

U.S. ENVIRONMENTAL PROTECTION AGENCY

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

06738-3	

EPA Reg. Number:

Date of Issuance:

10/29/21

| -

NOTICE OF PESTICIDE:

X Registration
Reregistration
(under FIFRA, as amended)

Name of Pesticide Product:

Term of Issuance:

Conditional

Aktive Disinfecting Wipes

Name and Address of Registrant (include ZIP Code):

Jennifer Wolbers Chief Operating Officer, NVIP Vaxman Group 2231 Linwood Avenue Naples, FL 34112

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 (FIFRA).

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/registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:	Date:
	10/29/21
Demson Fuller, Product Manager 32 Regulatory Management Branch I Antimicrobials Division (7510P)	

EPA Form 8570-6

- 2. You are required to comply with the data requirements described in the DCI identified below:
 - a. Didecyl Dimethyl Ammonium Chloride GDCI-069149-30869
 - b. Alkyl Dimethyl Benzyl Ammonium Chlorides GDCI-069105-30882

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

- 3. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
- 4. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 96738-3."
- 5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process, FIFRA section 12(a)(1)(B). Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Assurance.

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 05/28/2021

If you have any questions, please contact Michael Varco by phone at 703-347-0403, or via email at Varco.Michael@epa.gov.

Sincerely,

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

Enclosure: Product Label

All words phrases, or symbols in [] and bolded are OPTIONAL

AKTIVE!

Disinfecting Wipes

ADDITIONAL BRAND NAMES

Great Expectations Disinfecting Wipes
Casey's Disinfecting Wipes
Walgreens Disinfecting Wipes
Up & Up Disinfecting Wipes
The OhSo Co. Disinfecting Wipes

For use on environmental surfaces

ACTIVE INGREDIENTS:

SARS-CoV2 and

Bactericidal Tested

ACCEPTED

10/29/2021

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

96738-3

DANGER - PELIGRO

{Note to reviewer: In accordance in 40 CFR 156.66 (d) all First Aid statements, as prescribed, will appear on the front panel of the product label.}

KEEP OUT OF REACH OF CHILDREN

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

DO NOT USE AS A DIAPER WIPE OR FOR PERSONAL CLEANSING

[See side], [rear], [back], attached panel label for additional precautionary statements.

Contents: 750 Wipes

[750 Presaturated Wipes Mega Bucket (18 cm x 15 cm)]

Net Weight: 7.5 lbs./ 3.4kilograms

Contents: 500 Wipes

[500 Presaturated Wipes (18 cm x 15 cm)]

Net Weight: 5 lbs. / 2.25 kilograms

Contents: 160 Wipes

[160 Presaturated Wipes (18 cm x 15 cm)]

Net Weight: 1.6 lbs. / 725 grams

EPA.REG.No.96738 MASTER LABEL

Contents: 75 Wipes

[75 Presaturated Wipes (18 cm x 15 cm)] Net Weight:

12 oz / 340 grams Contents: 50 Wipes

[SO Presaturated Wipes (18 cm x 15 cm)] Net Weight: 8 oz/

225 grams

Contents: 35 Wipes

[35 Presaturated Wipes (18 cm x 15 cm)] Net Weight:

5.6 oz/ 165 grams

Contents: 20 Wipes

[20 Presaturated Wipes (18 cm x 15 cm)] Net Weight:

3.2 oz/ 95 grams

WIPES Disinfecting Wipes

Fresh Scent

Use Anytime. Stay Clean.

Kills <u>99.9%</u> of the pathogens tested! (Staphylococcus aureus (ATCC 6538), Salmonella enterica (ATCC 10708), Pseudomonas aeruginosa (ATCC 15442) and SARS-CoV-2 on hard, nonporous surfaces)

Kills pandemic 2020 SARS-CoV2 associated with COVID-19 on hard, non-poruous surfaces.

AKTIVE! Disinfecting Wipes are effective only on the following pathogens in 10 [ten] minutes at 20°C/68°F on hard non-porous surfaces when used as directed.

Staphylococcus aureus (ATCC 6538)

Salmonella enterica (ATCC 10708)

Pseudomonas aeruginosa (ATCC 15442)

PREPERATION OF DISPENSER 750, 500, 160, 75 and 35 count: Before using, open the lid, take the wipe from the center of the roll, and pass it through the hole in the lid. Remaining wipes feed automatically for next use. Always reseal hinged cap after each use to insure moisture retention.

PREPERATION OF DISPENSER 50 and 20 count: Before using, open the seal, take the wipe from the center, and pass it through the hole in the pouch. Remaining wipes feed automatically for next use. Always reseal pouch after each use to insure moisture retention.

DIRECTONS FOR USE: It is a violation of U.S Federal law to use this product in a manner inconsistent with its labeling. This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly to the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contact intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be saved to preclean or decontaminate critical or semi-critical medical devices which does not ordinarily penetrate

the blood barrier or otherwise enter normally sterile areas of the body. This product may be saved to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection. This product is not for use on the inhalation therapy and/or pulmonary diagnostic equipment.

DISINFECTION: Thoroughly wet hard, non-porous surfaces with a wipe keep visibly wet during entire 10 minutes and allow to air dry. Use as many wipes as required for the treated surface to remain visibly wet for the entire contact time. For use on a general disinfectant, on hard, non-porous, inanimate surfaces [See list of surfaces]. You may use a wipe to pre-clean the surface to be disinfected, thoroughly repeat with a fresh wipe for disinfection. When used on food contact surfaces use potable water rinse after disinfection.

DEODORIZING: Wipe hard, non-porous surfaces thoroughly to eliminate odors from bathrooms, industrial process processes, fecal matter, urine, burns, smoke, mildew and mold, decay, stale air, tobacco, sickrooms, and musty closets.

CLEANING: To clean surfaces, wipe thoroughly with a fresh wipe, which may be-used to deodorize at the same time as cleaning. [refer to list of recommended surfaces] and [similar areas]. When used to clean a hard non-porous surface prior to disinfection, a second wipe can be used for disinfection.

All words phrases, or symbols in [] and bolded are OPTIONAL

THE ACTIVITY OF WIPES AGAINST SARS-CoV-2, a causative agent of COVID-19, on hard, nonporous surfaces.

AKTIVE! inactivates the SARS-CoV-2 on hard non-porous surfaces when used at a contact time of 2 minutes at room temperature {20-25°C). AKTIVE! kills SARS-CoV-2 on pre-cleaned environmental hard, non-porous surfaces.

STORAGE AND DISPOSAL:

Store in cool area. Keep away from heat or open flame. Do not reuse wipes. Dispose of used wipe in trash.

Non-refillable container. Do not reuse or refill this container. Then offer for recycling, if available, or puncture and dispose of in a sanitary landfill, or by incineration.

PRECAUTIONARY STATEMENT:

Hazard to Humans and Domestic Animals

DANGER. CORROSIVE: Causes irreversible eye damage. Harmful if swallowed or absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin. Wear goggles, face shield or safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the restroom. Remove and wash contaminated clothing before reuse.

FIRST AID:

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after first 5 minutes, then continue rinsing eye.
- Call Poison Control Center or doctor for treatment advice.

If on skin or clothing:

- · Take off contaminated clothing.
- Rinse skin immediately with water for 15 to 20 minutes.
- · Call a Poison Control Center or doctor for treatment advice.

If Swallowed:

- Call a Poison Control Center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- · Do not induce vomiting unless told to do so by a Poison Control Center or doctor
- Do not give anything by mouth to an unconscious person.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Have product container or label with you when calling a Poison Control Center or doctor for treatment advice.

For emergency information on (product, use, etc.), call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific Time (PT) seven days a week. During other times call the Poison Center 1-800-222-1222.

Manufactured for U.S.A by: VAXMAN Group 2015 LTD.

Sold by: Hall Global dsa AKTIVE Health LLC

Gordon 14 Haifa, Israel 2231 Linwood Ave, Naples, FL 34112

EPA Reg. No. 96738 EPA Est No. 96738-ISR-001 EPA Est No. 90856-FL-001 For product emergency, contact Chem-Tel at 1-800-377-8988. For technical information call 1- 616-560-8229. For an SDS, contact AKTIVE GROUP, LLC at 800-257-1513 or visit. www.aktivehealth.com and request documents.

Optional Marketing claims:

- Virucidal
- Disinfecting
- Deodorizing
- Cleaning Wipes
- For use on hard non-porous surfaces only [see list of use sites)

This product (AKTIVE!) is a broad-spectrum hard non-porous surface disinfectant that has been shown to be effective against (Staphylococcus aureus, Salmonella enterica Pseudomonas aeruginosa)

- This product has demonstrated effectiveness against Staphylococcus aureus, Salmonella enterica, Pseudomonas aeruginosa on hard non-porous surfaces.
- Kills pandemic 2020 SARS-CoV-2 associated with COVID-19 on hard, non-porous surfaces.
- KILLS:

Staphylococcus aureus [ATTC 6538)

Salmonella enterica [ATTC 10708)

Pseudomonas aeruginosa [ATTC 15442)

AKTIVE! Disinfecting Wipes

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Note to reviewer: The following are optional text

Areas of use:

For use on hard, non porous surfaces in:

Hospital Emergency medical settings Veterinary facilities

Medical offices Emergency rooms Industrial plants

Dental offices Intensive care units Industrial facilities

Clinics physician offices Sickrooms Salons

Health care offices Orthopedics offices Spas

Ambulances patient rooms
Nursing facilities
Health clubs

Recovery rooms Respiratory therapy rooms Bathrooms Schools

X-Rayrooms

Musty closets School buses
Cat. Lab

Janitorial rooms

Laboratories

Exam rooms Kitchens

For use on hard, non porous

surfaces in:

Stainless steel Formica Plastic Glass tables Glass surfaces

Metal Equipment Meta/Carts Chart Racks Exam Tables Hard, non-porous beds

Springs Frames Wheel chairs Walkers Counter tops

Counters Cabinets Operating room hard surfaces Ambulance equipment and surfaces

[can be used for] external surfaces and/ or anesthetic equipment Chairs Tubs

Sinks Exterior surfaces of toilets Basins Laundry Hampers Telephones

Baskets Wastebaskets Waste Carts Light fixtures Door knob

Office Machinery Cages Razors and razor blades Combs Mirrors

Clipper blades Clippers Cutters Cutter Blades Shears Exterior hard surfaces or

Office Furniture

tanning beds