



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

June 27, 2022

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Coleen Gerber
Agent
Evonik Active Oxygens, LLC
2005 Market Street, Suite 3200
Philadelphia, PA 19103

Subject: Notification per PRN 98-10 – Adding ABN, Logo, and Updating Company
Name and Address
Product Name: Certainty
EPA Registration Number: 65402-12
Received Date: 03/10/2022
Action Case Number: 00345256

Dear Ms. Gerber:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

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) 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. 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 have any questions, you may contact Terria Northern via email at northern.terria@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "T. Northern".

Registration Risk Manager
Regulatory Management Branch II
Antimicrobial Division

Certainty

ABN: Clarity 22

EPA Registration No. 65402-12

EPA Est. No. 65402-NY-001

ACTIVE INGREDIENTS:

Peroxyacetic Acid 22%

Hydrogen Peroxide 10%

OTHER INGREDIENTS: 68%

TOTAL: 100%

KEEP OUT OF REACH OF CHILDREN

DANGER – POISON



[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 product label.]

Certainty is for use in aseptic food processing on food packaging materials to achieve commercial sterility.

Certainty is for use as an antimicrobial rinse of Pre-cleaned or New Returnable or Non-Returnable Containers. Not for Use in CA.

Certainty is for use in oilfield and gas-field well operations. Not for Use in CA.

 **EVONIK** is a trademark of Evonik Active Oxygens, LLC



Manufactured by:

Evonik Active Oxygens, LLC

a subsidiary of Evonik Corporation

2005 Market St Ste 3200

Philadelphia PA 19103-7014

Net Contents: _____

Precautionary Statements
Hazards 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 protective eyewear, 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. 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.

Physical or Chemical Hazards

Strong oxidizing agent. Mix only with water. At temperatures exceeding 156°F (69°C), decomposition of Certainty could occur, releasing oxygen. The oxygen released could initiate or promote combustion of other materials.

Environmental Hazards

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.

Any solution released from the system should be diluted with water and tested for residuals to ensure that there is less than 3 ppm peroxygen remaining.

First Aid

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

- 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 a poison control center or doctor.
 - Do not give anything by mouth to an unconscious person.

- 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 doctor for treatment advice.

- 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 eye.
 - Call a poison control center or doctor for treatment advice.

- If inhaled**
- Move person to fresh air.
 - If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible.
 - Call a poison control center or doctor for further treatment advice.

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

EMERGENCY TELEPHONE NUMBERS (24 HOURS)

MEDICAL: COLLECT 303-389-1409

TRANSPORTATION: 800-424-9300

OTHER: COLLECT 716-879-0400

DIRECTIONS FOR USE

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

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.

Food Packaging Materials

Apply Certainty on the exterior and interior of food containers and closure systems (caps, seals, etc.). Apply 4200 ppm peroxyacetic acid (13 fl. oz. of Certainty/5 gallons of sterile deionized water) at a minimum 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.

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 21 CFR parts 108, 110, 113, and/or 114. Use in an aseptic food processing operation includes testing required for the process validation.

Food Processing Equipment

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

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

1. Remove gross soil particles from equipment surfaces.
2. Clean surfaces thoroughly.
3. Rinse thoroughly with potable water.
4. Apply 4200 ppm peroxyacetic acid (13 fl. oz. of Certainty/5 gallons of sterile deionized water) at a minimum temperature of 149°F (65°C). Use immersion, coarse spray or circulation techniques to apply Certainty.
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 21 CFR Parts 108, 110, 113, and/or 114. Use in an aseptic food processing operation includes testing required for the process validation.

Antimicrobial Rinse of Pre-cleaned or New Returnable or Non-Returnable Containers (Not for Use in CA)

To reduce the number of nonpathogenic beverage spoilage organisms: *Byssoschlamys fulva*, *Pediococcus damnosus*, *Lactobacillus buchneri*, and *Saccharomyces cerevisiae*, use 0.69 to 7.10 fluid ounces of product per 5 gallons of water. This provides 265 to 2700 ppm peroxyacetic acid and 121 to 1227 ppm hydrogen peroxide. After applying the antimicrobial rinse, allow containers to drain thoroughly. Optional rinse with sterile or potable water.

Certainty may be mixed with the non-foaming agent, Peradigm™ and applied at room temperature or at a minimum of 77°F (25°C). (Approved for Use in CA)

1. Mix a minimum of 0.33 fluid ounce Certainty with Peradigm in 4.5 gallons of water.
2. Add a maximum of 43 fluid ounces of Peradigm to the dilute solution and bring total volume to 5 gallons. This provides 125 ppm peroxyacetic acid and 58 ppm hydrogen peroxide.
3. Apply solution, allowing a minimum contact time of 30 seconds.
4. Rinse with sterile or potable water (optional).

Drilling Muds, Fracturing Fluids, Well Squeezed Fluids – (Not for use in CA)

For the preservation of drilling muds, workover and completion fluids and other product susceptible to contamination, pre-mix with the fluid or add directly at the point of use at 2.56 fluid ounces per 1000 gallons of water (5 ppm of Peroxyacetic acid and 2.3 ppm of Hydrogen Peroxide) to 51.5 fluid ounces per 1000 gallons of water (100 ppm of Peroxyacetic Acid and 45 ppm of Hydrogen Peroxide) as required. Depending on the severity of the contamination, initial application may be added up to 515 fluid ounces per 1000 gallons of water (1000 ppm of Peroxyacetic acid and 455 ppm of Hydrogen Peroxide).

Flooding, Injection and Produced Water – (Not for Use in CA)

For Water Flooding operations, add initially at 2.56 fluid ounces per 1000 gallons of water (5 ppm of Peroxyacetic acid and 2.3 ppm of Hydrogen Peroxide) to 51.5 fluid ounces per 1000 gallons of water (100 ppm of Peroxyacetic Acid and 45 ppm of Hydrogen Peroxide) and repeat until control is achieved. Subsequent treatment may be continued on a weekly basis or as required.

Injection wells associated with gas storage systems may be treated up to 100 ppm of Peroxyacetic Acid and 45 ppm of Hydrogen Peroxide when diluted in the formation water. Any additional top-up water should be treated as required.

For hydrostatic systems, apply 2.56 fluid ounces per 1000 gallons of water (5 ppm of Peroxyacetic acid and 2.3 ppm of Hydrogen Peroxide) to 51.5 fluid ounces per 1000 gallons of water (100 ppm of Peroxyacetic Acid and 45 ppm of Hydrogen Peroxide) depending on the water quality and the duration of the shut-in.

Pipeline and Tank Maintenance – (Not for Use in CA)

For microbial control in water-bottoms in crude and refined hydrocarbon storage tanks, piping and transportation systems. Apply 2.56 fluid ounces per 1000 gallons of water (5 ppm of Peroxyacetic acid and 2.3 ppm of Hydrogen Peroxide) to 51.5 fluid ounces per 1000 gallons of water (100 ppm of Peroxyacetic Acid and 45 ppm of Hydrogen Peroxide) in the aqueous phase, directly injected into the water-bottom, pipeline or may be added to the hydrocarbon phase. Treatment may be applied daily or monthly for both storage and transportation systems as needed.

Dispose of unused solution according to the storage and disposal directions.

STORAGE AND DISPOSAL

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

STORAGE: NEVER RETURN CERTAINTY 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 decomposition, isolate container, douse container with cool water and dilute with large volumes of water.

Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at temperatures below 86°F (30°C). Do not store on wooden pallets.

DISPOSAL

Pesticide Disposal

Certainty which is to be discarded should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

Container **Handling**

Nonrefillable containers less than 5 gallons. Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available, or place [or put] in trash or sanitary landfill. 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 ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix

tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Nonrefillable containers greater than or equal to 5 gallons.

Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available, or place [or put] in trash or sanitary landfill. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Empty drums are not returnable to [Evonik Active Oxygens, LLC](#) unless special arrangements have been made. Dispose of drums in accordance with local, state, and Federal regulations.

All Refillable containers. Refillable container. Refill this container with pesticide 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 mix tank. Fill the 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. Repeat this rinsing procedure two more times. Return to [Evonik Active Oxygens, LLC](#) for reuse. If unable to return to [Evonik Active Oxygens, LLC](#) offer for recycling if available or place [or put] in trash or sanitary landfill.

Procedure for Leak or Spill

Stop leak if this can be done without risk. Shut off ignition sources; no flames, smoking, flares, or spark producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water. Undiluted material should not enter confined spaces. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods of disposal may vary by location, regulatory agencies should be contacted prior to disposal.

Note: Before using Certainty on metal surfaces, it is recommended that the diluted solution be tested on a small area to determine compatibility.

Optional Background Graphic:



4879-8901-7876, v. 3