



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OPPTS/OPP/RD/TRB/PRODUCT CHEMISTRY TEAM

WASHINGTON, D.C. 20460

DATE: June 8, 2006

SUBJECT: Product Chemistry Review of ET-016 Technical

FROM: Linda L. Kutney
Product Chemistry Team
Technical Review Branch/RD (7505C)

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

DP BARCODE: 324996
DECISION: 363043
EPA REG. NO.: 81959-RA
REGISTRANT: Etigra LLC
USE: Insecticide
PC CODE: 129099
PRIA CODE: R-31

INTRODUCTION:

In a letter dated 12-6-05, Pyxis Regulatory Consulting, Inc., on behalf of the Registrant, Etigra LLC, has submitted product chemistry data to support the registration of ET-016 Technical. ET-016 contains a label claim of 99.0% imidacloprid and is to be produced in China. The proposed basic CSF is dated 12-5-05.

The Registrant is claiming substantially similarity to Bayer's product, Reg No 264-755, but no offer to pay or compensation has been offered to Bayer.

The product chemistry data has been submitted under MRIDs 467097-01 through 467097-14.

BARCODE: 324996 **REG NO:** 81959-RA **PRODUCT:** ET-016 Technical
SUMMARY OF FINDINGS:

Guideline 830.1900 (Submittal of samples) is required upon registration of the new Chinese site (40CFR 58.190) to the EPA Analytical Lab, 701 Mapes Rd, Ft. Meade, MD, 20755-5350.

1. The current label states that this technical is intended for manufacture of pesticides. All product chemistry requirements for manufacturing products apply.

2. The Registrant requested that the following product chemistry guideline studies be waived because of the substantial similarity to Reg No 264-755, because of the intended packaging and/or because they were not required for a tgai (MRID 467097-14):

- 830.6313 (Stability to Sun, Temps, Metals, Metal Ions)
- 830.6315 (Flammability)
- 830.6316 (Explodability)
- 830.6317 (Storage Stability)
- 830.6319 (Miscibility)
- 830.6320 (Corrosion Characteristics)
- 830.6321 (Dielectric Breakdown)
- 830.7100 (Viscosity)

3. The Registrant requested that the following product chemistry guideline studies be waived because of the substantial similarity to Reg No 264-755 and because the tgai is a solid and the requirements are only for a liquid tgai (MRID 467097-14):

- 830.7220 (Boiling Point)
- 830.7950 (Vapor Pressure)

BARCODE: 324996 **REG NO:** 81959-RA **PRODUCT:** ET-016 Technical
TRB CONCLUSIONS:

1. The proposed technical is not substantially similar to the registered technical having Reg No 264-755, from product chemistry point of view, due primarily to differences in their impurity profiles. Another difference is that the proposed technical also has a density of 0.84 much less than that of the registered technical, 1.54.
2. A potentially toxic nitrosamine derivative was identified as being a possible degradate or impurity, present below the level of 1 ppm (See Confidential Appendix-formation of impurities).
3. The product chemistry data corresponding to guideline reference 830 Series Subgroup B (Physical/Chemical Properties) for the technical satisfy the requirements of 40CFR 158.190 and are acceptable, except as noted below.
4. Because the technical is intended for manufacture of pesticides, all product chemistry requirements for manufacturing products apply. The following waiver requests are therefore not be granted:
 - 830.6315 (Flammability)
 - 830.6316 (Explodability)
 - 830.6317 (Storage Stability)
 - 830.6319 (Miscibility)
 - 830.6320 (Corrosion Characteristics)
 - 830.6321 (Dielectric Breakdown)
5. The following product chemistry guideline studies may be waived because they do not apply to a solid:
 - 830.7100 (Viscosity)
 - 830.7220 (Boiling Point)
 - 830.7950 (Vapor Pressure)
6. The proposed label contains extra verbage in its storage and disposal statement. The phrase "or by incineration" should be deleted from the sentences, "Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke."
7. Samples must be submitted to the EPA Analytical Laboratory in Fort Meade prior to registration.

Table 1: Manufacturing and Impurity Data

GLN	Requirement	MRID	Status ¹	Details
830.1550	Product identity and composition	CSF	A	The nominal concentration of tgai and all certified limits on the CSF are supported by the 5-batch analysis.
830.1600	Description of materials used to produce product	46709701	A	The product specification sheets (MSDS) for the starting materials were submitted.
830.1650	Description of production process	46709701	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 description in Confidential Appendix).
830.1670	Discussion of formation of impurities	46709701	A	The required information was submitted. A potentially toxic nitrosamine derivative was identified as a possible impurity, present below 1 ppm (See Confidential Appendix).
830.1700	Preliminary analysis	46709702	A	See summary in Confidential Appendix. HPLC analysis
830.1750	Certified limits	46709702	A	The nominal concentration of tgai and all certified limits on the CSF are supported by the 5-batch analysis. (See Confidential Appendix).
830.1800	Enforcement analytical method	46709702	A	See description in Appendix HPLC analysis
830.1900	Submission of Samples	-	N	Provide samples prior to Registration.

¹ A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable.

Table 2: Physical and Chemical Properties

GLN	Requirement	MRID	Status ¹	Result ² or Deficiency
830.6302	Color	467097-03	A	Off-White
830.6303	Physical state	467097-03	A	Powder
830.6304	Odor	467097-03	A	Weak Characteristic
830.6313	Stability to normal and elevated temperatures, metals, and metal ions.	467097-14	A	Must be submitted for an MUP. Testing of stability to metals and metal ions may be waived (metal containers are not used).
830.6314	Oxidation Reduction: chemical incompatibility	467097-05	A	Stability at 54 ± 2C for 14 days with no or little change in appearance, pH, %ai and water content.
830.6315	Flammability	467097-14	N	Stable to oxidizing or reducing agents (water, kerosene, potassium permanganate, monoammonium phosphate, zinc powder).
830.6316	Explodability	467097-14	N	Must be submitted for a Manufacturing Use Product.
830.6317	Storage stability	467097-14	N	Must be submitted for a Manufacturing Use Product. Data reflecting storage in commercial packaging under ambient conditions for one year is required, with results reported at 0,

Table 2: Physical and Chemical Properties

GLN	Requirement	MRID	Status ¹	Result ² or Deficiency
				3, 6, 9 and 12 months.
830.6319	Miscibility	467097-14	N	Must be submitted for a Manufacturing Use Product.
830.6320	Corrosion characteristics	467097-14	N	Must be submitted for a Manufacturing Use Product. 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 with the storage stability test.
830.6321	Dielectric Breakdown Voltage	467097-14	N	Must be submitted for a Manufacturing Use Product.
830.7000	pH	467097-06	A	6.73 ± 0.03
830.7050	UV/Visible absorption	467097-07	A	Molar absorption Coefficients: pH 6.85: 13718.8 @ 212.0 nm, Abs. 0.605 22789.1 @ 270.0 nm, Abs. 1.005 pH 1.70: 12316.8 @ 212.0 nm, Abs 0.521 21631.2 @ 270.0 nm, Abs 0.915 pH 12.38: 10638.3 @ 219.0 nm, Abs 0.450 13286.1 @ 268.0 nm, Abs 0.562
830.7100	Viscosity	467097-03	A	NA Technical Not a liquid @ 20°C.
830.7200	Melting point/ Melting range	467097-08	A	143.6 ± 0.1 °C
830.7220	Boiling point/ Boiling range	467097-14	A	NA Solid

Table 2: Physical and Chemical Properties

GLN	Requirement	MRID	Status ¹	Result ² or Deficiency
830 7370	Dissociation constant-water	467097-10	A	NA Did not dissociate in acid or base. Has no dissociation constant.
830. 7550	Partition coefficient	467097-11	A	log Pow = 0.58 ± 0.01
830. 7840	Water solubility: volumetric flask method	467097-12	A	0.72 g/L @ pH 5.0 0.61 g/L @ pH 7.0 0.62 g/L @ pH 9.0
	Solubility in organic solvents	467097-13	A	8.58 g/l in Methanol 0.77 g/L in n-Octanol 0.0427 g/L in Hexane
830. 7950	Vapor pressure	467097-14	A	NA Solid

¹ A = Acceptable; N = Not Acceptable (see Deficiency); NA = Not applicable.

~~6/8/16 Product Chemistry Review - ET-016 Technical~~
(memo #s 46709706 & 46709709)

Page _____ is not included in this copy.

Pages 10 through 18 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.