



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

EPA Reg. Number:

2686-26

Date of Issuance:

4/23/25

NOTICE OF PESTICIDE:

☒ Registration

☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Hydrite PAA HP 22:10

Name and Address of Registrant (include ZIP Code):

Justin Roberts
Keller and Heckman, LLP, representing Hydrite Chemical Company
17385 Golf Parkway, Brookfield WI 53045
Electronic Transmittal: roberts@khlaw.com

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.

Signature of Approving Official:

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

Date:

4/23/25

2. You are required to comply with the data requirements described in the DCI Order identified below:
 - a. Peroxyacetic Acid: GDCI-063201-1125
 - b. Hydrogen Peroxide: GDCI-000595-1127

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI Order listed above, you may contact the Reevaluation Team Leader (Team 36): <https://www.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobials-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. 2686-26."
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:

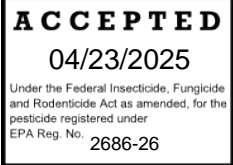
- Basic CSF dated 06/12/2024

The alternate brand name, "Hydroxysan 2210", has been added to the product record. If you have any questions, please contact Linda Amar by email at amar.linda@epa.gov.

Enclosure: Final Stamped Label

Hydrite PAA HP 22:10

{INDUSTRIAL} {LABEL}



Note to Reviewer: Marketing Claims may be used on front panel. Optional language may appear in any order."

OPTIONAL STATEMENTS:

For Use In Aseptic Food Processing And Food Packaging Materials To Achieve Sterility
Commercial Sterilant For Use In Aseptic Packaging And Aseptic Food Processing

[ACTIVE] INGREDIENTS	
Peroxyacetic Acid	22.0%
Hydrogen Peroxide	10.0%
INERT INGREDIENTS	68.0%
TOTAL.....	100.0%

KEEP OUT OF REACH OF CHILDREN [MANTENER FUERA DEL ALCANCE DE LOS NIÑOS]

DANGER/PELIGRO



POISON/VENENO

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.)

STRONG OXIDIZING AGENT

Note to Reviewer: In accordance with 40 CFR 156.68(d), all first aid statements, as prescribed, will appear on the front panel of the label."
Note to Reviewer: Bullet points and table will be used if label space permits, otherwise **First Aid** may appear in paragraph format."

FIRST AID	
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 immediately for treatment advice.
If on skin or clothing:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor immediately for treatment advice.
If inhaled:	<ul style="list-style-type: none">• 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 a poison control center or doctor immediately for treatment advice.
If swallowed:	<ul style="list-style-type: none">• 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 the 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.	
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 control center 1-800-222-1222. Have product container or label with you when calling a poison control center or doctor or going for treatment advice.	



"Hydrite Logo"

HYDRITE CHEMICAL CO.
17385 GOLF PARKWAY
BROOKFIELD, WI 53045
(262) 792-1450

OPTIONAL STATEMENTS:

See [left][right][side][back][inner][outer][attached] [insert][booklet][panel][carton][label] for [additional][precautionary statements].

For [chemical] [and][or] [medical] [and][or] [environmental] emergencies, call [insert name and/or number of emergency contact] [hours of operation] [24 hours a day] [7 days a week].

"Note to Reviewer: This referral statement may be organized in any order to be grammatically correct."

[See][Consult] [Additional][attached][Product Information][Bulletin][Sheet][insert][booklet][label] for [other][additional][directions for use][information] [claims][organisms][applications] [and] [proper][use directions].

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

DANGER - POISON. CORROSIVE. Fatal if swallowed or absorbed through skin. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Do not get in eyes, on skin, or on clothing. Do not breathe vapor or spray mist. Do not enter an enclosed area without proper respiratory protection, or when uncoupling of product transfer hoses. Wear appropriate protective eyewear such as goggles, face shield, or safety glasses, rubber gloves, coveralls over long-sleeved shirt and long pants, socks, chemical resistant footwear, and a NIOSH approved respirator with an organic vapor (OV) cartridge with a NIOSH approval number prefix TC-23C when handling. Wear coveralls over long-sleeved shirt and long pants, socks, chemical-resistant footwear, and chemical-resistant gloves (Barrier Laminate, or Butyl Rubber \geq 14 mils, or Nitrile Rubber \geq 14 mils, or Neoprene Rubber \geq 14 mils, or Natural Rubber \geq 14 mils, or Polyethylene, or Polyvinyl Chloride (PVC) \geq 14 mils, or Viton \geq 14 mils), and chemical-resistant apron when mixing and loading. 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.

PERSONAL PROTECTIVE EQUIPMENT (PPE): Handlers who may be exposed to the undiluted product through mixing, loading, application, or other tasks must wear: coveralls over long-sleeved shirt and long pants, rubber gloves, chemical resistant footwear plus socks, and protective eyewear (goggles or face shield).

Handlers who may be exposed to the diluted product during application or other tasks must wear: long-sleeved shirt, long pants, socks, and shoes.

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Requirements: Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

(If container is equal to or greater than 5 gal., the following statement must appear on the label.)

This pesticide is toxic to birds, mammals, fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with 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 your State Water Board or Regional Office of the EPA.

(If container is less than 5 gal., use the following as an alternate to the above statement.)

This product is toxic to birds, mammals, fish and aquatic invertebrates

PHYSICAL OR CHEMICAL HAZARDS

STRONG OXIDIZING AGENT. Mix only with water. At temperatures exceeding 156°F (69°C), decomposition of this product could occur, releasing oxygen. The oxygen released could initiate or promote combustion of other materials.

TABLE OF CONTENTS

"The Table of Contents is optional and when used, will be modified to reflect the contents of the market or collateral labeling."

FIRST AID 1

PRECAUTIONARY STATEMENTS..... 2

ENVIRONMENTAL HAZARDS 2

DIRECTIONS FOR USE 3

ASEPTIC FOOD PACKAGING 4

STORAGE AND DISPOSAL..... 6

ORGANISM LIST

PEROXY BASED STERILANT: This product is an effective commercial sterilant at 2.6 fl. oz. per 1 gal. of sterile deionized water {(3,810 ppm peroxyacetic acid and 1,890 ppm hydrogen peroxide)} at a minimum temperature of 149°F (65°C) and a minimum of 20 seconds for aseptic packaging of low acid foods:

Bacillus cereus {(ATCC 14579)

Bacillus spizizenii {(ATCC 19659)}

Clostridium sporogenes {(ATCC 3584)}

DIRECTIONS FOR USE

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

{Please read entire label and use strictly in accordance with precautionary statements and directions.}

"Note to Reviewer (General Considerations): *Numbered instructions will be used if label space permits, otherwise may appear in paragraph format. The list of organisms can be formatted into paragraph form using a comma to separate organisms. Unit abbreviations can be spelled out. When choosing optional text, appropriate punctuation can be inserted or deleted. Equivalent use dilution ratios may be substituted within the directions."*

COMMERCIAL STERILANT FOR ASEPTIC PACKAGING OF LOW ACID FOOD

ASEPTIC FOOD PROCESSING OPERATIONS

This product may be used to achieve commercial sterility of food packaging prior to fill and of equipment used in aseptic food processing applications.

ASEPTIC FOOD PACKAGING MATERIALS

This product may be used alone or in combination with other processes as a commercial sterilant for aseptic packaging of low acid foods, such as {but not limited to}, commercial sterilization of aseptic filling systems and glass and plastic food packaging and their closures prior to filling, except for use on food packaging used in contact with infant formula or human milk or on aseptic filling equipment used to fill such packaging.

Apply this product on the exterior and interior of food containers and closure systems (caps, seals, etc.). Use 13 fl. oz. of this product per 5 gal. of sterile deionized water {(3,810 ppm peroxyacetic acid and 1,890 ppm hydrogen peroxide)} {(or equivalent use-dilution)} at a temperature of 149°F (65°C). The solution must remain in contact with the packaging surface for a minimum of 20 seconds. Rinse containers with sterile water prior to filling with processed food; in lieu of a rinse, films may be mechanically stripped of excess sanitizing solution.

No rinse treatment is required if:

1. solution application does not exceed 0.0175 mL treatment solution per ounce container capacity;
2. treatment solution has not been recycled;
3. no treatment solution with a concentration of higher than 4,500 ppm peroxyacetic acid (2,050 ppm hydrogen peroxide) has been added to the treatment solution reservoir.

This product may be used on food packaging as an aseptic packaging antimicrobial rinse in food packaging processing operation that has a scheduled process accepted by FDA. The aseptic food processing operation must comply with all applicable FDA regulations, including but not limited to Food Contact Notification (FCN) 2210, 21 CFR parts 108, 110, 113, and/or 114. Use in an aseptic food processing operation includes testing required for the process validation.

ASEPTIC FOOD PROCESSING EQUIPMENT

This product may be used to achieve commercial sterility of non-porous food manufacturing, packaging and filling equipment.

This product may be used as a manufacturing, filling (including rotary fillers) and packaging equipment.

1. Remove visible soil particles from equipment surfaces.
2. Clean surfaces thoroughly.
3. Rinse thoroughly with potable water.
4. Use 13 fl. oz. of this product per 5 gal. of sterile deionized water {(3,810 ppm peroxyacetic acid and 1,890 ppm hydrogen peroxide)} {(or equivalent use-dilution)} at a minimum temperature of 149°F (65°C). Use immersion, coarse spray or circulation techniques to apply this product.
5. Allow contact time of at least 20 seconds.
6. Allow to drain dry.
7. A final rinse with sterile water is required.

This product may be used on equipment used in aseptic packaging antimicrobial rinse in food processing operation that has a scheduled process accepted by FDA. The aseptic food processing operation must comply with all applicable FDA regulations, including but not limited to Food Contact Notification (FCN) 2210, 21 CFR Parts 108, 110, 113, and/or 114. Use in an aseptic food processing operation includes testing required for the process validation.

NON-PUBLIC HEALTH ANTIMICROBIAL RINSE OF PRECLEANED OR NEW RETURNABLE OR NON-RETURNABLE CONTAINERS: To reduce the number of nonpathogenic beverage spoilage organisms use 0.68 to 7.03 fluid ounces of product per 5 gallons of water. This provides 265 to 2,700 ppm peroxyacetic acid and 120 to 1,228 ppm hydrogen peroxide. After applying the antimicrobial rinse, allow containers to drain thoroughly. Optional rinse with sterile or potable water.

{FOR MECHANICAL OPERATIONS: Prepared use solution must not be reused for subsequent sterilization but may be reused for other purposes such as cleaning.}

{MATERIAL COMPATIBILITY}

Not recommended for use on copper, brass, granite, marble or zinc. Do not use on unsealed/uncoated marble or unsealed/uncoated terrazzo floors.

NOTE: This product at its use-dilution is compatible with stainless steel. If the product is intended to be used on any other surface, it is recommended that you apply to a smaller test area to determine compatibility before proceeding with its use.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store only in original container. {[Keep this product under locked storage sufficient to make it inaccessible to children or persons unfamiliar with its proper use.]} {[Keep container closed when not in use and under locked storage sufficient to make it inaccessible to children or persons unfamiliar with its proper use. Never return this product to the original container after it has been removed. Avoid all contaminants especially dirt, caustic, reducing agents, and metals. Contamination and impurities will reduce shelf life and can induce decomposition. In case of a decomposition, isolate container, douse container with cool water and dilute product with large volumes of water. Avoid damage to containers. [Protect pesticide containers from extreme heat and cold.] In case of spill, flood area with large quantities of water. Do not store in a manner where cross-contamination with other pesticides or fertilizers could occur.]}

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING: [Non-refillable containers equal to or less than 5 gallons:] Non-Refillable Container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container $\frac{1}{4}$ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for disposal. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or incineration, if allowed by state and local authorities.

[Refillable containers greater than 5 gallons:] Refillable Container. Refill this container with this product only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system for disposal. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this rinsing procedure two more times. Offer container for recycling if available or reconditioning if appropriate or place in trash.