

OCT 6 1997

Zeneca Inc.
1800 Concord Pike
Wilmington, DE. 19850-5457

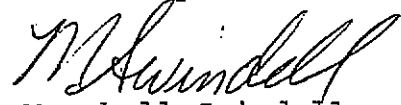
Subject: Proxel GXL
EPA Registration No. 10182-30
Notification Per PR-Notice 95-2
Your Notification Dated August 22, 1997

Dear Mr. Burt:

This will acknowledge receipt of your notification to add an "Indoor, Nonfood Site and Inks", to the technical information bulletin for PROXEL GXL, an antimicrobial submitted under the provisions of FIFRA section 3(c)9. Based on a review of the submitted material, the following comments apply.

The application is acceptable and the notification has been made a part of the records for this file.

Sincerely,



Marshall Swindell
Notification Coordinator
Antimicrobial Program Branch
Antimicrobial Division (7510W)

CONCURRENCES							
SYMBOL	7510W						
SURNAME	P. J. J. J.						
DATE	9/25/97						



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 10182-30	2. EPA Product Manager V. Noble M. SWINDELL	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) PROXEL GXL	PM# 31 33	
5. Name and Address of Applicant (Include ZIP Code) Zeneca Inc. 1800 Concord Pike Wilmington, DE 19850-5457 <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.)

Addition of an additional indoor nonfood site, inks, to the technical information bulletin for PROXEL GXL, an antimicrobial, via notification as per PR Notice 95-2.

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	
				<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"/> On Label <input type="checkbox"/> On Labeling accompanying product	
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 Mark E. Burt		Title Regulatory Manager		Telephone No. (Include Area Code) (302) 477-3129	
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 Regulatory Manager			
4. Typed Name Mark E. Burt		5. Date August, 22, 1997			

PROXEL® GXL

INDUSTRIAL MICROBIOCIDES

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: THIS 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.

EPA REG. NO. 30162-30

EPA EST. NO. 67003-NC-01

MANUFACTURED BY:

ACTIVE INGREDIENT:

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

INERT INGREDIENTS.....80.7%

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 RINSE 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.

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.

SEE ADDITIONAL PRECAUTIONS
ON SIDE PANEL

CONTENTS: LBS. NET MINIMUM
(APPROX. U.S. GALLONS)

ZENECA

ZENECA Specialties
Wilmington
Delaware 19897 USA
(302) 886-3000

A business unit of ZENECA Inc.

LOT NUMBER: PRODUCT CODE: PROXEL is a registered trademark of ZENECA Inc.

ZENECA Biocides

PROXEL® GXL Preservative

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 oxide slurries, tape joint compounds, 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. 10182-30. 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 penicillioides</i>
<i>Bacillus megaterium</i>	<i>Aspergillus niger</i>
<i>Escherichia coli</i>	<i>Alternaria radicina</i>
<i>Proteus vulgaris</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.

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: Polymer latices based on acrylate, butadiene, PVA and styrene for various applications, e.g., wax, floor polishes. Synthetic/rubber latices.	0.05-0.15
Oil-in-water emulsions: "Spin finish" solutions for use in the textile industry.	0.05-0.18
Emulsion paint: For preservation in the can.	0.05-0.15
Adhesives: Carboxymethylcellulose (CMC) and derivatives, animal glues, adhesives based on gelatin and latex.	0.05-0.25
Paper coating compositions: Rosin dispersions. Starch and casein based products.	0.05-0.15
Pesticide formulations: For product preservation. For ultimate use - dilution protection.	0.05-0.25
→ Inks	0.05-0.25

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% (5000ppm) PROXEL GXL are allowed.

Product	% PROXEL GXL (based on total weight of product)
Aqueous Mineral Slurries:	0.04-0.125
Tape joint compound:	0.08-0.25

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.

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 of 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

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Corrosive. Causes severe eye and skin damage. May cause allergic 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.

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

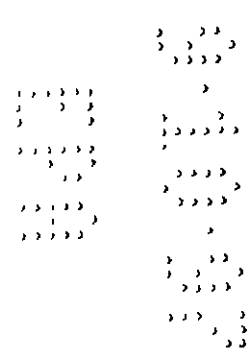
Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

SAFE HANDLING INFORMATION

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

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

For technical information, please contact Application Research and Technical Services: 302-886-8428.



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PROXEL is a registered trademark of ZENECA Ltd.



ISO 9002
FS 22484

FOR YOUR PROTECTION

ZENECA Inc. ("ZENECA") 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 ZENECA'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 ZENECA, and the buyer or user assumes the risk of any such use. ZENECA 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 ZENECA BE LIABLE FOR ANY SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, INCLUDING LOST PROFITS, ON ANY THEORY WHATSOEVER, INCLUDING NEGLIGENCE, and ZENECA'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 formula-

tions 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.

ZENECA Biocides

1800 Concord Pike
Wilmington, DE 19897