant that can be used for a wide array of EPA listed applications. LEXX® disinfects hard, non-porous surfaces against *Staphylococcus aureus*, *Staphylococcus aureus (MRSA)*, *Pseudomonas aeruginosa*, *Escherichia coli*, *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *norovirus* and killing SARS-CoV-2 in one (1) minute (the emerging viral pathogen that causes COVID-19).

For food contact surface sanitizing, LEXX® kills >99.99999% (>7 log reduction) of *Escherichia coli*, *Staphylococcus aureus*, *Campylobacter jejuni*, *Listeria monocytogenes*, and *Salmonella enterica* bacteria in 30 seconds based on controlled studies conducted to support the EPA registration of LEXX®. LEXX® is also registered as a one-step cleaner/sanitizer for non-food contact surfaces based on producing >5-log reductions (>99.999%) of *Staphylococcus aureus* and *Enterobacter aerogenes* within 2 minutes. LEXX® is registered as a food contact-surface sanitizer, one-step cleaner/sanitizer for non-food contact surfaces, and general-purpose cleaner in Canada. A total of eight patents have been issued for LEXX®. Four US Patents (Numbers 10,076,115, 10,568,325, 10,918,105 and 11,028,348), one Australian Patent (No. 2015328570), one Canadian Patent (No. 2967764), one Chinese Patent (No. ZL201580066369.5) and one Hong Kong Patent (No. 1241402).

LEXX® is 100% comprised of ingredients that are registered for various food uses. The main associated human toxicities are moderate and reversible eye and skin irritation for the concentrated product. The end-use diluted product (1:128 dilution for food contact surface uses, 1:64 dilution for non-food contact surfaces uses, and 1:32 dilution for disinfectant uses) is expected to cause none to minimal eye and skin irritation. Based on the ingredients, LEXX® has minimal environmental toxicity and is readily biodegradable. In addition to its sanitizer properties, LEXX® excels at a wide array of cleaning tasks, controls slime buildup, and prevents the formation of mold and mildew on multiple types of hard, non-porous surfaces such as metal, porcelain/ceramic, plastic, rubber, laminate and vinyl. Besides the nature of LEXX® ingredients, its benefits include that one product can be used for cleaning followed by sanitizing food contact surfaces, as a one-step cleaner/sanitizer for non-food contact surfaces, and as a broad-spectrum hospital/healthcare grade disinfectant. LEXX® is non-corrosive and eliminates the degradation of building infrastructure seen with the use of harsh chemical disinfectants containing ingredients such as Chlorine, Bleach, Quats and others. Based on laboratory testing, LEXX® has limited pathogen resistance.

As an antimicrobial food contact surface sanitizer, LEXX® complies with the food tolerances in 40CFR180.940 and 40CFR180.950. LEXX® is registered in all US states. LEXX® is NSF-listed as a Category D2 sanitizer which is acceptable for use as a sanitizer on all surfaces not always requiring a rinse in and around food processing areas. LEXX® is labeled in accordance with the EPA registered label and does not require the use of Personal Protective Equipment (PPE) when using the concentrate or end-use diluted forms. Although the EPA regulations do not require a Safety Data Sheet (SDS), a US Occupational Safety and Health Administration (OSHA) compliant SDS is available for end users of LEXX®, if desired.

### INTRODUCTION

LEXX® is comprised of naturally-derived, environmentally responsible ingredients with the main associated human toxicity being moderate and reversible skin and eye irritation for the concentrated

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product. The product has comparative cleaning efficacy to similar synthetic cleaners; however, in addition to its cleaning ability, it can also be used to sanitize previously-cleaned food contact surfaces, as a one-step cleaner/sanitizer for non-food contact surfaces, and, as a broad spectrum hospital/healthcare grade disinfectant. LEXX® excels at a wide array of cleaning tasks, controls slime buildup, and prevents the formation of mold and mildew on multiple types of hard, non-porous surfaces including metal, porcelain, plastic, rubber, laminate, and vinyl. A single product can be used to clean hard, non-porous surfaces followed by sanitizing the food contact surfaces, as a one-step cleaner/sanitizer for non-food contact surfaces, and as a broad-spectrum hospital/healthcare grade disinfectant.

ProNatural Brands LEXX® is based on foundational principles which provide to the consumer full disclosure of the product's compositional ingredients and their related purposes. LEXX® is self-preserving eliminating the need for any synthetic preservatives. The following sections review the formulation ingredients, chemical properties, application and use directions, safety, efficacy, and regulatory compliance of LEXX®.

### **PATENTS**

Eight Patents – Four US (Numbers 10,076,115, 10,568,325, 10,918,105 and 11,028,348), one Australian (No. 2015328570), one Canadian (No. 2967764), one Chinese (No. ZL201580066369.5) and one Hong Kong (No. 1241402).

### **INGREDIENTS AND CHEMICAL PROPERTIES**

LEXX® contains the following percentage of ingredients:

#### **ACTIVE INGREDIENT**

Citric acid.....**25.0%**

#### **OTHER INGREDIENTS**

Water, sodium lauryl sulfate, isopropyl alcohol, sodium bicarbonate, and decanoic acid.....**75.0%**

**TOTAL.....100.0%**

The purpose and source of each ingredient is as follows:

- Citric acid
  - Sanitizer active ingredient (kills bacteria) and buffer (helps maintain pH during cleaning).
  - Natural ingredient derived from the fermentation of glucose (sugar).
- Water
  - Diluent and solvent.
  - Natural ingredient.
- Sodium lauryl sulfate
  - Biobased surfactant that provides strong soil removal and cleaning properties.
  - Naturally-derived ingredient derived by the sulfation of coconut oil.
- Isopropyl alcohol (also known as isopropanol or rubbing alcohol)
  - Solvent and stabilizer.

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- Commercial supplies are currently made using a synthetic process but it can be produced via fermentation of biomass (natural process). However, there are currently no commercially-available sources of biologically-fermented isopropyl alcohol. Since isopropyl alcohol can be produced via fermentation but commercial supplies are not currently available, it is considered a naturally-derived ingredient (i.e., a synthetic ingredient that is the same as one found in nature). Once commercial supplies of isopropyl alcohol are available, these will be used and the ingredient will then be considered natural.
- Sodium bicarbonate (also known as baking soda)
  - Buffer- helps maintain pH during cleaning.
  - Natural ingredient, typically mined from the earth, but can be made synthetically.
- Decanoic acid
  - Fatty acid that provides hard water tolerance.
  - Natural ingredient derived from splitting plant oils.

LEXX® concentrate is a clear liquid that is stable at room temperature and at high temperatures (e.g., 130°F [54°C]). It does not freeze until about 12°F (-11°C). If the product freezes, it should be warmed to room temperature and then mixed well. After thorough mixing, the product is fully functional. LEXX® has a pH of approximately 2.2 – 2.5 for the concentrate and approximately 2.5 – 3.0 for the diluted product.

LEXX® contains isopropyl alcohol (isopropanol), which is a flammable substance. Due to a flash point of 46°C, LEXX® is classified as combustible and should not be used on electrical equipment. Since LEXX® contains 4.9% (w/w) isopropyl alcohol (alcohols) and >50% water (i.e., the product is aqueous), it is exempt (see 49CFR173.150(e)) and is not classified as a hazardous substance for US Department of Transportation (DOT) transportation purposes.

LEXX® was tested in a standard Preservative Challenge study to confirm that the formulation was self-preserving. The testing was successfully passed when the product was spiked with cultures that included *Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Aspergillus brasiliensis*, or *Candida albicans*.

LEXX® was tested for its corrosiveness in two separate studies conducted by independent laboratories.

In the first study, LEXX® was tested for its corrosiveness to mild steel, stainless steel, aluminum, copper, and, elastomers, PVC plastic. No significant corrosion was observed for any substrate when submerged in a diluted solution (1:128 dilution) and incubated at 40°C for up to 2 weeks.

In the second study, LEXX® was tested for its corrosiveness to plastics (clear PETE, polycarbonate, Teflon, polysulfone, polypropylene, PBT, Delrin, HDPE, and acetal), rubber (NBR and silicon), and metal (301, 303, 304L, 316L, 17-4PH, 17-7PH stainless steel grades, and other metal parts such as nickel-plated metal). LEXX® was diluted 1:128 per the food contact surface sanitizing instructions and heated to ~110° F. The materials were soaked for a total of 30 days and the diluted solution was replaced twice per week to keep the sanitizer “fresh”. No significant adverse effects were noted on the materials except for a nickel-plated metal part for which the nickel plating was removed after 30 days; however, based on the corrosion rate for this test and the typical use of LEXX® in sanitizing food-processing equipment, nickel plated parts would be expected to last approximately 50 years since the current test was a highly exaggerated accelerated exposure.

## **APPLICATIONS AND DIRECTIONS FOR USE**

LEXX® is an EPA registered broad spectrum hospital/healthcare grade disinfectant. LEXX® is also an EPA registered sanitizer for cleaning and sanitizing food processing equipment, utensils, and hard, non-porous surfaces including glass; glazed ceramic and porcelain surfaces; laminates; metals; plastics; sealed natural and stone surfaces; sealed cement surfaces; and sealed tile. LEXX® is a single product that can be used as a broad-spectrum hospital/healthcare grade disinfectant, as a food contact surface sanitizer, and as a one-step cleaner/sanitizer for non-food contact surfaces.

### *Disinfecting*

LEXX® can be used for disinfecting hard, non-porous surfaces in a wide array of use areas (e.g., hospitals, healthcare facilities, gym/healthcare facilities, bathrooms, airplanes, trains, cars, food service facilities, hotels/motels, locker rooms, nursing homes, restaurants, restrooms, schools, and veterinary facilities). To disinfectant surfaces using LEXX®, first make a cleaning solution by diluting 1 to 4 fluid oz. of LEXX® per 1 gallon of water. Clean surfaces by applying cleaning solution to surface via various means such as low-pressure spray, wiping, brushing, or dipping. Rinse surface with potable water. Then make disinfecting solution by diluting 4 fluid oz. of LEXX® per 1 gallon of water (1:32 dilution). Disinfect surfaces by applying solution to surface via various means such as low-pressure spray, wiping, brushing, or dipping. Allow disinfectant to completely wet surfaces for at least ten minutes. Drain, wipe, or remove any excess and allow disinfected surfaces to air dry. No rinsing is required. Do not reuse the solution. Read the LEXX® (Concentrate or Ready to Use) product label for complete use directions.

### *Food Contact Surface Sanitizing*

For sanitizing food contact surface uses, dilute LEXX® 1:128 (e.g., 1 ounce of LEXX® concentrate in 1 gallon of water). The surface needs to be cleaned first with LEXX® by spraying, mopping, flooding, or similarly applying the diluted sanitizer directly on the food processing equipment, surface, or soiled area. For heavy soils, scrub with a scrub brush or appropriate tool. Wipe clean with a dry or damp towel or cloth or rinse with water. Following cleaning, the surface can be sanitized with a 1:128 dilution of LEXX® by spraying, mopping, flooding, or similarly applying the diluted sanitizer directly on the food processing equipment, surface, or soiled area. Let the product contact the treated surface for at least 1 minute to sanitize. Do not reuse the solution. Read the LEXX® product label for complete use directions.

### *Non-Food Contact Surface Sanitizing*

For non-food contact surface uses, dilute LEXX® 1:64 (e.g., 2 ounces of LEXX® concentrate in 1 gallon of water). The surface can be simultaneously cleaned and sanitized with a single application. For heavily soiled areas, clean excess dirt first. Apply LEXX® to the surface by spraying, mopping, flooding, or similarly applying the diluted cleaner/sanitizer directly on the non-food contact surface or soiled area. Allow cleaner/sanitizer to completely wet surfaces for at least two minutes. Clean soil from the surface by wiping, mopping, or other means. For heavy soils, scrub with a scrub brush or appropriate tool. Drain, wipe, or remove any excess and allow sanitized surfaces to air dry. No rinsing is required. Do not reuse the solution. Read the LEXX® (Concentrate or Ready To Use) product label for complete use directions.

**SAFETY ASSESSMENT**

As part of the EPA registration, LEXX® concentrate was tested for acute toxicity. The following table summarizes the results of the six acute toxicity studies that were conducted with the concentrated solution:

Test	Results	EPA Toxicity Category	Basis
Acute Oral Toxicity (Rats)	>5000 mg/kg	IV	Testing of concentrated product
Acute Dermal Toxicity (Rats)	>5000 mg/kg	IV	Testing of concentrated product
Acute Inhalation Toxicity (Rats)	>2 mg/L	IV	Testing of concentrated product
Acute Eye Irritation (Rabbits)	Moderate eye irritant	III	Testing of concentrated product
Acute Dermal Irritation (Rabbits)	Moderate skin irritant	III	Testing of concentrated product
Dermal Sensitization (Guinea Pig)	Not a sensitizer	IV	Testing of concentrated product

NOTE: EPA Toxicity Categories are ranked from I (most hazardous) to IV (least hazardous)

The studies demonstrated that LEXX® exhibits low oral, dermal, and inhalation toxicity and skin sensitization (EPA Toxicity Category IV- the least hazardous categorization). Likely due to the presence of citric acid (a natural acid found at high concentrations in citrus fruits such as orange, lemons, limes, and grapefruit) and sodium lauryl sulfate (a biobased surfactant), concentrated LEXX® was moderately irritating to rabbit eyes and skin. The irritation was fully reversible and was classified as EPA Toxicity Category III, which requires the statement of “CAUTION” on the label. Due to LEXX®’s low toxicity profile, it is not considered a hazardous material (HAZMAT) for US DOT transportation purposes.

In addition to the acute toxicity data, the low hazard posed by each ingredient is further confirmed based on three additional factors- listing in the EPA’s Safer Choice safer chemical ingredients list, approval as food additives by the US Food and Drug Administration (FDA), and publicly available toxicity information and experience with each ingredient.

The US EPA maintains a list of ingredients that are classified as to human and environmental hazard as part of their Safer Choice certification program. The list can be found at:

<http://www2.epa.gov/saferchoice/safer-ingredients>.

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Ingredients are categorized as follows:

- Green Circle
  - The chemical has been verified to be of low human health and environmental concern based on experimental and modeled data.
- Green Half-Circle
  - The chemical is expected to be of low human health and environmental concern based on experimental and modeled data. Additional data would strengthen the confidence in the chemical's safer status.
- Yellow Triangle
  - The chemical has met Safer Choice Criteria for its functional ingredient-class, but has some hazard profile issues. Specifically, a chemical with this code is not associated with a low level of hazard concern for all human health and environmental endpoints. While it is a best-in-class chemical and among the safest available for a particular function, the function fulfilled by the chemical should be considered an area for safer chemistry innovation.
- Grey Square
  - This chemical will not be acceptable for use in products that are candidates for the Safer Choice label.

All of the ingredients in LEXX® are green circle (the least hazardous categorization for human and environmental toxicity). Overall, LEXX® exhibits a minimal risk of inducing adverse effects in humans or to the environment. LEXX® is expected to be biodegradable since each organic ingredient is biodegradable (Appendix A summarizes the publicly-available biodegradability data for each ingredient in LEXX®).

As another indication of the low hazard posed by each ingredient, the approval of each ingredient for use in food by the FDA was assessed as listed in the US Code of Federal Regulations (CFR). The following are the direct food use approvals for each ingredient in LEXX®:

- Water
  - No specific listing- Generally Recognized as Safe (GRAS).
- Sodium lauryl sulfate
  - 21CFR172.822- listed as a Direct Food Additive for use as an emulsifier in or with egg whites, as a whipping agent for preparing marshmallows, as a surfactant in fumaric acid-acidulated dry beverage base and fruit juice drinks, and as a wetting agent in the partition of high and low melting fractions of crude vegetable oils and animal fats.
- Citric acid
  - 21CFR184.1033- listed as GRAS with no limitation other than current good manufacturing practice.
- Isopropyl alcohol (also known as isopropanol or rubbing alcohol)
  - 21CFR172.515- listed as a Direct Food Additive for use as a synthetic flavoring substance or adjuvant.
- Sodium bicarbonate

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- 21CFR184.1736- listed as GRAS with no limitation other than current good manufacturing practice.
- Decanoic acid
  - 21CFR172.860- listed as a Direct Food Additive for use as a lubricant, binder, or defoaming agent and as a component in the manufacture of other food-grade additives.

The third piece of evidence for the low hazard posed by each ingredient is general public information on the toxicity of each ingredient to humans. Decanoic acid and sodium bicarbonate exhibit low human and environmental toxicity. Isopropyl alcohol can cause some adverse effects at high concentrations (e.g., when drinking large amounts of isopropyl alcohol); however, the concentration of isopropyl alcohol in LEXX® is low (4.9% w/w) and presents a minimal human health and environmental hazard. Citric acid is a weak acid that can cause reversible eye and skin irritation and sodium lauryl sulfate is a biobased surfactant that can also cause reversible eye and skin irritation. Therefore, concentrated LEXX® has the potential to cause moderate and reversible eye and skin irritation and this is listed on the product label. Once diluted to end-use concentrations (i.e., 1:32, 1:64, or 1:128), LEXX® is expected to cause none to minimal eye and skin irritation. Citric acid exhibits low environmental toxicity. Overall, based on the ingredients, LEXX® is expected to have minimal human and environmental toxicity and is expected to readily biodegrade in the environment.

LEXX® Liquid Sanitizer and Cleaner Concentrate has an acid pH to help kill bacteria. The pH for the concentrate is approximately 2.2 – 2.5 and approximately 2.5 – 3.0 for the diluted product. When a product has a pH <2.0 or >11.5, there is potential concern for severe irritation or corrosion of living tissue. Since the pH of concentrated LEXX® is >2.0 and <11.5, the concern is low and this was confirmed with the eye and skin irritation testing conducted with the concentrated product, which demonstrated that LEXX® is a moderate and reversible eye and skin irritant. When diluted to end-use concentrations (i.e., 1:32, 1:64, or 1:128), LEXX® is expected to cause none to minimal eye and skin irritation.

The primary storage containers for LEXX® are made from high density polyethylene (HDPE), polypropylene, polystyrene, or other plastics. The containers are not expected to have any impurities or contaminants that would leach into the liquid product and cause a safety issue.

### **LEXX® DISINFECTANT AND SANITIZER EFFICACY**

#### *BROAD SPECTRUM HOSPITAL/HEALTHCARE DISINFECTANT FOR A WIDE ARRAY OF USE AREAS:*

As part of the LEXX® EPA registration, the efficacy of LEXX® at killing seven common disease-causing pathogens (*Staphylococcus aureus*, *Staphylococcus aureus* [MRSA], *Pseudomonas aeruginosa*, *Escherichia coli*, *Klebsiella pneumoniae* [CRE], *Acinetobacter baumannii* [MDR], and Feline calicivirus strain F-9 [EPA-approved surrogate for norovirus]) was tested according to an EPA-required test protocol (AOAC Use-Dilution method) under strict Good Laboratory Practices (GLPs) by an independent third party laboratory. Two to three separate batches of LEXX®, all formulated with citric acid (the active ingredient) below the EPA Lower Certified Limit (LCL), were tested to confirm reproducibility of the testing. LEXX® was diluted 1:32 in hard water (i.e., 1 part of LEXX® with 31 parts of 200 ppm hard water) and bacteria coated on metal cylinders were exposed to the diluted LEXX® for 10 minutes. The cylinders were removed, residual LEXX® neutralized, and viable bacteria cultured. Depending on the organism tested, anywhere from 10 to 60 metal cylinders were included. Bacterial growth from any cylinder was considered a failure for that replicate. Per EPA criteria, only a given number of cylinders could



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have growth for a given type of bacteria. Viral testing criteria was based on log reductions. The following tables summarize the results of the testing:

Test Microorganism	Test Substance	Test Substance Lot Number	Contact Time	Number of Carriers Tested	Number of Negative Carriers (no growth)	Number of Positive Carriers	Passed EPA Criteria
<i>S. aureus</i> (ATCC 6538)	LEXX® Diluted 1:32 in 200 ppm Hard Water	3001-EF1	10 minutes	60	57	3	Yes
		3002-EF2		60	58	2	Yes
		3003-EF3		60	59	1	Yes
<i>S. aureus</i> MRSA (ATCC 33591)	LEXX® Diluted 1:32 in 200 ppm Hard Water	3001-EF1	10 minutes	10	10	0	Yes
		3002-EF2		NA	NA	NA	NA
		3003-EF3		10	10	0	Yes
<i>P. aeruginosa</i> (ATCC 15442)	LEXX® Diluted 1:32 in 200 ppm Hard Water	3001-EF1	10 minutes	60	59	1	Yes
		3002-EF2		60	59	1	Yes
		3003-EF3		60	56	4	Yes
<i>E. coli</i> (ATCC 11229)	LEXX® Diluted 1:32 in 200 ppm Hard Water	3001-EF1	10 minutes	10	10	0	Yes
		3002-EF2		NA	NA	NA	NA
		3003-EF3		10	10	0	Yes
<i>K. pneumoniae</i> (CRE) (ATCC BAA-2146)	LEXX® Diluted 1:32 in 200 ppm Hard Water	3001-EF1	10 minutes	10	10	0	Yes
		3002-EF2		NA	NA	NA	NA
		3003-EF3		10	10	0	Yes
<i>A. baumannii</i> (MDR) (ATCC BAA-1605)	LEXX® Diluted 1:32 in 200 ppm Hard Water	3001-EF1	10 minutes	10	10	0	Yes
		3002-EF2		NA	NA	NA	NA
		3003-EF3		10	10	0	Yes

**NOTES:**

- NA = not applicable- only two batches tested for amended registration per EPA testing requirements

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Test Microorganism	Test Substance	Test Substance Lot Number	Contact Time	Plate Recovery Control ( $\log_{10}$ TCID <sub>50</sub> )	Virus Test Film ( $\log_{10}$ TCLD <sub>50</sub> )	Log Reduction Compared to Initial #'s Control	Passed EPA Criteria
<i>Feline calicivirus, Strain F-9: EPA approved surrogate for norovirus (ATCC VR-782)</i>	LEXX® Diluted 1:32 in 200 ppm Hard Water	3001-EF1	10 minutes	4.35	≤1.10	≥3.25	Yes
		3002-EF2		NA	NA	NA	NA
		3003-EF3		6.10	≤2.10	≥4.00	Yes

**NOTES:**

- NA = not applicable- only two batches tested for amended registration per EPA testing requirements
- TCID<sub>50</sub> (Tissue Culture Infectivity Dose) represents the endpoint dilution where 50% of the cell cultures exhibit cytopathic effects due to infection by the test virus
- TCLD<sub>50</sub> (Tissue Culture Lethal Dose) is the dose required to kill 50% of the test viruses after the given exposure time

In conclusion, LEXX® met the EPA disinfectant efficacy requirements in the EPA-approved and GLP-compliant studies for the tested broad-spectrum hospital/healthcare grade bacteria and virus.

In March 2022, the efficacy of LEXX® at killing Severe Acute Respiratory Syndrome-Related Coronavirus (SARS-CoV-2) (COVID-19 Virus) was tested according to an EPA-required test protocol under strict Good Laboratory Practices (GLPs) by an independent third party laboratory using three lots of test substance with virus.

Sterilized glass petri dishes were used as test carriers, inoculated with a 0.4 mL of Fetal Bovine Serum (FBS) in virus inoculum and exposed to a diluted 1:32 LEXX® solution (i.e., 1 part of LEXX® with 31 parts of 200 ppm unsoftened tap water) for one minute.

After the one-minute contact time, the test substance was neutralized with 2.0 mL of neutralizer. The mixture was scraped from the surface of the carrier and incubated for six days. After the six days, the plates were scored and recorded for test-substance specific cytotoxic effects and/or virus-specific cytopathic effect.

The following table summarize the results of the testing:

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Test Microorganism	Test Substance	Test Substance Lot Number	Contact Time	Plate Recovery Control (log <sub>10</sub> TCID <sub>50</sub> )	Virus Test Film (log <sub>10</sub> TCLD <sub>50</sub> )	Log Reduction Compared to Initial #'s Control	Passed EPA Criteria
<i>Severe Acute Respiratory Syndrome-Related Coronavirus 2</i> (ATCC CRL-1586)	LEXX® Diluted 1:32 in 200 ppm Hard Water	22A040	1 minute	5.75	≤2.10	≥3.25	Yes
		22B042		5.75	≤2.10	≥3.25	Yes
		22C047		5.75	≤2.10	≥3.25	Yes

**SANITIZER FOR FOOD CONTACT SURFACES:**

As part of the EPA registration, the efficacy of the LEXX® at killing five common, food-borne pathogens (*Escherichia coli*, *Staphylococcus aureus*, *Campylobacter jejuni*, *Listeria monocytogenes*, and *Salmonella enterica*) was tested according to an EPA-required test protocol (AOAC Germicidal and Detergent Sanitizing Action of Disinfectants) under strict GLPs by an independent third-party laboratory. Two to three separate batches of LEXX®, all formulated with citric acid (the active ingredient) below the EPA LCL, were tested to confirm reproducibility of the testing. LEXX® was diluted 1:128 in hard water (i.e., 1 part of LEXX® with 127 parts of 300 ppm hard water) and bacteria were exposed to the diluted LEXX® for 30 seconds. An aliquot was removed, neutralized, and viable bacteria cultured. The following table summarizes the results of the testing:

Test Microorganism	Test Substance	Test Substance Lot Number	Contact Time	CFU/ml	Percent Reduction to Initial #'s Control	Log Reduction Compared to Initial #'s Control
<i>E. coli</i> (ATCC 11229)	LEXX® Diluted 1:128 in 300 ppm Hard Water	1001-EF1	30 seconds	<2.27	>99.9999985%	>7.83
		1002-EF2		<2.27	>99.9999985%	>7.83
		1003-EF3		<2.27	>99.9999985%	>7.83
<i>S. aureus</i> (ATCC 6538)	LEXX® Diluted 1:128 in 300 ppm Hard Water	1001-EF1	30 seconds	<2.27	>99.9999986%	>7.87
		1002-EF2		<2.27	>99.9999986%	>7.87
		1003-EF3		<2.27	>99.9999986%	>7.87
<i>C. jejuni</i> (ATCC 29428)	LEXX® Diluted 1:128 in 300 ppm Hard Water	2001-EF1	30 seconds	<10	>99.999996%	>7.44
		2002-EF2		<10	>99.999996%	>7.44
		NA		NA	NA	NA
<i>L. monocytogenes</i> (ATCC 15313)	LEXX® Diluted 1:128 in 300 ppm Hard Water	2001-EF1	30 seconds	<10	>99.9999992%	>8.07
		2002-EF2		<10	>99.9999992%	>8.07
		NA		NA	NA	NA
<i>S. enterica</i> (ATCC 10708)	LEXX® Diluted 1:128 in 300 ppm Hard Water	2001-EF1	30 seconds	<10	>99.9999993%	>8.16
		2002-EF2		<10	>99.9999993%	>8.16
		NA		NA	NA	NA

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### NOTES:

- NA = not applicable- only two batches tested for amended registration per EPA testing requirements
- CFU = colony forming units
- The limit of detection (LOD) was 2.27 CFU/ml for *E. coli* and *S. aureus* and 10 CFU/ml for *C. jejuni*, *L. monocytogenes*, and *S. enterica*. Results below the LOD are noted as <2.27 or <10 CFU/ml, respectively.

In conclusion, LEXX® exhibited very potent sanitizing efficacy in the EPA-approved and GLP-compliant studies for food-contact surface sanitizing use. For the five organisms and two to three batches of product that were tested, no growth of the organisms was noted demonstrating strong sanitizing efficacy of LEXX® when diluted 1:128 in 300 ppm hard water.

### SANITIZER FOR NON-FOOD CONTACT SURFACES:

As part of the EPA registration, the efficacy of the LEXX® at killing two common pathogens (*Staphylococcus aureus* and *Enterobacter aerogenes*) was tested according to an EPA-required test protocol (ASTM E1153-14 Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food contact Surfaces) under strict GLPs by an independent third party laboratory. Three separate batches of LEXX®, all formulated with citric acid (the active ingredient) below the EPA LCL, were tested to confirm reproducibility of the testing. LEXX® was diluted 1:64 in hard water (i.e., 1 part of LEXX® with 63 parts of 200 ppm hard water) and bacteria were exposed to the diluted LEXX® for 2 minutes. A 5% fetal bovine serum soil load was included with the bacterial inoculum to simulate efficacy of LEXX® as a one-step cleaner/sanitizer. An aliquot was removed, neutralized, and viable bacteria cultured. The following table summarizes the results of the testing:

Test Microorganism	Test Substance	Test Substance Lot Number	Contact Time	CFU/ml	Percent Reduction to Initial #'s Control	Log Reduction Compared to Initial #'s Control
<i>E. aerogenes</i> (ATCC 13048)	LEXX® Diluted 1:64 in 200 ppm Hard Water	2001-EF1	2 minutes	<10	>99.9993%	>5.1
		2002-EF2		<10	>99.9996%	>5.4
		2003-EF3		<10	>99.9996%	>5.4
<i>S. aureus</i> (ATCC 6538)	LEXX® Diluted 1:64 in 200 ppm Hard Water	2001-EF1	2 minutes	21.2	>99.9997%	5.6
		2002-EF2		<10	>99.99989%	>5.9
		2003-EF3		<10	>99.99986%	>5.9

### NOTES:

- CFU = colony forming units
- The limit of detection (LOD) was 10 CFU/ml. Results below the LOD are noted as <10 CFU/ml.

In conclusion, LEXX® exhibited very potent one-step cleaning and sanitizing efficacy in the EPA-approved and GLP-compliant studies. Greater than 5-log reduction in bacteria counts was noted when LEXX® was diluted 1:64 in 200 ppm hard water. In addition, a soil load was included in the studies to obtain approval for LEXX® as a one-step cleaner/sanitizer.

**CLEANING EFFICACY**

LEXX® was tested by an independent third party laboratory for its cleaning ability in a standardized test similar to the Consumer Specialty Products Association (CSPA) test DCC-17 (Greasy soil test method for evaluating spray-and-wipe cleaners used on hard, non-glossy surfaces, 2003). Soil prepared according to DCC-17 was coated on ceramic, plastic, and painted steel test plates (coupons). As a conservative assessment, LEXX® was diluted 1:128 according to the label directions for food contact surface use prior to use in the test. The more concentrated non-food contact surface (1:64) and disinfectant (1:32) dilutions of LEXX® are expected to have even greater cleaning ability. The test formulation was sprayed on the soil and then wiped in a standardized manner. The percent of soil removal was gravimetrically measured for each coupon and test formulation. Two widely available antibacterial cleaners were included for comparison. The results of the testing are outlined in the following table:

Test Coupon	Percent Soil Removal (%)		
	LEXX® Liquid Sanitizer and Cleaner (1:128 Dilution)	7 <sup>th</sup> Generation Disinfecting Multi-Surface Cleaner	Formula 409 Antibacterial All Purpose Cleaner
Ceramic	95.88	92.09	98.61
Plastic	96.33	94.90	98.37
Painted Steel	94.10	85.31	97.44
<b>OVERALL AVERAGE</b>	<b>95.44</b>	<b>90.67</b>	<b>98.14</b>

Overall, LEXX® exhibited excellent cleaning performance with over 95% soil removal for all surfaces combined and with similar soil removal for each type of surface tested. The cleaning efficacy was comparable to the Formula 409 comparator (i.e., the results were within experimental variability of the test) and superior to the 7<sup>th</sup> Generation comparator.

**REGULATORY COMPLIANCE**

US EPA

LEXX® is registered with the EPA for disinfectant and sanitizer uses. LEXX® is a broad-spectrum hospital/healthcare grade disinfectant, a food contact surface sanitizer that complies with the food tolerances in 40CFR180.940 and 40CFR180.950, and a one-step non-food contact surface cleaner/sanitizer. LEXX® is registered in all US states. LEXX® containers are labeled in accordance with the EPA registered stamped label and do not require the use of PPE when using the concentrate or end-use diluted forms.

Based on the ability of LEXX® to kill norovirus, a small, non-enveloped virus, LEXX® is approved to disinfect areas contaminated by emerging viral pathogens designated by the Centers for Disease Control and Prevention (CDC) that fall into the “enveloped virus” or “large, non-enveloped virus” classes, including SARS-CoV-2 (the emerging viral pathogen that causes COVID-19).

Canada

LEXX® is registered as a food contact surface sanitizer, one-step cleaner/sanitizer for non-food contact surfaces, and general-purpose cleaner in Canada.

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### NSF

LEXX® is NSF-listed as a Category D2 sanitizer which is acceptable for use as a sanitizer on all surfaces not always requiring a rinse in and around food processing areas. A potable water rinse is not required following the use of LEXX®.

### Other

Concentrated LEXX® may cause moderate eye and skin irritation and the product label reflects this. Per the EPA registered label for LEXX®, no PPE is required to use concentrated or end-use diluted LEXX®. Once diluted to the end-use dilution (i.e., 1:32, 1:64, or 1:128), the product is expected to cause none to minimal eye and skin irritation.

Since LEXX® is an EPA-regulated disinfectant and food- and non-food contact surface sanitizer, the Volatile Organic Carbon (VOC) content is regulated by the California Environmental Protection Agency (CalEPA). Concentrated LEXX® contains 4.9% (w/w) VOC (isopropyl alcohol). When diluted to the minimum recommended dilution on the label (i.e., 1:32), the diluted product contains 0.172% VOC. The VOC level of diluted LEXX® (0.172%) is well below the CalEPA VOC limit for sanitizers and disinfectants of 1.0%. The VOC content of diluted LEXX® is also well below the EPA VOC limit for general purpose cleaners (EPA does not regulate the VOC content of sanitizers) of 10%.

LEXX® is not classified as a hazardous substance for US DOT transportation purposes since it exhibits minimal human toxicity and it contains ≤24% alcohol (isopropanol) and is an aqueous solution (i.e., ≥50% water) (see 49CFR173.150(e)).

The EPA antimicrobial regulations do not require an SDS for food- and non-food contact surface sanitizers and disinfectants; however, many businesses require an SDS regardless of whether the product is regulated by the EPA or by OSHA. Therefore, an SDS, compliant with OSHA regulations and the current Globally Harmonized System of Classification and Labelling of Chemicals (GHS) standard, is available for end users of LEXX®, if desired.

***IMPORTANT NOTE:*** *OSHA does not regulate LEXX® since LEXX® is registered and regulated solely by the EPA. Users of LEXX® must follow the LEXX® label directions and information to ensure user safety and not the SDS directions and information since OSHA [and the associated SDS] does not regulate LEXX® and the SDS does not apply for assessing user safety.*

### CONCLUSIONS

LEXX®™ (Liquid Disinfectant, Sanitizer, and Cleaner Concentrate and Ready To Use formulation) is an US Environmental Protection Agency (EPA)-registered, naturally-derived, broad spectrum hospital/healthcare grade disinfectant, sanitizer (food and non-food contact surfaces), and general-purpose cleaner. LEXX® is a broad-spectrum hospital/healthcare grade disinfectant that can be used for a wide array of applications. LEXX® disinfects hard, non-porous surfaces against *Staphylococcus aureus*, *Staphylococcus aureus (MRSA)*, *Pseudomonas aeruginosa*, *Escherichia coli*, *Klebsiella pneumoniae*, *Acinetobacter baumannii*, and *norovirus*. Based on the ability of LEXX® to kill norovirus, a small, non-enveloped virus, LEXX® is approved to disinfect areas contaminated by emerging viral pathogens designated by the Centers for Disease Control and Prevention (CDC) that fall into the “enveloped virus”

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or “large, non-enveloped virus” classes, including SARS-CoV-2 (the emerging viral pathogen that causes COVID-19).

For food contact surface sanitizing, LEXX® kills >99.99999% (>7 log reduction) of Escherichia coli, Staphylococcus aureus, Campylobacter jejuni, Listeria monocytogenes, and Salmonella enterica bacteria in 30 seconds based on controlled studies conducted to support the EPA registration of LEXX®. LEXX® is also registered as a one-step cleaner/sanitizer for non-food contact surfaces based on producing >5-log reductions (>99.999%) of Staphylococcus aureus and Enterobacter aerogenes within 2 minutes. LEXX® is registered as a food contact-surface sanitizer, one-step cleaner/sanitizer for non-food contact surfaces, and general-purpose cleaner in Canada. A US Patent has been issued for LEXX® (U.S. Patent No. 10,076,115).

LEXX® is comprised of ingredients that are registered for various food uses. The main associated human toxicities are moderate and reversible eye and skin irritation for the concentrated product. The end-use diluted product (1:128 dilution for food contact surface uses, 1:64 dilution for non-food contact surfaces uses, and 1:32 dilution for disinfectant uses) is expected to cause none to minimal eye and skin irritation. Based on the ingredients, LEXX® is expected to have minimal environmental toxicity and is expected to readily biodegrade. In addition to its sanitizer properties, LEXX® excels at a wide array of cleaning tasks, controls slime buildup, and prevents the formation of mold and mildew on multiple types of hard, non-porous surfaces such as metal, porcelain/ceramic, plastic, rubber, laminate and vinyl. Besides the nature of LEXX® ingredients, its benefits include that one product can be used for cleaning followed by sanitizing food contact surfaces, as a one-step cleaner/sanitizer for non-food contact surfaces, and as a broad-spectrum hospital/healthcare grade disinfectant. Since LEXX® is non-corrosive, it avoids the degradation of building infrastructure seen with the use of harsh chemical disinfectants. Based on laboratory testing, LEXX® has limited pathogen resistance.

As an antimicrobial food contact surface sanitizer, LEXX® complies with the food tolerances in 40CFR180.940 and 40CFR180.950. LEXX® is registered in all US states. LEXX® is NSF-listed as a Category D2 sanitizer which is acceptable for use as a sanitizer on all surfaces not always requiring a rinse in and around food processing areas. LEXX® is labeled in accordance with the EPA registered label and does not require the use of Personal Protective Equipment (PPE) when using the concentrate or end-use diluted forms. Although the EPA regulations do not require a Safety Data Sheet (SDS), a US Occupational Safety and Health Administration (OSHA) compliant SDS is available for end users of LEXX®, if desired.

### Available LEXX Products:

- LEXX Disinfectant (Concentrate Gallons)
- LEXX Disinfectant – Vanilla Scent (Concentrate Gallons)
- LEXX Disinfectant – Vanilla Scent (32 oz Ready To Use Spray Bottle)
- LEXX Sanitizer (Concentrate Gallons)
- LEXX Sanitizer (Case of 72, 2 oz Cups)
- LEXX Sanitizer (32 oz Ready To Use Spray Bottle)
- LEXX Fruit and Vegetable Wash (32 oz Spray Bottle)

## APPENDIX A

### **Brief Synopsis of the Publicly-Available Biodegradation Data for the Ingredients in LEXX®**

#### **INTRODUCTION**

A search for publicly available biodegradation data for the ingredients in LEXX® was conducted at TOXNET (<http://toxnet.nlm.nih.gov/>). This is a government run database that has data on many different properties of commonly used chemicals, including biodegradation data. Biodegradation data was obtained for each organic (carbon-containing) ingredient in LEXX® and are summarized below. Based on a review of the data, all ingredients are expected to be biodegradable resulting in LEXX® also being biodegradable.

#### **INGREDIENT INFORMATION**

##### Citric acid

**AEROBIC:** The biodegradability of citric acid was determined in six different tests and results found it to be well degraded in all tests(1). Citric acid achieved 93% DOC removal in a coupled units test (sludge inoculum), 85% DOC removal after 1 day in a Zahn-Wellens test (sludge inoculum), 100% DOC removal in an AFNOR test (42 days, germs inoculum simulating polluted river water), 100% DOC removal in a Sturm test (42 days, sewage treatment plant effluent), 100% DOC removal in an OECD screening test (19 days, effluent simulating surface water), and 90% BODT in a closed bottle test (30 days, effluent simulating surface water)(1). Citric acid reached 53% of its theoretical BOD in 5 days using a sludge inoculum(2). Citric acid, present at 500 mg/L, reached 46% of its theoretical oxygen demand in 12 hours using a phenol acclimated activated sludge inoculum(3). Citric acid, present at 500 mg/L, reached 98.4% of its theoretical BOD in 22 to 24 hours using an activated sludge inoculum at 2,228 mg/L(4). Citric acid (1% w/v) displayed BOD values of 6,410 and 6,040 mg/L using a defined microbial mixture and sewage inoculums, respectively(5). Citric acid, present at 10 mg/L, reached 66.4% and 67.3% of its theoretical BOD after 5 days using freshwater and seawater inoculums, respectively(6).

*[(1) Gerike P, Fischer WK; Ecotox Environ Safety 3: 159-73 (1979) (2) Heukelekian H, Rand MC; J Water Pollut Contr Assoc 27: 1040-53 (1955) (3) McKinney RE et al; Sew Indust Wastes 28: 547-57 (1956) (4) Placak OR, Ruchhoft CC; Sewage Works J 19: 423-40 (1947) (5) Sharma A et al; Bull Environ Contam Toxicol 57: 34-40 (1996) (6) Takemoto S et al; Suishitsu Odaku Kenkyu 4: 80-90 (1981)] \*\*PEER REVIEWED\*\**

**ANAEROBIC:** Citric acid, present at 800 mg/L, exhibited a degradation rate of 77.2 (12.7 mg/g-VSS/day) with a lag phase of 3 days in 39 days under sulfate reducing conditions, indicating that the compound is biodegradable under anaerobic conditions (1).

*[(1) Hollingsworth J et al; Chemosphere 59: 1219-1228 (2005)] \*\*PEER REVIEWED\*\**



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PURE CULTURE: In NASA wastewater inoculated with batch microbial cultures, citric acid (5 mg/mL) was degraded more than 50% after 15 days by *Achromobacter* sp.(1).

[(1) *Nwankwoala AU et al; Biodegradation 10: 105-12 (1999)*] \*\*PEER REVIEWED\*\*

ENVIRONMENTAL ABIOTIC DEGRADATION: A citric acid aqueous solution (pH 1), with a hydroxy radical concentration of  $1 \times 10^{-17}$  mol/L, had a reaction rate constant of  $3.0 \times 10^{-7}$  L/mol-sec at room temperature(1). This corresponds to a calculated half-life of 73 years(1). Citric acid is not expected to undergo hydrolysis in the environment due to the lack of functional groups that hydrolyze under environmental conditions(2). Citric acid absorbs light at wavelengths up to 260 nm(3) and, therefore, is not expected to be susceptible to direct photolysis since sunlight consists of wavelengths above 290 nm(SRC).

[(1) Anbar M, Neta P; *Int J of Appl Radiation and Isotopes 18:493-523 (1967)* (2) Lyman WJ et al; *Handbook of Chemical Property Estimation Methods*. Washington, DC: Amer Chem Soc pp. 7-4, 7-5 (1990) (3) NIST; NIST Chemistry WebBook. Citric acid (77-92-9). NIST Standard Reference Database No. 69, June 2005 Release. Washington, DC: US Sec Commerce. Available from, as of Sept 6, 2013: <http://webbook.nist.gov> \*\*PEER REVIEWED\*\*

ENVIRONMENTAL BIOCONCENTRATION: An estimated BCF of 3 was calculated for citric acid(SRC), using a log Kow of -1.64(1) and a regression-derived equation(2). According to a classification scheme(3), this BCF suggests the potential for bioconcentration in aquatic organisms is low(SRC).

[(1) Avdeef A; *Seminar on Ionization and Lipophilicity*. Log P values measured by pION Inc., Brookline, MA (A. Avdeef and C. Berger) (1997) (2) US EPA; Estimation Program Interface (EPI) Suite. Ver. 4.1. Nov, 2012. Available from, as of Sept 6, 2013: <http://www.epa.gov/oppt/exposure/pubs/episuitedi.htm/> (3) Franke C et al; *Chemosphere 29: 1501-14 (1994)*] \*\*PEER REVIEWED\*\*

### Sodium Lauryl Sulfate

ENVIRONMENTAL BIODEGRADATION: SURFACTANTS ARE TREATED WITH PSEUDOMONAS TO DECOMPOSE THEM IN WASTEWATER. LF 2102 BACTERIA CULTURE WAS TREATED WITH SOLN CONTAINING 1000 PPM DODECYL ALCOHOL SULFATE. DECOMP WAS 100%.

[NEGI T ET AL; JPN KOKAI TOKKYO KOHO PATENT NUMBER 78 75381 07/04/78 (LION FAT & OIL CO, LTD)] \*\*PEER REVIEWED\*\*

DISSOLVED ORGANIC CARBON ELIMINATION RATE FROM ACTIVATED SLUDGE WAS 80-100% FOR LAURYL SULFATE.

[SCHEFER W, WALCHLI O; *CHIMIA 34(8) 349 (1980)*] \*\*PEER REVIEWED\*\*

AEROBIC: Dodecyl sulfate, present at approximately 50 mg/l, reached 70% of its theoretical BOD (93% DOC removal) in 2 weeks using an activated sludge inoculum at 30 mg/l and the Japanese MITI test(1). Initially present at approximately 10 mg/l, 69% DOC removal was measured after 28 days (preceded by a 14 day acclimation period) using the Sturm method(2).

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[(1) Gerike P, Fischer WK; *Ecotox Environ Safety* 3: 159-73 (1979) (2) Huddleston RL, Allred RC; *Devel Indust Microbiol* 4: 24-38 (1963)] \*\*PEER REVIEWED\*\*

**ENVIRONMENTAL BIOCONCENTRATION:** An estimated BCF of 71 was calculated for dodecyl sulfate (SRC), using an estimated log Kow of 2.4(1) and a regression-derived equation(2). According to a classification scheme(3), this BCF suggests the potential for bioconcentration in aquatic organisms is moderate.

[(1) Meylan WM, Howard PH; *J Pharm Sci* 84: 83-92 (1995) (2) Meylan WM et al; *Environ Toxicol Chem* 18: 664-72 (1999) (3) Franke C et al; *Chemosphere* 29: 1501-14 (1994)] \*\*\*PEER REVIEWED\*\*

### Isopropyl alcohol (also known as isopropanol or rubbing alcohol)

**AEROBIC:** Degradation of isopropanol with municipal waste water for 5 and 20 days resulted in a theoretical oxygen demand (ThOD) of 7% and 70%, respectively(1). Degradation of 3, 7 and 10 mg/L of isopropanol with filtered sewage seed in fresh water resulted in a ThOD of 28% in 5 days and 78% in 20 days(2). In 2 other studies, the ThOD for isopropanol using domestic waste water was 66% and 74% in 5 days(1). Isopropanol was 99% degraded with acclimated activated sludge at 20 deg C (52 mg COD/g-hr rate)(3). Filtered sewage seed resulted in a ThOD of 49% and acclimated sewage seed resulted in a ThOD of 72% after 5 days(4). Degradation of isopropanol with sewage at 20 deg C for 5 days resulted in a ThOD of 58% (avg 4 results)(5). In domestic waste water, diluted with salt water, a ThOD of 13% in 5 days and 72% in 20 days was observed(1). Biodegradation of 3, 7, and 10 mg/L of isopropanol with filtered sewage seed in salt water resulted in a ThOD of 13% in 5 days and a ThOD of 72% in 20 days(2). Isopropanol, present at 100 mg/L, reached 86% of its theoretical BOD in 2 weeks using an activated sludge inoculum at 30 mg/L in the Japanese MITI test which determined isopropanol to be ready biodegradable(6).

[(1) WHO; *Environmental Health Criteria 103, 2-Propanol*. Geneva, Switzerland: WHO International Program on Chemical Safety. pp. 1-77 (1990) (2) Price KS et al; *J Water Pollut Control Fed* 46: 63-77 (1974) (3) Pitter P; *Water Res* 10: 231-5 (1976) (4) Bridie AL et al; *Water Res* 13: 627-30 (1979) (5) Heukelekian H, Rand MC; *J Water Pollut Control Assoc* 29: 1040-53 (1955) (6) NITE; *Chemical Risk Information Platform (CHRIP). Biodegradation and Bioconcentration*. Tokyo, Japan: Natl Inst Tech Eval. Available from, as of Sept 30, 2011: [http://www.safe.nite.go.jp/english/kizon/KIZON\\_start\\_hazkizon.html](http://www.safe.nite.go.jp/english/kizon/KIZON_start_hazkizon.html) \*\*PEER REVIEWED\*\*

**ANAEROBIC:** Typical isopropanol removal efficiencies for an anaerobic lagoon treatment facility, with a retention time of 15 days, were 50% after loading with dilute waste, and 69 and 74% after loading with concentrated wastes(1). In closed bottle studies, isopropanol was completely degraded anaerobically by an acetate-enriched culture, derived from a seed of domestic sludge(1). The culture started to use cross-fed isopropanol, after 4 days, at a rate of 200 mg/L/day(1). In a mixed reactor with a 20-day retention time, seeded by the same culture, 56% removal was achieved in the 20 days following 70 days of acclimation to a final concentration of 10,000 mg/L(1). The avg percent removal of isopropanol in semi-pilot scale anaerobic lagoons was 50% in 7.5-10 days for dilute wastes with 60 ppm isopropanol and 69-74% in 20-40 days for concentrated wastes with 175 ppm isopropanol(2). Isopropanol was readily mineralized to methane and carbon dioxide under methanogenic conditions(3). The degradation rate of

isopropanol under these conditions in fuel impacted river sediments and industrial/sewage impacted creek sediments was 2.4 ppm C/day (82% of expected methane recovery) and 3.0 ppm C/day (91% of expected methane recovery), respectively(3). The degradation rate of isopropanol in a sediment slurry from a shallow anoxic aquifer under methanogenic conditions was 7.6 ppm C/day (112% of theoretical methane recovery)(4). In anaerobic bioreactor studies using a granular sludge inocula, isopropanol (at 125 ppm initial concentration) degraded with 115.5% of theoretical methane production over a 21-day incubation period(5); acetone was identified as a metabolite(5). In laboratory anaerobic sludge reactor tests using liquid hen manure as inoculum, isopropanol was degraded 100% in a 13-day incubation period with lag period(6).

[(1) WHO; *Environmental Health Criteria 103, 2-Propanol*. Geneva, Switzerland: WHO International Program on Chemical Safety. pp. 1-77 (1990) (2) Hovious JC et al; *Anaerobic Treatment of Synthetic Organic Wastes USEPA-12020 DIS 01/72 p. 41* (1972) (3) Mormile MR et al; *Environ Sci Technol* 28: 1727-32 (1994) (4) Sufliata JM, Mormile MR; *Environ Sci Technol* 27: 976-78 (1993) (5) Hollingsworth J et al; *Chemosphere* 59: 1219-1228 (2005) (6) Sklyar VI et al; *Appl Biochem Biotechnol* 81: 107-117 (1999)]  
\*\*PEER REVIEWED\*\*

**ENVIRONMENTAL ABIOTIC DEGRADATION:** The rate constant for the vapor-phase reaction of isopropanol with photochemically-produced hydroxyl radicals is  $5.07 \times 10^{-12}$  cu cm/molecule-sec at 25 deg C(1). This corresponds to an atmospheric half-life of about 3.2 days at an atmospheric concentration of  $5 \times 10^5$  hydroxyl radicals per cu cm(SRC). Isopropanol is considered to have low reactivity (class 2 of 5 where class 5 is high) in photochemical smog situations(2,3) having an ozone forming potential 68% that of toluene(3). A 20% decrease in isopropanol was observed after 5 hr in a smog chamber at 30 deg C containing 2 ppm isopropanol and 1 ppm nitrous oxides at 55% relative humidity(3). The rate constant for the vapor-phase reaction of isopropanol with nitrate radicals in night-time air is  $2.3 \times 10^{-15}$  cu cm/molecule-sec at 25 deg C(4). This corresponds to an atmospheric half-life of about 15 days at a night-time atmospheric concentration of  $2.4 \times 10^8$  nitrate radicals per cu cm (24-hr average)(5). Isopropanol is not expected to undergo hydrolysis in the environment due to the lack of hydrolyzable functional groups(6). The rate constant for the reaction of isopropanol with hydroxyl radicals in aqueous solution is  $1.0 \times 10^9$  L/mol-sec(7); this corresponds to an aquatic half-life of about 2.3 years at an aquatic concentration of  $1 \times 10^{-17}$  hydroxyl radicals per liter(8).

[(1) Kwok ESC, Atkinson R; *Estimation of hydroxyl radical reaction rate constants for gas-phase organic compounds using a structure-reactivity relationship: an update*. Riverside, CA: Univ CA, Statewide Air Pollut Res Ctr. CMA Contract No. ARC-8.0-OR (1994) (2) Levy A; *Amer Chem Soc Ser* 124: 70-94 (1973) (3) Farley FF; *Int Conf Photochem Oxidant Pollut Control* pp.713-27 USEPA-600/3-77-001b (1977) (4) Gramatica P et al; *Atmos Environ* 37: 3115-3124 (2003) (5) Atkinson R et al; *Environ Sci Technol* 19: 87-90 (1985) (6) Lyman WJ et al; *Handbook of Chemical Property Estimation Methods*. Washington, DC: Amer Chem Soc pp. 7-4, 7-5 (1990) (7) Buxton GV et al; *J Phys Chem Ref Data* 17: 513-882 (1988) (8) Mill T et al; *Science* 207: 886-887 (1980)] \*\*PEER REVIEWED\*\*

**ENVIRONMENTAL BIOCONCENTRATION:** An estimated BCF of 3 was calculated in fish for isopropanol(SRC), using a log Kow of 0.05(1) and a regression-derived equation(2). According to a classification scheme(3), this BCF suggests the potential for bioconcentration in aquatic organisms is low(SRC).

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[(1) Hansch C et al; Exploring QSAR. Hydrophobic, Electronic, and Steric Constants. ACS Prof Ref Book. Heller SR, consult. ed., Washington, DC: Amer Chem Soc p. 7 (1995) (2) US EPA; Estimation Program Interface (EPI) Suite. Ver. 4.1. Jan, 2010. Available from, as of Sept 29, 2011: <http://www.epa.gov/oppt/exposure/pubs/epiSuitedl.htm> (3) Franke C et al; Chemosphere 29: 1501-14 (1994)] \*\*PEER REVIEWED\*\*

### Sodium bicarbonate (also known as baking soda)

Sodium bicarbonate contains a carbon atom but it is considered a mineral; therefore, biodegradation data do not apply.

### Decanoic Acid

AEROBIC: The 5 day BOD of decanoic acid, concn 100 ppm, was determined to be 8.52 mmol/mmol decanoic acid using acclimated mixed microbial cultures in a mineral salt medium(1). Decanoic acid, present at 10,000 ppm, reached 45 to 53% and 46 to 54% of its theoretical BOD in 5 and 20 days, respectively, using a sewage inoculum(2). Decanoic acid, present at 10,000 ppm, reached 13, 45, and 46% of its theoretical BOD in 5, 10, and 20 days, respectively, using a sewage inoculum(3). In a similar study, decanoic acid, present at 10,000 ppm, reached 49, 53, and 54% of its theoretical BOD in 5, 10, and 20 days, respectively, using an acclimated sewage inoculum(3). Decanoic acid, present at unknown concn, reached 9% of its theoretical BOD in 5 days using a sewage inoculum(4). Using the Warburg test method, decanoic acid, present at 500 ppm, reached 29 to 42% of its theoretical BOD in 1 day, using an activated sludge inoculum with a microbial population of 2,500 mg/L corrected for endogenous respiration(5). Biodegradation of 100 ppm decanoic acid using the cultivation method was 100% in river water and 100% in sea water after 3 days(6). The theoretical oxygen demand for 500 mg/L decanoic acid was determined to be 10.9%, 18.9%, and 23.4% after 6, 12, and 24 hours of exposure to activated sludge solids at 2,500 mg/L in the Warburg respirometer(7). An aerobic biodegradation screening study of decanoic acid, based on BOD measurements, using a sewage inoculum and an unknown decanoic acid concn, indicated 23% of its theoretical BOD over a period of 20 days(8). The biodegradation of 100 mg/L decanoic acid by non-acclimated activated sludge over an unspecified time period was determined to have 100% total organic carbon removal(9).

[(1) Babeu L, Vaishnav DD; J Indust Microbiol 2: 107-15 (1987) (2) Gaffney PE, Heukelekian H; J Water Pollut Control Fed 30: 673-79 (1958) (3) Gaffney PE, Heukelekian H; J Water Pollut Control Fed 33: 1169-83 (1961) (4) Dore M et al; Trib Cebedeau 28: 3-11 (1975) (5) Malaney GW, Gerhold RM; pp. 249-257 in Proc 17th Ind Waste Conf, Purdue Univ, Ext Ser 112 (1962) (6) Kondo M et al; Eisei Kagaku 34: 188-95 (1988) (7) Malaney GW, Gerhold RM; J Water Poll Control Fed 41: R18-R33 (1969) (8) Nieme GJ et al; Environ Toxicol Chem 6: 515-27 (1987) (9) Yonezawa Y et al; Kogai Shigen Kenkyusho Iho 12: 85-91 (1982)] \*\*PEER REVIEWED\*\*

ENVIRONMENTAL ABIOTIC DEGRADATION: The rate constant for the vapor-phase reaction of decanoic acid with photochemically-produced hydroxyl radicals has been estimated as  $1.1 \times 10^{-11}$  cu cm/molecule-sec at 25 deg C(SRC) using a structure estimation method(1). This corresponds to an atmospheric half-life of about 1.4 days at an atmospheric concentration of  $5 \times 10^5$  hydroxyl radicals per cu cm(1). Decanoic acid is not expected to undergo hydrolysis in the environment due to the lack of

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functional groups that hydrolyze under environmental conditions(2). Decanoic acid was present at 1.5 mg/L in the influent to a continuous retort water treatment cell; after 1, 3 and 5 weeks decanoic acid was not detected, and after 7 weeks decanoic acid was found at 108.6 mg/L, indicating adsorption followed by desorption(3).

[(1) Meylan WM, Howard PH; Chemosphere 26: 2293-99 (1993) (2) Lyman WJ et al; Handbook of Chemical Property Estimation Methods. Washington, DC: Amer Chem Soc pp. 7-4, 7-5, 8-12 (1990) (3) Syamsiah S et al; Fuel 72: 855-61 (1993)] \*\*PEER REVIEWED\*\*

ENVIRONMENTAL BIOCONCENTRATION: An estimated BCF of 3 was calculated in fish for decanoic acid(SRC), using a log Kow of 4.09(1) and a regression-derived equation(2). According to a classification scheme(3), this BCF suggests the potential for bioconcentration in aquatic organisms is low(SRC).

[(1) Hansch C et al; Exploring QSAR. Hydrophobic, Electronic, and Steric Constants. ACS Prof Ref Book. Heller SR, consult. ed., Washington, DC: Amer Chem Soc p. 81 (1995) (2) Meylan WM et al; Environ Toxicol Chem 18: 664-72 (1999) (3) Franke C et al; Chemosphere 29: 1501-14 (1994)] \*\*PEER REVIEWED\*\*