80285-1 4/14/2011 1/7

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Promchemie AG
5145 Forest Run Trace, Suite B
Alpharetta, GA 30022-4504

APR 14 2011

AGENT: McDermott Will & Emery.
600 Thirteenth Street, N. W.
Washington, D. C. 20005-3096

Attention: Christopher M. Lahiff

Subject: Promex 10S
EPA Registration No. 80285-1
Notification Dated February 25, 2011

The amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

Proposed Amendment

- To update the Technical Information Bulletin (TIB)

General Comments

Please note that the TIB has been treated as an amendment and not a notification and a stamped copy of the "accepted" TIB is enclosed for your records.

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 (7510P)

Enclosure

PromChemie AG
PROMEX™ 10S Technical Information Bulletin

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™10S, an aqueous solution 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 clear light color, with attendant advantages.

PROMEX™10S 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 or 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™10S is registered with the U.S. Environmental Protection Agency and has been granted EPA registration Number 80285-1.

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™10S, 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/in^2 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/in^2 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)

ACCEPTED
with COMMENTS
EPA Letter Dated:

APR 14 2011

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

Properties of PROMEX™10S

Composition:	A solution of 1,2-Benzisothiazolin-3-one at 9% average in **propylene glycol** & water
Physical form and appearance:	Clear amber liquid.
Viscosity:	124 mm^2/s at 20°C
Specific gravity:	1.12 at 25°C
pH	10.1 at 25°C
Boiling point:	~100°C
Solubility:	Soluble in water
Stability:	Stable under all normal storage conditions

[For use with ABN: PROMEX CLEAR

Properties of PROMEX™ CLEAR

Composition:	A solution of 1,2-Benzisothiazolin-3-one at 9% average **in water**
Physical form and appearance:	Clear amber liquid.
Viscosity:	124 mm^2/s at 20°C
Specific gravity:	1.05 at 25°C
pH	10.1 at 25°C
Boiling point:	~100°C
Solubility:	Soluble in water
Stability:	Stable under all normal storage conditions

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DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

PROMEX™10S 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 0.04 - 0.70% PROMEX™ 10S is almost invariably sufficient. In dilute fluid systems, spoilage is usually controlled with dosages not greater that 0.18%. Control of mold growth, particularly on paste products of high solids content, may occasionally require demand dosages above 0.50%. Do not use concentrations greater than 1.0%.

Trials at different concentrations are recommended. Typical applications, and the suggested range of concentrations on which trials can be based, are:

Type of material to be protected	**Lbs PROMEX™10S to use per 1000 Lb of material to be protected**
Latices, such as: polymer latices based on monomers such as acrylate, butadiene, PVA or styrene; synthetic rubber/latex	1 to 5 lb (0.10 - 0.50%)
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™ 10S in metalworking fluid concentrate (to be diluted before use) to 3.0 % to reduce the possibility of dermal sensitization.	1 to 3.6 lb (0.10 – 0.36%)
Paints and coatings, such as aqueous coatings, water-based paints, and emulsion paints	1 to 5 lb (0.10 – 0.50%)
Inks and font solutions	1 to 5 lb (0.10 – 0.50%)
Water-based adhesives, including animal glues, adhesives based on carboxymethylcellulose (CMC) and derivatives, gelatin and/or latex	1 to 5 lb (0.10 – 0.50%)
Aqueous slurries of **pigments** such as titanium dioxide slurries or of **minerals** such as kaolin, calcium carbonate, calcium sulfate, or magnesium sulfate	0.8 to 2.5 lb (0.08 - 0.25%)
Building and construction materials, such as caulks, sealants, grouts, spackling, ready-mixed cement and wallboard compounds, and tape joint compounds	1.6 to 5 lb (0.16 – 0.50%)
Pesticide formulations, including in-can protection and protection of use dilutions	1 to 5 lb (0.10 – 0.50%)
Home cleaning products, including floor waxes and polishes, surface cleaners, window cleaners, and dish detergents	1 to 3 lb (0.10 – 0.30%)
Liquid laundry additives, including laundry detergents, fabric softeners, and stain removers	1 to 3 lb (0.10 – 0.30%)
Car care products, including car washing products, car waxes, and silicone emulsions	1.5 to 3 lb (0.15 – 0.30%)
Oil recovery materials ***(Not for use in California)***, 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	1 to 3 lb per 1000 lb of **fluid** (0.10 – 0.30%), **or** 30 to 90 lb per 1000 lb of **dry** polysaccharide added to fluid
Secondary oil recovery injection water ***(Not for use in California)*** containing additives, such as polymer micellar/polymer waterfloods using thickeners such as xanthan gum and/or polyacrylamides	0.3 to 3 lb (0.03 – 0.30%) of total weight of fluid

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Type of material to be protected	Lbs PROMEX™10S to use per 1000 Lb of material to be protected
Leather processing solutions, to preserve the solutions	0.5 to 4 lb (0.05 – 0.40%)
Fresh animal skins and hides, to preserve the integrity of the hides and skins before or during processing. 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 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.	2 to 48 pounds (26 fluid ounces to 5.0 gallons) of PROMEX™ 10S per 1000 pounds of hides or skins
Paper coatings to be used in papermaking, including rosin dispersions, starch and casein based products	1 to 3 lb (0.10 – 0.30%)

Pulp & paper mill system slime control *(Not for use in California)*

The preferred method of addition is by **shock dosing** because this ensures that a high concentration of PROMEX™10S 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™10S 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™10S are suggested **for trial:**

Shock dosing: If this preferred method is adopted, add 5 to 18 ounces of PROMEX™10S 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™10S 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™10S into the recirculated backwater at a rate of 14 to 17ounces for each **ton** of paper produced during the dosing period.

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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.

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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 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.

For technical information, literature, sample and order information, please contact PromChemie AG at the following address:

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FL-9490 Vaduz, Liechtenstein
Phone (011) 423-236-1818

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