Manufacturing process information may be entitled to confidential treatment

DP BARCODE No.: <u>D336942</u> REG. No.: <u>70506-122</u> PRODUCT NAME: <u>UPI Imidacloprid Technical</u>

<u>Insecticide</u>

DATE: 05 / SEP / 2007

SUBJECT: PRODUCT CHEMISTRY REVIEW OF TGAI/MP [X] EP []

DP BARCODE No.: <u>D336942</u> REG. No.: 70506-122 PRODUCT NAME: <u>UPI Imidacloprid technical Insecticide</u>

COMPANY: United Phosphorous Incorporation

PCC: 129099; Decision No.: 375022; ACTION CODE: 570

FOOD USE []; MRID No: 470442-01

INTEGRATED FORMULATION: Yes [X] No []

FROM: Shyam B. Mathur,

Product Chemistry Team Leader Technical Review Branch/RD (7505P)

TO: Dani Daniel / John Hebert, RM 07

Insecticide-Rodenticide Branch / RD (7505P)

INTRODUCTION

The product chemistry data for the proposed UPI Imidacloprid TGAI/MUP were reviewed previously (see PCR dated 10-30-06; DP329849). In this report it was determined that all the product chemistry requirements are fulfilled, except for the guideline 830.1620 (description of production process). The registrant was informed that additional data on this guideline are required to satisfy the data requirements. On January 23, 2007, the registrant submitted the additional information on the guideline 830.1620 for the evaluation by the Agency. TRB has been asked to evaluate the additional data submitted and determine its acceptability.

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SUMMARY OF FINDINGS

- 1. The nominal concentration of the active ingredient in the proposed TGAI/MUP is 98% which concurs with the product label claim nominal concentration.
- 2. As described in previous report (MRID No. 46833501; DP 329849) the imidacloprid 98% TGAI/MUP is produced by United Phosphorous, Ltd. at its plant in Gujarat, India by a the equipment types, duration of each process step, chemical reactions, and a process flow chart which indicated recovered effluents were provided. The additional information provided in MRID No. 470442-01 described the amounts of the chemicals used in each step of the synthesis and the yields of the products obtained in each step of the synthesis. The data submitted corresponding to guideline 830.1620 (description of production process) satisfy the data requirements of 40CFR§158.162.

CONCLUSIONS

TRB has evaluated the additional data submitted for the guideline 830.1620 (description of manufacturing process) and has concluded that it is acceptable. All the product chemistry data requirements for the proposed UPI Imidacloprid TGAI/MUP are now satisfied.

Page _	is not included in this copy.
Pages	2 through 4 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 1	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)
r	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.

 $^{^{\}star}$ 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.