

PURE HARD SURFACE

TECHNICAL REPORT



PURE HARD SURFACE: TECHNICAL REPORT

PRODUCT DESCRIPTION:

PURE Hard Surface is a colorless, odorless, ready-to-use disinfectant and sanitizer for use on hard non-porous, environmental surfaces, including food contact surfaces.

INGREDIENTS:

ACTIVE INGREDIENTS:	Silver†	0.003 %
	Citric Acid	4.846 %
OTHER INGREDIENTS:		95.151 %
TOTAL:		100.000 %

† Electrolytically generated silver ions stabilized in citric acid as Silver Dihydrogen Citrate

REGISTRATION:

PURE Hard Surface is registered with the U.S. Environmental Protection Agency.

EPA REG. NO.: 72977-5-73912

EPA EST. NO.: 72977-CA-001

U.S. Patent(s) 6,197,814; 6,583,176

Other patents pending

PURE HARD SURFACE: TECHNICAL REPORT

DIRECTION FOR USE:

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

DISINFECTION:

AREAS OF APPLICATION:

Homes, offices, hospitals, restaurants, schools, hotels, restrooms, recreational facilities, public transport vehicles.

Use on painted, glazed tile, plastic, metal, glass and glazed porcelain.

For other areas, test in an inconspicuous area before use.

TO DISINFECT HARD, NON-POROUS SURFACES:

Pre-clean surfaces prior to disinfecting. Apply PURE Hard Surface to the surface until thoroughly wet for the contact time as listed. Wipe dry with a clean towel.

RESIDUAL PROTECTION: When used as directed, this product provides residual protection from *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella enterica* up to 24 hours after initial application. Do not touch treated surface after application if residual protection is to be maintained.

BACTERIA:

ORGANISM	CONTACT TIME*
<i>Pseudomonas aeruginosa</i>	30 seconds
<i>Salmonella enterica</i>	30 seconds
<i>Staphylococcus aureus</i>	2 minutes
<i>Listeria monocytogenes</i>	2 minutes
Vancomycin resistant <i>Enterococcus faecium</i> (VRE)	2 minutes
Methicillin resistant <i>Staphylococcus aureus</i> (MRSA)	2 minutes
Community Associated MRSA (CA-MRSA)	2 minutes
Community Associated MRSA (CA-MRSA-PVL)	2 minutes
<i>Escherichia coli</i> O157:H7	2 minutes
<i>Acinetobacter baumannii</i>	2 minutes
<i>Campylobacter jejuni</i>	2 minutes
Carbapenem resistant <i>Escherichia coli</i>	2 minutes
Carbapenem resistant <i>Klebsiella pneumoniae</i>	2 minutes
Carbapenem resistant <i>Klebsiella pneumoniae</i> , NDM-1	2 minutes

VIRUSES:

ORGANISM	CONTACT TIME*
HIV type 1	30 seconds
Rotavirus	30 seconds
Human Coronavirus	30 seconds
Avian Influenza A	30 seconds
Influenza A	30 seconds
Influenza A (H1N1)	30 seconds
Swine Influenza A (H1N1)	30 seconds
Respiratory Syncytial Virus	30 seconds
Adenovirus Type 2	30 seconds
Herpes Simplex Type 1	60 seconds
Murine Norovirus	60 seconds
Norovirus	60 seconds
Rhinovirus	60 seconds
Polio Type 2	60 seconds
Hepatitis B Virus (HBV)	60 seconds
Hepatitis C Virus (HCV)	60 seconds

FUNGUS:

ORGANISM	CONTACT TIME*
Trichophyton mentagrophytes (Athlete's Foot Fungus)	5 minutes

*Contact times based upon EPA Stamped label dated August 3, 2011

PURE HARD SURFACE: TECHNICAL REPORT

SANITIZATION OF FOOD CONTACT SURFACES

AREAS OF APPLICATION:

Restaurants, homes, food processing plants, food storage areas, supermarkets, kitchens schools, hotels and dining halls. Use on painted, glazed tile, plastic, metal, glass and glazed porcelain. For other areas, test in an inconspicuous area before use.

TO SANITIZE FOOD CONTACT SURFACES:

Pre-clean surfaces prior to using this product. Do not use this product on utensils, dishes or glassware.

CONSUMER APPLICATIONS:

Spray, pour or spread PURE Hard Surface on surface until thoroughly wet. Let stand for 60 seconds and wipe with a clean towel or allow to air dry. No rinsing is required. This product kills 99.999% of *Escherichia coli* and *Staphylococcus aureus*.

COMMERCIAL APPLICATIONS:

To sanitize food processing equipment and other hard surfaces in food processing locations, dairies, restaurants and bars:

CLEAN, RINSE SANITIZE:

Prior to application, remove gross food particles and soil by pre-flush or pre-scrape and when necessary, pre-soak. Thoroughly wash objects to be sanitized with a good detergent or cleaner followed by a potable water rinse prior to applying sanitizer. No potable water rinse is allowed after application as a sanitizer.

Apply this product by spraying or by total immersion. Surfaces must remain wet for 60 seconds. If the surface cannot be washed and rinsed, clean thoroughly in an appropriate fashion prior to sanitizing.

This product is a ready to use sanitizer that eliminates 99.999% of the following bacteria in 60 seconds:

Escherichia coli, *Staphylococcus aureus*.

FEDERALLY INSPECTED FACILITIES:

Prior to use in a federally inspected meat and poultry plants and dairies, food products and packaging materials must be removed from the room or carefully protected. A potable water rinse is not permitted following the use of this product as a sanitizer on previously cleaned hard, non-porous surfaces, provided that the surfaces are adequately drained before contact with food so that little or no residue remains.

Apply product to pre-cleaned hard surfaces thoroughly wetting surfaces with a cloth, mop, sponge, sprayer or by immersion. Surfaces should remain wet for 1 minute followed by adequate draining and air drying.

This product is a ready to use sanitizer that eliminates 99.999% of the following bacteria in 60 seconds:

Escherichia coli, *Staphylococcus aureus*.

BEVERAGE DISPENSING EQUIPMENT SANITIZER DIRECTIONS:

For sanitizing of bottling or pre-mixed dispensing equipment after cleaning thoroughly rinse equipment with a potable water rinse. Fill equipment with this product and allow it to remain in the equipment for at least 60 seconds. Sanitizing solution should be drained from the system. To insure the removal of flavors, it is suggested that during changeover between products the system should be cleaned, rinsed and flushed with the sanitizing solution for at least 1 minute. Drain thoroughly and allow to air dry before reuse. No potable water rinse is allowed.

FOR SANITIZING IN FISHERIES, MILK, WINE, CITRUS, POTATO & ICE CREAM PROCESSING PLANTS:

For use as a sanitizer on conveyor belts and equipment to reduce or eliminate odors in the processing area. Also for use on filling equipment to reduce bacteria. Follow directions for sanitizing food contact surfaces.

PURE HARD SURFACE: TECHNICAL REPORT

MECHANISM OF ACTION

BACTERICIDAL/FUNGICIDAL ACTION:

The active ingredient in PURE Hard Surface is Silver Dihydrogen Citrate (SDC), a worldwide patented technology. SDC provides silver ions stabilized in citric acid.

The bacterial outer membrane is called the cell wall. Bacterial cell walls are made of peptidoglycan which provides protection and rigidity to the organism. The exact membrane constitution depends on the type of bacteria. SDC utilizes a multiple prong attack against microorganisms. SDC targets an organism's cell wall. Silver ions are highly attracted to sulfur-containing thiol groups found in metabolic and structural proteins bound to the membrane surface. SDC targets these critical proteins and destroys their structure. This disruption of the organism's membrane function and integrity lyses the membrane and the organism dies.

Unlike traditional antimicrobials, bacteria are actually attracted to SDC because they recognize citric acid as a food source. This "Trojan Horse" attack allows SDC to easily enter the microorganism through membrane transport proteins. Once inside the organism, SDC binds to DNA and intracellular proteins causing irreversible damage to the DNA and protein structure. Metabolic and reproductive functions halt, and the organism dies.

VIRUCIDAL ACTION:

Viruses are much smaller than bacterial and fungal cells and do not have metabolic activity. Viruses present fewer targets sites on which a biocide can act. Silver targets the viral envelope or capsid and the viral nucleic acid. Silver not only destroys the viral envelope or capsid, preventing the virus from attaching to a host cell, it also destroys the infectious component of the virus, the nucleic acid.

MICROBIOLOGICAL TEST DATA

BACTERIAL TEST METHODS:

For registration with the US Environmental Protection Agency (US EPA), disinfection efficacy is tested following either the AOAC Use Dilution Test Method or the AOAC Germicidal Spray Products Test Method. In each method, cultures of bacteria are dried onto a number of small carriers (stainless steel penicylinders in the Use-Dilution test or glass slides in the AOAC Germicidal Spray Products Test). Once dried, the carriers must contain a bacteria concentration of at least 10^4 . These carriers are exposed to the disinfectant for a specified contact time and then transferred to test tubes containing growth medium and a neutralizing agent to stop the action of the disinfectant. The carriers are incubated for 48 hours. The tubes are then examined for growth or no growth. To pass a 60 carrier test, three batches are tested and 59 out of 60 carriers must show no growth for each product batch. To pass a 10 carrier test, two batches are tested and all 10 carriers must show no growth.

To make general broad spectrum claims a disinfectant must show efficacy against a *Staphylococcus aureus* (Gram positive bacteria) and *Salmonella enterica* (Gram negative bacteria). To make claim for use in and hospital/medical environments a disinfectant must show efficacy against *Pseudomonas aeruginosa* (nosocomial bacteria). Other bacteria may be tested to obtain additional claims.

ORGANISM	# OF CARRIERS EXPOSED	# OF CARRIERS SHOWING GROWTH	CONTACT TIME	CARRIER POPULATION
<i>Pseudomonas aeruginosa</i> (ATCC#15442)	180	0	30 seconds	10^6
<i>Staphylococcus aureus</i> (ATCC#6538)	180	2	2 minutes	10^6
<i>Salmonella enterica</i> (ATCC#10708)	180	0	30 seconds	10^5
<i>Listeria monocytogenes</i> (ATCC#19111)	20	0	2 minutes	10^6
Vancomycin resistant <i>Enterococcus faecium</i> (VRE) (ATCC#700221)	20	0	2 minutes	$10^{4.5}$
Methicillin resistant <i>Staphylococcus aureus</i> (MRSA) (ATCC#700698)	20	0	2 minutes	10^5
Community Associated MRSA (CA-MRSA) (NRS123, USA 400)	20	0	2 minutes	10^6
Community Associated MRSA (CA-MRSA-PVL) (NRS 192)	20	0	2 minutes	10^6
<i>Escherichia coli</i> O157:H7 (ATCC#43888)	20	0	2 minutes	$10^{4.5}$
<i>Acinetobacter baumannii</i> (ATCC#19606)	20	0	2 minutes	10^6
<i>Campylobacter jejuni</i> (ATCC#29428)	20	0	2 minutes	10^6
Carbapenem resistant <i>Escherichia coli</i>	20	0	2 minutes	10^5
Carbapenem resistant <i>Klebsiella pneumoniae</i>	20	0	2 minutes	10^5
Carbapenem resistant <i>Klebsiella pneumoniae</i> , NDM-1	20	0	2 minutes	10^5

PURE HARD SURFACE: TECHNICAL REPORT

MICROBIOLOGICAL TEST DATA (CONT.)

VIRAL TEST METHODS:

The US EPA accepts carrier based virucidal test methods to support virucidal activity of a disinfectant which are modifications of the AOAC Use Dilution Test or the AOAC Germicidal Spray Products Test. Each virus claimed must be tested in an appropriate test system using a cell line which supports the growth of the virus.

The method as outlined in the EPA Disinfectant Technical Science section (DIS-TSS 07) states:

To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of two different batches of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface (petri dish, glass slide, steel cylinder, etc.) for a specified exposure period at room temperature. The virus is then assayed by an appropriate virological technique.

In order for the data to be considered valid, the following criteria must be met:

- 1: Virus concentration after drying must be at least 10^4 .
- 2: Complete inactivation of the viruses at all dilutions is required. If cytotoxicity is evident, at least a 3 log reduction of virus concentration must be demonstrated beyond the cytopathic effect.
- 3: Cell controls must be negative for infectivity.

ORGANISM	DRIED VIRUS CONTROL	LOG REDUCTION	CONTACT TIME
HIV type 1- Strain HTLV IIIB	$10^{5.25}$	≥ 3.75	30 seconds
Herpes Simplex Type 1 VR-733 F(1) Strain (ATCC VR-733)	10^6	≥ 5.5	60 seconds
Rotavirus (Strain WA, Ottawa)	$10^{4.5}$	≥ 4.0	30 seconds
Human Coronavirus (ATCC VR-740)	$10^{4.5}$	≥ 4.0	30 seconds
Influenza A (H1N1) (ATCC VR-1469)	$10^{6.5}$	≥ 6.0	30 seconds
Swine Influenza A (H1N1) (ATCC VR-333)	$10^{6.75}$	≥ 6.25	30 seconds
Respiratory Syncytial Virus (ATCC VR-26)	$10^{4.75}$	≥ 4.25	30 seconds
Adenovirus Type 2 (ATCC VR-846)	$10^{6.0}$	≥ 5.5	30 seconds
Murine Norovirus (MNV-1.CW1)	$10^{6.5}$	≥ 6.0	60 seconds
Norovirus -as Feline Calicivirus (ATCC VR-782)	$10^{6.0}$	≥ 5.88	60 seconds
Avian Influenza A (ATCC VR-2072)	$10^{4.75}$	≥ 4.25	30 seconds
Influenza A (ATCC VR-544)	$10^{6.5}$	≥ 6.0	30 seconds
Rhinovirus (ATCC VR-1147)	$10^{4.5}$	≥ 4.0	60 seconds
Polio Type 2 (ATCC VR-1002)	$10^{4.5}$	≥ 3.0	60 seconds
Hepatitis B Virus (HBV)	10^6	≥ 5.79	60 seconds
Hepatitis C Virus (HCV)	$10^{5.25}$	≥ 4.93	60 seconds

FUNGAL TEST METHODS:

For registration with the US EPA, efficacy against pathogenic fungi is determined by following the AOAC Fungicidal Test Method or modifications of either the AOAC Use Dilution Test Method modified or the AOAC Germicidal Spray Products Test Method which meet the criteria of the AOAC Fungicidal Test Method. The carrier method is outlined below.

The disinfectant is placed in a water bath and allowed to equilibrate to a temperature of $20.0\text{ }^\circ\text{C} \pm 0.5\text{ }^\circ\text{C}$. Carriers will be inoculated with test culture. Carriers must have a minimum concentration of 10^4 after drying. Each contaminated and dried carrier is placed into a test tube containing test substance for the specified contact time and then transferred to test tubes containing growth medium and a neutralizing agent to stop the action of the disinfectant. The carriers are incubated for an appropriate time based upon the test organism. The tubes are examined for growth or no growth. To pass a 60 carrier test, two batches are tested and 59 out of 60 carriers must show no growth for each product batch. To pass a 10 carrier test, two batches are tested and all 10 carriers must show no growth.

ORGANISM	# OF CARRIERS EXPOSED	# OF CARRIERS SHOWING GROWTH	CONTACT TIME
Trichophyton mentagrophytes (Athlete's Foot Fungus) ATCC#9533	10	0	5 minutes

PURE HARD SURFACE: TECHNICAL REPORT

MICROBIOLOGICAL TEST DATA (CONT.)

FOOD CONTACT SURFACE SANITIZER TEST METHODS:

Sanitizers applied to food contact surfaces are defined as incidental food additives under the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 201 et seq.), and require establishment of a food additive tolerance or an exemption for the need for a tolerance. In addition, to support registration with the US EPA, the product must show efficacy following the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants (AOAC 960.09) test method.

In this method, cultures of each test organism are grown in an appropriate broth and grown to an acceptable concentration. In duplicate for each test organism, 1 mL of the concentrated culture is inoculated into a flask containing 99 mL of the test product for the contact time of 30 seconds. After the contact time has elapsed, aliquots of the organism/test substance are neutralized and plated to analyze for surviving microorganisms as compared to the untreated control. Acceptable results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. The EPA requires that labels directions state a minimum contact time of 1 minute for sanitization of food contact surfaces.

ORGANISM	DRIED VIRUS CONTROL	LOG REDUCTION	CONTACT TIME	% REDUCTION
<i>Staphylococcus aureus</i>	8.0 x 10 ⁷	≥10 ⁷	30 seconds	>99.999
<i>Escherichia coli</i>	9.4 x 10 ⁷	≥10 ⁷	30 seconds	>99.999

Note: No surviving organisms were detected for all three lots in all replicates for both test organisms.

All efficacy studies performed on the product to substantiate the efficacy claims are performed at third party laboratories which are recognized for their expertise in AOAC test methods. The test labs include:

ATS Labs (formerly AppTec Laboratories), Minnesota USA
Nelson Laboratories, Utah USA
Bioscience Laboratories, Inc., Montana USA

Studies are available for review upon request.

PURE HARD SURFACE: TECHNICAL REPORT

SAFETY DATA:

FROM THE EPA LABEL REVIEW MANUAL:

The EPA determines the Toxicity Category based on the Acute Toxicity Data provided by the registrant. Here is the rating system utilized by the EPA:

STUDY	CATEGORY I	CATEGORY II	CATEGORY III	CATEGORY IV
Acute Oral	Up to and including 50 mg/kg	> 50 thru 500 mg/kg	> 500 thru 5000 mg/kg	> 5000 mg/kg
Acute Dermal	Up to and including 200 mg/kg	> 200 thru 2000 mg/kg	> 2000 thru 5000 mg/kg	> 5000 mg/kg
Acute Inhalation ¹	Up to and including 0.05 mg/liter	> 0.05 thru 0.5 mg/liter	> 0.5 thru 2 mg/liter	> 2 mg/liter
Primary Eye Irritation	Corrosive (irreversible destruction of ocular tissue) or corneal involvement or irritation persisting for more than 21 days	Corneal involvement or other eye irritation clearing in 8-21 days	Corneal involvement or other eye irritation clearing in 7 days or less	Minimal effects clearing in less than 24 hours
Primary Skin Irritation	Corrosive (tissue destruction into the dermis and/or scarring)	Severe irritation at 72 hours (severe erythema or edema)	Moderate irritation at 72 hours (moderate erythema)	Mild or slight irritation at 72 hours (no irritation or slight erythema)
SIGNAL WORD	DANGER	WARNING	CAUTION	NONE REQUIRED

¹ 4 hr exposure

A Signal Word is required based on the Toxicity category assigned to a pesticide by the EPA. For Category IV products, no Signal Word is required and no first aid statements are required. The Signal Word is determined by the most severe toxicity category assigned to the five acute toxicity studies or by the presence of methanol in concentrations of 4% or more.

**PURE Hard Surface falls into US EPA Category IV based on all of the toxicity data.
The product does not require a Signal Word or First Aid statements to be listed on the label.**

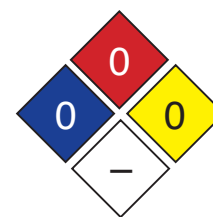
HMIS RATING:

Hazardous Material Identification System

Health	0
Flammability	0
Reactivity	0

NFPA:

National Fire Protection Association



PURE HARD SURFACE: TECHNICAL REPORT

PHYSICAL DATA:

Appearance	Clear, colorless liquid
Odor	Practically odorless
pH	2
Specific Gravity (H ₂ O=1)	1
Solubility	Water soluble
VOC Content (% Wt.)	0.00% (0.000 lbs/gallon)
Flash Point	> 212°F

STORAGE AND DISPOSAL:

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

PESTICIDE STORAGE: Store in a cool, dry area away from direct sunlight at temperatures above freezing.

PESTICIDE DISPOSAL: Nonrefillable Container*. Refill only with this product. Do not reuse or refill except as described in the directions for use. If empty: Place in trash or offer for recycling if available. Rinse thoroughly before discarding in trash or recycling.

**As defined by the EPA, a Nonrefillable Container is one that is not intended to be refilled with pesticide for sale. This term applies to bottles which are intended to be refilled with the same product more than once for use but not for sale or distribution.*

QUESTIONS?

For Customer Service please call: (619) 596-8600

Customer Service Hours of Operation Mon-Fri 8am-5pm PST

Distributed by PURE Bioscience, Inc.

NASDAQ: PURE



VOICE: **619.596.8600** | FACSIMILE: **619.596.8790**
1725 GILLESPIE WAY | EL CAJON, CALIFORNIA 92020
NASDAQ: **PURE**

©2011 PURE Bioscience, Inc. **PUREBIO.COM**

