UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

16/DEC/2005

MEMORANDUM

Subject:	Name of Pesticide Product:	Rotam Abamectin Technical	
	EPA File Symbol:	81598-R	
	DP Barcode:	D324491	
	Decision No.:	350156	
	PC Code:	122804	Abamectin

From: Eugenia McAndrew, Biologist
Technical Review Branch
Registration Division (7505C)

To: Thomas Harris, RM Team 07
Insecticide-Rodenticide Branch
Registration Division (7505C)

Applicant: Rotam LTD
7/F, Cheung Lee Street
Chai Wan, Hong Kong

FORMULATION FROM LABEL:

Active Ingredient:			% by wt.
122804	Abamectin	CAS No. 65195-56-4 and 65195-55-3	94.0%
Inert Ingredients:			6.0%
		Total:	100.0%

ACTION REQUESTED:

The Product Manager requests:

> This is a new generic technical. The original submission included product chemistry, acute product toxicology and a CSF dated 10/15/04. The company revised the CSF on 6/2/05. They redid the product chemistry but did not redo the acute product toxicology. The new CSF is higher % a.i. (went from 94% to 98%) and has fewer impurities (see CSF). The original formula was already a DANGER signal word.
>
> I need a memo addressing two issues:
>
> 1) State that the Rotam technical 81598-R is substantially similar to the Syngenta technical 100-895 from an acute toxicology viewpoint.
>
> 2) Address whether all or some of the acute tox studies done on the original CSF can be used with the new CSF.

BACKGROUND:

Rotam LTD previously submitted acute oral toxicity, acute dermal toxicity, primary eye irritation, primary skin irritation and dermal sensitization studies in support of registration of Rotam Abamectin Technical, EPA File Symbol 81598-R. The five studies were reviewed and classified as acceptable in a prior TRB memo (Hanson; D310857; EPA File Symbol 81598-R; 17/DEC/2004). No acute inhalation study was submitted. The company claimed similarity to another technical, Affirm Technical, EPA Reg. No. 100-895. The acute inhalation toxicity study was cited from 100-895. The CSF submitted was dated October 14, 2004 with 94% a.i.

Rotam Ltd. has now submitted a revised CSF dated June 2, 2005 with 98% a.i. The label claim on both the original and revised CSFs is 94% a.i. The Risk Manager is asking if the acute toxicity data referenced above may be used to support registration of the revised formulation.

RECOMMENDATIONS:

We have compared the CSFs of the original and revised formulations. Even though the % of active ingredient is higher in the revised CSF, we do not believe that the increase in a.i. warrants the need for new acute toxicity studies. The acute toxicity data submitted previously (MRID 463850-06 to -10) may be used to support registration of the proposed product. The signal word will remain DANGER.

For purposes of acute inhalation toxicity, the proposed product, 81598-R, is substantially similar to the cited product, 100-895. The acute inhalation toxicity study cited from 100-895 (MRID 45623010) may be used to support registration of 81598-R.

The label claim for the % of a.i. must agree with the CSF, i.e., 98%.

The acute toxicity profile for Rotam Abamectin Technical, EPA File Symbol 81598-R, is:

Acute oral toxicity	I	Acceptable	MRID 46385006
Acute dermal toxicity	IV	Acceptable	MRID 46385007
Acute inhalation toxicity	II	Cited	MRID 45623501
Primary eye irritation	III	Acceptable	MRID 46385008
Primary skin irritation	IV	Acceptable	MRID 46385009
Dermal sensitization	Negative	Acceptable	MRID 46385010

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

PRODUCT ID #: 081598-00001

PRODUCT NAME: Rotam Abamectin Technical

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals:

SIGNAL WORD: DANGER POISON ☠

Restricted Use Pesticide due to toxicity categories. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.

Fatal if swallowed. May be fatal if inhaled. Causes moderate eye irritation. Do not breathe dust. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

First Aid:

If swallowed:
-Call a poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to by a poison control center or doctor.
-Do not give anything to an unconscious person.

If inhaled:
-Move the person to fresh air.
-If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
-Call a poison control center or doctor for further treatment advice.

If in eyes:
-Hold eye open and rinse slowly and gently with water for 15-20 minutes.
-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
-Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: Note to RM/Registrant: The proposed label should contain a Note to Physician which addresses the category I Acute Oral Toxicity. The following statements are suggested types of information that may be included, if applicable:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.