



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 19, 2021

Christina M. Swick
Lewis & Harrison, LLC
2461 South Clark Street, Suite 710
Arlington, VA 22202

Subject: PRIA Label Amendment – Revising Labeling Claims
Product Name: Wyandotte Sanifect D2
EPA Registration Number: 833-3
Received Date: 02/22/2021
Action Case Number: 00292172

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. Pursuant to 40 CFR 156.10(a)(6), 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.


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.

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

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with FIFRA section 6. If you have any questions, please contact Terria Northern via email at northern.terria@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Steven Snyderman". The signature is written in a cursive style with a horizontal line underneath the name.

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

Enclosure: Accepted label



Sanifect D2

[Ready to Use]

[Quick Drying]

[Highly Evaporative]

[Ideal for Water Sensitive][Environments or Areas]

[Ideal for Water Sensitive Equipment]

[No Rinse][Required]

[Hard, Non-porous Food Contact Surface Sanitizer Without Rinse]

[Kills 99.999% of bacteria on hard, non-porous food contact surfaces [in 60 seconds]]

[Sanitizes hard, non-porous food contact surfaces in 60 seconds]

[Surface Cleaner & Sanitizer]

[For Use on Hard, Non-porous Food Contact Surfaces]

[Cleans and Sanitizes hard, non-porous Food Contact Surfaces]

Disinfectant/Virucidal*

ACCEPTED

08/19/2021

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

EPA Reg. No. 833-3

EPA Reg. No. 833-3

EPA Est. No. 833-PA-1, 35939-GA-1, 47862-CA-1, 83199-SD-1, 40849-GA-1, 1270-TX-1

Active Ingredients:

Isopropyl Alcohol 50.0000%

Alkyl (60% C14, 30% C16, 5% C12, 5% C18)

dimethylbenzyl ammonium chloride0.0100%

Alkyl (50% C12, 30% C14, 17% C16, 3% C18)

dimethyl ethylbenzyl ammonium chloride0.0100%

Other Ingredients 49.9800%

TOTAL 100.0000%

KEEP OUT OF REACH OF CHILDREN WARNING

SEE SIDE PANEL FOR FIRST AID AND PRECAUTIONARY STATEMENT

NET CONTENTS:

Batch No.:

CHEMTREC EMERGENCY 800-424-9300

(Chemtrec Customer Number: 837)



Nonfood Compounds
Category Code D2
Reg.#150333

HMIS HAZARD RATING	
HEALTH	2
FLAMMABILITY	3
REACTIVITY	0
PERSONAL PROTECTION	B

[Bracketed text] is optional; text in {braces} is informational to the reviewer.

DIRECTIONS FOR USE

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

CLEANING IN WET AND DRY ENVIRONMENTS

Remove visible food particles and soil from surface. Apply this product without dilution to the surface. Wipe clean. Allow to dry. A water rinse after applying this product to clean is acceptable in wet environments.

SANITIZING OF FOOD PROCESSING EQUIPMENT AND OTHER HARD NON-POROUS FOOD CONTACT SURFACES

This product is recommended for sanitizing food processing equipment, dairy equipment, food utensils, dishes, silverware, glasses, sink tops, countertops, refrigerated storage and display equipment. Pre-clean dirty surfaces prior to sanitizing. This product may be used to pre-clean. To sanitize, apply by spray, wipe, sponge, or total immersion. Surfaces must be thoroughly wetted and remain wet for 1 minute. Apply to sink tops, countertops, refrigerated storage and display equipment by spray, wipe, sponge, or brush. Surfaces should remain wet for at least 1 minute followed by adequate draining and air-drying. Dishes, silverware, glasses, cooking utensils and other similar size food processing equipment can be sanitized by immersion in this product. Always use fresh solution for this application. No potable water rinse is required. This product is an effective sanitizer against *Staphylococcus aureus* [(ATCC 6538)], *Escherichia coli* [(ATCC 11229)], *Listeria monocytogenes* [(ATCC 19117)], and *Salmonella enterica* [(ATCC 10708)] on hard, non-porous surfaces.

DISINFECTION

For disinfecting inanimate, pre-cleaned, hard, non-porous surfaces such as chairs, countertops, drawer pulls, carts, baskets, tables, cabinets, telephones, plastic surfaces, glazed ceramic, glazed porcelain, chrome, stainless steel, aluminum, laminated surfaces, and other related hard surfaces in hospitals, operating rooms, medical clinics, nursing homes, laboratories, schools, day-care centers, funeral homes.

Pre-clean surfaces prior to disinfecting. This product may be used to pre-clean. To disinfect, apply with a sponge, wipe, mechanical sprayer, or by total immersion. When applied with a mechanical spray, spray should be coarse. Surfaces must be sprayed until thoroughly wetted. Treated surfaces must remain wet for 5 minutes. Allow surfaces to air dry. Do not rinse.

Bacteria

This product is an effective disinfectant according to the AOAC Use-Dilution Test method on hard, non-porous surfaces against: *Staphylococcus aureus* [(ATCC 6538)], *Salmonella enterica* [(ATCC 10708)] *Pseudomonas aeruginosa* [(ATCC 15442)].

Viruses

This product is an effective virucidal disinfectant against the following viruses on hard non-porous surfaces: Human Adenovirus Type 5 [(ATCC VR-5)], Human Coronavirus [(ATCC VR-470)], and Avian Influenza A (H3N2) [(ATCC VR-2072)].

{The following statement will appear on container labels only if healthcare use sites are listed on the label}

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 clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

[Bracketed text] is optional; text in {braces} is informational to the reviewer.

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.

The statements shall be made 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.

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

- 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 (contact time):</i>
Enveloped virus	Adenovirus Type 5 [(ATCC VR-5)]

This product [-or- Wyandotte Sanifect D2] has demonstrated effectiveness against viruses similar to {Insert name of emerging enveloped virus} on hard, nonporous surfaces. Therefore, this product [-or- Wyandotte Sanifect D2] can be used against {Insert name of emerging enveloped virus} when used in accordance with the directions for use against Adenovirus Type 5 on hard, nonporous surfaces. Refer to the CDC -or- OIE website at {Insert pathogen-specific website address} for additional information.

{Insert name of illness/outbreak} is caused by {Insert name of emerging enveloped virus}. This product [-or- Wyandotte Sanifect D2] kills similar viruses and therefore can be used against {Insert name of enveloped emerging virus} when used in accordance with the directions for use against Adenovirus Type 5 on hard, nonporous surfaces. Refer to the {CDC -or- OIE} website at {Insert pathogen-specific website address} for additional information.

[Bracketed text] is optional; text in {braces} is informational to the reviewer.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact you State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Open dumping is prohibited. Store only in the original container. Do not reuse empty container. Keep this product under locked storage sufficient to make it inaccessible to children or other people unfamiliar with its proper use. Store in a cool dry area, away from flames, sparks, or other sources of heat or ignition. If ignited, use a dry chemical or CO₂ extinguisher. If a large quantity is spilled, dilute with water and mop or wipe dry.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may 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 container (or equivalent) promptly after emptying. Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

FIRST AID		HOT LINE NUMBER
If in eyes	<ul style="list-style-type: none">• 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 eye.• Call a poison control center or doctor for treatment advice.	Have the product container or label with you when calling a poison control center or doctor, or going for treatment. NATIONAL PESTICIDE INFORMATION CENTER: 1-800-858-7378
PRECAUTIONARY STATEMENTS HAZARDS 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 safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse.		
PHYSICAL OR CHEMICAL HAZARDS		
Flammable. Keep away from heat and open flame.		
UN 1993 Flammable Liquids, N.O.S. (Isopropanol), 3, PG II, ER Guide No.128		



Manufactured by:
ALEX C. FERGUSON, LLC
550 DEVELOPMENT AVENUE
CHAMBERSBURG, PA 17201