

US EPA ARCHIVE DOCUMENT

**DP BARCODE No.:** D344537; **REG. No.:** 42750-104; **PRODUCT NAME:** Imidacloprid Technical

**DATE:** 28 / DEC /2007

**SUBJECT:** **FEE.PRODUCT CHEMISTRY REVIEW OF TGAI/MP [X] EP [ ]**  
**DP BARCODE No.:** D344537 **REG. No.:** 42750-104  
**PRODUCT NAME:** Imidacloprid Technical  
**COMPANY:** Albaugh Incorporation  
**PCC:** 129099; **Decision No.:** 384226; **ACTION CODE:** R34  
**FOOD USE [X]**  
**INTEGRATED FORMULATION: Yes [X] No [ ]**

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

*S. Mathur*  
*12/28/07*  
*m*

**TO:** Kable Davis / Venus Eagle, RM 01  
Insecticide-Rodenticide Branch / RD (7505P)

### INTRODUCTION

The registrant has submitted an application to amend the registration of the imidacloprid technical produced at an alternate production site [REDACTED]. The amendment reflects the production of the TGAI/MUP by [REDACTED]. In support of this amendment, the registrant has submitted an alternate formulation CSF #1 (dated 09-14-07) supported by five batch analysis under MRID No. 472323-01. The basic formulation CSF (dated 03-15-07) indicated the production site for the TGAI/MUP [REDACTED]. TRB has been asked to evaluate the CSF for alternate formulation and the supporting product chemistry data and determine their acceptability.

### SUMMARY OF FINDINGS

1. The nominal concentration of the active ingredient imidacloprid in the alternate formulation is 98.0%. The average concentration of the active ingredient was found to be 98.0% as determined by five batch analysis. The product label claim for the active ingredient is 98.0%.
2. The alternate formulation CSF #1(dated 09-14-07) is filled out correctly and completely. The nominal concentration of the active ingredient (98%) concurs with the product label claim nominal concentration (98.0%). The alternate CSF #1 is in compliance with PR Notice 91-2 and 40CFR§152.43. The impurity profile of the accepted basic CSF (dated 03-15-05) and the proposed alternate CSF#1 (dated 09-14-07) is very similar. Both the CSF's have same impurities and which differ slightly in their concentration levels. The physical-chemical characteristics mentioned on the CSF's are very similar.
3. The product chemistry data submitted corresponding to guideline 830.1700 (preliminary analysis) supports the proposed alternate CSF#1 (dated 09-14-07). The five batches of imidacloprid TGAI/MUP, produced at new facility [REDACTED] were analyzed to determine: the active ingredient purity profile (Albaugh's Analytical Methods No. 0657B & 0657D), quantification of the AI by Albaugh's Analytical Method No. 0657A, and identification and quantification of impurities. The impurities were identified by MS/LC and quantified against an imidacloprid analytical standard using Albaugh's Analytical Methods No. 0657B & 0657D. The analytical methods were validated for precision, linearity, accuracy, LOD, and LOQ under the experimental parameters [MRID No. 472323-01].

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**CONCLUSIONS**

TRB has evaluated the product chemistry data submitted to support the alternate formulation CSF #1 (dated 9-14-07) and has determined that:

1. The data submitted for the guideline 830.1700 (preliminary analysis) is acceptable.
2. The data submitted for five batch analysis supports the proposed alternate formulation CSF #1 (dated 09-14-07). The proposed alternate formulation CSF #1 is substantially similar to the accepted CSF for basic formulation (dated 3-15-05) in chemical composition and physical-chemical characteristics. The proposed alternate CSF #1 (dated 9-14-07) is acceptable.

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830.1550. Product Identity & composition: (MRID No. 472323-01)

Common name: Imidacloprid

IUPAC Chemical Name: 1-(6-chloro-3-pyridylmethyl)-*N*-nitroimidazolidin-2-ylideneamine

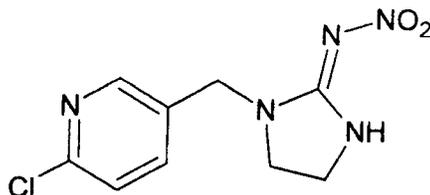
Empirical Formula:  $C_9H_{10}ClN_5O_2$

Molecular Weight: 255.661

CAS Number: 138261-41-3

Molecular weight: 255.661

Chemical Structure:



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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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