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

SEP 22 2010

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Danielle A. Larochelle
Registration Product Manager
Bayer CropScience LP
2 T.W. Alexander Drive, P.O. Box 12014
Research Triangle Park, NC 27709, USA

Subject: EPA Registration No. 264-1113 – BAFI SDN (MUP)
Decision Number: 431322 – PRIA Category B681
Your application to register an alternate formulation
Manufacturing site – Pennsylvania, USA
EPA Establishment No. 00068-PA-001
Application dated February 19, 2010 (Bayer)
Submission: 871369 (MRID 47973701) received March 02, 2010.
Submission: 872047 (MRID 48049301) received April 8, 2010.
Submission: 877445 (MRID 48110401) received June 18, 2010.
Submission: 881898 (MRID 48159501) received July 22, 2010
Confidential Statement of Formula (CSF) dated September 17, 2010.
Label amendment submission dated September 14, 2010.
Data Evaluation Record (DER) dated September 09, 2010.
PRIA due date September 23, 2010

Dear Ms. Larochelle:

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(5), is acceptable provided that you:

1. Submit and/or cite all data required for registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

2. Only use inert ingredients that are approved by the US EPA Office of Pesticide Programs to formulate this product. You have agreed to use the inert ingredients that have been previously approved for EPA Registration No. 264-1113 – BAFI SDN (MUP) in MRID 4643302.

3. Conduct and submit the results of the following quality assurance and quality control (QA/QC) tests conducted on site at the manufacturing facility in PA for this pesticide product on five batches of the formulated product produced in that facility:
   a. Spore Counts
   b. Presence of foreign microorganisms
   c. Presence of pathogens

4. Conduct and submit the results from a genetic analysis by ribotyping for strain level identification on five batches of the formulated product produced at the manufacturing facility in Pennsylvania. This testing must be conducted by a commercial laboratory/accredited laboratory. You have indicated that the product will be released for shipment only after strain confirmation is received from this testing laboratory.

5. The results of the testing of five production batches described in 3 and 4 above must be submitted and found acceptable by the Agency on or before one year from the date of this amendment letter.

6. Any batches with unintentional ingredients of toxicological concern must be destroyed.

7. Submit three (3) copies of the revised final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

If you do not comply with these terms, the registration will be subject to cancellation in accordance with FIFRA section 6(b). Your release for shipment of the amended product constitutes acceptance of these conditions.

The DER, dated September 09, 2010, can be used in support of this registration amendment at this Merck, PA facility pending receipt and evaluation of the analysis of five production batches as noted in points 3-6 above.

A stamped copy of the final draft label was enclosed for your records in connection with D426922 for manufacture of this product in Mexico. You can use that label for manufacture in the Merck, PA facility provided that you use the EPA Establishment No. 00068-PA-001 for the Merck facility on the label when manufacturing under this approved CSF, dated September 17, 2010.

If you have further questions regarding this matter, please email Shanaz Bacchus at *bacchus.shanaz@epa.gov* or call her on 703-308-8097.

Sincerely,

Sheryl Reilly, Ph.D. Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division (7511P)