CropScience

December 14, 2006

Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

Attention: Mr. Thomas Harris, Team 7, Insecticide-Rodenticide Branch

Dear Mr. Harris,

Re: **Application for Registration of a New Product Containing the Active Ingredients Thiodicarb (EPA Reg. No. 264-343) and Imidacloprid (EPA Reg. No. 264-755)**
Product Name: AERIS™ Seed-Applied Insecticide/Nematicide
Proposed Use: Cotton Seed Treatment

Enclosed for review is an application for the registration of a new end use product, AERIS™ Seed-Applied Insecticide/Nematicide, which contains the active ingredients Thiodicarb and Imidacloprid. AERIS is a flowable formulation for use as a seed treatment for cotton. Tolerances in/on cotton are established for both active ingredients. Additionally, formulations containing Thiodicarb and Imidacloprid are currently registered for use as seed treatments for cotton, e.g., EXP3 Seed Applied Nematicide/Insecticide (Thiodicarb), 264-1048, and GAUCHO 480 Flowable (Imidacloprid), 264-957. Both of these products are flowable formulations similar to AERIS.

Based on the similarity between AERIS and the existing Thiodicarb and Imidacloprid formulations cited above, we are requesting a waiver from the requirement to conduct some of the acute toxicity studies normally required for the registration of a new product. Instead, Bayer CropScience proposes to rely on existing acute toxicity studies for LARVIN® 3.2 (264-379) which support the registration of EXP3 (264-1048). Justifications for the waiver request are provided in volume 4 of this submission.

A risk assessment for workers who treat cotton seed with AERIS and for workers planting treated seed was conducted using data from EPA HED Policies 14 and 15 and is enclosed in support of the proposed registration. All short term and intermediate term MOEs exceeded 100 for loader/applicators and combined activities wearing the label required protective equipment and for baggers, sewers, and planters of treated cotton seed wearing long pants and a long-sleeved shirt. In addition, cancer risks for all activities are below 1.0×10^{-4}, indicating no unacceptable cancer risks from seed treatment uses of AERIS.

Attached in support of this action are the following documents:

- A completed Application for Registration (EPA Form 8570-1) of a new product.
- A completed Certification with Respect to Citation of Data Form and data matrices.
- Five (5) copies of the proposed label.
- Two (2) copies of the Basic and Alternate Confidential Statements of Formula (CSFs).
- A product chemistry study for AERIS, Report No. PC/06-004PC.
- An acute oral toxicity study for AERIS, Study No. 20284.
- A waiver request for some of the acute toxicity testing requirements, Reference No. daL-088-870.
- A risk assessment for workers who treat cotton seed and workers who plant treated seed, Reference No. daL088-06-875.

Please call me at 919/549-2718 if you have any questions or need additional information. You may also reach me by email at Danielle.Larochelle@bayercropscience.com .

Sincerely,

Danielle A. Larochelle
Registration Product Manager

Corr. # daL088-06

Bayer CropScience

VOLUME 1 of 5

TRANSMITTAL DOCUMENT

AERIS™ Seed-Applied Insecticide/Nematicide
EPA Registration No. 264-XXX

Bayer CropScience
RTP
P.O. Box 12014
RTP, NC 27709
Tel 919 549 2000

Submission of Data in Support of the Registration of a New End Use Product

Transmittal Date
December 14, 2006

Company Official: _____

Company Name: Bayer CropScience

Company Contact: Danielle A. Larochelle

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BIBLIOGRAPHY OF SUBMITTED REPORTS

Volume 1 of 5: Transmittal Document

Volume 2 of 5: Hines, D. (2006) The physical characterization of Imidacloprid – Thiodicarb end-use product. OPPTS Guidelines Series 830. Bayer CropScience. Report Number PC/06-004PC. October 30, 2006. 18pp.

MRID # **47010901**

Volume 3 of 5: Lowe, C. (2006) Imidacloprid Thiodicarb 600 FS (L1524-D3) – Acute Oral Toxicity Up and Down Procedure in Rats. OPPTS Guidelines 870.1100. Eurofins | Product Safety Laboratories. Laboratory Study Number 20284. October 10, 2006. 18pp.

MRID # **47010902**

Volume 4 of 5: Tobia, A. (2006) Waiver Request for Acute Toxicity Testing Requirements for AERIS™ Seed-Applied Insecticide/Nematicide. OPPTS Guidelines 870.1200, 870.1300, 870.2400, 870.2500, 870.2600. Bayer CropScience LP. Reference No. daL088-06-870. September 27, 2006. 10pp.

MRID # **47010903**

Volume 5 of 5: Lunchick, C. (2006) AERIS™ Cotton Seed Treatment Worker Risk Assessment. Guidelines Series 875 Part A. Bayer CropScience. Reference No. daL088-06-875. October 17, 2006. 11pp.

MRID # **47010904**