

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

October 19, 2016

Georgia Anastasiou Agent for PromChemie AG PromChemie AG c/o Lewis & Harrison, LLC 122 C Street, Suite 505 Washington, D.C. 20001

Subject: Label Amendment – Increasing the dosage rate for bacteria control Product Name: Promex 20D EPA Registration Number: 80285-3 Application Date: 9/21/16 Decision Number: 522359

Dear Ms. Anastasiou:

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.

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

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with FIFRA section 6. If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at <u>heffernan.aline@epa.gov</u>.

Sincerely,

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Julie Chao, Product Manager 33 Regulatory Management Branch 1 Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure: Accepted Label

ACCEPTED

Oct 19, 2016 Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the

esticide registered under

EPA Reg. No. 80285-3

PROMEX[™] 20D

For industrial use only as an antimicrobial to protect aqueous compositions such as latices, oil-in-water emulsions, paints and coatings, inks and font solutions, water-based adhesives, aqueous pigment or mineral slurries, building and construction compositions, pesticide formulations, home cleaning products, liquid laundry additives, car care products, oil recovery materials, secondary oil recovery fluids, paper or textile coating compositions, pulp and paper mill systems, or leather processing solutions, or intended to protect fresh animal hides or skins

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER Corrosive. Causes irreversible eye damage. Causes skin bums. May be fatal if inhaled. Harmful if swallowed. Harmful if absorbed through skin. Do not get in eyes, on skin or on clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wear protective eye wear (goggles or face shield). Do not breathe vapor or mits spray. Wear a respirator with an organic vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number TC-14G), or a NIOSH approved respirator with an organic vapour (OV) cartridge or canister with any R, P or HE prefilter.

When mixing and loading wear a chemical-resistant apron. When cleaning equipment wear a chemical resistant apron. Wear coveralls worn over long sleeved shirt and long pants, chemical resistant footwear, socks, and chemical resistant gloves (barrier laminate butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride or viton).

User Safety Requirements

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

User Safety Recommendations

User should wash hands before, eating, drinking, chewing gum, using tobacco, or using the toilet. User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing.

WARRANTIES AND WARRANTY DISCLAIMERS

PromChemie AG ("PROM") warrants that this product conforms to the chemical description on the label and that it is reasonably fit for the purposes stated on the label when used in accordance with PROM's directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions, or under conditions not reasonably foreseeable to PROM, and the buver assumes the risk of any such use. PROM DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY. IN NO EVENT SHALL PROM BE LIABLE FOR ANY SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES. INCLUDING LOST PROFITS. ON ANY THEORY WHATSOEVER, INCLUDING NEGLIGENCE, and PROM's sole liability and Buyer's and User's exclusive remedy shall be limited to the refund of the purchase price. Statements concerning the use of products or the formulations described therein are not to be construed as recommending the infringement of any patent and no liability for infringement arising out of any such use is assumed by PROM.

Manufactured for: PromChemie AG Austrasse 79, P.O. Box 26 FL-9490 Vaduz, Liechtenstein Telephone (Int'I): +(011) 423-236-1818 EPA Reg. No. 80285-3 EPA Est. No. 70815-GA-001

PROMEX[™] is a registered trademark of Prom Chem Ltd, licensed to PromChemie AG.

ACTIVE INGREDIENT:

1,2-Benzisothiazolin-3-one	19.0%
INERT INGREDIENTS:	81.0%
TOTAL:	100.0%

KEEP OUT OF REACH OF CHILDREN DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

	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 the first 5 minutes, then continue rinsing eye. Call a poison control center or 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 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 mouth-to- mouth if possible. Call a poison control center or doctor for further treatment advice. 		
IF SWALLOW -ED	 Call a poison control center or doctor immediately for treatment advice. Have a 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. 		
Have the Pro control cente NOTE TO PH the use of ga pneumonia h	NTROL CENTER: CALL 1-800-222-1222 duct container or label with you when calling a poison r or doctor, or going for treatment. IYSICIAN: Possible mucosal damage may contraindicate stric lavage. This Product may pose an aspiration azard. Measures against circulatory shock and respiratory nd convulsion may be needed.		



DIRECTIONS FOR USE

(Extract from Technical Information Bulletin for PROMEX[™] 20D) It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

PROMEX[™] 20D is an effective preservative in most aqueous compositions. The concentration required to give protection depends on several factors. These include the susceptibility of the system to microbiological degradation, the extent to which micro-organisms can gain access, the species involved, pH, temperature, and length of time for which protection is required. For protection against bacterial attack, a concentration within the range 0.02-0.35% PROMEX[™] 20D is almost invariably sufficient. The control of mold growth, particularly on paste products of high solids content, may occasionally require demand dosages above 0.25%. In dilute fluid systems, spoilage is usually controlled with dosages not greater than 0.09%. Do not use at concentration greater than 0.5%.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. **PESTICIDE STORAGE:** Protect from frost. If frozen, allow to thaw and stir well before use

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 DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 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. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

EMERGENCIES: In emergency situations, such as spills, fire, or exposure, call 1-800-424-9300

ENVIRONMENTAL HAZARDS

This product is toxic to fish. 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 your State Water Board or Regional Office of the EPA. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not apply in marine or estuarine oil fields.

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