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

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

March 9, 2011

DP BARCODE: 387501

MRID : 482888-01

SUBJECT: Bioban MT 20 Antimicrobial
(Name of Product)

REG. NO.: 707-GER

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [ ] OR End-use Product [x]

INGREDIENTS:

PC Code(s)	CAS Number	Active Ingredient(s):
107104	2682-30-4	2-Methyl-4-isothiazolin-3-one (MIT)

TEST LAB: Rohm & Haas, Spring House, PA, USA
Harlan Laboratories Ltd, Derbyshire, UK

SUBMITTER: Rohm & Haas

GUIDELINE: Product Chemistry Group A & B

ORGANIZATION: AD\PSB\CTT

REVIEWER: Earl Goad

APPROVED BY: Karen P. Hicks

APPROVED DATE: March 9, 2011

COMMENT:

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

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

March 9, 2011

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. 707-GER
Product Name: Bioban MT 20 Antimicrobial
DP Barcode: 387501

CODE: (A540) New Product; Non-Fast Track

DATE DUE: April 1, 2011

FROM: Earl Goad, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Marshall Swindell PM#33/Zebora Johnson
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: Rohm & Haas Co.

PRODUCT FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
2-Methyl-4-isothiazolin-3-one (MIT)	20.
Other Ingredient(s):	
Total:	100.

BACKGROUND:

Rohm and Haas Company has submitted an application for registration of a new end-use product, BIOBAN MT 20 Antimicrobial. EPA File Symbol 707-GER. The product is an industrial microbiocide for use in polymer lattices, mineral dispersions, adhesives, tackifiers, paints and coatings, commercial photo-processing systems, photographic emulsions, printing fluid, building materials, in-can preservation, electronic chemicals, and metal working fluids. The product is produced by a non-integrated system. The source of the active ingredient is from an EPA registered product.

The data package included:

1. A letter from the applicant to EPA, dated October 27, 2010.
2. Confidential Statement of Formula (CSF) for the basic formulation, dated October 27, 2010.
3. A draft label (pin punched 11·08·10).
4. One product chemistry study (MRID 482888-01) containing both groups A and B.

FINDINGS:

1. Confidential Statement of Formula.
   The Information on the CSF appears to be accurate and complete.

2. Product Label.
   The following revisions to the product label are recommended:

   a. Beneath the "Storage and Disposal" heading of the product label, add the following statement: "Do not contaminate water, food, or feed by storage or disposal or cleaning of equipment." This statement is currently located under the "Pesticide Storage" subheading of the product label.
   b. Place the "Storage and Disposal" section of the product label in a text box for prominence.
   c. Under the "Pesticide Storage" section of the product label, add instructions that specify what to do if the product leaks or spills from the product container.
   d. Add page numbers to each page of the product label.

3. Product Chemistry Groups A & B.
   a. Product Chemistry Group A. To satisfy OPPTS 830.1750 (Certified Limits) requirements, a signed certification statement must be provided, as requested under OPPTS 830.1750(g). See Table A for further details.
   b. All Group B product chemistry data requirements applicable to end-use products have been met. See Table B of this report for further details.

CONCLUSION:

The basic CSF dated October 27, 2010 is acceptable. Several recommended improvements are suggested for the product label. Some study data for product chemistry groups A and B were obtained using similarly formulated products at ~10 and 50% active ingredient. The data were submitted as "waiver requests". CTT found this bridging data to be acceptable.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system Yes[X] No [ ]
- Are all TGAIs used registered? Yes [X] No [ ]
- Integrated formulation system Yes[ ] No [X]

- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [ ] No [X]

Note: This product is not intended for food contact use. All formulation components have PC codes. The product consists of the active ingredient and water.

c. Physical state of product: *Liquid*

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.
Yes [ ] No [X]

e. The NCs and CLs are acceptable. Yes [X] No [ ]

f. Active ingredient	NC (%)	LCL (%)	UCL (%)
2-Methyl-4-isothiazolin-3-one	20	19	21

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]

- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X]No [ ]

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes [ ] No [ ] Not applicable [X]

Note: Waivers from OPPTS 830.6315 (Flammability/ Flame Extension) and OPPTS 830.6316 (Explodability) requirements were requested.

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).
Yes [ ] No [ ]

Note: OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics) requirements have been satisfied by presentation of data on similarly formulated products at difference concentrations of the active ingredient which are all formulated from the exact same registered source of the active ingredient.

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	482888-01 and CSF
830.1600 Description of Materials	A	482888-01 and CSF
830.1620 Production Process[2]	NA	
830.1650 Formulation Process[3]	A	482888-01
830.1670 Formation of Impurities[4]	A	482888-01
830.1700 Preliminary Analysis[5]	*[Not required for products produced by a non-integrated system.]*	
830.1750 Certified Limits[6]	A – Standard certified limits (or limits within the standard certified limit range) were proposed. G – A signed certification statement must be provided, as requested under OPPTS 830.1750(g).	482888-01 and CSF
830.1800 Enforcement Analytical Method[7]	A – A copy of an HPLC method was provided for determining active ingredient content in the product.	482888-01
830.1900 Submittal of Samples	*[Samples are to be provided on a case-by-case basis for end-use products.]*	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	The product has a very pale straw/ yellow color at 20.0±0.5°C, based on visual assessment.	482888-01
830.6303 Physical State	A	The product is a transparent liquid with no precipitation or sedimentation at 20.0±0.5°C, based on visual assessment.	482888-01
830.6304 Odor	A	The product is odorless at 20.0±0.5°C, by nasal inhalation.	482888-01
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA	*[Not required for end-use products.]*	
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	No significant oxidation, reduction, or chemical incompatibility was observed when the product was mixed with distilled water, monoammonium phosphate, zinc granules, and aqueous acidic sodium chloride. Some phase separation was observed. Testing was conducted in compliance with GLP. Note: The label states: "Do not contaminate with strong oxidizing or reducing agents."	482888-01
830.6315 Flammability/ Flame Extension	A	The product is a 20% solution of the active ingredient, MIT, in water. The active ingredient, MIT, is not a flammable substance. It does not self ignite, does not propagate a flame, and has an autoignition temperature of 396°C at 1012 mbar. The product can, therefore, be considered to be a non-combustible liquid. EC Directive 92/69/EEC Method A.9 and CIPAC MT 12 were referenced. [Waiver requested.]	482888-01

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6316 Explodability	A	The product is a water-based 20% solution of MIT. The physical properties of water (low vapor pressure, no autoignition temperature, no flammability limits) strongly indicate that this material does not have the potential for explosion. Similarly, MIT is not an explosive material. Consequently, the product does not present any explodability potential. EC Directive 92/69/EEC Method A.14 was referenced. [Waiver requested.]	482888-01
830.6317 Storage Stability	A	The product is a 20% solution of the active ingredient, MIT, in water. Two-year storage stability studies have been conducted for both Kordek 573F Biocide (50% MIT in water) and Kordek MLX Microbiocide (10% MIT in water). Both of these formulations are stable for 2 years at 25°C. Given that the % MIT in BIOBAN MT 20 Antimicrobial falls between the % MIT in these two stable formulations, it is concludes that this 20% formulation will also be stable for 2 years at 25°C. Note: Results provided demonstrate stability of the 10% MIT product (9.7% label claim nominal concentration) over 24 months at 20.0-32.2°C. Concentrations at each test interval were within the standard certified limit range. Testing was conducted in compliance with GLP. Note: Results provided demonstrate stability of the 50% MIT product (50% label claim nominal concentration) over 24 months at 20.0-32.2°C. Concentrations at each test interval were within the standard certified limit range. Testing was conducted in compliance with GLP. [Waiver requested.]	482888-01
830.6319 Miscibility[1]	A	The product was determined to be miscible with hexane, water, and methanol and immiscible with kerosene at 25±1°C. CIPAC MT 23 was referenced. Testing was conducted in compliance with GLP.	482888-01

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6320 Corrosion Characteristics	A	Corrosion characteristics are routinely determined in combination with storage stability testing (see OPPTS 830.6317 above). The commercial containers used for BIOBAN MT 20 Antimicrobial are the same as those used for the previously tested 50% MIT and 10% MIT products. No change in the condition of the containers was seen after 2 years at 25°C in those studies. It is concluded that BIOBAN MT 20 Antimicrobial will be equally stable in the commercial containers. Note: Results demonstrate that the 10% MIT product (9.7% label claim nominal concentration) is not corrosive to its packaging after storage for 24 months at 20.0-32.2°C. There was no evidence of corrosion. The container material was not identified. Testing was conducted in compliance with GLP. Note: Results demonstrate that the 50% MIT product (50% label claim nominal concentration) is not corrosive to its packaging after storage for 24 months at 20.0-32.2°C. There was no evidence of corrosion. Testing was conducted in compliance with GLP. The product label states: "This product is corrosive to mild steel. Do not store or transport in unlined metal containers." [Waiver requested.]	482888-01
830.6321 Dielectric Breakdown Voltage	A	Not applicable. The product is not for use with electrical equipment.	482888-01
830.7000 pH[2]	A	The mean pH of the product was reported to be 6.54 at 25°C. A 1% aqueous dispersion of the product was tested. Two determinations were made. CIPAC MT 75 was referenced. Testing was conducted in compliance with GLP.	482888-01
830.7050 UV/Visible Absorption	NA	*[Not required for end-use products.]*	

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7100 Viscosity	A	The mean viscosity of the product was reported to be 1.55 mm^2/s at 20.0±0.5°C and 0.961 mm^2/s at 40.0±0.5°C (as determined using a capillary viscometer). Two determinations were made at each temperature. OECD Guideline No. 114 was referenced. Testing was conducted in compliance with GLP.	482888-01
830.7200 Melting Point/Melting Range	NA	*[Not required for end-use products.]*	
830.7220 Boiling Point/Boiling Range	NA	*[Not required for end-use products.]*	
830.7300 Density/Relative Density/Bulk Density	A	The mean density of the product was reported to be 1.06 x 10^3 kg/m^3 at 20.0±0.5°C (using a pycnometer). Two determinations were made. EC Directive 92/69/EEC Method A.3 was referenced. Testing was conducted in compliance with GLP.	482888-01
830.7370 Dissociation Constants in Water	NA	*[Not required for end-use products.]*	
830.7550/830.7560/830.7570 Partition Coefficient	NA	*[Not required for end-use products.]*	
830.7840/830.7860 Water Solubility	NA	*[Not required for end-use products.]*	
830.7950 Vapor Pressure	NA	*[Not required for end-use products.]*	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water