

464-659

11/16/2004

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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NOV 16 2004

The Dow Chemical Company
1500 E. Lake Cook Road
Buffalo Grove, IL 60089

Attention: Abigail Trueblood
Regulatory Specialist

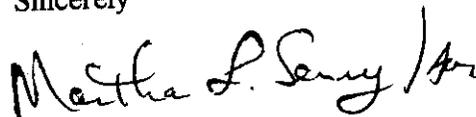
Subject: BIOBAN P-1487 Antimicrobial Agent
EPA Registration No. 464-659
Notification Dated October 19, 2004

This will acknowledge receipt of your notification to include the additional packaging sizes (32, 64, 96 oz and 1 gallon) and modification to the Directions for Use, 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 added to 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							



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The Dow Chemical Company
1500 E. Lake Cook Road
Buffalo Grove, IL 60089

October 19, 2004

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1801 Bell Street
Arlington, VA 22202

ATTN: Marshall Swindell/PM33

Re: Notification of Packaging Sizes and Modification of Directions for Use
BIOBAN P-1487™ Antimicrobial Agent (EPA Reg. No. 464-659)

Dear Mr. Swindell:

The Dow Chemical Company wishes to notify USEPA of the following changes to the registration of BIOBAN P-1487 Antimicrobial Agent:

- additional packaging sizes (32, 64, 96 oz and 1 gal)
- addition of a chart within the Directions for Use in Hydrocarbon Preservation to be used with the smaller packaging sizes

Enclosed are the following:

- EPA Form 8570-1 *Application for Registration* (with attached sheet)
- One copy of the proposed label

If you have any questions concerning this submission, please contact me at (847)808-3555.

Thank you for your assistance.

Sincerely,

Abigail Trueblood
Regulatory Specialist
attrueblood@dow.com



	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 464-659	2. EPA Product Manager M. Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BIOBAN P-1487^{PM} Antimicrobial Agent	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) The Dow Chemical Company 1803 Building Midland, MI 48674 <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"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.
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Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of additional packaging sizes (32, 64, 96 oz and 1 gallon) and inclusion of table in Directions for Use for small package sizes. Please see attached sheet for additional statement.

Section - III

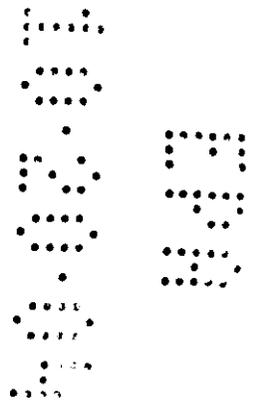
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" 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 checked="" type="checkbox"/> Container		4. Size(s) Retail Container 55, 5 and 1 gal; 96, 64 & 32 oz	
5. Location of Label Directions <input checked="" type="checkbox"/> On label		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 Abigail Trueblood	Title Regulatory Specialist	Telephone No. (Include Area Code) 847-808-3555
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 Specialist	
4. Typed Name Abigail Trueblood	5. Date 10-19-04	

Explanation Cont.

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 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.



BIOBAN P-1487TM

ANTIMICROBIAL AGENT

Active Ingredient:

4-(2-Nitrobutyl)morpholine . . . 81% by wt
 4,4'-(2-Ethyl-2-nitrotrimethylene)
 dimorpholine 5% by wt
 Inert Ingredients: 14% by wt
 Total 100%

E.P.A. Registration No. 464-659

E.P.A. Est. 48301-LA-1

KEEP OUT OF REACH OF CHILDREN

DANGER

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

**CAUSES SEVERE EYE DAMAGE
 AND SKIN BURNS · MAY CAUSE
 ALLERGIC SKIN REACTION ·
 HARMFUL OR FATAL IF
 SWALLOWED OR ABSORBED
 THROUGH THE SKIN**

Do Not Get In Eyes, On Skin, On Clothing ·
 Causes Skin Sensitization · Wear Goggles Or
 Face Shield and Rubber Gloves When
 Handling · Wash Thoroughly After Handling ·
 Avoid Breathing Vapor Or Mist · Avoid
 Contamination Of Food · Do Not Take
 Internally



THE DOW CHEMICAL COMPANY

Midland, Michigan 48674 U.S.A.

(989)636-4400

* Trademark of THE DOW CHEMICAL COMPANY

77117-3/31/2003-1749 Active

FIRST AID:	
IF IN EYES:	<ul style="list-style-type: none"> Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eyes. Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	<ul style="list-style-type: none"> 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:	<ul style="list-style-type: none"> 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:	<ul style="list-style-type: none"> Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferable mouth to mouth, if possible. Call a poison control center or doctor for further treatment.
HOT LINE NUMBER	
IN CASE OF AN EMERGENCY endangering life or property involving this product, call collect (989)636-4400. 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.	

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and wildlife. 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.

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.

DIRECTIONS FOR USE

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

FOR USE IN METALWORKING FLUIDS DIE CAST LUBRICANTS, AND MOLD-RELEASE AGENTS

To control the growth of microorganisms in fluids used as lubricants in metalworking operations, metal die cast applications, and mold release agents utilized in the manufacture of plastics.

In concentrates. BIOBAN P-1487 is soluble in organic solvents and may be incorporated by the manufacturer in the fluid concentrate. It normally will be stable in such concentrates as long as the pH is maintained above 6. However, long-term stability tests should be carried out by the manufacturer on his specific formulations to ensure that the concentrate does not contain ingredients incompatible with BIOBAN P-1487 stability. The amount to be incorporated will depend on the dilution factor recommended to be used when the concentrate is diluted for use. For efficient bacteriostatic activity, a concentration of 1000 ppm in the diluted fluid is suggested.

In diluted fluid. An initial concentration of 1000 ppm of BIOBAN P-1487 is normally sufficient to control gross microbial contamination of freshly diluted fluids for a period of several weeks at ambient temperatures. The degree of control is influenced by the composition of the fluid, the pH, the conditions of use, and other factors. Under conditions of severe microbial contamination, a concentration of BIOBAN P-1487 as high as 3000 ppm may be required temporarily.

Maintenance dosage. Periodic addition of BIOBAN P-1487 to the fluid will extend its activity in controlling gross microbial contamination after the initial charge. Additions of 100 ppm to 200 ppm of BIOBAN P-1487 at weekly intervals usually are recommended.

Note. Transitory eye irritation can occur from exposure to vapors produced during the use of fluids containing BIOBAN P-1487. Should eye irritation occur, further exposure should be prevented by vacating the area or by using protective goggles.

FOR USE IN HYDROCARBON PRESERVATION

To control the growth of problem microorganisms associated with the fuel.

In general use. Add BIOBAN-P-1487 to storage tanks or for control of microbial growth in diesel oil, fuel oil, gasoline, kerosene. Treatment may be performed by slug dosage or by intermittent metering to attain a concentration of 135-1000 BIOBAN P-1487.

For packages less than 1 gallon, refer to the chart below

TREATMENT RATIOS (IN OUNCES)

BIOBAN P-1487 Dose	Shock Treatment	PPM in Fuel	Maintenance Treatment
1 Ounce	20 Gallons	390	55 Gallons
16 ounces	320 Gallons	390	880 Gallons
96 Ounces	2000 Gallons	375	5280 Gallons

For storage above water. Add 1 gallon of BIOBAN P-1487 to 1000 gallons of water in the bulk storage system to achieve a concentration of approximately 1000ppm. To facilitate mixing, dissolve each gallon of BIOBAN P-1487 in 100 gallons of water and add this solution directly to the water phase in the tank with agitation.

For storage in tanks without intentional water. Add 0.125 of BIOBAN P-1487 directly to each 1000 gallons of hydrocarbon to obtain a concentration of approximately 135-1000 ppm.

In a fuel-treatment pre-mix. BIOBAN P-1487 may be mixed with other fuel additive for addition to fuel. The end user must add sufficient BIOBAN P-1487 to the pre-mix to provide 135-1000 ppm of BIOBAN P-1487 in the treated fuel.

FOR USE IN ADHESIVE AND INDUSTRIAL EMULSIONS (NON-FOOD USE)

For control of microbial contamination in resin, latex or other based emulsions, asphalt emulsions or to inhibit the growth of microorganisms in adhesives, add 0.025-0.1% (250-1000 ppm) BIOBAN P-1487. The addition of BIOBAN P-1487 should be as a final step in the manufacturing process, after any heating when the product has cooled to below 100° F.

FOR USE IN INKS (NON-FOOD USE)

To inhibit the growth of microorganisms during storage use of water-based inks.

In can preservation. Add BIOBAN P-1487 in the final step manufacturing process, after any heating and when the product cooled to below 110° F. BIOBAN P-1487 should be dosed 1000 ppm based on the final formulation volume. BIOBAN P-1487 may be added press side at a concentration of 250-1000 ppm.

FOR USE IN PAINT SPRAY BOOTH WASH WATER

BIOBAN P-1487 is used to control the growth of microorganisms in paint spray booth wash waters. Add tankside and circulate the system to mix thoroughly. Concentrations of 250-1000 ppm BIOBAN P-1487 should be attained. One gallon of BIOBAN P-1487 to each 1000 gallons of wash water will achieve a concentration of approximately 1000 ppm.

DISINFECTANT LIQUID,
 TOXIC, N.O.S.
 (4-(2-NITROBUTYL) MORPHOLINE)
 UN3142
 Apply Toxic PG III 6 label.