

US EPA ARCHIVE DOCUMENT

DATE: 04/10/08

SUBJECT: Product Chemistry Review of IMIDACLOPRID TECHNICAL INSECTICIDE

FROM: Indira Gairola
Product Chemistry Team
Technical Review Branch/RD (7505P)

IG
04/10/08

SB
4/15/08

TO: Venus Eagle / Dani Daniel PM 01
Insecticide/Rodenticide Branch /RD (7505P)

DP BARCODE No.: 350530

Reg. No. 83529-1

COMPANY: SHARDA USA LLC

PCC: 129099

Decision No. 390678

Chemical Name: (IUPAC, ANSI, etc.) Imidacloprid

CAS No. 138261-41-3

USE: Insecticide

SHARDA USA LLC is submitting application for additional source for technical grade Imidacloprid for the subject product IMIDACLOPRID TECHNICAL INSECTICIDE. IMIDACLOPRID TECHNICAL INSECTICIDE will be produced at an alternate site [REDACTED] Applicant has submitted pertinent data to support the same. Basic CSF submitted is dated 03/06/08.

Details are listed below:

SUMMARY OF FINDINGS:

1. Applicant SHARDA USA LLC. has submitted MRID#473686-01 for Product Chemistry data to support alternate formulation registration of IMIDACLOPRID TECHNICAL INSECTICIDE.
2. The submitted package was reviewed and details of product chemistry data will be discussed in the following Pages.
3. The Alternate Formulation CSF dated 03/06/08 is filled out completely and correctly.

4. The certified limits are in compliance with 40 CFR158.350 (b) (2).
5. Average recovery of Imidacloprid technical ranged from acceptable level of 98.48-98.59% Mean Average =98.53%.

CONCLUSIONS:

TRB has reviewed the product chemistry data submitted for the above mentioned subject product and has concluded that:

1. Product Chemistry data requirements for subgroup A are satisfactory and fulfill the requirement of OPP test guidelines.
2. Certified limits are in compliance with 40CFR.350 (b) (2). See CONFIDENTIAL APPENDIX.
3. Average recovery of Imidacloprid technical ranged from acceptable level of 98.48-98.59% Mean Average =98.53%.
4. The Alternate Formulation CSF dated 03/06/08 is acceptable and meets the label claim.
5. It is stated that Sub Group A study was conducted in compliance of with GLP Standards as set forth in 40 CFR Part 160.
6. A statement of Quality Assurance is also included with this submission.

Sub Group 'A' Guidelines Series 830.1550-1900
 DP BAR CODE: 350530 File Symbol No.: 83529-1
 PRODUCT NAME: IMIDACLOPRID TECHNICAL INSECTICIDE

. Table 1: Manufacturing and Impurity Data for Glyphosate Acid TECHNICAL

GLN	Requirement	MRID	Status ¹	Details and/or Deficiency ²
830.1550	Product Identity & Disclosure of Ingredients		A	03/06/08
830.1620 830.1650 830.1650	Starting Materials & Manufacturing Process		A	MRID # 473686-01
830.1670	Discussion of Impurities		A	MRID # 473686-01
830.1700	Preliminary Analysis		A	MRID # 473686-01
830.1750	Certification of Limits		A	03/06/08
830.1800	Analytical Methods		A	MRID # 473686-01

¹ A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable. ² Refer to CBI Appendix A for details.

Page _____ is not included in this copy.

Pages 4 through 10 are not included in this copy.

The material not included contains the following type of information:

- Identity of product inert ingredients.
 - Identity of product impurities.
 - Description of the product manufacturing process.
 - Description of quality control procedures.
 - Identity of the source of product ingredients.
 - Sales or other commercial/financial information.
 - A draft product label.
 - The product confidential statement of formula.
 - Information about a pending registration action.
 - FIFRA registration data.
 - The document is a duplicate of page(s) _____.
 - The document is not responsive to the request.
 - Proprietary information pertaining to the chemical composition of an inert ingredient provided by the source of the ingredient.
 - Attorney-Client Privilege.
 - Claimed Confidential by submitter upon submission to the Agency.
 - Internal Deliberative Information.
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* The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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