

72674-12

10-29-2003

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OCT 29 2003

Avecia Biocides
1405 Foulk Road
P.O. Box 15457
Wilmington, DE 19850-5457

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

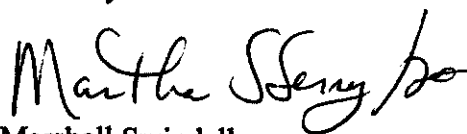
Subject: Proxel DL
EPA Registration No. 72674-12
Amendment Dated September 29, 2003

This will acknowledge receipt of your notification to include Marketing Directions for Use on the Container Label, 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 made a part of 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
Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 72674-12	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Proxel DL	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Avecia Inc., 1405 Foulk Road, P.O. Box 15457, 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.)

Notification to add marketing directions for use from the EPA Stamped Accepted Technical Information Bulletin to the EPA Stamped Accepted container label in order to assure that directions for use always accompany the product when shipped.

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) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
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 Mark E. Burt		Title Regulatory Manager		Telephone No. (Include Area Code) (302) 477-8129	
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 or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Manager			
4. Typed Name Mark E. Burt		5. Date September 29, 2003			

PR Notice 98-10 Certification Statement

Product: Proxel DL

EPA Reg. No.: 72674-12

Registrant: Avecia Inc.

Notification to: To add marketing directions for use from the EPA Stamped Accepted Technical Information Bulletin to the EPA Stamped Accepted Container label in order to assure that directions for use always accompany the product when shipped.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Company Agent: M.E. Burt

Title: Regulatory Manager

Date: September 29, 2003

Signature: M.E. Burt

(left side)

PROXEL® DL

INDUSTRIAL MICROBIOSTAT

A MICROBIOSTAT PRESERVATIVE FOR USE IN THE MANUFACTURE OF AQUEOUS COMPOSITIONS SUCH AS LATICES, OIL IN WATER EMULSIONS, (TEXTILE SPIN-FINISH SOLUTIONS, CUTTING OILS), EMULSION PAINTS, WATERBASE ADHESIVES, PAPER COATING COMPOSITIONS (CASEIN/ROSIN DISPERSIONS) AND PESTICIDE FORMULATIONS.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CORROSIVE. CAUSES SEVERE EYE AND SKIN DAMAGE. MAY CAUSE ALLERGIC SKIN REACTIONS. DO NOT GET IN EYES, ON SKIN OR ON CLOTHING. WEAR GOGGLES OR FACESHIELD AND RUBBER GLOVES WHEN HANDLING. HARMFUL OR FATAL IF SWALLOWED. AVOID CONTAMINATION OF FOOD. WASH THOROUGHLY WITH SOAP AND WATER AFTER HANDLING. REMOVE CONTAMINATED CLOTHING AND WASH BEFORE REUSE.

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 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.

MANUFACTURED FOR:

ACTIVE INGREDIENT:

1,2-BENZISOTHAZOLIN-3-ONE.....9%

INERT INGREDIENTS.....91%

KEEP OUT OF REACH OF CHILDREN.

DANGER

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 EYE. CALL A POISON CONTROL CENTER OR DOCTOR FOR TREATMENT ADVICE.

IF ON SKIN OR CLOTHING:

TAKE OFF CONTAMINATED CLOTHING. RINSE SKIN IMMEDIATELY WITH PLENTY OF WATER FOR 15-20 MINUTES. 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 DO SO BY A POISON CONTROL CENTER OR DOCTOR. DO NOT GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON.

MEDICAL EMERGENCY INFORMATION CENTER

1-800-286-7850

HAVE THE PRODUCT CONTAINER OR LABEL WITH YOU WHEN CALLING A POISON CONTROL CENTER OR DOCTOR, OR GOING FOR TREATMENT.

NOTE TO PHYSICIAN

PROBABLE MUCOSAL DAMAGE MAY CONTRAINDICATE THE USE OF GASTRIC LAVAGE.

SEE ADDITIONAL PRECAUTIONARY
STATEMENTS ON SIDE PANEL

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 64-0000-028 FOR DIRECTIONS FOR USE.

STORAGE AND DISPOSAL PROHIBITIONS:

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

PESTICIDE 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 PUNCTURE AND DISPOSE OF IN A SANITARY LANDFILL, OR BY OTHER PROCEDURES APPROVED BY STATE AND LOCAL AUTHORITIES.

FOR INFORMATION ON SPILLS,

CALL 1-800-424-2465

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

Avecia

Medical Emergency Information Center - 800-286-7850
Chemical Emergency Response Center - 800-424-2465

P.O. Box 10037
Wilmington,
Delaware 19836-0037
USA
800-425-5679

EPA REG. NO. 72674-12
EPA EST. NO. 67003-NC-01

LOT NUMBER:

PRODUCT CODE:
84183

PROXEL is a registered trademark of Avecia Inc.

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(right side)

CORROSIVE LIQUID, NOS
(CONTAINS SODIUM HYDROXIDE/1,2-BENZISOTHIAZOLIN-3-ONE)
UN 1760

DIRECTIONS FOR USE FROM THE PROXEL DL T.I.
BULLETIN

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

PROXEL DL 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 DL (BASED ON TOTAL WEIGHT OF PRODUCT)
LATICES:	0.1-0.3
POLYMER LATICES BASED ON ACRYLATE, BUTADIENE, PVA AND STYRENE FOR VARIOUS APPLICATIONS, E.G., WAS, FLOOR POLISHES, SYNTHETIC/RUBBER LATICES.	

OIL-IN-WATER EMULSIONS:	0.1-0.35
"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 CONCENTRATIONS OF PROXEL DL SHOULD BE LIMITED TO 3.0% MAXIMUM. THIS WILL GIVE A MAXIMUM RECOMMENDED USE LEVEL OF 0.30% PROXEL DL IN A 10:1 DILUTION OF THE CONCENTRATE AND REDUCE THE POSSIBILITY OF SKIN SENSITIZATION.

EMULSION PAINT:	0.1-0.3
FOR PRESERVATION IN THE CAN	

ADHESIVES:
CARBOXYMETHYLCELLULOSE (CMC)
AND DERIVATIVES, ANIMAL GLUES,
ADHESIVES BASED ON GELATIN
AND LATEX

PRODUCT	% PROXEL DL (BASED ON TOTAL WEIGHT OF PRODUCT)
PAPER COATING COMPOSITIONS: (FOR USE ONLY AS COMPONENTS OF PAPER AND PAPERBOARD) ROSIN DISPERSIONS. STARCH AND CASEIN BASED PRODUCTS.	0.1-0.3
PESTICIDE FORMULATIONS: FOR PRODUCT PRESERVATION FOR USE - DILUTION	0.1-0.5

BASED ON THE CURRENT LIMIT OF 0.1% 1,2-BENZISOTHIAZOLIN-3-ONE IN PESTICIDE FORMULATIONS, USE LEVELS UP TO 1.0% (10,000 PPM) PROXEL DL ARE ALLOWED.

GENERAL RECOMMENDATIONS

THE CONCENTRATIONS OF PROXEL DL REQUIRED TO CONTROL MICROORGANISMS DEPENDS ON SEVERAL FACTORS. THESE INCLUDE THE SUSCEPTIBILITY OF THE SYSTEM TO MICROBIAL DEGRADATION, THE EXTENT TO WHICH MICROORGANISMS CAN GAIN ACCESS, THE SPECIES INVOLVED, pH, TEMPERATURE, AND LENGTH OF TIME FOR WHICH CONTROL IS REQUIRED.

FOR PROTECTION AGAINST BACTERIAL ATTACK, A CONCENTRATION WITHIN THE RANGE 0.04-0.7% PROXEL DL IS ALMOST INVARIABLY SUFFICIENT.

THE CONTROL OF MOLD GROWTH, PARTICULARLY ON PASTE PRODUCTS OF HIGH SOLIDS CONTENT, MAY OCCASIONALLY DEMAND DOSAGES ABOVE 0.50%.

IN DILUTE FLUID SYSTEMS, SPOILAGE IS USUALLY CONTROLLED WITH DOSAGES NOT GREATER THAN 0.15%.

DATE: 01/17/03