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)

12/28/07

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].

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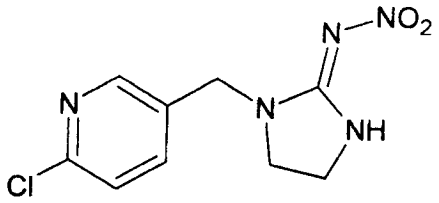
830.1550. Product Identity & composition: (MRID No. 472323-01)

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:



Page __4__ is not included in this copy.

Pages _____ through ___ 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.

__X__ 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.

Page ___ is not included in this copy.

Pages __5___ through __14__ 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.

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