

264-1113

9/14/2010

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

SEP 14 2010

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Note to File: EPA Reg. No. 264-1113, DER addendum

From: Shanaz Bacchus, Chemist/RAL
Microbial Pesticides Branch (7511P)
Biopesticides and Pollution Prevention Division

Subject: EPA Registration No. 264-1113 – BAFI SDN (MUP)
Decision Number: 426922 – PRIA Category B681
Your application to register basic formulation
Manufacturing site – Mexico (EPA Est. No. 087098-MEX-001)
Applications dated January 19, 2010 (AgroGreen) and
March 25, 2010 (Bayer)
Submission: 865785 (MRID 47963601) received January 20, 2010.
Submission: 871391 (MRID 48050201) received April 1, 2010
Submission: 877444 (MRID 48110301) received June 1, 2010
Submission: 871391 (MRID 48159501) received July 22, 2010
Confidential Statement of Formula dated February 19, 2010
Label amendment submission dated September 14, 2010
PRIA negotiated due date September 15, 2010
Data Evaluation Record J. Kough to Shanaz Bacchus, dated September
09, 2010

This addendum explains that the Data Evaluation Record (DER) dated September 09, 2010, from Dr. John Kough, Senior Scientist, BPPD, can only be used in support of Decision 426922. This amendment is for the basic formulation of BAFI SDN (MUP), EPA Reg. No. 264-1113 that is approved for manufacture in Mexico (EPA Est. No. 087098-MEX-001).

Bayer has applied for two amendments for the manufacture of the above-referenced pesticide:

1. Decision 426922 for a basic formulation to be manufactured in Mexico (EPA Est. No. 087098-MEX-001) supported by the data listed above.
2. Decision 431322 for an alternate formulation to be manufactured at the Cherokee Pharmaceuticals LLC plant (EPA Est #: 084961-PA-001) located at Riverside, PA 17868. The data submitted to support this

2014

proposed amendment registration are: MRIDs 47973701, 48049301, 48110401 and 48159501.

The enclosed DER contains an evaluation of studies (MRIDs 48110301, 48110401, 48159501) that were submitted in support of the basic CSF and label amendment for manufacture of BAFI SDN (MUP) in the Mexico plant. It also refers to the data from the Cherokee facility. However, EPA is aware that this facility has been inactivated since September 13, 2010. Bayer has requested an extension of the PRIA due date on Decision 431322 to December 23, 2010, in order to resolve issues regarding manufacture at this facility. This request is under consideration by the Agency. Bayer cannot cite this DER for the Cherokee facility until these issues are resolved.

BAFI SDN (MUP)

FOR THE FORMULATION OF BIO-NEMATICIDE PRODUCTS

Active Ingredient:

Bacillus firmus (strain I-1582)*100%

* Contains a minimum of 1 x 10¹¹ cfu/gram

EPA Reg. No. 264-1113

EPA Est. No.

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

For MEDICAL And TRANSPORTATION Emergencies **ONLY** Call 24 Hours A Day 1-800-334-7577
For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

If in eyes:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
<p align="center">For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577. Have the product container or label with you when calling a poison control center or doctor or going for treatment.</p>	

PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION.**

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Handlers must wear long sleeved shirts, long pants, shoes, socks and a dust/mist filtering respirator with a NIOSH prefix N-95, P-95 or R-95.

Environmental Hazards

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

IMPORTANT: Read the entire label before using this product.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

For manufacturing use only in formulating bio-nematicide products. The formulator is responsible for obtaining EPA registration of its products.

ACCEPTED

09/14/10

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 264-1113

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Avoid freezing. Store in original container only. Store in dry place.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container.

Rigid, nonrefillable containers

Triple rinse container (or equivalent) promptly after emptying. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Fiber Drums – nonrefillable

Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into mixing or disposal equipment. Then offer liner for recycling, if available, or dispose of liner in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. All such risks shall be assumed by the user or buyer.

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Net Contents: 220 lbs (100 kg); 44 lbs (20 kg)

PRODUCED FOR



Bayer CropScience

Bayer CropScience LP
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1-866-99BAYER (1-866-992-2937)

BAFI SDN (MASTER) Approved 07/21/09, Notification 06/30/10