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BARCODE: 315454 Reg. No. : 42750-RNU PRODUCT: Imidacloprid Technical



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OPPTS/OPP/RD/TRB/PRODUCT CHEMISTRY TEAM

WASHINGTON, D.C. 20460

DATE: October 24, 2005

SUBJECT: Product Chemistry Review of Imidacloprid Technical

FROM: Linda L. Kutney
 Product Chemistry Team *Linda L. Kutney 10/24/05*
 Technical Review Branch/RD (7505C) *SLB 10-24-05*

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

DP BARCODE: 315454
EPA REG. NO.: 42750-RNU
REGISTRANT: Albaugh, Inc.
USE: Insecticide
DECISION #: 355130
PC CODE #: 129099

INTRODUCTION:

Albaugh, Inc., has submitted product chemistry data to support the registration of "Imidacloprid Technical," to be produced in the [REDACTED]. The Registrant proposed that this technical insecticide is to be used on food crops listed in 40 CFR 180.472, for imidacloprid. They are also claiming substantial product chemistry similarity to Bayer's product, having Reg No 264-755.

The proposed basic CSF is dated 3/15/05.

The product chemistry data has been submitted under MRIDs 464994-02, -03, and -04.

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SUMMARY OF FINDINGS:

1. All submitted product chemistry guideline studies were satisfactory for the Imidacloprid Technical, Reg No 42750-RNU, except as noted in the conclusions.

TRB CONCLUSIONS:

- 1) "Imidacloprid Technical" is substantially similar to Bayer's product, having Reg No 264-755, with respect to product chemistry.
- 2) The basic CSF for Imidacloprid, dated 3/15/05, is acceptable.
- 3) Guideline 830.1900, Submittal of samples, is required upon registration.
- 4) The Registrant should send a copy of the analytical enforcement method (40CFR§158.180) to the EPA Analytical Lab, 701 Mapes Rd, Ft. Meade, MD, 20755-5350.
- 5) Registration of Imidacloprid is acceptable, from a product chemistry view point, providing the Registrant satisfies the following 830 Series Subgroup B (Physical/Chemical Properties) (40CFR§158.190) guidelines requirements, either via submission of data or via citation of data for the similar product (providing data compensation issues have been adequately addressed) :
 - a) 830.6314 (Oxidation-Reduction)
 - b) 830.6315 (Flammability)
 - c) 830.6316 (Explosibility)
 - d) 830.6317 (Storage Stability) - Required after 0,3,6,12 months of warehouse storage reflecting warehouse storage container and conditions
 - e) 830.6320 (Corrosion Characteristics) - Required after 0,3,6,12 months of warehouse storage reflecting warehouse storage container and conditions
 - f) 830.7370 (Dissociation Constant in water)
 - g) 830.7840 (Water Solubility) - Required for Solubility in Organic Solvents

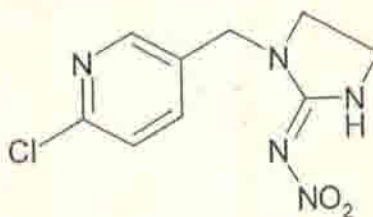
830.1550 PRODUCT IDENTITY-

1. FACT SHEET OF IMIDACLOPRID TECHNICAL

MRID
464994-03
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COMMON NAME: IMIDACLOPRID

STRUCTURAL FORMULA:



EMPIRICAL FORMULA: $C_9H_{10}ClN_5O_2$

RMM: 255.7

CAS REGISTRY NUMBER: 138261-41-3

CHEMICAL NAME:

CHEMICAL ABSTRACTS NAME:

1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine

IUPAC:

1-(6-chloro-3-pyridylmethyl)-N-nitroimidazolidin-2-ylideneamine

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Table 1: Manufacturing and Impurity Data for the TECH T/TGAL.				
GLN	Requirement	MRID	Status ¹	Details and/or Deficiency ²
830. 1550	Product identity and composition	CSF 3-15-05	A	--
830. 1600	Description of materials used to produce product	464994-03	A	The product specifications for the starting materials were submitted.
830. 1650	Description of production process	464994-03	A	The registrant provided detailed information about the synthesis of the technical. Amounts of each starting material and the conditions of the reaction were provided (See Summary in Confidential Appendix)
830. 1670	Discussion of formation of impurities	464994-03	A	The registrant provided the required information on the formation of impurities. No impurities of toxic concern were identified.
830. 1700	Preliminary analysis	464994-02	A	See description in Appendix, Method 0657A, the proposed analytical method was used for analysis of the ai. Methods 0657B-D were used to analyze for impurity content. Average nominal concentrations ranged from 97.2 – 98.4%
830. 1750	Certified limits	CSF 464994-03	A	NC on the CSF agrees with the label claim. The certified limits are acceptable and supported by the preliminary analysis.
830. 1800	Enforcement analytical method	464994-02	A	See description in Appendix HPLC analysis and UV quantification
830. 1900	Submission of Samples	--	N	Provide samples prior to Registration.

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

Table 2: Physical and Chemical Properties *See Note for acceptance condition				
GLN	Requirement	MRID	Status ¹	Result ² or Deficiency
830.6302	Color	464994-04	A	Off-White
830.6303	Physical state	464994-04	A	Crystalline Powder
830.6304	Odor	464994-04	A	None to a faint musty smell
830.6313	Stability to normal and elevated temperatures, metals, and metal ions.	464994-04	A	Thermally stable (up to 54C) to Iron powder, Iron (II) Acetate, Aluminum Powder and 10% Aluminum Acetate stored for up to 14 days.
830.6314	Oxidation Reduction: chemical incompatibility	--	N	Not submitted.
830.6315	Flammability	--	N	Not submitted.
830.6316	Explosibility	--	N	Not submitted.
830.6317	Storage stability	464994-04	N	Stable for 14 days at 54 C Data reflecting storage in commercial packaging under ambient conditions for one year is required, with results reported at 0, 3, 6, 9 and 12 months.
830.6319	Miscibility	464994-04	A	Not required. Solid.
830.6320	Corrosion characteristics	--	N	Testing is required in commercial packaging, under ambient conditions for one year, with results reported at 0, 3, 6, 9 and 12 months; this is usually done concurrently to the storage stability test.

Table 2: Physical and Chemical Properties *See Note for acceptance condition				
GLN	Requirement	MRID	Status ¹	Result ² or Deficiency
830.6321	Dielectric Breakdown Voltage	--	A	Not Required. Not used around electrical equipment.
830.7000	pH	464994-04	A	6.02
830.7050	UV/Visible absorption	464994-04	A	Maximum Molar absorptivity: 4.33 cm ² /mole at 270.0 nm (neutral, pH 7) 4.11 " " 212.0 " 4.33 cm ² /mole at 270.0 nm (acidic pH) 4.11 " " 212.0 " 4.19 cm ² /mole at 217 nm (basic pH) 3.95 " " 267.0 "
830.7100	Viscosity	--	A	NA Technical Not a liquid @ 20°C.
830.7200	Melting point/ Melting range	464994-04	A	141.5 – 142.5 @ 20°C
830.7220	Boiling point/ Boiling range	-	A	NA Not Required. Technical Not a liquid at 20°C
830.7300	Density/ relative density/ bulk density	464994-04	A	1.5613 g/ml @ 20°C
830.7370	Dissociation constants in water	--	N	Not submitted.
830.7520	Particle Size	--	N	Not submitted.
830.7550	Partition coefficient	464994-04	A	log Pow relative to Formamide (rT=1.117min) rT K=CapacityFactor

Table 2: Physical and Chemical Properties *See Note for acceptance condition				
GLN	Requirement	MRID	Status ¹	Result ² or Deficiency
830.7840	Water solubility Solubility in organics	464994-04	N	0.5 for 4-Acetylpyridine 2.320 1.077 1.0 for Acetanilide 2.624 1.349 1.7 for Acetophenone 5.285 3.731 1.9 for Nitrobenzene 6.240 4.586 2.1 for Me Benzoate 11.97 9.712 3.0 for Bromobenzene 34.21 29.63 0.57 for Imidacloprid 2.125 0.902 0.562 in Water at 30 C : 0.576 @ pH 4.0 0.532 @ pH 7.0 0.555 @ pH 9.0 Required for Solubility in Organic Solvents
830.7950	Vapor pressure	464994-04	A	5.2 x 10E-6 Pa @ 25 C
¹ A = Acceptable; N = Not Acceptable (see Deficiency); NA = Not applicable. ² For example, "brown" for 830.6302; "155° C" for 830.7200.				

Page ____ is not included in this copy.

Pages 8 through 9 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.

X 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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