United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7510P)

EPA739-R-07-005
September 2007

Reregistration Eligibility Decision for Bioban P-1487

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary risk assessments for the antimicrobial Bioban P-1487. The Reregistration Eligibility Decision (RED) for Bioban P-1487 was approved on September 24, 2007. Public comments and additional data received were considered in this decision.

Based on its review, EPA is now publishing its Reregistration Eligibility Decision (RED) and risk management decision for Bioban P-1487 and its associated human health and environmental risks. A Notice of Availability will be published in the *Federal Register* announcing the publication of the RED.

The RED and supporting risk assessments for Bioban P-1487 are available to the public in EPA's Pesticide Docket EPA-HQ-OPP-2007-0402 at: www.regulations.gov.

The Bioban P-1487 RED was developed through EPA's public participation process, published in the Federal Register on September 10, 2004, which provides opportunities for public involvement in the Agency's pesticide tolerance reassessment and reregistration programs. The public participation process encourages robust public involvement starting early and continuing throughout the pesticide risk assessment and risk mitigation decision making process. The public participation process encompasses full, modified, and streamlined versions that enable the Agency to tailor the level of review to the level of refinement of the risk assessments, as well as to the amount of use, risk, public concern, and complexity associated with each pesticide. Using the public participation process, EPA is attaining its strong commitment to both involve the public and meet statutory deadlines.

Please note that the Bioban P-1487 risk assessment and the attached RED document concern only this particular pesticide. This RED presents the Agency's conclusions on the dietary, occupational, and ecological risks posed by exposure to Bioban P-1487 alone. This document also contains both generic and product-specific data that the Agency intends to require in Data Call-Ins (DCIs). Note that DCIs, with all pertinent instructions, will be sent to registrants at a later date. Additionally, for product-specific DCIs, the first set of required responses will be due 90 days from the receipt of the DCI letter. The second set of required responses will be due eight months from the receipt of the DCI letter.

As part of the RED, the Agency has determined that Bioban P-1487 will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including submission of confirmatory data and labeling changes outlined in Section IV of the document. Sections IV and V of this RED document describe the labeling amendments for end-use products and data requirements necessary for continued registration of Bioban P-1487-containing products. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that accompanies this document.

Should a registrant fail to implement any of the requirements outlined in this document, the Agency will have concerns about the risks posed by Bioban P-1487. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency's action.

If you have questions on this document or the label changes relevant to this reregistration decision, please contact the Chemical Review Manager, Michelle Centra, at (703) 308-2476. For questions about product reregistration and/or the Product DCI that will follow this document, please contact Marshall Swindell at (703)-308-6341.

Sincerely,

Betty Shackleford for

Frank T. Sanders
Director, Antimicrobials Division

REREGISTRATION ELIGIBILITY
DECISION
for
Bioban P-1487

List D

CASE 3028

Approved By:

Frank T. Sanders
Director, Antimicrobials Division
September, 24 2007

Attachment

Table of Contents

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GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
APHIS	Animal and Plant Health Inspection Service
ARTF	Agricultural Re-entry Task Force
BCF	Bioconcentration Factor
CDC	Centers for Disease Control
CDPR	California Department of Pesticide Regulation
CFR	Code of Federal Regulations
ChEI	Cholinesterase Inhibition
CMBS	Carbamate Market Basket Survey
cPAD	Chronic Population Adjusted Dose
CSFII	USDA Continuing Surveys for Food Intake by Individuals
CWS	Community Water System
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DL	Double layer clothing {i.e., coveralls over SL}
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
EXAMS	Tier II Surface Water Computer Model
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FR	Federal Register
GL	With gloves
GPS	Global Positioning System
HIARC	Hazard Identification Assessment Review Committee
IDFS	Incident Data System
IGR	Insect Growth Regulator
IPM	Integrated Pest Management
RED	Reregistration Eligibility Decision
LADD	Lifetime Average Daily Dose
LC_{50}	Median Lethal Concentration. Statistically derived concentration of a substance expected to cause death in 50% of test animals, usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LCO	Lawn Care Operator
LD_{50}	Median Lethal Dose. Statistically derived single dose causing death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation), expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOEC	Lowest Observed Effect Concentration
mg/kg/day	Milligram Per Kilogram Per Day
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MRL	Maximum Residue Level

N/A	Not Applicable
NASS	National Agricultural Statistical Service
NAWQA	USGS National Water Quality Assessment
NG	No Gloves
NMFS	National Marine Fisheries Service
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NPIC	National Pesticide Information Center
NR	No respirator
OP	Organophosphorus
OPP	EPA Office of Pesticide Programs
ORETF	Outdoor Residential Exposure Task Force
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDCI	Product Specific Data Call-In
PDP	USDA Pesticide Data Program
PF10	Protection factor 10 respirator
PF5	Protection factor 5 respirator
PHED	Pesticide Handler's Exposure Data
PHI	Pre-harvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
PRZM	Pesticide Root Zone Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RPA	Reasonable and Prudent Alternatives
RPM	Reasonable and Prudent Measures
RQ	Risk Quotient
RTU	(Ready-to-use)
RUP	Restricted Use Pesticide
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SL	Single layer clothing
SLN	Special Local Need (Registrations Under Section 24C of FIFRA)
STORET	Storage and Retrieval
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TRAC	Tolerance Reassessment Advisory Committee
TTRS	Transferable Turf Residues
UF	Uncertainty Factor
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
WPS	Worker Protection Standard

ABSTRACT

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for Bioban P-1487 and is issuing its risk management decision. The risk assessments are based on review of the target database supporting the use patterns of currently registered products and additional information received through the public docket. After considering the revised risk assessments, comments received, and suggestions from interested parties, the Agency developed its risk management decision for uses of Bioban P-1487. As a result of this review, EPA has determined that Bioban P-1487-containing products are eligible for reregistration, provided that confirmatory data are submitted to the Agency and labels are amended accordingly. That decision is discussed fully in this document.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984 and amended again by the Pesticide Registration Improvement Act of 2003 to set time frames for the issuance of Reregistration Eligibility Decisions. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (EPA or the Agency). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

This document presents the EPA decision regarding the reregistration eligibility of the registered uses of Bioban P-1487. There are two active ingredients in the Bioban P-1487: 4-(2-nitrobutyl) morpholine (PC Code 100801); and 4,4'-(2-ethyl-2-nitromethylene) dimorpholine or 4,4'-(2-ethyl-2-nitro-1,3-propanediyl) bis (PC Code 100802).

Bioban P-1487, a mixture of the two active ingredients 4-(2-nitrobutyl) morpholine and 4,4'-(2-ethyl-2-nitromethylene) dimorpholine, is registered for indoor use as a materials preservative and as a microbial growth inhibitor of slime-forming fungi and bacteria. For inhibition of microorganism growth, Bioban P-1487 is applied to various sites, including industrial processes and water systems such as metalworking fluids; oil storage tank bottom water, fuel storage tank bottom water; and to diesel oil, fuel oil, gasoline, and kerosene, as a hydrocarbon preservative. As a materials preservative, Bioban P-1487 is formulated into products such as metal die cast lubricants, corrosion inhibiting metal coatings, mold-release agents (for the manufacture of plastics), and fuel conditioners (for diesel engines). It is not registered for any direct or indirect food uses. Therefore, tolerances have not been established for Bioban P-1487.

The Agency has determined that analysis of the potential need for a special hazard-based safety factor under the FQPA is not needed at this time. The Agency does not anticipate dietary, drinking water or residential exposures based on the registered use patterns. Therefore, an FQPA hazard analysis is not necessary at this time.

The risks summarized in this document reflect only the registered uses of the active ingredient, Bioban P-1487. The Food Quality Protection Act (FQPA) requires that the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect that would occur at a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for Bioban P-1487 and any other substances**.** Bioban P-1487 does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action,

therefore, EPA has not assumed that Bioban P-1487 has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of Bioban P-1487. In an effort to simplify the RED, the information presented herein is summarized from more detailed information which can be found in the technical supporting documents for Bioban P-1487 referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available in the Public Docket at http://www.regulations.gov (Docket ID #EPA-HQ-OPP-2007-0402).

This document consists of six sections. Section I is the introduction. Section II provides a chemical overview, a profile of the use and usage of Bioban P-1487 and its regulatory history. Section III, Summary of Bioban P-1487 Risk Assessments, gives an overview of the human health and environmental assessments, based on the data available to the Agency. Section IV, Risk Management, Reregistration, and Tolerance Reassessment Decision, presents the reregistration eligibility and risk management decisions. Section V, What Registrants Need to Do, summarizes the necessary label changes based on the risk mitigation measures outlined in Section IV. Finally, the Appendices list all use patterns eligible for reregistration, bibliographic information, related documents and how to access them, and Data Call-In (DCI) information.

II. Chemical Overview

A. Regulatory History

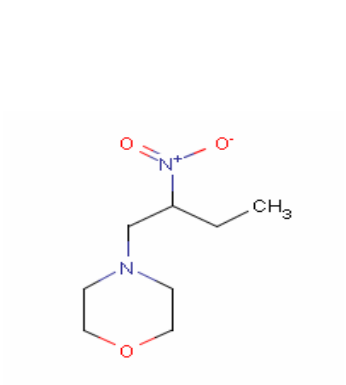
The first product containing Bioban P-1487 was registered on June 7, 1972. Currently, Bioban P-1487 consists of a mixture of two active ingredients: compound I: 4-(2-nitrobutyl) morpholine and compound II: 4,4'-(2-ethyl-2-nitromethylene) dimorpholine. This reregistration case therefore, consists of two active EPA PC codes: 100801 assigned to compound I and 100802 assigned to compound II. There are currently four antimicrobial products containing the Bioban P-1487 mixture of both active ingredients that are registered under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

B. Chemical Identification

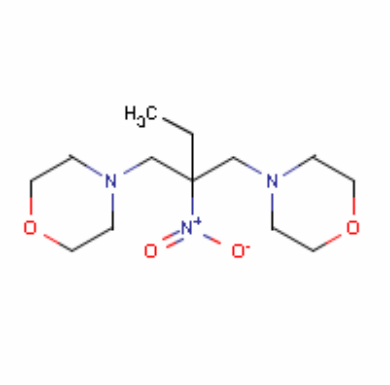
1. Chemical Identity of Bioban P-1487:

Chemical Name:	Compound I: 4-(2-nitrobutyl) morpholine (PC Code 100801) Compound II: 4,4'-(2-ethyl-2-nitromethylene) dimorpholine or 4,4'-(2-ethyl-2-nitro-1,3-propanediyl) bis (PC Code 100802)
Chemical Family:	Morpholines
Common/Trade Name:	Bioban P-1487 (Compound I + Compound II) Compound I: morpholine Compound II: dimorpholine
CAS Number:	Compound I: 2224-44-4 Compound II: 1854-23-5
Molecular Formula:	Compound I: $C_8H_{16}N_2O_3$ Compound II: $C_{13}H_{25}N3_2O_4$

Chemical Structures:



Compound I



Compound II

Table 1. Chemical Characteristics for Technical Grade Active Ingredient Bioban P-1487 (Compound I + Compound II)

Physical/Chemical Properties	
Molecular Weight	475.59
Color	Yellow to Brown (5 Gardner)
Physical State	Liquid
Odor	Mild fish-like odor characteristic of amines
Melting Point	-16.5 to 28.0 ^{o}C
Boiling Point	99 to 215 ^{o}C at 760 mmHg
Specific Gravity	1.075 to 1.077 at 25 ^{o}C
Solubility	11,000 mg/L at 20 ^{o}C 45% in Tripropylene glycol methyl ether 50% in Hexylene glycol 50% in Dipropylene glycol methyl ether 50% in Toluene
Vapor Pressure	20 to 43 mm Hg at 90 ^{o}C
pH	9.5 to 10.0
Stability	Indefinitely stable when stored at room temperature in original container
Oxidation/Reduction	N/A: Product does not contain any oxidizing or reducing agents
Octanol-Water Partition Coefficient (Log K_{OW})	0.18 to -0.54
Flammability	Flash Point: > 160 ^{o}F (~55 ^{o}C)
Explodability	N/A: Product not explosive

N/A = Not applicable

C. Use Profile

Information on the currently registered uses of Bioban P-1487-containing products and an overview of use sites and application methods follows. The detailed table of uses for Bioban P-1487 products eligible for reregistration is contained in Appendix A.

Type of Pesticide: Bacteriocide, Fungicide

Summary of Use:

Antimicrobial products containing Bioban P-1487 as an active ingredient are intended for use in industrial processes and water systems (Use Site VIII), and as a materials preservative for a variety of products (Use Site Category VII). Examples of these uses are listed below. For a detailed use description please refer to Appendix A.

Materials Preservatives:
Bioban P-1487 is used in metal die cast lubricants, corrosion inhibiting metal coatings, mold-release agents (for the manufacture of plastics), and fuel conditioners (for diesel engines).

Industrial Processes and Water Systems:
Bioban P-1487 is used in industrial processes and water systems such as metalworking fluids; oil storage tank bottom water, fuel storage tank bottom water; and diesel oil, fuel oil, gasoline, and kerosene, as a hydrocarbon preservative.

Target Pests: Deterioration/spoilage bacteria, slime-forming bacteria, slime-forming fungi

Formulation Types of Bioban P-1487: Soluble concentrates, ready-to-use solutions

Method and Rates of Application:

The methods and rates of application for Bioban P-1487-containing products vary greatly depending on use site. Please refer to Appendix A for more detailed application rates for each use site and methods of application.

Use Classification: General Use

Basic Manufacturers: The Dow Chemical Company

III. Summary of Bioban P-1487 Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to formulate the safety finding and regulatory decision for Bioban P-1487. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket EPA-HQ-OPP-2007-0402, and may also be accessed from www.regulations.gov. Hard copies of these documents may be found in the OPP public docket. The OPP public docket is located in Room S-4900, One Potomac Yard, 2777 South Crystal Drive, Arlington, VA 22202, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

The Agency's use of human studies in the Bioban P-1487 risk assessment is in accordance with the Agency's Final Rule promulgated on January 26, 2006, related to Protections for Subjects in Human Research, which is codified in 40 CFR Part 26.

A. Human Health Risk Assessment

1. Toxicity of Bioban P-1487

A brief overview of the toxicity studies used for determining endpoints in the risk assessment is outlined below in Table 2. Further details on the toxicity of Bioban P-1487 can be found in the "BIOBAN P-1487: Toxicology Disciplinary Chapter for the Issuance of the Reregistration Eligibility Decision (RED) Document," dated September 20, 2007; "BIOBAN P-1487: Revised Report of the Antimicrobials Division's Toxicology Endpoint Selection Committee (ADTC)," dated June 27, 2007; and "BIOBAN P-1487: Antimicrobials Division's Risk Assessment for Issuance of the Reregistration Eligibility Decision (RED) Document," dated September 20, 2007. These documents are available in the EPA Docket at: http://www.regulations.gov (Docket ID #EPA-HQ-OPP-2007-0402).

The Agency has reviewed all toxicity studies submitted to support guideline requirements for Bioban P-1487. Although the toxicological database is limited, it was determined that these data are sufficient to support a registration eligibility decision provided the registrant submits confirmatory toxicity data to support continued registration of Bioban P-1487-containing products.

The acute toxicity profile for Bioban P-1487 is presented below in Table 2. Bioban P-1487 was found to be moderately toxic (Toxicity Category III) by the oral route and severely toxic by the dermal route (Toxicity Category II). The Agency has no adequate inhalation toxicity data for Bioban P-1487. A study utilizing a one-hour exposure was submitted showing significant clinical toxicity (blood in the urine, porphyrin discharge, corneal opacity, and conjunctivitis) in the rat; however, this study was classified as unacceptable for regulatory purposes. Bioban P-1487 was shown to be a severe skin and eye irritant (Toxicity Category II and Toxicity Category I, respectively), as well as a dermal sensitizer.

Table 2. Summary of Acute Toxicity Data for Bioban P-1487

Guideline No.	Study Type	MRID #(s)	Results	Toxicity Category
870.1100	Acute oral toxicity	43558901	LD_{50} = 620 mg/kg (M+F); 81% ai	III
870.1200	Acute dermal toxicity	41677602	LD_{50} = 420 mg/kg (M+F); 92 % ai	II
870.1300	Acute inhalation toxicity (Purity not reported)	00094944	_____	Unacceptable study
870.2400	Acute eye irritation	41677603	Corrosive; 92 % ai	I
870.2500	Acute dermal irritation	41677604 (duplicate 41810802)	Severe irritant; 92 % ai	II
870.2600	Skin sensitization	MRID 42349201 Acc No. 259676	Sensitizer; 90 % ai	N/A

Notes: LC = Lethal Concentration; LD = Lethal Dose; NA = Not Applicable

General Toxicity Observations

Dermal reactions (erythema and edema) to Bioban P-1487 were evident at all dose levels tested in a 90-day subchronic dermal toxicity study conducted in rats. The hematocrit was slightly reduced in males as was the white blood cell count in females. Creatinine was reduced in males at all dose levels. Body weight was reduced in both sexes, in the absence of any changes in food consumption. At the high-dose level, acanthosis was observed at the site of skin application, and histological examination showed chronic inflammation of the urinary bladder in both males and females.

A developmental toxicity study in rabbits is not available. Other toxicity studies indicate that rabbits appear to be more sensitive to Bioban P-1487 than rats. In the rat developmental toxicity study submitted to the Agency, excessive salivation was observed at the mid- and high-dose levels of Bioban P-1487. Reduced body weight gain (36% and 12% reduction from control, respectively) was observed in maternal animals in the high-and mid-dose groups for the 0-20 day time period. There were no significant adverse effects on fetal body weight, crown-rump length, or external, visceral, or skeletal malformations at any dose tested. At the high-dose level there was a slight reduction in live fetuses per dam, and total implants per dam; however, the incidences of these effects were not significantly different from control. No data are available to assess the chronic toxicity of Bioban P-1487.

From the available repeat-dose toxicity study, there was no evidence of neurotoxicity in rats following dermal exposure to Bioban P-1487. Convulsions, catalepsy, and tremors were observed at a single oral dose of 800 mg/kg, but not at doses of 500 mg/kg or below in the acute oral toxicity studies. The Agency concluded that there is no concern for neurotoxicity resulting from exposure to Bioban P-1487 based on the appearance of these clinical signs only at an excessive dose that are not likely to be encountered from the registered uses of this chemical.

Carcinogenicity Classification

There were no data available to assess the carcinogenic potential of Bioban P-1487; therefore, a determination cannot be made at this time.

Mutagenicity Potential

Bioban P-1487 was found to be negative for mutagencity in the absence or presence of S9 activation in *Salmonella typhimurium* strains TA98, TA100, TA1535, and TA1537. There was no evidence of chromosome aberration induction in the absence or presence of S9 activation in a chromosome aberration test using Chinese Hamster Ovary cells. Bioban P-1487 did not promote unscheduled DNA synthesis in rat hepatocyte cultures, nor did it induce a significant increase in micronuclei in mouse bone marrow cells in an *in vivo* mammalian erythrocyte micronucleus test. Therefore, Bioban P-1487 is not mutagenic or genotoxic.

The doses and toxicological endpoints selected for the Bioban P-1487 exposure scenarios are summarized in Table 3 below:

Table 3. Summary of Toxicological Endpoints for Bioban P-1487

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Dermal Short-Term (1-30 days)	**LOAEL (dermal)** = 30 mg/kg/day	**MOE** = 30 (3x inter-species extrapolation, 3x intra-species variation, 3x for use of a LOAEL value)	90-Day (Dermal) Subchronic Toxicity Study in Rats (MRID 42440001, 41619302) **LOAEL** = 30 mg/kg/day based on skin irritation (erythema and edema) at all doses tested.
Dermal Intermediate-Term (1-6 months)	**NOAEL (systemic)** = 300 mg/kg/day	**MOE** = 100 (10x inter-species extrapolation, 10x intra-species variation)	90-Day (Dermal) Subchronic Toxicity Study in Rats (MRID 42440001, 41619302) **LOAEL** = 1000 mg/kg/day based on decreased body weight, chronic inflammation of the urinary bladder in males and females.

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Dermal Long-Term (> 6 months)	**NOAEL (systemic)** = 300 mg/kg/day	**MOE** = 300 (10x inter-species extrapolation, 10x intra-species variation, 3x for use of a subchronic endpoint for the long-term endpoint)	90-Day (Dermal) Subchronic Toxicity Study in Rats (MRID 42440001, 41619302) **LOAEL** = 1000 mg/kg/day based on decreased body weight, chronic inflammation of the urinary bladder in males and females.
Inhalation (All Durations)	**NOAEL(maternal)** = 10 mg/kg/day	**MOE** = 300 (10x inter-species extrapolation, 10x intra-species variation, 3x for severe adverse effects observed in the acute inhalation toxicity study, the lack of repeat inhalation exposure study, severe skin irritation and dermal sensitization. An additional 10X is used to determine the need for additional data due to the need to use of route extrapolation in the assessment.	Developmental Toxicity Study in Rats (MRID 416738801, 41978802) **LOAEL** = 30 mg/kg/day based on excessive salivation and decreased body weight
Carcinogenicity (oral, dermal, inhalation)	No carcinogenicity data available for Bioban P-1487.		

Notes: UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level.

Dietary and Incidental Oral

Dietary and incidental oral endpoints were not selected for Bioban P-1487 based on the current registered use patterns.

Short-, Intermediate- and Long-term Dermal

The short-term LOAEL of 30 mg/kg/day is based on skin irritation (erythema and edema) at all doses tested in the 90-day dermal subchronic toxicity study in rats. The target MOE is 30 (3X inter-species extrapolation, 3X intra-species variation, 3X for use of a LOAEL). The target MOE was chosen because the established endpoint is for dermal irritation, not a systemic toxic effect. In addition, dermal irritation is considered a reversible and short-term effect, thus supporting a 10x uncertainty factor (3x for interspecies extrapolation and 3x for intraspecies variation). The additional 3X uncertainty factor has been added since no NOAEL was established in the study chosen to set the endpoint.

The intermediate- and long-term dermal NOAEL of 300 mg/kg/day is based on decreased body weight and chronic inflammation of the urinary bladder observed in male and female rats in the 90-day dermal toxicity study. The target MOE for intermediate-term dermal exposures is 100 (10X inter-species extrapolation, 10X intra-species variation). The target MOE, for long-

term dermal exposure is 300 (10x for inter-species extrapolation, 10x for intra-species variation, 3x for use of a subchronic endpoint for the long-term endpoint).

Short- and Intermediate-term Inhalation

The short- and intermediate-term inhalation NOAEL is 10 based on excessive salivation and decreased body weight observed at the LOAEL of 30 mg/kg/day in the developmental toxicity study conducted in rats. In the absence of route-specific data, it was conservatively assumed that inhalation absorption is equivalent to oral absorption (100%). The target MOE for Bioban P-1487 is 300 for short-, intermediate-, and long-term durations (10x for inter-species extrapolation, 10x for intra-species variation, 30x (3X for lack of repeat inhalation exposure data, severe adverse effects observed in the acute inhalation toxicity study, severe skin irritation and dermal sensitization, and 10X use of route-to-route extrapolation). The additional 10x uncertainty factor applied for route-to-route extrapolation is used to determine the need for confirmatory inhalation toxicity data and not for risk management purposes.

Endocrine Disruption Potential

EPA is required under the Federal Food Drug and Cosmetic Act (FFDCA), as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disrupting Screening Program (EDSP) have been developed, Bioban P-1487 may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

2. FQPA Safety Factor

The FQPA Safety Factor (as required by the Food Quality Protection Act of 1996) is intended to provide an additional 10-fold safety factor (10x), to protect for special sensitivity in infants and children to specific pesticide residues in food, drinking water, or residential exposures, or to compensate for an incomplete database. The Agency does not anticipate dietary, drinking water or residential exposures based on the registered use patterns. Therefore, an FQPA hazard analysis is not necessary at this time.

3. Dietary Risk Assessment

When conducting the dietary exposure assessment, all applications of a pesticide are assessed for any dietary concerns from direct food contact or indirect migration of the pesticide into foods, fruits and vegetables.

None of the currently registered uses of Bioban P-1487 are considered food use and are not likely to result in any indirect food migration of these chemicals into food, fruits or vegetables in residential settings. Further, Bioban -1487 is not used for potable water treatment and effluents containing this chemical are not expected to contact fresh water environments. Therefore, a drinking water exposure assessment was not conducted. Therefore, the Agency did not conduct any dietary exposure assessment for Bioban P-1487 based on existing registered uses.

4. Residential Risk Assessment

No products containing Bioban P-1487 are labeled for residential use. Furthermore, occupational use of Bioban P-1487-containing products as a materials preservative in metalworking fluids and fuels is not expected to result in any appreciable exposures in a residential setting. As a result, no residential risk assessment has been conducted.

5. Aggregate Risk Assessment

The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require "that there is a reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information." Aggregate exposure typically includes exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure.

An aggregate risk assessment was not conducted for Bioban P-1487. There are no dietary or residential uses nor are there any post-application exposures that would occur in a residential setting.

6. Occupational Risk

a. Summary of Use Pattern and Formulations

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Bioban P-1487 is used as an antimicrobial pesticide (e.g., materials preservative, industrial processes and water systems, hydrocarbon preservation, and metal working fluids). Occupational risk assessed for exposure at the time of application is termed "handler" exposure. Post-application occupational exposures occur when workers re-enter sites treated with a pesticide. Application parameters used in the risk assessment are generally defined by the physical nature of the formulation (e.g., formula and packaging), by the equipment required to deliver the chemical to the use site and by the application rate required to achieve an efficacious dose.

Exposure scenarios assessed for the occupational uses of Bioban P-1487 are shown in Table 4. These scenarios were selected to be representative of the majority of uses and provide high-end estimates of dermal, or inhalation exposure to Bioban P-1487. In addition, this table shows the maximum application rate associated with the representative use and the appropriate EPA Registration number for the product label.

Table 4. Representative Exposure Scenarios Associated with Occupational Exposures to Bioban P-1487

Representative Use	Method of Application	Exposure Scenario	EPA Registration Number	Application Rate
Material Preservatives				
Metalworking fluid	• Liquid pour • Liquid pump	ST and IT Handler (worker pouring preservative into fluid being treated): dermal and inhalation	464-659	0.26% a.i. by weight (3000 ppm × 86% a.i.)
	• Use of treated metalworking fluid	ST and IT/LT Machinist: dermal and inhalation		
Fuel	• Liquid pour • Liquid pump	ST and IT Handler: dermal and inhalation	464-678	0.088% a.i. by weight (1350 ppm × 64.6% a.i.)

[1]Unit exposure values for liquid pour and pump preservation materials were assumed to be representative of exposure related to the addition of Bioban to hydrocarbon fuels.

b. Occupational Handler Exposure

Occupational risks for all potentially exposed populations are measured by a Margin of Exposure (MOE), which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL) from toxicological studies. In the case of Bioban P-1487, the target MOE for intermediate-term dermal exposures is 100. The target MOE for short- and intermediate-term inhalation exposures is 300.

The Agency evaluated representative occupational handler scenarios using maximum application rates from product labels to determine dermal and inhalation exposures to Bioban P-1487. The majority of the scenarios were assessed using proprietary Chemical Manufacturers Association (CMA) data to estimate potential risks. However, for the metalworking fluid machinist scenario, the Agency applied the ChemSTEER model. The model is available at www.epa.gov/opptintr/exposure/docs/chemsteer.htm.

The "preservation of materials" refers to the scenario of a worker adding the preservative to the material being treated (metalworking fluid, fuel, etc.) through either liquid pour or liquid

pump methods. Liquid pour refers to a worker transferring the antimicrobial product from a small container to an open vat. Liquid pump refers to a worker transferring the preservative by connecting/disconnecting a chemical metering pump from a tote or by gravity flow.

Risks were assessed for the intermediate-term duration for dermal exposures and short- and intermediate-term durations for inhalation exposures for occupational handlers using the appropriate toxicological endpoints. Short-term dermal exposures were not assessed for occupational uses other than the machinist handling metal working fluids. The dermal irritation via short-term exposures for handlers other than the machinist will be mitigated through the use of personal protective equipment (PPE) as specified on the product labels.

For these exposure scenarios, the total MOEs that account for combined exposures via dermal and inhalation routes, were not calculated for occupational use scenarios because the toxicological endpoints for dermal and inhalation exposures differ.

For more information on the assumptions and calculations of potential exposure risks of Bioban P-1487 to workers, refer to the "Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document for Bioban P-1487," dated September 5, 2007 and the "BIOBAN P-1487: Antimicrobials Division's Risk Assessment for Issuance of the Reregistration Eligibility Decision (RED) Document," dated September 20, 2007.

c. Occupational Handler Risk Summary

The Agency has assessed the potential dermal and inhalation risks to occupational handlers from exposure to Bioban P-1487, including materials preservatives and metalworking fluids in an industrial setting.

The calculated intermediate-term dermal and short- and intermediate-term inhalation MOEs are shown in Table 5. All of the dermal MOEs are above the target MOE of 100 and all of the inhalation MOEs are above the target MOE of 300. Therefore the intermediate-term dermal and short- and intermediate-term inhalation exposures are not of concern.

Table 5. Short- and Intermediate-Term Exposures and Risks for Occupational Handlers using Bioban P-1487

Exposure Scenario	Method of Application	Unit Exposure (mg/lb a.i.)		App. Rate	Quantity Handled/ Treated per day	Absorbed Daily Dose (mg/kg/day)[b]		MOE[c]	
		Dermal[a]	Inhalation			Dermal IT	Inhalation ST/IT	Dermal (Target MOE = 100) IT	Inhalation (Target MOE = 300) ST/IT
Preservation of Metalworking Fluids	Liquid pour	0.184	0.0085	0.26% a.i. by weight	2,502 lbs	0.017	0.00079	18,000	13,000
	Liquid pump	0.312	0.00348	0.26% a.i. by weight	2,502 lbs	0.029	0.00032	10,000	31,000
Preservation of Hydrocarbons	Liquid pour	0.135	0.00346	0.088% a.i. by weight	16,000 lbs	0.027	0.00069	11,000	14,000
	Liquid pump	0.00629	0.000403	0.088% a.i. by weight	160,000 lbs	0.013	0.0008	24,000	12,000

ST = short-term, IT = intermediate-term, N/A= No data available, NC = Not conducted

a All dermal unit exposure estimates used for occupational handler scenarios$_r$ epresent exposures incurred assuming the use of PPE (at least a$_l$ ong-sleeve shirt and long pants plus chemical-resistant gloves), as specified on the product labels.

b Absorbed Daily dose (mg/kg/day) = [unit exposure (mg/lb ai) * absorption (1.0 for both inhalation and dermal) * application rate * quantity treated / body weight (70 kg).

c MOE = NOAEL (mg/kg/day) / Absorbed Daily Dose [Where$_{inte}$ rmediate-term NOAEL = 300 mg/kg/day for dermal exposure and the short-term and immediate term NOAEL = 10 mg/kg/day for inhalation exposure.

d. Occupational Post-application Exposure

Occupational post-application exposures occur from handling or using treated end products. Screening-level assessments were conducted for intermediate-and long-term inhalation exposure for workers handling treated products. These risk estimates were developed using Occupational Safety and Health Administration's (OSHA) Permissible Exposure Limit (PEL) for oil mist. For more information on the assumptions and calculations of potential exposure risks of Bioban P-1487 to workers, refer to the "Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document for Bioban P-1487," dated September 5, 2007 and the "BIOBAN P-1487: Antimicrobials Division's Risk Assessment for Issuance of the Reregistration Eligibility Decision (RED) Document," dated September 20, 2007.

e. Occupational Post-application Risk Summary

Table 6 shows the dermal doses and resulting MOEs for a machinist working with metalworking fluids. The short-term dermal exposure is not of concern because the MOE of 65 is above the target MOE of 30. The intermediate- and long-term MOE value of 5,500 is above the respective target MOEs of 100 for intermediate-term, and 300 for long-term exposures. Therefore, the intermediate- and long-term dermal exposures are not of concern.

Table 6. Short- Intermediate-, and Long-term Dermal Exposures and Risks for Machinist Exposure to Metalworking Fluids

Exposure Scenario	Percent Active Ingredient	Exposure Duration	Hand Surface Area (cm^2)	Film thickness (mg/cm^2)	Frequency (event/day)	Exposure [a]	Dermal MOE (Target MOE is 30 for ST, 100 for IT, and 300 for LT) [b]
Machinist - two hand immersion	0.258%	ST	N/A	10.3	N/A	2.7E-02	65
		IT/LT	840	1.75	1	5.4E-02	5,500

a For ST, exposures are calculated as a.i. per area of skin exposed (mg/cm^2) = (% active ingredient × film thickness (10.3 mg/cm^2). For IT/LT, exposures are calculated as an Absorbed Daily Dose normalized to body weight (mg/kg/day) = [(% active ingredient × surface area of hands × film thickness (1.75 mg/cm^2) × Frequency (event/day)] / Body weight (70 kg).

b MOE = NOAEL (mg/kg/day) / exposure, where exposure is a.i. per skin area (mg/cm^2) for ST and Absorbed Daily Dose (mg/kg/day) for IT/LT. [Where: ST LOAEL = [(30mg/kg/day X 0.231 kg (rat average body weight M/F)/4 cm^2] =1.77 mg/cm^2, , where 4 cm2 is the rat surface area used to apply the chemical and IT/LT NOAEL = 300 mg/kg/day for dermal exposures].

Table 7 shows the short- and intermediate-term inhalation doses and resulting MOEs for a machinist working with end products treated with Bioban P-1487 metalworking fluids. The inhalation MOE for short-, intermediate-, and long-term exposures to Bioban is above the target MOE of 300; therefore post-application inhalation exposure from metalworking fluids is not a concern.

Table 7. Inhalation Post-Application Exposures and Risks

Exposure Scenario	Percent Active Ingredient	OSHA PEL (mg/m^3)	Inhalation rate (m^3/hr)	Exposure Duration (hrs/day)	ST/IT/LT Absorbed Daily Dose[a] (mg/kg/day)	ST/IT/LT Inhalation MOE (Target MOE is 300) [b]
Machinist	0.258%	5	1.25	8	1.8E-03	5,400

a Absorbed daily dose (mg/kg/day) = % active ingredient × OSHA PEL (mg/m^3) × Inhalation rate (m^3/hr) × exposure duration (hr/day) / body weight (70 kg).

b MOE = NOAEL (mg/kg/day) / absorbed daily dose (mg/kg/day) [Where: ST/IT/LT NOAEL = 10 mg/kg/day for inhalation exposures].

7. Human Incident Data

The Agency reviewed available sources of human incident data for incidents relevant to Bioban P-1487. EPA consulted the following sources of information for human poisoning incidents related to Bioban P-1487 use: (1) OPP Incident Data System (IDS) - The Office of Pesticide Programs (OPP) Incident Data System contains reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992; (2) California Department of Pesticide Regulation (1982-2004) – The California Department of Pesticide Regulation pesticide poisoning surveillance program consists of reports from physicians of illness suspected of being related to pesticide exposure since 1982; (3) National Pesticide Information Center (NPIC) - NPIC is a toll-free information service supported by OPP that provides a ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991; (4) National Poison Control Centers (PCC) (1993 – 1996); and (5) Published Scientific Literature on Incidents.

In the data available to the Agency, no reports of serious illness have been associated with human exposure to Bioban P-1487.

B. Environmental Risk Assessment

A summary of the Agency's environmental fate and risk assessment of Bioban P-1487 is presented below. The uses of Bioban P-1487 are considered indoor uses and were not assessed as the Agency does not anticipate environmental exposure. For a detailed discussion of all aspects of the environmental risk assessment, refer to the Environmental Risk Assessment in the "Bioban P-1487 Ecological Hazard and Environmental Risk Assessment Chapter," dated September 20, 2007; and the "Environmental Fate Assessment Bioban P-1487 for the Reregistration Eligibility Decision (RED) Document," dated September 20, 2007.

1. Environmental Fate and Transport

The Agency has reviewed the available environmental fate studies and reports submitted for Bioban P-1487 to conduct an environmental fate assessment. These data indicate that Bioban P-1487 has a high vapor pressure (16 mm Hg) at room temperature, is highly water soluble, and is not hydrolytically or photolytically stable under abiotic and buffered conditions. In water, the half life of Bioban P-1487 varies depending on pH: 5 (22 hours), 7 (44 hours), and 9 (46 hours). Although Bioban P-1487 does not readily biodegrade

in water or soil, it is not likely to contaminate surface or ground water, as it is hydrolytically unstable with half lives of less than two days. Determinations showed that Bioban P-1487 has a log Kow of 1.7 making it unlikely to bind with soils, and therefore mobile in soils.

a. Bioaccumulation in Terrestrial and Aquatic Organisms

Aquatic metabolism studies indicate that Bioban P-1487 is stable to microbial degradation and bioaccumulation in terrestrial or aquatic organisms is not likely to occur. Therefore, the bioaccumulation potential of Bioban P-1487 is not of concern to the Agency.

2. Ecological Risk

Generally, the Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations based on environmental fate characteristics and pesticide use data. However, the uses of Bioban P-1487 are considered "indoor" or limited use patterns by the Agency. A summary of the submitted data is provided below.

a. Ecological Toxicity

For the use patterns of Bioban P-1487, avian acute oral toxicity testing [(850.2100), preferably using the bobwhite quail], freshwater fish acute toxicity testing [(850.1075), preferably the rainbow trout], freshwater invertebrate acute toxicity testing (850.1010), and terrestrial and aquatic plant testing are generally needed for the technical grade active ingredient (TGAI) to establish toxicity and to support the registered uses of this chemical.

Based on the results of mammalian studies, Bioban P-1487 was shown to be moderately toxic (Toxicity Category III) by the oral route and severely toxic (Toxicity Category II) by the dermal route of exposure. It is severely irritating to the skin and eyes (Toxicity category II and I, respectively), as well as a dermal sensitizer. Bioban P-1487 is also considered to be highly toxic via the inhalation route of exposure (toxicity category I).

The results from the avian acute toxicity and dietary studies are summarized in Table 8. These data indicate that Bioban P-1487 is practically non-toxic to both mallard duck and bobwhite quail. All of the submitted avian studies were determined to be supplemental and do not meet guideline requirements. The acute oral LD_{50} is greater than 100 mg/kg; therefore, no hazard statement for birds is needed on the labels at this time.

Table 8. Avian Acute Oral and Subacute Dietary Toxicity for Bioban P-1487

Test and Organism	Results LC_{50} (mg/L) or LD_{50} (mg/kg)	Toxicity Category	Comments	Reference
Acute Oral Toxicity LD_{50} Mallard Duck (A*nas*	$LD_{50} > 1000$	Practically non-toxic	Supplemental study	Fink, R. and Beavers, J. 1990 MRID 93055001

Test and Organism	Results LC_{50} (mg/L) or LD_{50} (mg/kg)	Toxicity Category	Comments	Reference
platyrhynchos)				
Eight day dietary LC_{50} Bobwhite Quail (*Colinus virginianus*)	LC_{50} > 3692	Practically non-toxic	Supplemental study	Fink, R. and Beavers, J. 1990 MRID 93055002
Eight day dietary LC_{50} Mallard Duck (*Anas platyrhynchos*)	LC_{50} > 3692 NOEC = 2076	Practically non-toxic	Supplemental study	Fink, R. and Beavers, J. 1990 MRID 93055003

Freshwater fish toxicity studies using the technical grade active ingredient are used to establish potential toxicity to fish. Data are generally needed for only one species when chemical use sites occur in an indoor setting only or the use patterns are limited, as is the case for Bioban P-1487. The preferred test species are rainbow trout (a coldwater fish) or bluegill sunfish (a warm water fish). Two freshwater fish acute toxicity studies were submitted to the Agency. Results of these studies (Table 9) show that the toxicity ranges from 0.75 mg/L to 0.83 mg/L, indicating that Bioban P-1487 is highly toxic to both rainbow trout and bluegill sunfish, respectively. Since the observed toxicity is < 1.0 ppm, product labeling typically must state: "This pesticide is toxic to fish."

Table 9. Freshwater Fish Acute Toxicity for Bioban P-1487

Test and Organism	Results LC_{50} (mg/L)	Toxicity Category	Comments	Reference
Acute Toxicity LC_{50} Rainbow Trout (*Onchorynchus mykiss*)	LC_{50} = 0.75	Highly toxic	Core study	Griffen, J. and Thompson, C. 1990. MRID 93055005
Acute Toxicity LC_{50} Bluegill Sunfish (*Lepomis macrochirus*)	LC_{50} = 0.83	Highly toxic	Core study	Griffen, J. and Thompson, C. 1990. MRID 93055004

A freshwater aquatic invertebrate toxicity test (preferably using *Daphnia magna* or *Daphnia pulex*) conducted with the TGAI is needed to establish the toxicity of a pesticide to aquatic invertebrates. No studies testing the toxicity of Bioban P-1487 to aquatic invertebrates were submitted to the Agency.

Terrestrial and aquatic plant testing was conducted to support the registered uses of Bioban P-1487. As shown in Table 10, Bioban P-1487 was toxic to freshwater alga at microgram concentrations.

Table 10. Terrestrial and Aquatic Plant Toxicity for Bioban P-1487

Test and Organism	Results (mg/L)	Toxicity Category	Comments	Reference
96-hr. Toxicity Test Freshwater Alga (*Selenastrum capricornutum*)	EC_{50} (growth rate) = 0.844 EC_{50} (% inhibition) = 0.352 EC_{50} (cell density) = 0.356 NOEC = 0.049	None given	Core Study	Kirk, H.D. et al. 2002 MRID 47005504

b. Ecological Exposure and Risk

The Agency has evaluated the indoor uses of Bioban P-1487 being considered for reregistration. Avian, freshwater and estuarine/marine aquatic organisms and plants are not expected to be exposed to Bioban P-1487 because of the chemical's indoor use pattern. No modeling was conducted because Bioban P-1487 does not have any uses in once-through cooling tower, antifoulant, ballast water or wood treatment.

c. Risk to Listed Species

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and andronomus listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species." 50 C.F.R. 402.02.

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2) the Environmental Protection Agency, Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). After the Agency's screening-level risk assessment is performed, if any of the Agency's Listed Species LOC Criteria are exceeded for either direct or indirect effects, a determination is made to identify if any listed or candidate species may co-occur in the area of the proposed pesticide use. If determined that listed or candidate species may be present in the proposed use areas, further biological assessment is undertaken. The extent to which listed species may be at risk then determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

Bioban P-1487 is used indoors to control microbial growth in diesel oil, gasoline, kerosene storage tanks, fuel tanks, resin, latex or other water based emulsions and typically would fall into this category. For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a "no effect" determination. The materials preservative uses of Bioban P-1487 fall into this category.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing Bioban P-1487 as an active ingredient. The Agency has completed its review of these generic data and has determined that the data are sufficient to support reregistration of all supported products containing Bioban P-1487.

The Agency has completed its assessment of the occupational and ecological risks associated with the use of pesticide products containing the active ingredient Bioban P-1487. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient Bioban P-1487, the Agency has sufficient information on the human health and ecological effects of Bioban P-1487 to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that Bioban P-1487-containing products are eligible for reregistration provided that: (i) current data gaps and confirmatory data needs are addressed; and (ii) label amendments are made as described in Section V. Appendix A summarizes the uses of Bioban P-1487 that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of Bioban P-1487 and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of Bioban P-1487, the Agency has determined that Bioban P-1487 products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement the submission of confirmatory data as well as the label changes identified in this document, the Agency may take regulatory action to address this lack of information for Bioban P-1487. If all changes outlined in this document are fully complied with, then no risks of concern exist for the registered uses of Bioban P-1487 and the purposes of this determination.

B. Public Comments and Responses

Through the Agency's public participation process, the EPA worked with stakeholders and the public to reach the regulatory decision for Bioban P-1487. EPA released its preliminary risk assessment for Bioban P-1487 for public comment on July 6, 2007. The Agency received minimal comments during the 60-day public comment period on the Bioban P-1487 risk assessment and supporting science documents, which closed on September 4, 2007.

C. Regulatory Position

The Agency has determined that, if confirmatory data are submitted as described in this document and labels are amended to ensure that appropriate PPE is on all product labels, human health risks as a result of exposures to Bioban P-1487 are within acceptable levels. In other words, EPA has concluded that Bioban P-1487 meets FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as exposures to Bioban P-1487 from all possible sources.

a. Determination of Safety to U.S. Population

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with Bioban P-1487. The Agency has determined that Bioban P-1487, with amendments and changes specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of Bioban P-1487. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of Bioban P-1487.

b. Determination of Safety to Infants and Children

EPA has determined that the currently registered uses of Bioban P-1487, with changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers the toxicity, use practices, and environmental behavior noted above for the general population, but also takes into account the possibility of increased susceptibility to the toxic effects of Bioban P-1487 residues in this population subgroup.

There are no dietary or residential uses nor are there any post-application exposures that would occur in a residential setting. Therefore, an aggregate risk assessment was not conducted for Bioban P-1487. In addition, Bioban -1487 is not used for potable water treatment and effluents containing this chemical are not expected to contact fresh water environments. Therefore, a drinking water exposure assessment was not conducted.

c. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA

authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, Bioban P-1487 may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

d. Cumulative Risks

Risks summarized in this document are those that result only from the use of Bioban P-1487. The Food Quality Protection Act (FQPA) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for Bioban P-1487. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

D. Regulatory Rationale

The Agency has determined that Bioban is eligible for reregistration provided that additional data identified in this RED confirm this decision and label amendments are made to ensure that all labels contain appropriate PPE requirements. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document.

1. Human Health Risk Management

No human health risk mitigation measures are necessary for the antimicrobial use of Bioban P-1487 at this time. Additional data are required to confirm the decisions outlined in this document. The following toxicity study are needed for Bioban P-1487:

- Chronic Toxicity/Carcinogenicity Study in Rodents (OPPTS 870.4300).

2. Environmental Risk Management

No environmental risk mitigation measures are necessary for the antimicrobial use of Bioban P-1487 at this time. The Agency recognizes that the currently registered uses of Bioban P-1487 are limited to indoors.

3. Other Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing Bioban P-1487. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

4. Listed Species Considerations

a. The Endangered Species Act

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and andronomus listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species."50 C.F.R. 402.02.

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2) the Environmental Protection Agency, Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). After the Agency's screening-level risk assessment is performed, if any of the Agency's Listed Species LOC Criteria are exceeded for either direct or indirect effects, a determination is made to identify if any listed or candidate species may co-occur in the area of the proposed pesticide use. If determined that listed or candidate species may be present in the proposed use areas, further biological assessment is undertaken. The extent to which listed species may be at risk then determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment and are considered to fall under a "no effect" determination. The materials preservative uses of Bioban P-1487 fall into this category.

b. General Risk Mitigation

Bioban P-1487 end-use products (EPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing Bioban P-1487 specific to federally listed species, the Agency needs to address potential risks from other end-use products. Therefore, the Agency requires that users adopt all listed species risk mitigation measures for all active ingredients in the product. If a product contains multiple active ingredients with conflicting listed species risk mitigation measures, the more stringent measure(s) should be adopted.

V. What Registrants Need to Do

The Agency has determined that Bioban P-1487 is eligible for reregistration provided that: (i) additional data that the Agency intends to require confirm this decision and (ii) label amendments are made. To implement this decision, the registrants must amend their product labeling to incorporate the label statement set forth in the Label Changes Summary Table in Section B below (Table 24). The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

For Bioban P-1487 technical grade active ingredient products, the registrant needs to submit the following items:

Within 90 days from receipt of the generic data call-in (DCI):

1. Completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and

2. Submit any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

1. Cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Michelle Centra at (703) 308-2476 with questions regarding generic reregistration.

By US mail:

Document Processing Desk
Michelle Centra
Office of Pesticide Programs
(7510P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

By express or courier service:

Document Processing Desk
Michelle Centra
Office of Pesticide Programs
(7510P)
U.S. Environmental Protection Agency
One Potomac Yard, Room S-8845
2777 South Crystal Drive
Arlington, VA 22202

For end-use products containing the active ingredient Bioban P-1467, the registrant needs to submit the following items for each product.

Within 90 days from the receipt of the product-specific data call-in (PDCI):

1. Completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and

2. Submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

1. Two copies of the confidential statement of formula (EPA Form 8570-4);

2. A completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";

3. Five copies of the draft label incorporating all label amendments outlined in Table 23 of this document;

4. A completed form certifying compliance with data compensation requirements (EPA Form 8570-34);

5. If applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and

6. The product-specific data responding to the PDCI.

Please contact Marshall Swindell at (703) 308-6341 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:

Document Processing Desk
Marshall Swindell
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

By express or courier service:

Document Processing Desk
Marshall Swindell
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of Bioban P-1487 has been reviewed and determined to be substantially complete. However, the following additional data requirements have been identified by the Agency as confirmatory data requirements and are included in the generic data call in (DCI) for this RED.

Confirmatory toxicological data must be submitted to fully characterize the following hazards: combined chronic toxicity/carcinogenicity study to assess potential chronic toxicities as well as define the carcinogenic potential of Bioban P-1487 since there is the potential for long-term exposures due to the metal working fluid use.

The following ecological toxicity data must be submitted to fully characterize the invertebrate hazards: acute toxicity to freshwater invertebrates (preferably using *Daphnia magna* or *Daphnia pulex*).

The requested toxicolgy and ecological study are outlined in Table 11.

Table 11. Confirmatory Data Requirements for Bioban P-1487

Guideline Study Name	New OPPTS Guideline Number
Combined Chronic Toxicity/Carcinogenicity-Rat	870.3800
Acute Freshwater Invertebrate Study[1]	850.1010

[1] Needed if use patterns are expanded beyond those evaluated in this RED.

2. Labeling for Technical and Manufacturing Use Products

To ensure compliance with FIFRA, technical and manufacturing-use product (MP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The Technical and MP labeling should bear the labeling contained in Table 12, Label Changes Summary Table.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. A product-specific data call-in will be issued at a later date.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 12, Label Changes Summary Table.

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision document. Persons other than the registrant may generally distribute or sell such products for 52 months from the approval of labels reflecting the mitigation described in this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy," *Federal Register*, Volume 56, No. 123, June 26, 1991.

a. Label Changes Summary Table

In order to be eligible for reregistration, all product labels must be amended to incorporate the risk mitigation measure outlined in Section IV of the Bioban P-1487 RED. The following table describes how language on the labels should be amended.

Table 12. Labeling Changes Summary Table

Description	Amended Labeling Language	Placement on Label
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This product is toxic to fish and aquatic invertebrates. 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 Pollution 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."	Precautionary Statements
End Use Products Intended for Occupational Use		
PPE Requirements	"Wear a long-sleeve shirt, long pants, shoes, socks, and chemical-resistant gloves."	*Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals*

VI. APPENDICES

Appendix A. Table of Use Patterns for Bioban P-1487

Use Site	Formulation/ Reg. No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Industrial processes and water systems.				
Metalworking Fluids	464-674 (Ready-to use)	Not Listed	A dose of 1000 to 2000ppm 2500ppm for fouled systems	None Listed
	464-659 (Soluble Concentrate)	Not Listed	In concentrates: 1000ppm Diluted Fluid: 1000-3000ppm Maintenance: 100 to 2000ppm at weekly intervals	None Listed
Hydrocarbon Preservations	464-674 (Ready-to use)	Add to storage tanks	Add 2.2 gallons of product to each 1,000 gallons of water / concentration of 1000ppm	None Listed
	464-678 (Ready-to use)	Add to Storage tanks: slug dose or intermittent metering	180- 350ppm product to water	None Listed
Materials preservatives				
Die Cast Lubricants and mold release agents	464-674 (Ready-to use)		1,000 to 2,000ppm for initial treatment 2,500ppm for fouled systems.	None Listed
Diesel fuel Conditioner	464-665 (Ready-to use)	Pour into Fuel tank	Entire Contents (12 oz) to 10 – 26 gallon fuel tank	None Listed

Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

Guide To Appendix B

Appendix B lists the **generic** (not product specific) data requirements which support the re-registration of Bioban P-1487. These requirements apply to Bioban P-1487 in all products, including data requirements for which a tech nical grade active ingredient is the test substance. The data table is organized in the following formats:

1. **Data Requirement** (Columns 1 and 2). The data requirements are listed by Guideline Number. The first column lists the new Part 158 Guideline numbers, and the second column lists the old Part 158 Guideline numbers. Each Guideline Number has an associated test protocol set forth in the Pesticide Assessment Guidance, which are available on the EPA website.

2. **Guideline Description** (Column 3). Identifies the guideline type.

   Use Pattern (Column 4). This column indicates the standard Antimicrobial Division use patterns categories for which the generic (not product specific) data requirements apply. The number designations are used in Appendix B.

3.
   (1) Agricultural premises and equipment
   (2) Food handling/ storage establishments premises and equipment
   (3) Commercial, institutional and industrial premises and equipment
   (4) Residential and public access premises
   (5) Medical premises and equipment
   (6) Human water systems
   (7) Materials preservatives
   (8) Industrial processes and water systems
   (9) Antifouling coatings
   (10) Wood preservatives
   (11) Swimming pools
   (12) Aquatic areas

   3. **Bibliographic Citation** (Column 5). If the Agency has data in its files to support a specific generic Guideline requirement, this column will identify each study by a "Master Record Identification (MRID) number. The listed studies are considered "valid" and acceptable for satisfying the Guideline requirement. Refer to the Bibliography appendix for a complete citation of each study.

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Composition	7, 8	00034980, 41995101
830.1600 830.1620 830.1650	61-2A	Starting Materials and Manufacturing Process	7, 8	00034980, 41995101
830.1670	61-2B	Formation of Impurities	7, 8	00034980, 41995101
830.1700	62-1	Preliminary Analyses	7, 8	00034980, 41995101
830.1750	62-2	Certification of Limits	7, 8	00034980, 41995101
830.1800	62-3	Analytical Method	7, 8	00034980, 41995101
830.6302	63-2	Color	7, 8	00034980, 41995101
830.6303	63-3	Physical State	7, 8	00034980, 41995101
830.6304	63-4	Odor	7, 8	00034980, 41995101
830.7200	63-5	Melting Point	7, 8	00034980, 41995101
830.7220	63-6	Boiling Point	7, 8	00034980, 41995101
830. 7300	63-7	Density	7, 8	00034980, 41995101
830.7840 830.7860	63-8	Solubility	7, 8	00034980, 41995101
830.7950	63-9	Vapor Pressure	7, 8	00034980, 41995101
830.7000	63-12	pH	7, 8	00034980, 41995101
830.6317	63-13	Stability	7, 8	00034980, 41995101
830.6314	63-14	Oxidation/Reduction: chemical incompatibility	7, 8	00034980
830.6315	63-15	Flammability	7, 8	00034980
830.6316	63-16	Explodability	7, 8	00034980
830. 7300	63-7	Density	7, 8	00034980, 41995101

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
830.7840 830.7860	63-8	Solubility	7, 8	00034980, 41995101
830.7950	63-9	Vapor Pressure	7, 8	00034980, 41995101
ECOLOGICAL EFFECTS				
850.2100	71-1	Avian acute oral toxicity test – Mallard/duck	7, 8	93055001
850.2200	71-2	Avian dietary toxicity test – Quail	7, 8	93055002
850.1075	72-1	Fish acute toxicity test – Bluegill Sunfish	7, 8	93055004
850.1075	72-1	Fish acute toxicity – Rainbow Trout	7, 8	93055005
850.1010	72-2	Acute Daphnid Study	7,8	Data Gap
850.5400	123-2	Green algae – *Selenastrum capricornutum* (*Pseudokerscheneria subcapitatum*)	7, 8	47005504
TOXICOLOGY				
870.1100	81-1	Acute oral toxicity - Rat	7, 8	43558901
870.1200	81-2	Acute dermal toxicity – Rabbit	7, 8	41677602
870.1300	81-3	Acute inhalation toxicity – Rat	7, 8	Data Gap
870.2400	81-4	Acute eye irritation – Rabbit	7, 8	41677603
870.2500	81-5	Acute dermal irritation	7, 8	41677604, 41810802
870.2600	81-6	Skin sensitization	7, 8	00104805
870.3250	82-3	90-Day dermal toxicity	7, 8	Not needed
870.3700	83-3	Prenatal developmental toxicity study	7, 8	41673801, 41978802
870.4300	83-5	Combined chronic toxicity/carcinogenicity	7,8	Data Gap
870.5100	84-2	Bacterial reverse mutation test	7, 8	41619301
870.5300	84-2	In vitro mammalian cell gene mutation test	7, 8	45655301
870. 5375	84-2	In vitro mammalian chromosome aberration test	7, 8	41298502, 41567901
870.5550	84-2	Unscheduled DNA synthesis in mammalian cells in culture	7, 8	41298503
870.5385	84-2	Mammalian bone marrow chromosomal aberration test	7, 8	47005501, 46965903
870.7485	85-1	Metabolism and pharmacokinetics	7,8	Not needed

ENVIRONMENTAL FATE				
835.2110	161-1	Hydrolysis as a function of pH	7, 8	43494001
835.3110	None	Ready biodegradability	7, 8	47005502
Non-Guideline	Non-Guideline	Soil partition co-efficient	7, 8	45900901

Appendix C: Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP Public Docket EPA-HQ-OPP-2007-0402, and may also be accessed from www.regulations.gov. Hard copies of these documents may be found in the OPP public docket. The OPP public docket is located in Room S-4900, One Potomac Yard, 2777 South Crystal Drive, Arlington, VA 22202, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: http://www.regulations.gov (EPA-HQ-OPP-2007-0402).

These documents include:

Risk Assessment and Supporting Science Documents:

- Bioban P-1487: Antimicrobials Division's Risk Assessment for Issuance of the Reregistration Eligibility Decision (RED) Document. Case No. 3028, PC Code: 100801, 100802, DP Barcode: 338285. 9/20/07, Jenny Tao, Risk Assessor.

- Bioban P-1487: Toxicology Disciplinary Chapter for the Issuance of the Reregistration Eligibility Decision (RED) Document. Case No. 3028, PC Code: 100801, 100802, DP Barcode: 338284. 9/20/07, Jenny Tao, Senior Toxicologist.

- BIOBAN P-1487: Revised Report of the Antimicrobials Division's Toxicology Endpoint Selection Committee (ADTC). 6/27/07, Tim McMahon, Ph.D., Chair, ADTC.

- Product Chemistry Science Chapter. PC Codes 100801, 100802, Case 3028, Antimicrobials Division, 6/20/07, A. Najm Shamim, Ph.D., Chemist.

- DIETARY EXPOSURE ASSESSMENT OF BIOBAN P-1487 FOR REREGISTRATION ELIGIBILITY DECISION Case No. 3028, PC Code: 100801, 100802, DP Barcode: 340643. 6/21/07, A. Najm Shamim, Ph.D. Chemist.

- Occupational and Residential Exposure Assessment for Bioban BIOBAN P-1487^{TM} Antimicrobial Agent [4-(2-nitrobutyl)morpholine and 4,4'-(2-ethyl-2-nitrotrimethylene)dimorpholine]. Case No.: 3028, DP Barcode: D338283, 9/5/07, Siroos Mostaghimi, Ph.D., Senior Scientist.

- Environmental Fate Risk Assessment of BIOBAN P-1487 for the Reregistration Eligibility Decision (RED) Process. Case No. 3028, PC Code: 100801, 100802, DP Barcode: 340652. 9/20/07, A. Najm Shamim, Ph.D., Chemist.

- Environmental Effects Assessment of 4-(2-nitrobutyl) morpholine (Bioban P-1487) for the Reregistration Eligibility Decision (RED) Document. Case No.: 3028, DP Barcode: D340653, 9/20/07, David C. Bays, Microbiologist.

Appendix D. Citations Considered to be Part of the Data Base Supporting the Reregistration Decision (Bibliography)

MRID Number	Citation
00034980	Commercial Solvents Corporation (1969). CSC^(R)IBiocide P-1487. (Unpublished study received Jun 25, 1969 under 271-30; submitted by International Minerals and Chemical Corp., Terre Haute, Ind.; CDL:001945-A).
00094944	Goldenthal, E.I.; Wazeter, F.X.; Dean, W.P. (1973) Acute Inhalation Toxicity Study (LC_{50}) in Albino Rats: 267-009; Report No. PLR-11. (Unpublished study received Jan 14, 1981 under 271-30; prepared by International Research and Development Corp., submitted by International Minerals & Chemical Corp., Terre Haute, Ind.; CDL:244383-F)
00104805	Wilbur, S. (1978) P-1487 Skin Sensitization: SW78/11. (Unpublished study received Apr 25, 1979 under 271-30; submitted by Inter- national Minerals & Chemical Corp., Terre Haute, IN; CDL: 238693-A.
41298502	Desai, L. (1989) Chromosome Aberrations in Chinese Hamster Ovary (CHO) Cells: Bioban P-1487 Antimicrobial Agent: Lab Project Number 89G-0095. Unpublished study prepared by Toxikon Corp. 15 p.
41298503	Desai, L. (1989) Unscheduled DNA Synthesis in Rat Liver Primary Cell Cultures: Bioban P-1487 Antimicrobial Agent: Lab Project Number 89G-0094. Unpublished study prepared by Toxikon Corp. 12 p.
41567901	Desai, L. (1989) Chromosome Aberration in Chinese Hamster Ovary (CHO) Cells: Lab Project Number: 89G-0095. Unpublished study prepared by Toxikon Corp. 6 p.
41619301	Lynn, S. (1990) Ames Mutagenicity Assay: Bioban P1487: Lab Project Number: 90G/0526. Unpublished study by Toxikon Corp. 14 p.
41619302	Griffin, T. (1990) Subchronic 90-Day Dermal Toxicity Study of Bio- ban P-1487 in Rats: Lab Project Number: 890202. Unpublished study prepared by Coulston International, Inc. 311 p.
41673801	Griffin, T. (1990) A Teratology Study of Bioban P-1487 in Rats: Final Report: Lab Project Number: 890402. Unpublished study prepared by Coulston International, Inc. 84 p.

41677602 Kreuzmann, B. (1990) Acute Dermal Toxicity in Rabbits—Median Lethal Dosage Determination: Lab Project Number: 90-4091-21 (B). Unpublished study prepared by Hill Top Laboratories, Inc. 109 p.

41677603 Kreuzmann, B. (1990) Primary Eye Irritation Study in Rabbits: Bioban P-1487: Lab Project Number: 90-4091-21 (D). Unpublished study prepared by Hill Top Laboratories, Inc. 14 p.

41677604 Kreuzmann, B. (1990) Primary Skin Irritation Study in Rabbits: Bioban P-1487: Lab Project Number: 90-4091-21 (C). Unpublished study prepared by Hill Top Laboratories, Inc. 14 p.

41810802 Kreuzmann, J. (1990) Primary Skin Irritation Study in Rabbits: Lab Project Number: 90-4091-21 (C). Unpublished study prepared by Hill Top Biolabs, Inc. 31 p.

41978802 Griffin, T. (1991) Supplemental Data to MRID No. 41673801: A Teratology Study of Bioban P-1487 in Rats. Unpublished study prepared by Consulton International, Inc. 12 p.

41995101 Bollmeier, A. (1990). Product Chemistry for Bioban P-1487. Unpublished study prepared by Angus Chemical Co. 28 p.

42440001 Griffin, T. (1992) Subchronic 90-day Dermal Toxicity Study of Bioban P-1487 in Rats (Limit Test): Lab Project Number: 910302. Unpublished study prepared by Coulston Research, Inc. 228 p.

43494001 Burke, B. (1994) Hydrolyses of 4-(2-Nitrobutyl) morpholine and 4,4'-(2-Ethyl-2-nitrotrimethylene)dimorpholine: Lab Project Number: PRT-23-4ANN-01: PRT-23-4ANN-01-003. Unpublished study prepared by Plant Research Technologies, Inc. 149 p.

43558901 Fitzgerald, G. (1995) Acute Oral Toxicity Study (in Rats): Bioban P-1487: Final Report: Lab Project Number: 94G-1937. Unpublished study prepared by Toxikon Corp. 18 p.

45655301 Linscombe, V.A., M.R. Schisler, and K.F. Treadway (2002) Evaluation of Bioban P-1487 in the mouse lymphoma (L5178Y TK +/-) forward mutation assay: Toxicology and Environmental Research and Consulting, Dow Chemical Company, Midland, MI, Laboratory ID 011110.

45900901 Estimating the Soil K_{oc} for a Series of Biocides by HPLC Using OECD method 121 by S.J. Gonsoir, M.A. rivard, and M.K. Stock, 2002, Biocides TS and D, the Dow Chemical Company, Midland, Michigan.

46965903 Cifone, M.A. (2002) *In vivo/ in vitro* unscheduled DNA synthesis in rat primary hepatocyte cultures at two time points with a dose range-finding assay with Bioban P-1487: Covance Laboratories, VA, Study No. 23622-0-494, Dow No. 021036, August 25, 2002.

47005501 Spencer, P.J. (2003) Evaluation of Bioban P-1487 in the mouse bone marrow micronucleus test. Toxicology and Environmental Research and Consulting, Dow, Midland, MI, Study 020146, March 14, 2003.

47005502 Gonsior, S.; Stock, M.; Rivard, M. (2002) Evaluation of the Ready Biodegradability of Bioban P-1487 Biocide using the OECD Method 301F: Manometric Respirometry Test. Project Number: 011131. Unpublished study prepared by Dow Chemical Co. 31 p.

47005504 Kirk, H.D., Staley, J.L., McClymont, E.L., and McFadden, L.G. 2002. Bioban P-1487: Growth Inhibition test with the Freshwater Green Alga, S*elenastrum capricornutum P*rintz. Study No. 021001. Conducted by Toxicology & Environmental Research and Consulting, The Dow Chemical Company.

93055001 Fink, R. and Beavers, J.B. 1990. Bioban P-1487: An Acute Oral Toxicity Study with the Mallard Duck. Project No. 170-103. Conducted by Wildlife International, LTD.

93055002 Fink, R. and Beavers, J.B. 1990. Bioban P-1487; Eight-day Dietary LC50 in Bobwhite Quail. Project No. 170-101. Conducted by Wildlife International, LTD MRID 93055003. Fink, R. and Beavers, J.B. 1990. Bioban P-1487: Eight-day Dietary LC50 in Bobwhite Quail. Project No. 170-102. Conducted by Wildlife International. LTD.

93055004 Griffen, J. and Thompson, C.M. 1980. Acute Toxicity of Bioban P-1487 to Bluegill Sunfish (*Lempomis machrochirus*). Project No. 25061. Conducted by Analytical Bio Chemistry Laboratories.

93055005 Griffen, J. and Thompson, C.M. 1980. Acute Toxicity of Bioban P-1487 to the Rainbow Trout (*Salmo gairdneri*). Project No. 25145 Conducted by Analyical Bio Chemistry Laboratories.

Supporting Documentation

A Memo from Roxolana Kashuba to Steven Bradburry, Director EFED, April 2006

Dang. 1997. The Use of Models for Estimating Exposure and Risk of Antimicrobials in Metalworking Fluids. AAMA MWF Symposium, September 15-19, 1998.

The Estimation Programs Interface (EPI) Suite. Windows based suite of physical/chemical properties and environmental estimation models developed by the US EPA's Office of Prevention, Pesticides, and Toxic Substances (OPPTS) and Syracuse Research Institute (SRC). http://www.epa.gov/opptintr/exposure/docs/EPISuitedl.htm

.

FDA. 2003, A Guidance For Industry: Preparations of Food Contact Notifications and Food Additive Petitions for Food Contact Substances, Chemistry Recommendations. Final Guidance, April 2003. http://www.cfsan.fda.gov

FDA. 2003. Sanitizing Solutions: Chemistry Guidance for Food Additive Petitions, January 2003. http://www.cfsan.fda.gov

SIMetric. 2005. Mass, Weight, Density, or Specific Gravity of Bulk Materials. http://www.simetric.co.uk/si_materials.htm, last accessed February 2007.

U.S. Environmental Protection Agency (EPA). 1992. A Laboratory Method to Determine the Retention of Liquids on the Surface of Hands. Prepared by C. Cinalli, C. Carter, A. Clark, and D. Dixon, under EPA Contract No. 68-02-4254. EPA-747/R-92-003. Exposure Evaluation Division, Office of Pollution Prevention and Toxics. September 1992.

U.S. Environmental Protection Agency (EPA). 1997. Exposure Factors Handbook. Volume I-II. Office of Research and Development. Washington, D.C. EPA/600/P-95/002Fa.

U.S. Environmental Protection Agency (EPA). 1998. PHED Surrogate Exposure Guide. Estimates of Worker Exposure from the Pesticide Handler Exposure Database Version 1.1. Washington, DC: U.S. Environmental Protection Agency.

U.S. Environmental Protection Agency (EPA). 1999. Chemical Manufacturers Association Antimicrobial Exposure Study. Washington, DC. DP Barcode D247642.

U.S. Environmental Protection Agency (EPA). 2002. Bioban P-1487 - Report of the Antimicrobials Division Toxicology Endpoint Selection Committee. Revised on January 25, 2007.

Appendix E. Generic Data Call-In

The Agency intends to issue a Generic Data Call-In at a later date. See Chapter V of the Bioban P-1487 RED for a list of studies that the Agency plans to include in the Generic Data Call-in.

Appendix F. Product Specific Data Call-In

The Agency intends to issue a Product Specific Data Call-In at a later date.

Appendix G. Batching of Bioban P-1487 Products for Meeting Acute Toxicity Data Requirements for Reregistration

The Agency will complete the batching for Bioban P-1487 at a later date.

Appendix H. List of All Registrants Sent the Data Call-In

A list of registrants sent the data call-in will be posted at a later date.

Appendix I. List of Available Related Documents and Electronically Available Forms

Pesticide Registration Forms are available at the following EPA internet site: http://www.epa.gov/opprd001/forms/.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit
www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit that contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

    a. 83-3 Label Improvement Program—Storage and Disposal Statements

    b. 84-1 Clarification of Label Improvement Program

    c. 86-5 Standard Format for Data Submitted under FIFRA

    d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)

    e. 87-6 Inert Ingredients in Pesticide Products Policy Statement

    f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement

    g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments

    h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

    Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)

    a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment

    b. EPA Form No. 8570-4, Confidential Statement of Formula

    c. EPA Form No. 8570-27, Formulator's Exemption Statement

    d. EPA Form No. 8570-34, Certification with Respect to Citations of Data

    e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)

   a. Registration Division Personnel Contact List

   b. Biopesticides and Pollution Prevention Division (BPPD) Contacts

   c. Antimicrobials Division Organizational Structure/Contact List

   d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)

   e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)

   f. 40 CFR Part 158, Data Requirements for Registration (PDF format)

   g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' Web Site

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

   National Technical Information Service (NTIS)
   5285 Port Royal Road
   Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.

4. The National Pesticide Information Center (NPIC) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: http://npic.orst.edu/

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner

encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.