

80285-3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

11/17/2004

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NOV 17 2004

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

AGENT: Edward C. Gray
McDermott, Will and Emory
600 13th Street, N.W.
Washington, D. C. 20005

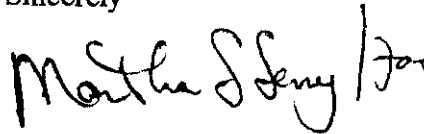
Subject: Promex 20D
EPA Registration No. 80285-3
Notification Received Date October 26, 2004

This will acknowledge receipt of your notification to reinstate the "Note To Physician" statement back on the label, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

The notification is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely



Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

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

ACTIVE INGREDIENT:
1,2-benzisothiazolin-3-one 19.0%
INERT INGREDIENTS81.0%
Total100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

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: <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.
SKIN	If skin irritation or dermal exposure: <ul style="list-style-type: none"> • 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: <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 for further treatment advice.
INGESTION	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 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.



mark of Prom Chem Ltd,
EPA Reg. No. 80285-____
EPA Est. No. _____

Manufactured for: PromChemie AG
Austrasse 79, P.O. Box 26,
FL-9490 Vaduz, Liechtenstein
(011) 423-236-1818

EPA Reg. No. 80285-3
EPA Est. No. 81110-GBR-001

NET WEIGHT:

BATCH NO:

DIRECTIONS FOR USE (continued)

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Typical applications, and the **suggested** range of concentrations on which trials can be based, are:

Type of Material To Be Protected	Lbs PROMEX™ 20D To Use Per 1000 Lb Of Material To Be Protected
Latices , such as: polymer latices based on acrylate, butadiene, PVA or styrene; synthetic rubber/latex; for various applications.	0.5 to 1.5 lb (0.05 - 0.15 %)
Oil-in-water emulsions such as textile spin-finish solutions, cutting/rolling oils, soluble oils (metal and engineering industries), and photographic emulsions. Note: limit amount of PROMEX™ 20D in metalworking fluid concentrate (to be diluted before use) to 3.0 % to reduce the possibility of dermal sensitization.	0.5 to 1.8 lb (0.05 - 0.18 %)
Paints and coatings , such as aqueous coatings, water-based paints, and emulsion paints	0.5 to 2.5 lb (0.05 - 0.25%)
Inks and font solutions	0.5 to 2.5 lb (0.05 - 0.25%)
Water-based adhesives , including animal glues, adhesives based on carboxymethylcellulose (CMC) and derivatives, gelatin and/or latex	0.5 to 2.5 lb (0.05 - 0.25%)
Aqueous slurries of pigments such as titanium dioxide or of minerals such as kaolin, calcium carbonate, calcium sulfate, or magnesium sulfate	0.4 to 1.25 lb (0.04 - 0.125 %)
Building and construction compositions , such as tape joint compounds, caulks, and sealants	0.8 to 2.5 lb (0.08 - .25 %)
Pesticide formulations , including in-can protection and protection of use dilutions	0.5 to 2.5 lb (0.05 - 0.5%)
Home cleaning products , including floor waxes and polishes, surface cleaners, window cleaners, and dish detergents	0.5 to 1.5 lb (0.05 - 0.15 %)
Liquid laundry additives , including laundry detergents, fabric softeners, and stain removers	0.5 to 1.5 lb (0.05 - 0.15 %)
Car care products , including car washing products, car waxes, and silicone emulsions	0.75 to 1.5 lb (0.075 - 0.15 %)
Oil recovery materials , such as drill muds, packer fluids, and completion fluids, containing polysaccharide fluid loss control agents and/or thickeners such as starch, guar, or xanthan gum	0.5 to 1.5 lb per 1000 lb of fluid (0.05 - 0.15 %), or 15 to 45 lb per 1000 lb of dry polysaccharide added to fluid (1.5 - 4.5%)
Secondary oil recovery injection water containing additives, such as polymer or micellar/polymer waterfloods using thickeners such as xanthan gum and/or polyacrylamides	0.15 to 1.5 lb (0.015 - 0.15 %) of total weight of fluid
Leather processing solutions -to preserve the solutions	0.25 to 2 lb (0.025 - 0.2 %)
Fresh animal skins and hides -To preserve the integrity of fresh animal hides and skins before or during processing. Add the appropriate quantity of PROMEX™ 20D to the brine solution during the curing operation or treat hides or skins with an appropriately diluted aqueous solution during other portions of the processing operation. The specific use rate and contact time needed to control microbial attack will depend on the degree of decomposition of the hides or skins prior to treatment.	1 to 24 pounds (13 fluid ounces to 2.5 gallons) of PROMEX™ 20D per 1000 pounds of hides or skins
Paper coatings and textile coatings , including rosin dispersions, starch and casein based products	0.5 to 1.5 lb (0.05 - 0.15 %)
<p>Pulp & paper mill system slime control--The preferred method of addition is by shock dosing because this ensures that a high concentration of PROMEX™ 20D is present in the system for several hours. If a slime control agent is added by continuous methods over periods of several hours, its concentration in the system at all times is low. This can lead to the development of resistant organisms, which is less likely to occur when the shock dosing method is used. It is not possible to give precise recommendations as to the quantity of PROMEX™ 20D to add to control slime formation, because the magnitude of the problem varies greatly from mill to mill, depending on the furnish employed, the cleanliness of the mill system, and the additional nutrients (for example, starch) that may be added to the stock. The following quantities of PROMEX™ 20D are suggested for trial: Shock dosing: If this preferred method is adopted, add 2.5 to 9 ounces of PROMEX™ 20D for each ton of paper produced per day as a single shock dose, the actual quantity to be used depending on the severity of the slime problem. This addition may be made to any part of the stock preparation or backwater system. Alternatively, the addition may be made to those parts of the system where it is known that slime deposits accumulate. Continuous addition: If this method is adopted, add PROMEX™ 20D continuously for either the single period of 8 hours during every 24 hours or for two separate periods of 4 hours during every 24 hours. Meter PROMEX™ 20D into recirculated backwater at a rate of 7 to 8.5 ounces for each ton of paper produced during the dosing period.</p>	

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

WARRANTY 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 re 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.

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%.

See other panel for directions for specific applications.

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McDermott
Will & Emery

Boston Brussels Chicago Düsseldorf London Los Angeles Miami Milan
Munich New York Orange County Rome San Diego Silicon Valley Washington, D.C.

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Edward C. Gray
Senior Regulatory Consultant
egray@mwe.com
(202) 756-8184

October 27, 2004

Mr. Marshall Swindell
Team Leader, Team 33
Antimicrobial Division, Mail Code 7504C - NOTIF
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Re: PromChemie AG; EPA Reg. Nos. 80285-1 -2, and (-3) Notification per PR Notice 98-10;
Correction of inadvertently deleted language

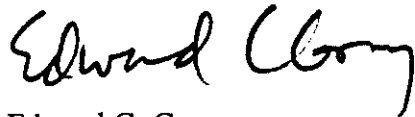
Dear Mr. Swindell:

On September 9, 2004, you approved amendments to the three subject registrations. We have discovered that by mistake, due to a word processing error, the "Note to Physician" statement was deleted by us from the front panel of each of the labels that we submitted and you approved. This notification is to inform you that the language is being restored to the labels and to serve to document this change.

For each product, a completed Form 8570-1 (with continuation page) and a copy of the corrected label are attached.

Thank you for your consideration of this request.

Sincerely yours,



Edward C. Gray
Senior Regulatory Consultant

Attachments



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 United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration	OPP Identifier Number <hr/>
	<input type="checkbox"/> Amendment	
	<input checked="" type="checkbox"/> Other	

Application for Pesticide - Section I

1. Company/Product Number 80285-3	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Promex 20D	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) PromChemie AG Austrasse 79, P.O. Box 26 FL-9490 Vaduz, Liechtenstein <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.
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Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of insertion of inadvertently deleted "Note to Physician" language, per PR Notice 98-10 (continued on attached page)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No			<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container <hr/>		5. Location of Label Directions <input type="checkbox"/> _____	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Edward C. Gray	Title U.S. Agent	Telephone No. (Include Area Code) 202-756-8184
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Det. Application Received (Stamped) <div style="border: 1px dashed black; width: 100px; height: 100px; margin: 0 auto;"></div>
2. Signature 	3. Title U.S. Agent	<div style="border: 1px dashed black; width: 100px; height: 100px; margin: 0 auto;"></div>
4. Typed Name Edward C. Gray	5. Date 27 Oct 2004	

Section II. Explanation (continued):

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Nature of change: Add back language "NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage." to front panel.

This language was on the approved label before the most recent amendment. It was omitted inadvertently (covered up by another block of text in MS Word) from the label we submitted , which you approved on 9 Sep 2004.