

09/01/2005

SEP 1 2005

PromChemie AG,
c/o Edward C. Gray
600 13th Street, N.W.
Washington, D. C. 20005

Subject: PROMEX 10D
EPA Registration No. 80285-3
Your Notification Dated August 4, 2005

This will acknowledge receipt of your notification to correct errors in the Technical Information Bulletin, 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
Antimicrobial Division (7510C)

CONCURRENCES

SOL							
NAME							
E							

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.

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

August 4, 2005

Document Processing Desk - NOTIF
Office of Pesticide Programs(7504C)
U. S. Environmental Protection Agency
Room 266A, 2d floor, Crystal Mall 2
1801 S. Bell Street
Arlington, VA 22202-4501

Re: Transmittal Letter; EPA Reg. Nos. 80285-3;
Notification to correct errors in the Technical Information Bulletin

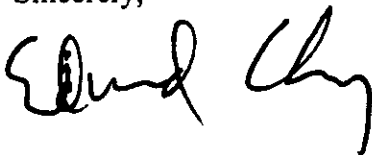
Dear Sir or Madam:

Enclosed is a completed application form regarding a product, EPA Reg. No. 80285-3, registered by PromChemie AG, for whom I am the US Agent. The form informs EPA that several errors in the technical information bulletin for the product were discovered and will be corrected in the bulletins distributed to customers.

Please forward this 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

Enclosure

U.S. practice conducted through McDermott Will & Emery LLP.

600 Thirteenth Street, N.W. Washington D.C. 20005-3096 Telephone: 202.756.8000 Facsimile: 202.756.8087 www.mwe.com



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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 80285-1	2. EPA Product Manager Marshall 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, c/o Edward C. Gray 600 13th St. NW Washington, DC 20005 <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.)

When an amendment to this product's registration was submitted in June 2004 (approved in September 2004) to add food uses, several mistakes were made on page 1 of the revised Technical Information Bulletin (TIB). In the section entitled "Properties of PROMEX tm 20D" a wrong set of properties (pertaining to a different product) was included by mistake. The correct set of properties as approved in the original registration of the product will be included in the TIB in lieu of the mistaken information. In addition, for accuracy, in the TIB section headed "Summary" the words aqueous solution" will be changed to "aqueous dispersion" and in the TIB section headed "General" the words "clear light color" will be changed to "light color". Finally, under "U.S. Regulatory Clearances the correct product name "Promex 20D" will be substituted for "Promex 10S". A corrected copy of the page is attached.

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
Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product		<input 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 both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title U.S. Agent	
4. Typed Name Edward C. Gray	5. Date 4 August 2005	

General

Many aqueous dispersions and emulsions can be spoiled during storage and use due to the growth in them of bacteria, fungi, molds, or other microorganisms. PROMEX™20D, an aqueous dispersion of 1,2-benziso-thiazolin-3-one (BIT), is an efficient microbial preservative for many aqueous systems, 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 light color, with attendant advantages.

PROMEX™20D protects against growth of microbial agents in aqueous systems such as the following:

Latices, such as polymer latices based on monomers such as acrylate, butadiene, PVA, or styrene; synthetic rubber/latex

Water-based adhesives, including animal glues, carboxymethylcellulose (CMC) and derivatives, and adhesives based on gelatin and/or latex

Aqueous slurries of pigments, such as titanium dioxide, or of **minerals**, such as kaolin, calcium carbonate, calcium sulfate, or magnesium sulfate

Oil in water emulsions, such as textile spin-finish solutions, cutting/rolling oils, soluble oils (metal and engineering industries), and photographic emulsions

Paints and coatings, such as aqueous coatings, water-based paints, and emulsion paints

Inks and font solutions

Building and construction materials, such as caulks, sealants, grouts, spackling, ready-mixed cement and wallboard compounds, and tape joint compounds

Pesticide formulations, including in-can protection and protection of use dilutions

Cleaning products, including floor waxes and polishes, surface cleaners, window cleaners, and dish detergents

Liquid laundry additives, including laundry detergents, fabric softeners, and stain removers

Car care products, including car washing products, car waxes, and silicone emulsions

Oil recovery materials, such as drill muds, packer fluids, and completion fluids

Secondary oil recovery injection water with additives

Leather processing solutions, to protect the solution

Fresh animal hides and skins, to preserve the integrity of the hides and skins before or during processing

Paper coatings to be used in papermaking, including rosin dispersions and starch and casein based products

Pulp & paper mill system slime control by shock dosing or continuous dosing

U.S. REGULATORY CLEARANCES:

PROMEX™20D is registered with the U.S. Environmental Protection Agency and has been granted EPA registration Number 80285-3.

Under 40 CFR 180.1001(d) its components are exempt from the requirement for a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticides applied to growing agricultural crops. Not more than 0.1% of the active ingredient, BIT, is allowed in such pesticide formulations.

BIT, the active ingredient of PROMEX™20D, is cleared for use under the following FDA clearances:

- 21 CFR 175.105, as a preservative of adhesives
- 21 CFR 176.170, as preservative for paper coating compositions, at level not to exceed 0.01 mg/in² of finished paper or paperboard in contact with fatty & aqueous food
- 21 CFR 176.180, as preservative for paper coating compositions, at level not to exceed 0.02 mg/in² of finished paper or paperboard in contact with dry food
- 21 CFR 176.300, slimicides (in manufacture of food-contact paper or paperboard) at level not to exceed 0.06 lb per ton of dry weight fiber
- 21 CFR 177.2600(c)(4)(ix), uncured latex rubber (consult regulation for limitations)

Properties of PROMEX™20D

Composition:	An aqueous dispersion of 1,2-Benzisothiazolin-3-one at 19% av. in very fine particle form.
Physical form and appearance:	Opaque white liquid
Viscosity:	348 mPa.s, at 20°C
Specific gravity:	1.05, at 20°C
pH	5.45 A (tested as 1% weight/weight aqueous dispersion) at 25°C using CIPAC Method MT75.
Boiling point:	~100°C
Solubility:	Soluble in water
Stability:	Stable under all normal storage conditions.

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