



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 5, 2020

Christina M. Swick
Authorized Agent for The Chemours Company FC, LLC
Lewis & Harrison
2461 South Clark St., Suite 710
Arlington, VA 22202

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: Glyclean Hard Surface Cleaner
EPA Registration Number: 71654-5
Application Date: April 7, 2020
Decision Number: 561715

Dear Ms. Swick:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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 are 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 Rhinovirus Type 37 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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,



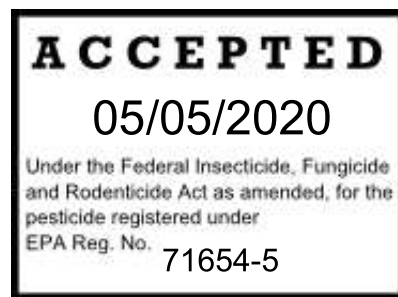
Steven Snyderman, Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: stamped label

NOTE TO REVIEWER: <denotes optional text>, e. g. <optional>

GLYCLEAN® HARD SURFACE CLEANER

ACTIVE INGREDIENT: Glycolic acid 5.0%
OTHER INGREDIENTS: 95.0%
TOTAL: 100.0%



Keep Out of Reach of Children

WARNING

FIRST AID STATEMENTS

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.

Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call 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 the poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.

Call poison control center or doctor for further treatment advice.

HOTLINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-441-3637 for emergency medical treatment information.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Have the product container or label with you when calling poison control center or doctor or going for treatment.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

WARNING

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear (such as goggles). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using toilet. Remove contaminated clothing and wash clothing before reuse. Harmful if swallowed or inhaled. Avoid breathing spray mist. Do not use with chlorine bleach or any other chemical product.

EPA Registration No. 71654-5

EPA Establishment No. XXXXX-YY-ZZ

The Chemours Company FC, LLC

1007 Market Street

Wilmington, DE 19898

LIMITED WARRANTY AND DISCLAIMER

The manufacturer warrants that this product conforms to its chemical description and is reasonably fit for the purpose stated on the label only when used in accordance with label directions under normal conditions of use. The manufacturer makes no other express or implied warranties either of merchantability or fitness for a particular use. Handling, storage, and use of the product by buyer or user are beyond the control of the manufacturer and seller. Risks such as ineffectiveness, or other unintended consequences, resulting from failure to follow directions will be assumed by the buyer or user. To the extent permitted by law, the manufacturer or seller will not be held liable for consequential, special or indirect damages resulting from the handling, storage or use of this product.

GLYCLEAN® HARD SURFACE CLEANER:

CLEANS AND DISINFECTS MOST HARD NON-POROUS SURFACES IN 1-STEP KILLS VIRUSES* AND BACTERIA.

A 10-minute contact time is necessary for disinfection

* Herpes Simplex Virus Type 1, Rhinovirus Type 37, and Influenza Virus Type A2

KILLS HOUSEHOLD GERMS:

Staphylococcus aureus <ATCC 6538>

Salmonella enterica <ATCC 10708> <(Salmonella)>

Pseudomonas aeruginosa <ATCC 15442> <(Pseudomonas)>

<Escherichia coli> <ATCC 11229>

<Escherichia coli O157:H7> <ATCC 43888>

< Herpes Simplex Virus Type 1>

<Rhinovirus Type 37>

<Influenza Virus Type A2>

<CLEANS & DEODORIZES>

<ANTIBACTERIAL>

<DISINFECTANT>

<DISINFECTS THE SURFACE AS IT CLEANS>

<CLEANS DISINFECTS AND DEODORIZES>

<NON-STAINING FORMULA>

<ELIMINATES OFFENSIVE ODORS>

<DISINFECTS WITHOUT CHLORINE ODORS.

<[PRODUCT NAME]....<TUB>, <TILE>, <SINK>, < TOILET+>

<FOAMING ACTIONSEE IT CLEAN!>

<HEAVY DUTY CLEANING>

<SAFE FOR WHITE OR COLORED HARD NON-POROUS SURFACES>

<DEODORIZES – LEAVES A FRESH CLEAN SCENT>

<THICK LIQUID>

<REMOVES STUBBORN RUST & HARD WATER STAINS>

<CONTAINS NO <PHOSPHATES>

<CONTAINS BIODEGRADABLE CLEANING AGENTS>

<CLEANS AND DESTROYS LIMESCALE>

<DISINFECTS WITHOUT HARSH CHEMICALS>

<WILL NOT HARM PLUMBING OR SEPTIC SYSTEMS>

<QUICKLY ELIMINATES HARD WATER STAINS, MINERAL DEPOSITS AND RUST STAINS>

<THE FOAMING ACTION QUICKLY AND EFFECTIVELY CLEANS ALL YOUR BATHROOM SURFACES>
<FOAMING ACTION.....SEE IT WORK! ... CLEANS AND DEODORIZES>
<CUTS THROUGH SOAP SCUM, GREASE AND GRIME>

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

Household Use

To Clean and Disinfectant: This product can be used to clean and disinfectant hard, non-porous surfaces. Apply the product full strength with a clean sponge or cloth until the surface is thoroughly wet. Let stand for 10 minutes and then wipe clean with a wet sponge or cloth or rinse the surface with water. For heavily soiled surfaces, a precleaning is required. Do not use with chlorine bleach or any other chemical product. If used on a food preparation surfaces, all food must be removed prior to application.

To Clean: Use this product to clean hard, non-porous surfaces. Prior to use, mix ¼ cup of this product with one gallon of water. Apply the diluted solution with a clean sponge, cloth, mop or brush to surfaces and keep surfaces wet for 10 minutes. Then wipe clean with a wet sponge or cloth or rinse with water. Do not use with chlorine bleach or any other chemical product. If used on a food preparation surfaces, all food must be removed prior to application.

Commercial/Industrial Use

To Clean and Disinfectant: This product can be used to clean and disinfectant hard, non-porous surfaces. This product can be used on all non-food contact surfaces including the exterior surfaces of appliances. Apply the product full strength with a clean sponge or cloth until the surface is thoroughly wet. Let stand for 10 minutes and then wipe clean with a wet sponge or cloth or rinse the surface with water. For heavily soiled surfaces, a precleaning is required. Do not use with chlorine bleach or any other chemical product.

To Clean: Use this product to clean hard, non-porous surfaces. This product can be used on all non-food contact surfaces including the exterior surfaces of appliances. Prior to use, mix ¼ cup of this product with one gallon of water. Apply the diluted solution with a clean sponge, cloth, mop or brush to surfaces and keep surfaces wet for 10 minutes. Then wipe clean with a wet sponge or cloth or rinse with water. Do not use with chlorine bleach or any other chemical product.

† Use only on exterior toilet surfaces.

[Note to Reviewer: For Institutional Use]

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store in a cool, dry area. Always store pesticides in the original container. Store out of reach of children.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Triple rinse (or equivalent). Then offer for recycling or reconditioning. If not available, puncture and dispose in sanitary landfill.

[Note to Reviewer: For Household/Residential Use]

STORAGE AND DISPOSAL

Store out of reach of children. Store in a cool, dry area away from food and pet food.

Nonrefillable container. Do not reuse or refill this container. Wrap (container) and put in trash or offer for recycling if available.

Net Contents:

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.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large Non-Enveloped Viruses

<i>For an emerging viral pathogen that is a/an...</i>	<i>...following the directions for use for the following supporting organism(s) on the label:</i>
Enveloped virus	Rhinovirus Type 37
Large, non-enveloped virus	Rhinovirus Type 37

Glyclean Hard Surface Cleaner has demonstrated effectiveness against viruses similar to [name of emerging enveloped or large, non-enveloped virus] on hard, non-porous surfaces. Therefore, Glyclean Hard Surface Cleaner can be used against [name of emerging enveloped or large, non-enveloped virus] when used in accordance with the directions for use against Rhinovirus Type 37 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 enveloped or large, non-enveloped virus]. Glyclean Hard Surface Cleaner kills similar viruses and therefore can be used against [name of emerging enveloped or large, non-enveloped virus] when used in accordance with the directions for use against Rhinovirus Type 37 on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.