INTRODUCTION

The registrant has submitted an application to amend the registration of the imidacloprid technical produced at an alternate production site. The amendment reflects the production of the TGAI/MUP by TRB. 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 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 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].
DP BARCODE No.: D344537; REG. No.: 42750-104; PRODUCT NAME: Imidacloprid Technical

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.
Common name: Imidacloprid

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

Empirical Formula: C₉H₁₀ClN₃O₂
Molecular Weight: 255.661
CAS Number: 138261-41-3
Molecular weight: 255.661

Chemical Structure:
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.

• 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.
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.