



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

EPA Reg. Number:

88341-11

Date of Issuance:

11/2/21

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Pure 100

Name and Address of Registrant (include ZIP Code):

Sherri Gray
T.A. Comb, LLC
1241 N. Ellis Street
Bensenville, IL 60106

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

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

Date:

11/2/21

1. You are required to comply with the data requirements described in the DCI identified below:
 - a. Chlorine Dioxide GDCI- 020503-1567, GDCI-020503-29674
 - b. Sodium chlorite: GDCI-020502-156, GDCI-020502-29789

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>

2. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 88341-11.”
3. Submit one copy of the final printed label for the record before you release the product for shipment.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels (“Guidance”), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.
2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)

C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page
(www.cdc.gov/hai/outbreaks)

ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).

A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is small non-enveloped, large non-enveloped, and enveloped.

B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.

4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE's publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.
5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Feline Calicivirus is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 11/2/2021

If you have any questions, please contact Aidan Fife by phone at 703-347-8522, or via email at fife.aidan@epa.gov.

Sincerely,

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

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

Enclosure

Pure 100

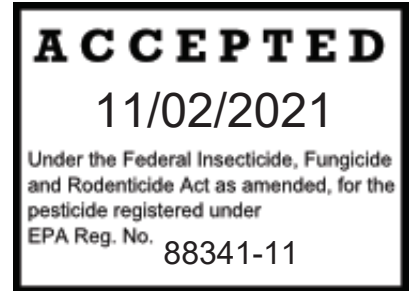
ACTIVE INGREDIENT:

Chlorine dioxide..... 0.013%

OTHER INGREDIENTS:..... 99.987%

TOTAL..... 100.00%

KEEP OUT OF REACH OF CHILDREN



EPA Reg. No. 88341-RR

EPA Est. No.

Manufactured for:

T.A. Comb, LLC

1241 N Ellis

Bensenville, IL 60106

Net Contents:

Pure 100 is a broad spectrum disinfectant, hospital disinfectant and virucide for RESIDENTIAL, COMMERCIAL & HOSPITAL use.

Pure 100 Disinfectant & Odor Remover for everyday disinfecting in the kitchen and bathroom, quick clean-ups, and spot treatment. Pure 100 kills bacteria and viruses and eliminates odor in homes, offices, facilities, and other environments. Essential for homes with children and pets. Kills bacteria and viruses on food-contact surfaces with no rinse required, and eliminates odor at a molecular level, not by masking with fragrance.

Pure100 Features:

- Full strength and ready to use
- Hospital disinfectant with lowest toxicity category—gentle enough for daily disinfecting
- Heavy duty odor eliminator—gets rid of bad odors by attacking the source of the problem, not by masking
- Neutral pH
- No volatile organic compounds (VOCs)
- No harsh chemicals, no nauseous fumes

Effective disinfectant that kills:

- Feline Calicivirus (as a surrogate virus for Norovirus), ATCC VR-782, Strain F-9
- Hepatitis A virus, ATCC Camden (HM-175 strain), Strain HM-175
- Pseudomonas aeruginosa (ATCC 15442)
- Salmonella enterica (ATCC 10708)
- Staphylococcus aureus (ATCC 6538)

For use in:

Homes, vehicles, schools, daycare, gyms, locker rooms, sports gear, hospitals, nursing homes, laundry rooms, veterinary, ambulances, laboratories, restaurants, boats, ships, federally inspected meat & poultry processing plants, farms, animal pens and poultry houses, egg processing premises, hatcheries, swine premise sanitation, refrigerated storage units, HVAC and AC systems, airplanes, trains, trucks, buses, automobiles, recreational vehicles, botanical facilities, commercial greenhouses, customer/public areas, floral shops, garden centers, horticultural facilities, plant growing chambers, plant growing facilities, plant growing rooms, plant holding areas, greenhouse equipment, greenhouse films, plant display racks, plant grow shelves.

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Contains a dilute oxidizing agent. Refer to manufacturer's care instructions before using equipment or devices.

Pre-Cleaning Instructions: Remove visible soil by cleaning. Spray product straight onto soils, scrub and wipe clean with a dry paper towel or cloth.

TO DISINFECT HARD NON-POROUS SURFACES: For disinfecting pre-cleaned hard non-porous surfaces such as glass, plastic, painted wood, laminate, chrome, stainless steel, polyurethane coated hardwood floors, glazed ceramic tile, sealed concrete & linoleum floors.

Types of items include: Exterior of appliances, bed frames, cabinet handles, wheelchairs, child car seats, counters, cribs, doorknobs, tables, tubs, exterior toilet surfaces, faucet handles, handrails, jungle gyms,

keyboards, light switch covers, patio furniture, showers, sinks, stovetops, telephones, toys, walls, waste containers.

Application: Apply Pure 100 undiluted full strength to pre-cleaned hard non-porous surfaces, wetting thoroughly with spray, sponge, mop, or by immersion in solution. Allow surfaces to remain visibly wet for 10 minutes for virus inactivation and bacteria disinfection. For immersion, replace solution daily, or more frequently if it becomes significantly soiled or diluted. **FOGGING AND MISTING:** Pure 100 can be applied by fogging or misting to disinfect hard, nonporous surfaces. Apply by fogging or misting until surface is moist using equipment. Carefully protect all food and food packaging materials prior to treatment. Vacate treatment area and do not reenter until air is clear (minimum 1 hour to reentry).

TO DEODORIZE: Pure 100 works by oxidation, not by masking of odors. Eliminates odors caused by fire smoke, tobacco smoke, musty odors, stale-cooking odors. Simply spray, fog, or wipe on full strength and let air dry. When fogging to deodorize apply 1 quart per 2000 cubic ft. following fogger manufacturer's directions for use. **TO DEODORIZE HVAC SYSTEM DUCTWORK:** Spray Pure 100 into system intake vents while system fan is running. Allow enough spray time for Pure 100 to contact air duct system surfaces. Repeat application, as necessary.

TO USE AS A PRECLEANER OR POSTCLEANER: Spray a light even coating over soiled area (until wet). Allow to remain visibly wet for 60 minutes. Deep clean following your machine's guide.

TO SANITIZE NON-FOOD CONTACT HARD NON-POROUS SURFACES: *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708), *Staphylococcus aureus* (ATCC 6538), apply product full strength as a one-step cleaner sanitizer (5% organic soil load) by wetting thoroughly with spray, sponge, mop, or by immersion in solution and let stand 10 minutes. Wipe and allow to air dry. No rinse required. For immersion, replace solution daily, or more frequently if it becomes significantly soiled or diluted.

HOSPITALS/HEALTHCARE FACILITIES: Pure 100 cleans, disinfects, and deodorizes hard, nonporous hospital and medical surfaces in one step with no rinsing required. Pure 100 is a one-step germicidal* disinfectant cleaner and deodorant designed for general cleaning and disinfecting of hard, nonporous inanimate surfaces, when use-directions for disinfection are followed. Removes dirt, grime, fungus, mold, food residue, blood and other organic matter commonly found in hospitals and in health care facilities. It also eliminates odors leaving restroom surfaces smelling clean and fresh. Use where odors are a problem.

TO DISINFECT FOOD CONTACT SURFACES: *Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708), and *Pseudomonas aeruginosa* (ATCC 15442) disinfection of food contact surfaces (food processing equipment, tables, counters, appliances, etc.). Pre-clean and rinse with potable water to remove gross food particles then wet thoroughly with full strength Pure 100 and allow to air dry.

STORAGE AND DISPOSAL: Store in original closed container in a cool, dry, place away from heat and open flame. Do not allow product to become overheated in storage. Avoid prolonged storage temperature above 40°C, 90°F. This may cause increased degradation of the product, which will decrease product effectiveness. Non-refillable -or- Refill only with this product. Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container. **CONTAINER DISPOSAL:** Rinse and offer empty container for recycling. If recycling is not available, discard container in trash. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Discard excess or used product solution in drain with running water.

This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, or (2) contacts intact mucous membranes but which do not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical devices prior to sterilization or high-level disinfection.

Pathogen*	Strain	Contact Time
Feline Calicivirus (as a surrogate virus for Norovirus)	ATCC VR-782 Strain F-9	10 Minutes
Hepatitis A virus	ATCC Camden Strain HM-175	10 Minutes
Pseudomonas aeruginosa	ATCC 15442	10 Minutes
Salmonella enterica	ATCC 10708	10 Minutes
Staphylococcus aureus	ATCC 6538	10 Minutes

Emerging Viral Pathogens

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.

(Note to the reviewer: The statements shall be made through the following communication outlets: technical literature distributed exclusively to veterinarians, 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 meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

- Enveloped Viruses
- Large, Non-Enveloped Viruses
- Small, 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
Large, non-enveloped virus	Feline calicivirus
Small, non-enveloped virus	Feline calicivirus Hepatitis A Virus

Acceptable claim language:

[Product name] has demonstrated effectiveness against viruses similar to **[name of emerging virus]** on hard, **[non-porous surfaces]**. Therefore, **[product name]** can be used against **[name of emerging virus]** when used in accordance with directions for use against **[name of supporting virus(es)]** 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]**. **[Product name]** kills similar viruses and therefore can be used against **[name of emerging virus]** when used in accordance with the directions for use against **[name of supporting virus(es)]** on **[hard, non-porous surfaces]**. Refer to the **[CDC or OIE]** website at **[website address]** for additional information.

WARRANTY STATEMENT

T.A. Comb, LLC warrants that this product complies with the specifications expressed on the label. To the extent consistent with applicable law, **T.A. Comb, LLC** makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose.