MAY 3 1 2004

Avecia, Inc. 1405 Foulk Road Wilmington, DE 19850-5457

Attention: Mark E. Burt, Ph.D Regulatory Manager

Subject: Proxel GXL Industrial Microbiostat EPA Registration No. 72674-11 Amendment Dated April 23, 2001

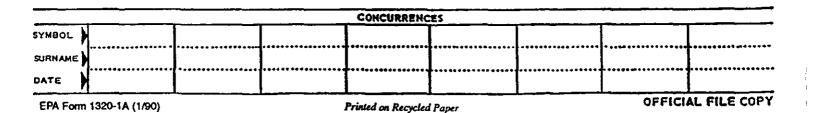
The amendment referred to above, submitted in connection with registration under the FIFRA sec. 3(c)(7)(A), to add the following use patterns to the Directions for Use: Laundry Additive, Liquid Laundry Detergents, Fabric Softeners and Stain Remover, is acceptable, provided that you:

- 1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
- 2. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:
- a. The heading "Statement of Practical Treatment" must be changed to "First Aid" and the statements must be revised as follows:

#### IF IN EYES:

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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 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 by a poison control center or doctor.

# IF ON SKIN:

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

#### 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.

- b. In the Storage and Disposal section, change the subheading "Storage" to "Pesticide Storage".
- 3. Submit two (2) copies of your final printed labeling before you release the product for shipment.

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 bearing the labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

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

Sincerely Martha Sterm Hon

Marshall Swindell

Product Manager 33

Regulatory Management Branch 1 Antimicrobial Division (7510C)

Enclosure

# PROXEL® GXL

# INDUSTRIAL MICROBIOSTAT

FOR INDUSTRIAL USE ONLY AS A MICROBIOSTAT PRESERVATIVE FOR AQUEOUS COMPOSITIONS SUCH AS OIL IN WATER EMULSIONS, LATICES, EMULSION PAINTS, WATER BASED ADLESIVES, CASEINROSIN DISPERSIONS, TEXTILE SPIN-FINISH SOLUTIONS, PESTICIDE FORMULATIONS, AQUEOUS SLURRIES, TITANIUM DIOXIDE SLURRIES, TAPE JOINT COMPOUND, LEATHER PROCESSING SOLUTIONS, AND FOR THE PRESERVATION OF FRESH ANIMAL HIDES AND SKINS

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

#### DANGER

CORROSIVE. CAUSES SEVERE EYE & SKIN DAMAGE. MAY CAUSE ALLERGIC SKIN DAMAGE. MAY CAUSE ALLERGIC SKIN REACTIONS. DO NOT GET IN KEEP OUT OF REACH OF CHILDREN. STORAGE AND DISPOSAL PROHIBITIONS:

EYES, ON SKIN OR CLOTHING. WEAR GOGGLES OR FACESHIELD AND RUBBER GLOVES WHEN HANDLING. HARMFUL OR FATAL IF SWALLOWED, INHALED OR ABSORBED THROUGH THE SKIN. AVOID CONTAMINATION OF FOOD.

DANGER

T. I. BULLETIN 00013 FOR DIRECTIONS FOR USE.

THOUSE.

THOUSE.

TO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL OPEN DUMPING IS PROHIBITED.

STORAGE:
PROTECT FROM FROST, IF FROZEN, AL-

ENVIRONMENTAL HAZARDS:
THIS PRODUCT IS TOXIC TO FISH, DO
NOT DISCHARGE EFFLUENT CONTAINING THIS PRODUCT INTO LAKES,
STREAMS, PONOS, ESTUARIES,
QCEANS 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.

EPA REG. NO. 72674-11 EPA EST. NO. 67003-NC-01

MANUFACTURED BY:

ACTIVE INGREDIENT:

1.2-BENZISOTHIAZOLIN-3-ONE......19.3% INERT INGREDIENTS......80.7%

FIRST AID:
IN CASE OF CONTACT, IMMEDIATELY FLUSH
EYES OR SKIN WITH PLENTY OF WATER FOR AT
LEAST 15 MINUTES. FOR EYES, CALL A PHYSICIAN. REMOVE AND WASH CONTAMINATED
CLOTHING BEFORE REUSE. IF SWALLOWED,
DRINK PROMPTLY LARGE QUANTITIES OF WATER. AVOID ALCOHOL CALL A PHYSICIAN IMMEDIATELY.

NOTE TO PHYSICIAN: POSSIBLE MUCOSAL DAMAGE MAY O DICATE THE USE OF GASTRIC LAVAGE. DAMAGE MAY CONTRAIN-

#### DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING. SEE T. I. BULLETIN 00013 FOR DIRECTIONS FOR USE.

STORAGE:
PROTECT FROM FROST, IF FROZEN, AL-LOW TO THAW AND STIR WELL BE-FORE USE.

PESTICIDE DISPOSAL:
PESTICIDE WASTES ARE ACUTELY
HAZARDOUS. IMPROPER DISPOSAL
OF EXCESS PESTICIDE SPRAY MXTURE 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.

ACCEPTED with COMMENTS in EPA Letter Dated:

MAY 3 1 2001

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

72674-11

SEE ADDITIONAL PRECAUTIONARY STATEMENTS ON SIDE PANEL

CONTENTS: . (APPROX.

LBS. NET MINIMUM U.S. GALLONS)

Medical Emergency Information Center - 800-286-7850 Chemical Emergency Response Center - 800-424-2466

P.O. Box 15457 Wilmington Delaware 19850-5457 USA 800-435-8679

LOT NUMBER:

PRODUCT CODE:

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PROXEL is a registered trademark of Avecia Inc.

# Proxel GXL

# Preservative

# **Summary**

PROXEL® GXL, an aqueous solution of 1,2-benziso-thiazolin-3-one, is an efficient microbiostat preservative for aqueous compositions such as oil in water emulsions, latices, emulsion paints, water based adhesives, casein and rosin dispersions, textile spin-finish solutions, pesticide formulations, aqueous slurries, titanium dioxide slurries, tape joint compounds, specialty and household products, leather processing solutions, and for the preservation of fresh animal hides and skins.

PROXEL GXL is registered with the Environmental Protection Agency and has been granted EPA Registration No. 72674-11. Its components are also cleared by EPA for use under 40 CFR 180.1001 (d) for agricultural use.

#### **General**

Many aqueous dispersions and emulsions can be seriously impaired during storage and use due to the growth in them of bacteria and fungi such as:

Staphylococcus aureus Salmonella typhosa Klebsiella pneumoniae Bacillus subtilis Bacillus megaterium Escherichia coli Proteus vulgaris Pseudomonas
aeruginosa
Rhizopus stolonifer
Aspergillus
pencilloides
Aspergillus niger
Alternaria radicina
Tricophyton
mentagrophytes

# **Technical Information Bulletin**

PROXEL GXL is an effective preservative against growth of the above microbial agents in the aqueous systems listed and exhibits:

- a. Effective control of a wide range of organisms at economic concentrations.
- b. Long-term storage stability.
- Ease of use due to its liquid form and good compatibility in most aqueous compositions.

# Properties of PROXEL GXL

Composition:

A solution of 1,2-benzisothiazolin-

3-one at 19.3% ave in

dipropylene glycol and water.

Physical Form

and Appearance: Dark brown liquid

Viscosity (25°C)

Brookfield:

500 centipoise (approx.)

Specific Gravity

(25°C/25°C):

pH, 10% (25°C):

Density (25°C):

Initial Boiling

Point:

Solubility:

Stability:

1.13 (approx) 12 (approx)

9.5 lb/gal (approx)

100°C

Soluble in water at use dilutions Stable under all normal storage conditions. Maintain the pH above approximately 4. The active agent is heat stable and

non-volatile. Protect from frost.

ACCEPTED with COMMENTS in EPA Letter Dated:

MAY 3 1 2001

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

72674-11

**MASTER** 

# ACCEPTED with COMMENTS in EPA Letter Dated:

MAY 3 1 2001

# **Directions for Use**

Under the Federal Insecticide,

It is a violation of Federal Law to use this the actions. lered under EPA Reg. No. a manner inconsistent with its labeling. 71674-11 PROXEL® GXL is an effective preservative in most aqueous compositions. Typical applications, and the suggested range of concentrations on which trials can be based, are:

> % PROXEL GXL (based on total weight of product)

Latices:

0.05 - 0.15

Polymer latices based on acrylate, butadiene, PVA and styrene for various applications, e.g., wax, floor polishes, Synthetic/rubber latices.

Oil-in-water emulsions:

**Product** 

0.05 - 0.18

"Spin finish" solutions for use in the textile industry. Cutting/ rolling oils. Soluble oils\* (metal and engineering industries).

\*We suggest that the addition to metal-working fluid concentrates of PROXEL GXL should be limited to 1.5% maximum. This will give a maximum recommended use level of 0.15% PROXEL GXL in a 10:1 dilution of the concentrate and reduce the possibility of skin sensitization.

Emulsion paint:

0.05-0.15

For preservation in the can.

Adhesives:

0.05-0.25

Carboxymethylcellulose (CMC) and derivatives, animal glues, adhesives based on gelatin and latex.

Paper coating compositions:

0.05-0.15

Rosin dispersions.

Starch and casein based

products.

Pesticide formulations:

0.05-0.25

For product preservation. For ultimate use - dilution

protection.

PROXEL GXL is exempt from tolerance under 40CFR 180.1001(d); materials exempted from the requirements of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops only. Based on the current 180.1001(d) limit of 0.1% BIT in formulations, use levels up to 0.5% (5000 ppm) PROXEL GXL are allowed.

**Product** 

% PROXEL GXL (based on total weight of product)

Aqueous Mineral Slurries: Tape joint compound

. 0.04-0.125 0.08-0.25

Fungicide, and Rodenticide Act as Specialty Products and Household Products:

Home Cleaning Products:

0.05-0.15

Floor cleaners, floor waxes & polishes, surface cleaners, window cleaners, dish detergents.

Laundry Additives:

0.05 - 0.15

Liquid laundry detergents fabric softeners, stain

removers.

Car Care Products:

0.075-0.15

Car washing products, car waxes, silicone emulsions.

# Preservation of Fresh Animal Hides and Skins

To preserve the integrity of fresh animal hides and skins prior to or during processing, use 13 fluid ounces to 2.5 gallons (1.0-24 lbs) of PROXEL GXL per 1000 pounds of hides or skins. Add the appropriate quantity of PROXEL GXL 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 upon the degree of decomposition of the hides or skins prior to treatment.

# **Leather Processing Solutions**

Use PROXEL GXL at levels of 0.025-0.2% for the preservation of leather processing solutions.

#### Slime Control

There are two methods of adding slimicides to paper mill systems: shock dosing and continuous dosing.

The preferred method of addition is by shock dosing since this ensures that a high concentration of PROXEL GXL is present in the system for several hours. When a slime control agent is added by continuous methods over periods of several hours, its concentration in the system at any time is low. This can lead to the development of resistant organisms, an effect that is less likely to occurwhen the shock dosing method is used.

It is not possible to give precise recommendations as to the quantity of PROXEL GXL to add to control slime formation, since the magnitude of the problem varies greatly from mill to mill, depending on

the furnish employed, the cleanliness of the milk system, and the additional nutrients (for example, starch) that may be added to the stock.

The following quantities of PROXEL GXL are suggested for trial:

# (a) Shock Dosing

Between 70 and 260 grams (2 1/2 - 9 oz. av.) of PROXEL GXL for each ton of paper produced per day should be added as a single daily shock dose, the actual quanity 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 unknown that slime deposits accumulate.

# (b) Continuous Addition

If this method is adopted, PROXEL GXL should be added 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.

PROXEL GXL should be metered at the rate of 195-230 grams (7-8.3 oz. av.) for each ton of paper produced during the dosing period. Preferably, this addition should be made to the recirculated backwater.

#### **Bacterial Control for Oil Recovery Systems**

PROXEL GXL is an effective preservative in most aqueous oil recovery products, and the suggested range of concentration on which trials can be based, are:

Drilling fluids, packer fluids, completion fluids:

Polysaccharide fluid loss control agents and thickeners such as starch, guar, and xanthan gum 0.05-0.15% on fluid weight or 1.5-4.5 on the dry polysaccharide weight.

Subsurface injection waters such as polymer and micellar/polymer waterfloods:

Thickeners such as xanthan gum and polyacrylamides 0.015-0.15% on solution weight

# **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 0.02-0.35% PROXEL GXL is almost invariably sufficient.

The control of mold growth, particularly on paste products of high solids content, may occasionally demand dosages above 0.25%.

In dilute fluid systems, spoilage is usually controlled with dosages not greater than 0.09% the COMMENTS in EPA Letter Dated:

Keep Out of Reach of Children

MAY 3 1 2001

# **DANGER**

Precautionary Statements

Under the Federal Insecticide, Pungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

# Hazardous to Humans and Domestic Animals

Corrosive. Causes severe eye and skin damage. May cause allergic skin reaction. Do not get in eyes, on skin or clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed, inhaled or absorbed through the skin. Avoid contamination of food.

First Aid: In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. If irritation continues call a physician. Remove and wash contaminated clothing before reuse. If swallowed, drink promptly large quantities of water. Avoid alcohol. Call a physician immediately.

*Note to Physician:* Probable mucosal damage may contraindicate the use of gastric lavage.

#### **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 estaurine 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.

# Safe Handling Information

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

For technical information, literature, sample and order information, please contact Customer Services: 800-523-7391.

For more information, visit our website at www.aveciabiocides.com.

ACCEPTED with COMMENTS in EPA Letter Dated:

MAY 3 1 2001

Under the Federal Insecticide, Pungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

72674-11



PROXEL is a registered trademark of Avecia Inc.

# FOR YOUR PROTECTION

AVECIA Inc. ("AVECIA") 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 AVECIA'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 AVECIA, and the buyer or user assumes the risk of any such use. AVECIA DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WAR-

RANTY OF MERCHANTABILITY. (Statements herein, therefore, should not be construed as representations or warranties.)

IN NO EVENT SHALL AVECIA BE LIABLE FOR ANY SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, INCLUDING LOST PROFITS, ON ANY THEORY WHATSOEVER, INCLUDING NEGLIGENCE, AND AVECIAs 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.

#### **Avecia Biocides**

1405 Foulk Road Wilmington, DE 19850