

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 30 2004

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

AGENT: McDermott, Will and Emery
600 Thirteenth Street, N.W.
Washington, D. C. 2005-3096

Attention: Edward C. Gray

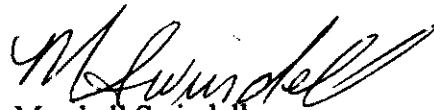
Subject: Promex 10S
EPA Registration No. 80285-1
Your Notification Dated June 7, 2004

This will acknowledge receipt of your notification to reflect changes in the Technical Information Bulletin due to typographical errors, 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							

McDermott Will & Emery

33

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

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

June 7, 2004

Document Processing Desk - NOTIF
Office of Pesticide Programs(7504C)
USEPA
Washington, DC 20460

Re: EPA Reg. Nos. 80285-1, -2, and -3;
Notifications to correct errors in Technical Information Bulletins;
Transmittal Letter

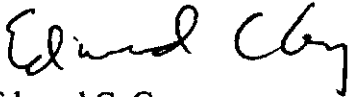
Dear Sir or Madam:

Enclosed are three completed application forms regarding three recently registered products, 80285-1, 80285-2, and 80285-3, all registered by PromChemie AG, for whom I am the US Agent. The three submissions are closely similar and all reflect corrections of mistakes in the Technical Information Bulletins for the products.

Please forward them to Mr. Marshall Swindell of Team 33, Antimicrobial Division.

Thank you for your consideration of this matter.

Sincerely,



Edward C. Gray
US Agent for PromChemie AG

Enclosures

WDC99 931872-1.070046.0011



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 80285-1	2. EPA Product Manager M. SWINDELL	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) PROMEX 10S	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"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

After your approval of this registration we discovered some errors in the nature of typos in the Technical Information Bulletin. On page 1, under Summary, the term "microbial preservative" should be "antimicrobial preservative". On page 2, in the section on Precautionary Statements, (1) the word "Hazardous" had been used instead of the correct word "Hazards" in the title of the first subsection; and (2) under "First Aid" we had inadvertently failed to include the "If Inhaled" paragraph that already appears on the approved label's First Aid paragraph. We also found minor type size anomalies. We were not sure that these all would qualify for non-notification changes under PR 98-10, although most of them clearly do, but they should qualify as notifications. These deficiencies have been corrected, and we have done some repaginating of the TBI to keep topics on single pages. A copy of the corrected TBI is attached.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container	<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 25KG / 200KG / 1000 KG		5. Location of Label Directions <input checked="" type="checkbox"/> LABEL AND TECH BULLETIN LABELING	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph Paper glued 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. Date Application Received (Stamped)
2. Signature 	3. Title U S Agent	
4. Typed Name Edward C. Gray	5. Date June 7, 2004	

Summary

PROMEX™ 10S, an aqueous solution of 1,2-Benzisothiazolin-3-one, is an efficient antimicrobial preservative for aqueous compositions such as: latices, oil in water emulsions, emulsion paints, water based adhesives, paper coating compositions, aqueous mineral slurries, tape joint compounds, leather processing solutions, and for the preservation of fresh animal hides and skins.

PROMEX™ 10S is registered with the Environmental Protection Agency and has been granted EPA registration No. 80285-1.

General

Many aqueous dispersions and emulsions can be spoiled during storage and use due to the growth in them of bacteria and fungi. PROMEX™ 10S is an effective preservative against growth of microbial agents in the aqueous systems listed, and exhibits:

- Effective control of a wide range of organisms at cost-effective concentrations.
- Long-term storage stability.
- Ease of use due to its liquid form and good compatibility in most aqueous compositions.
- A clear light color, with attendant advantages.

Properties of PROMEX™ 10S

Composition:	A solution of 1,2-Benzisothiazolin-3-one at 9% average in propylene glycol and water Clear straw color liquid.
Viscosity:	4.62 mm ² /s. at 20°C
Specific gravity:	1.07 at 25°C
pH	10.1 at 25°C using CIPAC Method MT75
Boiling point:	~100°C
Solubility:	Soluble in water
Stability:	Stable under all normal storage conditions at pH above 4.

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not use for any applications involving food or drinking water contact.

General Recommendations

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 0.04-0.50% PROMEX™ 10S is almost invariably sufficient. The control of mold growth, particularly on paste products of high solids content, may occasionally require demand dosages above 0.50%. Do not use at a rate above 1.0%.

In dilute fluid systems, spoilage is usually controlled with dosages not greater than 0.18%.

PROMEX™ 10S is an effective preservative in most aqueous compositions. Typical applications, and the suggested use rate upon which trials can be based, are:

Preservation of Fresh Animal Hides and Skins

To preserve the integrity of fresh animal hides and skins prior to or during processing, use 2 to 48 lbs (26 fluid ounces to 5 gallons) of PROMEX™ 10S per 1000 pounds of hides or skins. Add the appropriate quantity of PROMEX™ 10S to the brine solution during the curing operation or treat hides or skins with an appropriately diluted aqueous solution during other stages portions of the processing operation. The specific use rate and contact time needed to control microbial attack will depend upon the degree of decomposition of the hides or skins prior to treatment.

Type of material to be protected	USE RATE— Pounds of PROMEX™ 10S per 1000 pounds of material to be protected
<i>Latices:</i> Polymer latices based on acrylate, butadiene, PVA and styrene for various applications.	1 to 3 lb (0.1 - 0.3 %)
<i>Oil-in-water emulsions:</i> "Spin finish" solutions for use in the textile industry.	1 to 3.6 lb (0.10 - 0.36%)
<i>Emulsion paint:</i> For in-can preservation.	1 to 3 lb (0.1 - 0.30%)
<i>Adhesives:</i> Animal glues, carboxymethylcellulose (CMC) and derivatives, adhesives based on gelatin and latex.	1 to 5 lb (0.1 - 0.5%)
<i>Paper coating compositions:</i> Resin dispersions; starch and casein-based products.	1 to 3 lb (0.1 - 0.3%)
<i>Aqueous mineral slurries:</i> titanium dioxide slurries.	0.8 to 2.5 lb (0.08 - 0.25%)
<i>Tape joint compounds:</i>	1.6 to 2.5 lb (0.16 - 0.25%)
<i>Leather processing solutions:</i> to preserve the solution.	0.5 to 4 lb (0.05 - 0.4 %)

Precautionary Statements

Keep Out of Reach of Children

DANGER

Hazards to Humans and Domestic Animals

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.

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

If Swallowed: Call a poison control centre or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control centre doctor.

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 on Skin: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control centre or doctor for treatment. Wash contaminated clothing and footwear before reuse.

Poison Control Center:

Call 1-800-222-1222

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

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

Environmental Hazards

This product is toxic to fish. Do not discharge 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 and estuarine oil fields.

Storage and Disposal

Prohibitions

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.

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 by other procedures approved by state and local authorities.

**For information on spills, call
1-800-424-9300**

Safe Handling Information

Refer to the Material Safety Data Sheet (MSDS) available from PromChemie AG for information on the safe use, handling and disposal of this product.

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 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.

For technical information, literature, sample and order information, please contact PromChemie AG at the address below.

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