

80285-3

7/1/2011

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

NOTICE OF PESTICIDE:

Registration
[x] Reregistration

(under FIFRA, as amended)

EPA Reg.

Number:

80285-3

JUL

Date of

Issuance

1 2011

Term of Issuance:

Conditional

Name of Pesticide

Product:

Promex 20D

Name and Address of Registrant (include ZIP Code):

PromChemie AG
Austrasse 79, P. O. Box 26
FL-9490 Vaduz,
Liechtenstein

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration 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/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

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.

Based on your response to the 1,2-Benzisothiazolin-3-one RED, the EPA has reregistered this product subject to the comments recorded in the succeeding paragraph. This action is taken under the authority of section 4(g) (2) of the Federal Insecticide, Fungicide and Rodenticide Acts, as amended. Reregistration under this section does not eliminate the need for continual reassessment of pesticides. The EPA may require submission of data at any time to maintain the registration of the subject product.

1. Make the following label changes:

a. The EPA Registration Number to read "80285-3".

Signature of Approving Official:

Marshall Swindell
Product Manager Team-33
Regulatory Management Branch I
Antimicrobials Division (7510P)

[Handwritten signature of Marshall Swindell]

Date:

JUL 1 2011

b. Per the acute toxicity review and the Label Review Manual (7-4), the signal word section must be revised to read;

“DANGER POISON

[Inset skull and crossbones symbol]

c. Per the acute toxicity review, the heading “IF SKIN IRRITATION OR DERMAL EXPOSURE” in the first aid statements must be revised to read “IF ON SKIN OR CLOTHING”.

d. The Agency recommends that additional text be added to the Note to Physician that addresses acute dermal toxicity and eye and skin irritation concerns.

e. Per the acute toxicity review, the Hazards to Humans and Domestic Animals must be revised to read:

“DANGER

Fatal if absorbed through skin. Corrosive. Causes irreversible eye damage. Causes skin burns. Do not get in eyes, on skin, or on clothing. May be fatal if inhaled. Do not breathing vapor or spray mist. Harmful if swallowed. Avoid contact with skin, eyes or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wear goggles or face shield, coveralls worn over long-sleeved shirt and long pants, socks chemical-resistant footwear, chemical-resistant gloves made of barrier laminate, butyl, nitrile, or neoprene rubber, polyvinyl chloride or viton, a respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P or HE prefilter.”

f. The Agency recommends that the following User Safety Requirements text be added to the label:

“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.”

g. Per the acute toxicity review, the following User Safety Recommendations must be added to the label:

“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.

User should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing."

h. Per the product chemistry review, the storage and disposal section must be revised to comply with PR Notice 2007-4.

i. Under the STORAGE AND DISPOSAL heading, the word "PROHIBITIONS" must be deleted. The statement "Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited." Needs to be revised to read: "Do not contaminate water, food, or feed by storage or disposal." This statement must be placed in the beginning of the section in accordance with 40 CFR 156.10 and the PR Notice 83-3.

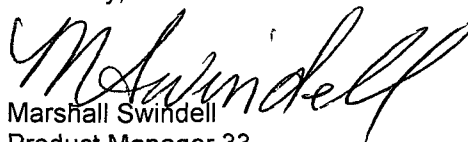
2. For additional labeling clarity and consistency, please refer to the enclosed EPA reviews.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec.6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Submit two (2) copies of the revised labeling bearing the labeling revisions listed above. A stamped copy of the label is enclosed for your records.

If you have questions concerning this matter, please contact me at (703) 308-6341 or by email at swindell.marshall@epa.gov or Martha L. Terry at (703) 308-6217 or by email at terry.martha@epa.gov.

Sincerely,



Marshall Swindell  
Product Manager 33  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Enclosures

# 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

Manufactured by:  
**PromChemie AG**  
**Austrasse 79, P.O. Box 26**  
**FL-9490 Vaduz, Liechtenstein**  
**Telephone (Int'l): +(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.



<b>NET WEIGHT</b>	441 LB / 200 KG
<b>AVG. GROSS WEIGHT</b>	461 LB / 209.1 KG
<b>AVG. TARE WEIGHT</b>	20 LB / 9.1 KG
<b>LOT / BATCH NO.</b>	

**PRECAUTIONARY STATEMENTS**  
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**  
**DANGER**  
**CORROSIVE. CAUSES SKIN BURNS AND IRREVERSIBLE EYE DAMAGE. MAY BE FATAL IF INHALED.**  
**HARMFUL IF SWALLOWED OR ABSORBED THROUGH SKIN.**  
 Do not get in eyes, on skin, or on clothing. Do not breathe vapor or spray mist. Wear goggles or face shield, chemical resistant gloves, long pants and long sleeved shirt. Wear a mask or pesticide respirator approved by the National Institute for Occupational Safety and Health. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

**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.

**STORAGE AND DISPOSAL**  
**PROHIBITIONS:** Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.  
**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:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.  
**EMERGENCIES:** In emergency situations, such as spills, fire, or exposure, call 1-800-424-9300

**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**  
**Call a poison control center or doctor immediately for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment.**

**EYES 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.

**SKIN If skin irritation or dermal exposure:**

- Take off contaminated clothes.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

**INHALATION 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.

**INGESTION If swallowed:**

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

**POISON CONTROL CENTER: CALL 1-800-222-1222**  
**NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.**

**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 0.02-0.25% 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%.

**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 buyer 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 infringer with any liability for infringement arising out of any such use assumed by PROM.

**ACCEPTED WITH COMMENTS**  
**EPA Letter Dated:**  
**JUL - 1 2011**

ESL080405 REV091708

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 80285-1

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