INTRODUCTION

The product chemistry data for the proposed UPI Imdacloprid TGA/MUP were reviewed previously (see PCR dated 10-30-06; DP 329849). 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.

SUMMARY OF FINDINGS

1. The nominal concentration of the active ingredient in the proposed TGA/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% TGA/MUP is produced by United Phosphorous, Ltd. at its plant in Gujarat, India by a [REDACTED] 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 Imdacloprid TGA/MUP are now satisfied.
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.