

Manufacturing process information may be entitled to confidential treatment

DATE OUT: 28 / January / 2008

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [X] EP []**
DP BARCODE No.: D344226 **EPA File Symbol No.:** 83851-L
PRODUCT NAME: Technical Imidacloprid
COMPANY: AmTide LLC.
FOOD USE [X] INTEGRATED FORMULATION []
PCC: 129099 **Decision No.** 383557
ACTION CODE: **R31**

FROM: Hari Mukhoty,
Product Chemistry Team
Technical Review Branch / RD (7505P)

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Handwritten initials and date: SJM 01/31/08

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

INTRODUCTION:

The Registrant has submitted a basic CSF for a new technical product, and has proposed a product specific label (both dated 9/6/2007) to support the registration of the proposed technical product under EPA File Symbol 83851-L. The registrant has claimed that the proposed technical product is substantially similar (me-too) in composition and labeling to the product under EPA Reg. No. 81959-16. TRB has reviewed the product chemistry data for the cited product on 6/8/2006 and has concluded that the cited product can be registered provided the registrant fulfills some Group B data requirements indicated in the review. The cited product is now conditionally registered. The label for the cited product was reviewed and found acceptable on 4/13/2007. The registrant submitted product chemistry data corresponding to Group A and Group B under MRID 472270-01, -02, -03 and -04. This proposed technical product may also be used for formulating into insecticide end-use products for terrestrial food crops.

The registrant did not provide any information to TRB with respect to the toxicological significance of impurities associated with the proposed technical product.

The TRB has been requested to evaluate the product chemistry data submitted for registration of the proposed product and to determine if the cited product is substantially similar to the proposed technical product.

SUMMARY OF FINDINGS:

1. The purity of the active ingredient in the product has been claimed to be 99.0%. The overall mean of five batch analysis is 99.92%. The registrant chose the nominal concentration at 99.0% to allow little room for the fluctuations of total impurities which ranged between [REDACTED]
2. The nominal concentration of the active ingredient in the proposed product is 99.0%. The certified limit of the nominal concentration is in compliance with 40 CFR§ 158.175 (b) (2).
3. The CSF of the basic formulation (dated 9/6/2007) is filled out completely and correctly. The nominal concentration of the active ingredient matches with the label claim. The CSF is in compliance with PR Notice 91-2.

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4. The data submitted for Subgroup A corresponding to guidelines 830.1550 (product identity and composition, 830.1600 (materials used to produce the product), 830.1620 (description of production process), 830.1670 (discussion of formation of impurities), 830.1750 (certified limits) satisfy the product chemistry data requirements of 40 CFR §158.320, 158.325, 158.330, 158.340, and 158.350 respectively [MRID 472270-01].

5. The method used corresponding to guideline 830.1700 (preliminary analysis) satisfy the data requirements of 40 CFR§158.345. The HPLC method was used to quantify the active ingredient and its associated impurities. Agilent 1100 series with PDA detector was used. The type of column used was Kromosil, C-18 [250 mm x 4.6 mm (i.d.), 5.0 µm particle size] and the detector was set at 252 nm wavelength. The specificity of imidacloprid and the associated impurities were also confirmed by HPLC and LC-MS separately. The aforesaid method can also be used to comply with 830.1800 of 40 CFR§158.355 [MRID 47227002].

6. The proposed technical product is considered substantially similar to the cited product because it is similar in composition and labeling to currently-registered cited product in ways that would not significantly increase the risk of unreasonable adverse effects on the environment [FIFRA 3(c) (3) (B) (1)].

7. The product chemistry data submitted for Group A for the proposed product are acceptable. Group B data from the cited product, with the exception of storage stability (830.6317) and corrosion characteristics (830.6320) studies, can be used to support the registration of the proposed technical product because the aforesaid two products are substantially similar [MRID Nos 47227001, - 03 and -04].

CONCLUSIONS:

1. TRB has reviewed the proposed basic CSF (dated 09/06/2007) for proposed technical product and has found it to be acceptable.

2. The product chemistry data submitted for the guidelines 830 Series Group A and Group B, with the exception of storage stability (830.6317) and corrosion characteristics (830.6320), are acceptable.

3. The registrant shall generate one year storage stability (830.6317) and corrosion characteristics (830.6320) data on the proposed product. It is required that the storage stability and corrosion characteristics observations be made at 0, 3, 6, 9, and 12 month intervals. The results must be submitted to the Agency in the electronic format and as well as a hard copy.

4. The registrant is required to give information with respect to the toxicological significance of the impurities associated with the active ingredient of the proposed product. However, the applicant did not provide any such information and therefore TRB is taking a disclaimer on that.

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PRODUCT CHEMISTRY DATA (SERIES 830 Group A)

Subgroup A	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity	A	47227001
830.1600. Beginning Materials	A	47227001
830.1620. Production Process	A	47227001
830.1670. Discussion of Impurities	A	47227001
830.1700. Preliminary Analysis	A	47227002
830.1750. Certified Limits (Basic CSF dated 9/6/2007)	A	47227001
830.1800. Enforcement Analytical Method	A	47227002

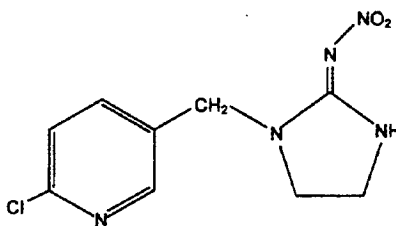
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~~CONFIDENTIAL APPENDIX~~

(830-1550) Product identity

Technical Imidacloprid contains 99.0% 1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine (CAS), (CAS No. 138261-41-3, Chemical Code 129099), and is substantially similar to Bayer CropScience's Imidacloprid Technical Insecticide, EPA Reg. No. 264-755.

The IUPAC name of imidacloprid is 1-(6-chloro-3-pyridylmethyl)-N-nitroimidazolidin-2-ylideneamine. The molecular formula for imidacloprid is $C_9H_{10}ClN_5O_2$ and it has a molecular weight of 255.7. Its structural formula is shown below:



Imidacloprid

Imidacloprid is a neonicotinoid insecticide that controls sucking insects by binding to postsynaptic nicotinic receptors in the insect's central nervous system. It is systemic in plants, and is a contact and stomach poison in insects. It is used as a seed treatment, as a soil treatment and as a foliar treatment in a variety of food crops and in ornamental plants. It is also effective against termites.

The detailed composition of Technical Imidacloprid is presented on a Confidential Statement of Formula, EPA Form 8570-4, which has been removed to the Confidential Attachment at Cross Reference Number 1.

Page _____ is not included in this copy.

Pages 5 through 13 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.

* 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.
