DATE OUT: 14 Sept 2005

SUBJECT: **EP [x] MP [ ] PRODUCT CHEMISTRY REVIEW**
DP BARCODE No.: D318499
REG./File Symbol No.: 81598-R
PRODUCT NAME: Rotam Abamectin Technical
COMPANY: Rotam Ltd.
FOOD USE: [ ] **PC CODE:** **122804**
Decision No. **350156** **Integrated Formulation [x]**

TO: RM #07, John Herbert/Thomas Harris
Insecticide-Rodenticide Branch
Registration Division (7505C)

FROM: Bruce F. Kitchens, Chemist
Technical Review Branch
Registration Division (7505C)

INTRODUCTION:

The registrant, Rotam Limited, is responding to a previous product chemistry review for the proposed manufacturing use product, Rotam Abamectin Technical. In that review, it was determined that a revised Confidential Statement of Formula (CSF) would have to be submitted to correct an error. In addition, the registrant has submitted additional preliminary analysis data for Rotam Abamectin Technical. TRB has also been asked to determine if the proposed product is substantially similar to EPA Reg. No. 100-895 Abamectin Technical. The active ingredient in this product is Abamectin at a label nominal concentration of 98.0%. This product is intended for use in the manufacture of insecticide end use products. In support of this request, the registrant has submitted a revised basic Confidential Statement of Formula (CSF) dated 02 June 2005, a draft label, and product chemistry data contained in MRID#s 465557-01 and 465634-01. The data contained in MRID# 465634-01 is intended to replace data contained in MRID# 465503-01. The Technical Review Branch (TRB) has been asked to review this submission.

SUMMARY OF FINDINGS:

TRB has reviewed this submission and reports the following findings:

1. This product is produced from an integrated formulation process. This means that the active ingredient is the result of intended chemical reactions. In addition, the manufacturing process has been modified to produce the

higher purity product. See confidential appendix for details.

2. The impurity profile has been adequately described. The registrant has not declared any impurities of toxicological concern.

3. The nominal concentration of the active ingredient listed on the proposed basic CSF and the draft label are the same.

4. The active ingredients' certified limits as proposed on the basic CSF are acceptable.

5. The comparison of the cited and proposed product reveals that both products have the same active ingredient, both products have different active ingredient concentrations 90% vs 98%, and both products have four common impurities while the cited product has eight impurities not found in the proposed product. Wider certified limits for the cited product were proposed and accepted by the Agency. The justification for the wider certified limits was based on manufacturing process variability.

CONCLUSIONS:

TRB has reviewed this submission and concludes the following:

1. The basic formula CSF for the proposed manufacturing use product, Rotam Abamectin Technical dated 02 June 2005 is acceptable.

2. This submission satisfies the data requirements as specified in 40 CFR 158.155, 158.160, 158.162, 158.167, 158.170, 158.175, and 158.180 with respect to product identity and composition, description of materials used to produce the product, description of production process, discussion of formation of impurities, preliminary analysis, certified limits, and enforcement analytical method.

3. This product has been determined to be substantially similar to EPA Reg. No. 100-895 Abamectin Technical MK-936 from a product chemistry standpoint only. While the active ingredient nominal concentrations are different, the proposed product's active ingredient nominal concentration falls within the active ingredient certified limits of the cited product.

PRODUCT CHEMISTRY DATA (GROUP A)

21. **Chemical IDs/Manufacture/ Analytical Information**	**Data Required Fulfilled**	**MRID No.**
830-1550 Product Identity and Composition	Y	465634-01
830-1600 Description of Materials Used to Produce the Product	Y	465634-01
830-1620 Description of Production Process	Y	465634-01
830-1650 Description of Formulation Process	NA	
830-1670 Discussion of Impurities	Y	465634-01
830-1700 Preliminary Analysis	Y	465557-01
830-1750 Certified Limits	Y	465634-01
830-1800 Enforcement Analytical Method	Y	465634-01

DER for

MRID #46555701 + 46563401

Page 4 is not included in this copy.

Pages _____ through _____ are not included.

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.

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.