

US EPA ARCHIVE DOCUMENT

Date: April 17, 2006

SUBJECT: Product Chemistry Review of Imidacloprid Technical TGAI/MUP

FROM: Shyam B. Mathur, PhD
Product Chemistry Team Leader
Technical Review Branch/RD (7505C)

S B Mathur
4/17/06
DM

TO: Dani Daniel / Daniel Kenny, RM 01
Insecticide-Rodenticide Branch / RD (7505C)

DP BARCODE: D325494
DECISION No.: 362867
File Symbol No.: 71368-AR
PRODUCT: Imidacloprid Technical TGAI/MUP
PCC: 129099
REGISTRANT: NuFarm Incorporation
USE: Insecticide

INTRODUCTION:

The registrant has submitted the product chemistry data to support the registration application for the proposed imidacloprid technical [REDACTED]. The product chemistry data corresponding to 830 series subgroup A and Subgroup B have been submitted under MRID Nos. 467219-01 thru 467219-08, 467076-01, 467076-02, 467076-02, 467076-08, and 467076-11. The registrant has also submitted a CSF for basic formulation (dated 11-30-05) and the product label. TRB has been asked to evaluate the product chemistry data submitted for the proposed TGAI/MUP.

SUMMARY OF FINDINGS:

1. The registrant has submitted a Confidential Statement of Formula for basic formulation (dated 11-30-05) for imidacloprid technical. The average purity of the technical/MUP is 98.0%, as determined by the five batch analysis. The proposed certified limits for the AI and impurities are based on the standard certified limits as set forth in 40CFR§158.175(b)(2). The product chemistry data submitted corresponding to guideline reference 830.1550 (product identity & composition) and 830.1750 (certified limits) satisfy the data requirements of 40CFR§158.155 and 158.175 respectively [MRID No. 467076-01 & 467076-02].
2. The product chemistry data submitted corresponding to guideline reference 830.1600 (description of material used to produce the product) satisfy the data requirements of 40CFR§ 158.160 [MRID No. 467076-01].
3. The product chemistry data submitted corresponding to guideline reference 830.1620 (description of production process) satisfy the data requirements for 40CFR§158.162. The imidacloprid technical was produced in a [REDACTED] between the two starting chemicals in the basic conditions. The applicant has provided the details of the chemical process with reaction conditions, equipment used, working up procedures, and quality assurance steps [MRID No. 467076-01].

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4. The product chemistry data submitted corresponding to guideline reference 830.1670 (discussion on the formation of impurities) satisfy the data requirements for 40CFR§158.167. During the production of imidacloprid technical, the registrant discussed and reported the formation of [REDACTED] major impurities present at the levels of [REDACTED] in addition to organic purities which are present [REDACTED] (each) with total of [REDACTED]. The registrant has provided discussion on the formation of these impurities. According to the registrant, none of the impurities identified are of toxicological significance [MRID No. 467076-01].
5. The data submitted corresponding the guideline reference 830.1700 (preliminary analysis) satisfy the data requirements of 40CFR§158.170. The study was conducted under GLP requirements in compliance with 40CFR§160. Five representative batches of the imidacloprid technical were analyzed for percent active ingredient and the impurities. The identification & quantification of the AI and impurities were determined by HPLC-UV (270 nm). The analytical methods were validated for accuracy, linearity, and precision [MRID No. 467219-01].
6. The data submitted corresponding the guideline reference 830.1800 (enforcement analytical method) satisfy the data requirements of 40CFR§158.180. The purity of the AI in the TGAI was determined by HPLC-UV (270 nm) method. The method was validated for precision, accuracy and linearity [MRID No. 464993-02].
7. The data submitted corresponding to guidelines 830 Series Subgroup B (physical-chemical properties) satisfy the data requirements of 40CFR§158.190, except on one year storage stability (830.6317) & corrosion characteristics (830.6320) studies which are in progress [MRID Nos. See the Table II].

MANUFACTURING PROCESS INFORMATION HAS BEEN REMOVED

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CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for imidacloprid TGAI / MUP and has concluded that:

1. All the product chemistry data submitted corresponding to 830 Series Subgroup A are acceptable.
2. The CSF for basic formulation (dated 11-30-05) is acceptable.
3. The data submitted corresponding to the 830 Series Subgroup B (physical-chemical properties) are acceptable except for one year storage stability (830.6317) & corrosion characteristics (830.6320) studies.
4. The registrant must generate studies corresponding to guidelines 830.6317(one year storage stability) and 830.6320 (corrosion characteristics). The observations must be made at 0, 3, 6, 9, & 12 months intervals during the one year storage stability study. The results must be submitted to the Agency along with an electronic format also.

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830.1550. Product identity & Composition: (MRID No. 467076-01)

Common Name: Imidacloprid

Chemical name (CAS): 1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine
(IUPAC): 1-(6-chloro-3-pyridylmethyl)-N-nitroimidazolidin-2-ylideneamine

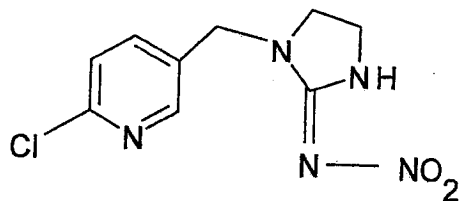
CAS No.: 138261-41-3

PC Code No.: 129099

Empirical formula: $C_9H_{10}ClN_5O_2$

Molecular Weight: 255.7

Structural formula:



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830 Series Subgroup B (Physical-Chemical Properties)

Table 2: Physical and Chemical Properties of : ImidaclopridTGAI/MUP				
GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	467219-02	A	Off white
830.6303	Physical state	" " "	A	Solid Powder
830.6304	Odor	" " "	A	Odor free
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	467219-03 467219-04	A	Stable at 54°C & RT for 14 days & also when treated with Zn dust, potassium dichromate, MAP, & turpentine
830.6314	Oxidation/reduction: chemical incompatibility	467219-04	A	None
830.6315	Flammability		NA	
830.6316	Explosibility		NA	
830.6317	Storage stability	" " "	G	
830.6319	Miscibility		NA	
830.6320	Corrosion characteristics		G	
830.7000	pH	467219-05	A	6.81 ± 0.01 at 20°C
830.7050	UV/Visible absorption	467076-08	A	See Note 1
830.7100	Viscosity		NA	
830.7200	Melting point	467219-06	A	144.1 ± 0.1°C
830.7220	Boiling point		NA	
830.7300	Density	467219-07	A	1.50 ± 0.03 g/ml at 20°C
830.7370	Dissociation constants in water (DC)	e-mail 40-14-06	A	Average value 6.70
830.7550	Partition coefficient	467076-11	A	Log Po/w = 0.617 ± 0.008 @ 20°C
830.7840	Water solubility:	467219-08 467076-13	A	529.4 ppm @ 20°C See Note 2
830.7950	Vapor pressure	e-mail 40-14-06	A	0.077 mPa (15°C); 0.158 mPa (20°C); 0.242 mPa (40°C); 0.098 mPa(20°C)*; 0.125 mPa (25°C)*

A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Upgrade (additional information required)

* values of vapor pressure at 20°C and 25°C were calculated using slope and intercept of regression line.

~~4/17/06 Product Chemistry Review - Imipenem
Technical (MNO #S/46721905 + 46721907)~~

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Pages 8 through 15 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.
- Internal deliberative information.
- Attorney-client communication.
- Claimed confidential by submitter upon submission to the Agency.
- Personal privacy Information

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.