



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

EPA Reg. Number:

98194-1

Date of Issuance:

6/11/21

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

DisinfeX Disinfecting Wipes

Name and Address of Registrant (include ZIP Code):

SENT TO:

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/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.
2. You are required to comply with the data requirements described in the DCI identified below:
 - a. DDAC GDCI-069165-30870
 - b. DDAC GDCI-069166-30875
 - c. DDAC GDCI-069149-30869
 - d. ADBAC GDCI-069105-30882

Signature of Approving Official:

Jacqueline Hardy
Jacqueline Hardy, Chief
Regulatory Management Branch II
Antimicrobials Division (7510P)

Date:

6/11/21

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. 98194-1."
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 04/27/2021

The following alternate brand names have been added to the product record:

- GREAT VALUE™ DISINFECTING WIPES
- HDX™ ANTIBACTERIAL DISINFECTING WIPES
- HOMELINE™ DISINFECTING WIPES

If you have any questions, please contact [REDACTED]

Enclosure: Stamped Label

Note to reviewer:

[Items in brackets [AAA] are optional and may/may not be included on final label]

{Items in braces {AAA} are for information purposes and will not appear on final label}

DisinfeX Disinfecting Wipes

[ALTERNATE BRAND NAMES: GREAT VALUE™ DISINFECTING WIPES, HDX™ ANTIBACTERIAL DISINFECTING WIPES, HOMELINE™ DISINFECTING WIPES]

[Disinfectant⁶] and/or [Virucide*] and/or [Sanitizer⁶] and/or [Anti-bacterial]

Kills Flu Virus*⁴

Active Ingredients:

Octyl decyl dimethyl ammonium chloride.....	0.0909%
Dioctyl dimethyl ammonium chloride.....	0.0364%
Didecyl dimethyl ammonium chloride.....	0.0545%
Alkyl (C14, 50%; C12, 40%; C16, 10%) dimethyl benzyl ammonium chloride	0.1212%
Other Ingredients:.....	99.6970%
Total.....	100.0000% ¹

ACCEPTED

06/11/2021

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under

EPA Reg. No. 98194-1

KEEP OUT OF REACH OF CHILDREN (KOROC)

CAUTION [PRECAUCIÓN]

See [left] [side] [right] [back] [bottom] panel for Precautionary Statements and First Aid

[Distributed by:]

[Manufactured for:]

[Marketed Through:]

██████████ (insert address and/or website)]

EPA Reg. No. _____

EPA Est. No. (as indicated on container)

Net Contents: insert # [premoistened] [towelettes] [wipes] [disinfecting] [antibacterial] [cleaning] [wet]
[multi- purpose] [touch-up] [pre-moistened cloths] [sheets]

Net Contents: (expressed as avoirdupois pounds and ounces)

[Minimum Wt.]

[optional: wipe dimensions:] X x X [inches] [in.]

[Barcode]

[DOT symbols]

[QR Code]

[Country of origin (insert country)]

[Manufactured in (insert country)]

{Note to Reviewer: for multi-packs}

[2][3][x]- [canister] [pack]

[[Bonus] Twin pack]

PRECAUTIONARY STATEMENTS**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

Caution. Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. 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 a Poison Control Center or a doctor for treatment advice.

If on Skin or Clothing:

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

If Swallowed:

- Call a Poison Control Center or a 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 a doctor.
- Do not give anything by mouth to an unconscious person.

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

For emergency information on this product, call the National Pesticide 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 Control Center 1-800-222-1222.

{Note to reviewer: Pages 3-5 are considered optional marketing language. All designators (i.e. asterisks and numbers) used throughout the label may be interchanged as needed on final printed label.}

CLEANING CLAIMS:

- Wipes Away [Tough] [Everyday] [Messes] [Grease] [Grime]

DISINFECTION CLAIMS:

- Kills 99.9% of Germs² [Bacteria] [Viruses*] [Bacteria and Viruses*]
- Kills Cold & Flu Virus [Viruses]*⁴
- Kills common household germs²
- Kills common [household][kitchen][bathroom] germs²
- Kills coronavirus^{4,5,8} that causes COVID-19 [SARS-CoV-2] [USA-WA-1/2020]
- [Kills] [Effective against] the virus^{4,5,8} that causes COVID-19 [SARS-CoV-2] [USA-WA-1/2020]
- [Kills] Germs² [Influenza Type A/Brazil, the Flu Virus,⁴ [Influenza] [A/Brazil/11/1978]] [Bacteria] [Bacteria and Viruses*] [Viruses*]
- Kills Salmonella enterica [ATCC 10708], Methicillin-Resistant Staphylococcus Aureus [ATCC 33592] & Flu Virus*⁴
- Kills [Wipes Out] 99.9% [of] [Listeria monocytogenes [ATCC 19117]] [MRSA] [Methicillin-Resistant Staphylococcus Aureus] [ATCC 33592]
- Wipes out^{4,5} 99.9% of COVID-19 virus⁸ [SARS-CoV-2] [USA-WA-1/2020]
- Wipes out^{4,5} 99.9% of the coronavirus⁸ that causes COVID-19 [SARS-CoV-2] [USA-WA-1/2020]
- Wipes out^{4,5} 99.9% of the virus⁸ that causes COVID-19 [SARS-CoV-2] [USA-WA-1/2020]

SANITIZATION CLAIMS:

- Kills 99.9% of bacteria in [just] 15 seconds[!]⁶
- 99.9% effective against [Staphylococcus aureus [ATCC 6538]], [Klebsiella pneumonia [ATCC 4352]], [Campylobacter jejuni [ATCC 29428]] in [just] 15 seconds[!]⁶

H1N1 CLAIMS:

- Kills Pandemic 2009 H1N1 influenza A virus⁴ [formerly called swine flu] [ATCC VR-1469. Strain A/PR/8/34].

USAGE CLAIMS:

- For Homes, Institutional and Industrial Use

SUBSTRATE CLAIMS:

- [Premoistened] [wet] disinfecting [textured] [antibacterial] [wipes] [towelettes] [cloths]

{Note to reviewer: A representative graphic of a substrate may be added to the label. Only a graphic of the substrate actually being used can be added to the final printed label.}

OTHER CLAIMS:

- Assembled in the USA *{Note to reviewer: can only be claimed if statement is accurate}*
- Comments?
- Contains No Phosphate
- Do not use for personal cleansing.
- Questions?
- Ready to Use

{Note to reviewer: The following is considered optional marketing language. Each item below also represents a graphic depicting the corresponding area of use. The graphics will only represent individual objects or outsides or insides of buildings as described below. No people, animal, or food will be depicted in graphics.}

[AREAS OF USE⁴]

Use [DisinfeX] Disinfecting Wipes [2] in:

- Airplanes
- Ambulances
- Emergency Vehicles
- Hospitals
- Medical Offices
- Nursing Homes
- Health Clubs
- Schools

{Note to reviewer: Each item below also represents a graphic depicting the corresponding type of surface. No people, animal, or food will be depicted in graphics.}

[TYPES OF SURFACES:]

[Use [DisinfeX] Disinfecting Wipes [2] on washable hard, nonporous surfaces of:]

{or}

[This product] will clean and disinfect⁵ washable hard, nonporous surfaces of:

- Computer keyboards
- Counters [countertops] [Bathroom] [Kitchen]
- Desks
- Doorknobs Faucets
- Non-Wooden Outdoor [patio] furniture except cushions and wood frames
- Shower [stalls] [walls] Sinks [bathroom, kitchen]
- Stoves⁷ [stovetops⁷]
- Telephones
- Exterior Toilet bowl surfaces
- Tub walls
- Tubs
- Walls
- Non-critical [medical] equipment surfaces
- Examining tables
- Stethoscopes
- Ultra-sound transducers and equipment
- Other hard nonporous surfaces [made of]:
- Glass
- Metal
- Plastic
- Stainless Steel
- Upholstery - vinyl and plastic

{Note to reviewer: Below claims will only be used if/when disinfection directions are included on final label}

[DisinfeX] Disinfecting Wipes [2] [are effective against⁵] [Kills⁵] [Removes⁵] [Destroys⁵]:

[Bacteria:]

- *Staphylococcus aureus* [Staph] [ATCC 6538]
- *Staphylococcus aureus* - Methicillin-Resistant [MRSA] [ATCC 33592]
- *Salmonella enterica* [Salmonella] [ATCC 10708]

- *Pseudomonas aeruginosa* [Pseudomonas] [ATCC 15442]
- *Campylobacter jejuni* [Campylobacter] [ATCC 29428]
- *Klebsiella pneumoniae* [Klebsiella] [ATCC 4352]
- *Escherichia coli* O157:H7 [E. coli O157:H7] [ATCC 35150]
- *Listeria monocytogenes* [ATCC 19117]

[Viruses:]

- *Human Coronavirus [ATCC VR-740, Strain 229E]
- *Influenza Type A Virus / Brazil [Influenza] [[the] Flu [Virus]] [A/Brazil/11/1978]
- *Influenza A Virus H1N1 [ATCC VR-1469, Strain A/PR/8/34]
- *Rotavirus [Diarrhea-causing virus]
- *SARS-Related Coronavirus 2 [SARS-CoV-2] [USA-WA-1/2020] [cause of COVID-19]^{4,8}
- *Hepatitis C Virus [HCV] [Oregon C24v-genotype 1 Strain]

{Note to reviewer: Below claims will only be used if/when sanitizing directions are included on final label}
[DisinfeX] Disinfecting Wipes [2] [are] [99.9%] [effective against⁶] [Kills⁶] [Removes⁶] [Destroys⁶]:

[Bacteria:]

- *Staphylococcus aureus* [Staph] [ATCC 6538]
- *Klebsiella pneumoniae* [Klebsiella] [ATCC 4352]
- *Campylobacter jejuni* [Campylobacter] [ATCC 29428]
- *Escherichia coli* O157:H7 [E. coli O157:H7] [ATCC 35150]
- *Listeria monocytogenes* [ATCC 19117]
- *Salmonella enterica* [Salmonella] [ATCC 10708]

{Note to Reviewer: These statements for claims against enveloped and large, non-enveloped viruses, shall not appear on marketed (final print) product labels.}

{Note to reviewer: Representative graphic of wipe tub and/or hand pulling out wipe fabric may be added to the label}

{For canister}

To Open Package:

Remove cover. Pull up [towelette] [wipe] [cloth] corner from center of roll. Thread through hole in the cover. Replace cover. Open center cap on cover to remove wipe. When not in use [When not using], close center cap [securely] to prevent moisture loss.

or

To Open Package: [Remove package seal[s]] [Remove safety seal[s]]. Open [Flip open lid [package]. To start [remove] [first] wipe [sheet] [wet cloth] take the edge of wipe from large opening to the small dispensing opening and pull up. [The next wipe [sheet] [wet cloth] [cloth] will pop up automatically.] [Always] close [snap] lid securely between uses [to retain moisture].

or

To Open Package: Flip open[up] the lid[cover][top][cap][dispensing lid]. Thread the wipe [first wipe][cloth][first cloth][sheet] through the dispensing lid and pull up to remove wipe from package. The next wipe [sheet][cloth] pops up automatically. Close lid securely between uses to retain moisture[prevent moisture loss].

or

To Open Package: Open dispenser and top of bag. Pull out the first wipe approximately 6 to 8 inches from the center of the roll. Place the entire bag inside of dispenser. Thread the wipe through the opening on the dispenser lid. Close the lid to retain moisture.

or

To Open Package: Open lid and pull from center of roll. The next sheet pops up automatically. When finished close lid to retain moisture.

DIRECTIONS FOR USE:

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

Do not use as a diaper wipe or for personal cleansing. This is not a baby wipe[!]
Do not flush [in toilet].

For plastic and painted surfaces, spot test on an inconspicuous area before use.
[This product or product name] will not harm most surfaces: including acrylic, sealed fiberglass and vinyl. Do not use on unpainted wood.
[Note: Not recommended for unpainted wood, natural marble or brass.]

TO CLEAN AND DEODORIZE:

Wipe surface with [wipe] [towelette] [cloth] [sheet]. Let air dry. Discard used [wipe] [towelette] [cloth] [sheet] in trash. Do not flush [in toilet].

[TO] CLEAN [CLEANING] AND DISINFECT [DISINFECTION / VIRUCIDAL* DIRECTIONS]:

Wipe hard, nonporous surface with [wipe] [towelette] [cloth] [sheet] until surface is visibly wet. [Use enough wipes to thoroughly wet surfaces.] [Use [enough] [extra] wipes to keep surfaces [visibly] wet for 4 minutes.] [Keep surfaces [visibly] wet for 4 minutes.] [Wipe surface and let it remain [visible] wet for 4 minutes.] Allow surface to remain wet for 4 minutes. *{Note to reviewer: if using claims for Rotavirus, the following sentence will be required:}* **[For Rotavirus [Diarrhea-causing virus], treated surfaces must remain wet for 10 minutes.]** [Let air dry.] [[Let] Permit surface to [air] dry.] If surfaces are visibly dirty, clean first with another [wipe] [towelette] [cloth] [sheet] before disinfecting. Discard used [wipe] [towelette] [cloth] [sheet] in trash. Do not flush [in toilet].

Rinse food contact surfaces with clean, potable water after disinfecting. Do not use to disinfect dishes,

glassware or utensils.

Note for reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following statements must be used:}

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, either into or in contact with the bloodstream or normally sterile areas of the body, or [2] contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. [This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.]

{or}

This product is not for use on medical device surfaces.

SANITIZING [DEODORIZING]:

To sanitize [deodorize] hard, non-porous, non-food contact surfaces; wipe surface, using enough [wipes] [towelettes] [cloths] to allow treated surface to remain wet for 15 seconds [for] [*Salmonella enterica*] [*Salmonella*] [ATCC 10708] [*Staphylococcus aureus*] [Staph] [ATCC 6538], [*Klebsiella pneumoniae*] [*Klebsiella*] [ATCC 4352], [*Campylobacter jejuni*] [ATCC 29428], [*Escherichia coli*] [O157:H7] [*E. coli* O157:H7] [ATCC 35150], and [*Listeria monocytogenes*] [ATCC 19117]. Let surface dry. For visibly soiled surfaces, clean visible dirt [from the surface] first.

TO CLEAN AND DEODORIZE: Wipe surface with wipe. Let air dry. Discard used wipe in trash. Do not flush [in toilet].

{Note to reviewer: Nonrefillable container}

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Keep securely closed. Nonrefillable container. Do not reuse or refill this container. Discard empty container in trash or recycle (if available).

FOOTNOTES:

¹Includes weight of absorbent wipe.

²For qualified claims insert some pathogens from pages 4-5.

Note to reviewer: *If a supplemental label is using the "Germs" claim, per the EPA Guidance on use of the term "Germs" in order to make an unqualified "germ" claim the supplemental label must list all 3 of the major classes of organisms: Virus, Bacteria, Fungi and label must bear disinfectant directions. In order to make a qualified "germ" claim the supplemental label must be a broad spectrum disinfectant and list additional claims against one of the following two major classes of organisms: Fungi or Viruses and must bear disinfectant directions. The front panel of the label for a qualified claim must contain a designator (such as **) that refers the user to the qualified statements that describes the type of germ the product is efficacious against. An unqualified claim can appear on front or back panel and does not require a designator.*

³Rinse toys with clean, potable water after disinfecting.

⁴On hard, non-porous, non-food surfaces.

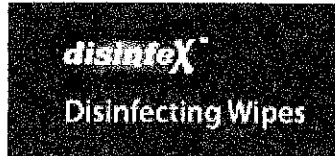
⁵When used according to the disinfection directions.

⁶When used according to the sanitization directions.

⁷Allow the surface to adjust to room temperature before disinfection.

⁸SARS-Related Coronavirus 2.

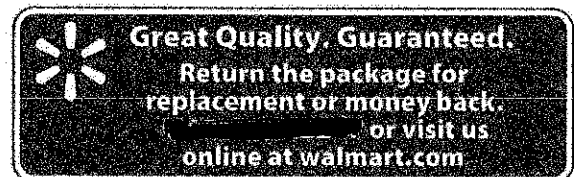
{Note to reviewer: The following are optional graphics. Specific images are subject to reasonable modifications (e.g., tweaks to product logo designs).}



Disinfecting Wipes

Antibacterial Disinfecting Wipes

Disinfecting Wipes



Tub and Shower Walls



Telephone



Stovetop



Door knob



Kitchen Countertops



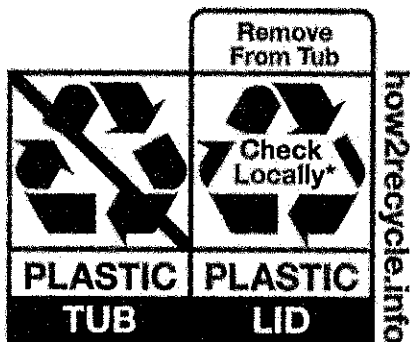
Faucet & Sink



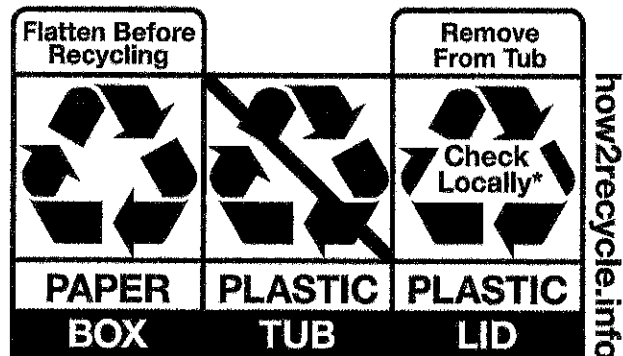
Exterior Toilet Bowl Surfaces



Non-Wooden Outdoor Patio Furniture Except Cushions & Wood Frames



*Not recycled in all communities



*Not recycled in all communities