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12/12/2000

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1/7

DEC 12 2000

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

Attention: Mark E. Burt
Regulatory Manager

Subject: Proxel GXL
EPA Registration No. 72674-11
Amendment Dated May 20, 2000

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to add specialty products and household products to directions for use, is acceptable, provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

a. Delete the section "Specialty products and Household Products under Laundry Additives: Liquid laundry detergents, fabric softeners, and stain removers". Please note that additional data (Risk Assessment) may be required to support this claim since, the data on file is not adequate to support these uses.

b. Change the heading "Statement of Practical Treatment" to "First Aid".

c. Change "See additional precautions on side panel" to "See additional precautionary statements on side panel".

d. Under the "Note to Physician" heading, delete the statement "Measures against circulatory shock, respiratory depression and convulsion may be needed."

2. Submit five (5) copies of final printed labeling before you release the product for shipment.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Page 2

Your release for shipment of the product bearing the amended 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,



Marshall Swindell

Product Manager 33

Regulatory Management Branch 1

Antimicrobial Division (7510C)

Enclosure

PROXEL® GXL

3/7

INDUSTRIAL MICROBIOSTAT

FOR INDUSTRIAL USE ONLY AS A MICROBIOSTAT PRESERVATIVE FOR AQUEOUS COMPOSITIONS SUCH AS OIL IN WATER EMULSIONS, LATICES, EMULSION PAINTS, WATER BASED ADHESIVES, CASEIN/ROSIN 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 REACTIONS. DO NOT GET IN 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.

ENVIRONMENTAL HAZARDS:
THE 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.

ACTIVE INGREDIENT:

1,2-BENZISOTHAZOLIN-3-ONE.....19.3%

INERT INGREDIENTS.....80.7%

KEEP OUT OF REACH OF CHILDREN

DANGER

STATEMENT OF PRACTICAL TREATMENT:

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 CONTRAINDICATE THE USE OF GASTRIC LAVAGE. MEASURES AGAINST CIRCULATORY SHOCK, RESPIRATORY DEPRESSION AND CONVULSION MAY BE NEEDED.

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 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.

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

SEE ADDITIONAL PRECAUTIONS
ON SIDE PANEL

CONTENTS:
(APPROX)

LBS. NET MINIMUM
U.S. GALLONS)

MANUFACTURED BY:

Avecia

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

REV. DATE: 10/20/99

LOT NUMBER:

PRODUCT CODE:

84300

PROXEL is a registered trademark of Avecia Inc.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

DEC 12 2000

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

72674-11

PROXEL® GXL

Preservative

Technical Information Bulletin

Summary

PROXEL® GXL, an aqueous solution of 1,2 benzisothiazolin-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:

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

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

- Effective control of a wide range of organisms at economic concentrations.
- 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):	1.13 (approx)
pH, 10% (25°C):	12 (approx)
Density (25°C):	9.5 lb/gal (approx)
Initial Boiling Point:	100°C
Solubility:	Soluble in water at use dilutions
Stability:	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 D-11

DEC 12 2000

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

72674-11

Avecia Biocides

MASTER COPY

Avecia

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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.

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:

Product	% 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.	ACCEPTED with COMMENTS DEC 12 2000

Oil-in-water emulsions:
"Spin finish" solutions for use in the textile industry. Cutting rolling oils. Soluble oils* (metal and engineering industries).

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 72674-11

*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.

Inks 0.05-0.25

Product	% PROXEL GXL (based on total weight of product)
Aqueous Mineral Slurries:	0.04-0.125
Tape joint compound	0.08-0.25
Specialty Products and Household Products	
Laundry Additives:	0.05-0.15
Liquid laundry detergents, fabric softeners, stain removers.	
Home Cleaning Products:	0.05-0.15
Floor cleaners, floor waxes & polishes, surface cleaners, window cleaners, dish detergents.	
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 occur when the shock dosing method is used.

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

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

Keep Out of Reach of Children

DANGER

Precautionary Statements

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.

Statement of Practical Treatment: 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. 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.

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.

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ISO 9002
FS 22484

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 AVECIA'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.

Avecia Biocides

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