US EPA ARCHIVE DOCUMENT

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

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 17, 2004

MEMORANDUM

Subject:	Name of Pesticide Product:	Abamectin Technical	
	EPA File Symbol:	81598-R	
	DP Barcode:	D310857	
	Decision No.:	350156	
	PC Code:	122804	Abamectin

From: Breann Hanson, Toxicologist
Technical Review Branch
Registration Division (7505C)

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

Applicant: Rotam Ltd.
7F., Cheung Tat Centre
18 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:

"Generic avermectin technical - Rotam. ACUTE TOXICOLOGY. Please review acute toxicology studies for new generic avermectin technical. MRIDs 463850-06, 463850-07, 463850-08, 463850-09, 463850-10. No study for inhalation, not sure why. Claims similarity to 100-895."

BACKGROUND: Rotam Ltd. has submitted a five pack of acute toxicity studies in support of registration for Abamectin Technical, EPA File Symbol: 81598-R. No acute inhalation study was submitted. The company claims similarity to another technical, Abamectin Technical, MK-936, EPA Reg. No. 100-895. The submission included a CSF and label for both the proposed and cited products, letter from the company and application. The studies were conducted at Huntingdon Life Sciences Ltd., Cambridgeshire, England with assigned MRID numbers 463850-06 through -10. The acute inhalation study for the cited product, 100-895, was previously reviewed in a TRB memo (Redden, D282622, EPA Reg. No. 100-895, 30/MAY/2002), which was then revisited in a 2004 TRB memo (Backus, D307721, EPA Reg. No. 100-895, 10/SEP/2004) in order to change the toxicity category of the study. Both the proposed and cited products are technical, MUPs.

RECOMMENDATIONS: The five studies have been reviewed and are classified as acceptable. The acute inhalation toxicity study mentioned above may be bridged to this product. The acute toxicity profile for 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: 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 PM/CRM/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.

Reviewer: Breann Hanson **Date:** Dec. 17, 2004
Risk Manager (EPA): Thomas Harris, RM 07

STUDY TYPE: Acute Oral Toxicity - SD rat; OPPTS 870.1100; OECD 423

TEST MATERIAL: Abamectin Technical (Avermectin b1a: 80%, Avermectin B1b: 20%; Batch#

625d; off white powder)

CITATION: Blanchard, E. (2002). Abamectin Technical Acute Oral Toxicity to the Rat (Acute Toxic Class Method). Project identity: LDA/042. Unpublished study prepared by Huntingdon Life Sciences Ltd. March 19, 2002. MRID 46386706.

SPONSOR: Rotam Ltd., 7F., Cheung Tat Centre, 18 Cheung Lee Street, Chai Wan, Hong Kong

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 46385006), 3 female Sprague-Dawley rats (Strain: CD, Age: 8-11 weeks, Weight: 218-221 g; Source: Charles River UK Ltd., Kent, England) were given a single oral dose of Abamectin Technical (Avermectin b1a: 80%, Avermectin B1b: 20%; Batcht#625d; off white powder) by oral gavage. The test material was formulated in corn oil and administered to the test animals at a dose of 50 mg/kg. Due to mortalities noted at this dosage no additional animals were dosed. Individual animal body weights were recorded prior to test substance administration and after death. Clinical checks for mortality were made at least twice daily. Checks for clinical signs of toxicity were made soon frequently on the initial study day, as well as for subsequent days. All animals were necropsied after death.

Two animals died on either study day 2 or 3 while the remaining animal was killed on humane grounds on study day 3. Loss in body weights were noted for all animals. Clinical signs of toxicity noted prior to death included loose faeces, body tremors, piloerection, abnormal gait, lethargy and irregular respiration. Two animals were also noted as having brown staining on the muzzle, shallow respiration, hunched posture, partially closed eyelids, reduced body temperature, irritable behaviour and prostration. was decreased activity on the initial study day. The remaining animal was noted as having swollen muzzle, flat posture, increased salivation and reduced body tone. These signs were noted in one animal immediately after dosing and 4 hours post-dosing in the remaining two animals. At necropsy, congestion of the brain or liver with thickened tissues of the heart, pallor of the liver and kidneys and atrophy of the spleen and caecum were noted. Also noted were congestion and fluid contents in the stomach and along the alimentary tract.

Oral LD_{50} Females < 50 mg/kg

Based on the LD_{50} in female rats, Abamectin Technical is classified as EPA Toxicity Category I.

This acute oral study is classified as acceptable. It does satisfy the guideline requirement for an acute oral study (OPPTS 870.1100; OECD 423) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Individual animals were dosed as follows:

Main Test

Animal No.	Sex	Dose level (mg/kg)	Sort-Term Outcome	Long-Term Outcome
FF1	F	50	D	D
FF2			D	D
FF3			D	D

S = survival D = death

A. Mortality - As noted in table.

B. Clinical observations - Two animals died on either study day 2 or 3 while the remaining animal was killed on humane grounds on study day 3. Loss in body weights were noted for all animals. Clinical signs of toxicity noted prior to death included loose faeces, body tremors, piloerection, abnormal gait, lethargy and irregular respiration. Two animals were also noted as having brown staining on the muzzle, shallow respiration, hunched posture, partially closed eyelids, reduced body temperature, irritable behaviour and prostration. was decreased activity on the initial study day. The remaining animal was noted as having swollen muzzle, flat posture, increased salivation and reduced body tone. These signs were noted in one animal immediately after dosing and 4 hours post-dosing in the remaining two animals.

C. Gross Necropsy - At necropsy, congestion of the brain or liver with thickened tissues of the heart, pallor of the liver and kidneys and atrophy of the spleen and caecum were noted. Also noted were congestion and fluid contents in the stomach and along the alimentary tract.

D. Reviewer's Conclusions: Agree with study author.

Reviewer: Breann Hanson **Date:** Dec. 17, 2004
Risk Manager (EPA): Thomas Harris, RM 07

STUDY TYPE: Acute Dermal Toxicity - SD Rat; OPPTS 870.1200; OECD 402

TEST MATERIAL: Abamectin Technical (Avermectin b1a: 80%, Avermectin B1b: 20%; Batch# 625d; off white powder)

CITATION: Blanchard, E. (2002) Abamectin Technical Acute Dermal Toxicity to the Rat. Project identity: LDA/043. Unpublished study prepared by Huntingdon Life Sciences Ltd. March 19, 2002. MRID 46385007.

SPONSOR: Rotam Ltd., 7F., Cheung Tat Centre, 18 Cheung Lee Street, Chai Wan, Hong Kong

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 46385007), 5/sex of Sprague-Dawley rats (Strain: CD; Age: 8-11 weeks; Weight: 252-263 g males, 241-252 g females; Source: Charles River UK Ltd., Kent, England) were dermally exposed to a single application of Abamectin Technical (Avermectin b1a: 80%, Avermectin B1b: 20%; Batch# 625d; off white powder) at 5,000 mg/kg. The test material was formulated in corn oil and applied to each exposure area, not less than 10% of the total BSA, covered with a porous gauze and then covered with a waterproof dressing for 24 hours. Individual animal body weights were recorded prior to test substance administration and again on days 8 and 15, or after death. Clinical checks for mortality were made twice daily. Checks for signs of toxicity and behavioural changes were made at frequent intervals on day 1 and twice daily thereafter for 15 days. Checks for dermal irritation were also made daily. All animals were necropsied on study day 15, or after death.

One female died on study day 9. This animal showed body weight loss. At necropsy congestion of the subcutaneous tissue, brain, heart and spleen with pallor of the kidneys and congestion in the stomach and along the alimentary tract were noted in this animal.

1/5 males and 4/5 females were noted as having body weight loss on study day 8, while the remaining female had low body weight gain on study day 15. No gross internal findings were observed at necropsy for the surviving animals.

Clinical signs of toxicity noted in all animals included irritable behaviour, hunched posture, piloerection and lethargy. Additionally, body tremors, abnormal gait, increased salivation, partially closed eyelids, flat posture, fast respiration and rales, ungroomed appearance, red rimmed eyelids, dull eyes and thin build were observed during the study. Signs of toxicity were first noted on study day 2 and persisted until study day 10 in some animals. Piloerection was still noted at study termination in 1 male and 1 female.

Dermal LD_{50} Males => 5,000 mg/kg
Females => 5,000 mg/kg
Combined => 5,000 mg/kg

Based on the LD_{50} of 5,000 mg/kg, Abamectin Technical is classified as EPA Toxicity Category IV.

This acute dermal study is classified acceptable. It does satisfy the guideline requirement for an acute dermal study (OPPTS 870.1200; OECD 402) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Dose (mg/kg)	Mortality/Number Tested		
	Males	Females	Combined
5000	0/5	1/5	1/10

A. Mortality - As noted in table.

B. Clinical observations - One female died on study day 9 and showed body weight loss.

1/5 males and 4/5 females were noted as having body weight loss on study day 8, while the remaining female had low body weight gain on study day 15.

Clinical signs of toxicity noted in all animals included irritable behaviour, hunched posture, piloerection and lethargy. Additionally, body tremors, abnormal gait, increased salivation, partially closed eyelids, flat posture, fast respiration and rales, ungroomed appearance, red rimmed eyelids, dull eyes and thin build were observed during the study. Signs of toxicity were first noted on study day 2 and persisted until study day 10 in some animals. Piloerection was still noted at study termination in 1 male and 1 female.

C. Gross Necropsy - At necropsy for the one female that died during the study, congestion of the subcutaneous tissue, brain, heart and spleen with pallor of the kidneys and congestion in the stomach and along the alimentary tract were noted in this animal. No gross internal findings were observed at necropsy for the surviving animals.

D. Reviewer's Conclusions: Agree with study author.

Reviewer: Breann Hanson **Date:** Dec. 17, 2004
Risk Manager (EPA): Thomas Harris, RM 07

STUDY TYPE: Primary Eye Irritation - NZW Rabbit, OPPTS 870.2400; OECD 405

TEST MATERIAL: Abamectin Technical (Avermectin b1a: 80%, Avermectin B1b: 20%; Batch# 625d; off white powder)

CITATION: Blanchard, E. (2002) Abamectin Technical Eye Irritation Study to the Rabbit. Project identity: LDA/045. Unpublished study prepared by Huntingdon Life Sciences Ltd. March 19, 2002. MRID 46385008.

SPONSOR: Rotam Ltd., 7F., Cheung Tat Centre, 18 Cheung Lee Street, Chai Wan, Hong Kong

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 46385008), 0.1 mL (59 mg) of Abamectin Technical (Avermectin b1a: 80%, Avermectin B1b: 20%; Batch# 625d; off white

powder) was instilled into the conjunctival sac of one eye of 4 adult male New Zealand albino rabbits (Source: Highgate Farm, Lincolnshire, England). One animal was treated in advance of the others to note any severe adverse response to being exposed to the test substance. This first animal had its treated eye rinsed with distilled water 30 seconds after instillation. The remaining 3 treated eyes were not rinsed after instillation. The untreated eye served as a control. Animals were then observed at 1, 24, 48, 72 hours and on day 4 (for one animal) post-instillation. Irritation was scored according to Draize. Observations for clinical signs of toxicity were noted daily.

No corneal opacity or iritis was noted in the eye which was rinsed with distilled water. One hour after instillation conjunctival redness (score 2) was noted, with the irritation decreasing thereafter and resolving by study day 4.

No corneal opacity or iritis was noted in the eyes which were not rinsed with distilled water. One hour after instillation conjunctival redness (score 2) was observed in 2 treated eyes. No other positive irritation was noted. Irritation decreased thereafter and resolved by study day 3.

The test substance is mildly irritating. In this study, Abamectin Technical is classified as EPA Toxicity Category III.

This study is classified as acceptable. It does satisfy the guideline requirement for a primary eye irritation study (OPPTS 870.2400; OECD 405) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS AND DISCUSSION:

Unwashed Eyes

Observations	Number "positive"/number tested				
	Hours				Day
	1	24	48	72	4
Corneal Opacity	0/3	0/3	0/3	0/3	03
Iritis	0/3	0/3	0/3	0/3	0/3
Conjunctivae:					
Redness*	2/3	1/3	0/3	0/3	0/3
Chemosis*	0/3	0/3	0/3	0/3	0/3

*Score of 2 or more required to be considered "positive"

A. Observations - No corneal opacity or iritis was noted in the eye which was rinsed with distilled water. One hour after instillation conjunctival redness (score 2) was noted, with the irritation decreasing thereafter and resolving by study day 4.

No corneal opacity or iritis was noted in the eyes which were not rinsed with distilled water. One hour after instillation conjunctival redness (score 2) was observed in 2 treated eyes. No other positive irritation was noted. Irritation decreased thereafter and completely resolved by study day 3.

B. Reviewer's Conclusions: Agree with the study author.

Reviewer: Breann Hanson **Date:** Dec. 17, 2004
Risk Manager (EPA): Thomas Harris, RM 07

STUDY TYPE: Primary Dermal Irritation - NZW Rabbit; OPPTS 870.2500; OECD 404

TEST MATERIAL: Abamectin Technical (Avermectin b1a: 80%, Avermectin B1b: 20%; Batch# 625d; off white powder)

CITATION: Blanchard, E. (2002) Abamectin Technical Skin Irritation Study to the Rabbit. Project identity: LDA/044. Unpublished study prepared by Huntingdon Life Sciences Ltd.. March 19, 2002. MRID 46385009.

SPONSOR: Rotam Ltd., 7F., Cheung Tat Centre, 18 Cheung Lee Street, Chai Wan, Hong Kong

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 46385009), 3 adult male New Zealand albino rabbits (Source: Harlan UK Ltd., Oxon, England) were dermally exposed to 0.5 g of Abamectin Technical (Avermectin b1a: 80%, Avermectin B1b: 20%; Batch# 625d; off white powder). At first only one animal was treated in order to clarify the irritant potential, with the test substance applied to three treatment sites and the exposure period varied between each site (3 minutes, 60 minutes, 4 hours). Subsequently, 2 additional animals were treated for 4 hours. The test substance was applied under a gauze pad, moistened with distilled water and then secured with a elastic adhesive dressing. All animals were then observed for 72 hours, with an additional observation being made for one animal on study day 5. Dermal irritation was scored according to the Draize system at 1, 24, 48 and 72 hours post-patch removal. One animals was also scored on study day 5. Animals were observed daily for signs of gross toxicity or ill health.

Following 4 hours of exposure to the test substance, very slight erythema (score 1) was noted in one animal 1 hour post-bandage removal. This irritation persisted through 72 hours, and was resolved by study day 5. No dermal irritation was noted in the remaining 2 animals at any point during the study.

In this study, the formulation is slightly irritating to the skin. Abamectin Technical is classified as EPA Toxicity Category IV.

This study is classified as acceptable. It does satisfy the guideline requirement for a primary dermal irritation study (OPPTS 870.2500; OECD 404) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

INDIVIDUAL SKIN IRRITATION SCORES

ERYTHEMA/EDEMA

Animal Number	Sex	Hours				Day
		1	24	48	72	5
3503	M	0/0	0/0	0/0	0/0	NA*
3507		0/0	0/0	0/0	0/0	NA*
3588		1/0	1/0	1/0	1/0	0/0
Severity of Irritation - Mean Score		0.33/0	0.33/0	0.33/0	0.33/0	0/0

* these animals were not observed on study day 5 due to no irritation noted during the study.

A. Observations - Following 4 hours of exposure to the test substance, very slight erythema (score 1) was noted in one animal 1 hour post-bandage removal. This irritation persisted through 72 hours, and was resolved by study day 5. No dermal irritation was noted in the remaining 2 animals at any point during the study.

B. Results - Test substance is slightly irritating to the skin.

C. Reviewer's Conclusions - Agree with study author.

Reviewer: Breann Hanson **Date:** Dec. 17, 2004
Risk Manager (EPA): Thomas Harris, RM 07

STUDY TYPE: Dermal Sensitization - Guinea Pig DH; OPPTS 870.2600; OECD 406

TEST MATERIAL: Abamectin Technical (Avermectin b1a: 80%, Avermectin B1b: 20%; Batch# 625c; off white powder)

CITATION: Coleman, D. (2002) Abamectin Technical Skin Sensitization to the Guines-Pig (Magnusson & Kligman Method). Project identity: LDA/046. Unpublished study prepared by Huntingdon Life Sciences Limited. March 25, 2002. MRID 46385010.

SPONSOR: Rotam Ltd., 7F., Cheung Tat Centre, 18 Cheung Lee Street, Chai Wan, Hong Kong

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID 46385010) with Abamectin Technical (Avermectin b1a: 80%, Avermectin B1b: 20%; Batch# 625c; off white powder), 15 female Hartley guinea pigs (Weight: 400-500 g; Source: D. Hall Staffordshire, UK) were tested using the Magnusson-Kligman Design method.

During the preliminary testing phase, appropriate concentrations of the test substance to be used were determined for the intradermal induction (test substance in a 5% w/v suspension in sterile water), topical induction (test substance in a 65% w/v suspension in sterile water), and topical challenge (test substance in a 65% w/v and 35% w/v suspension in sterile water).

The first induction phase involved 3, 0.1 mL intradermal paired injections into 10 guinea pigs of the test substance (test substance in a 5% w/v suspension in sterile water), test substance and Freund's Adjuvant (test substance in a 5% w/v suspension in a 50/50 mixture of Freund's Complete Adjuvant and sterile water), and Adjuvant alone (Freund's Complete Adjuvant at 50% v/v in sterile water). Paired injections were also administered to 10 naive control guinea pigs under the same conditions as in the treated group except that the test substance was omitted. Dermal irritation was noted 24 hours following the injections.

A second induction phase was then conducted consisting of a 0.4 mL topical application of the test substance in a 65% w/v suspension in sterile water applied directly to the dose site of the test animals, which was then left in place for 48 hours. The day before this second induction animals were treated with 0.5 mL of 10% w/w sodium lauryl sulphate in petrolatum. The control group were treated under the same conditions as in the treated group, except that the test substance was omitted. Dermal irritation was noted immediately following removal of the bandages.

Two weeks after the topical application of the induction phase the challenge phase was conducted by applying 0.2 mL of a topical application of test substance in a 65% w/v and 0.2 mL of a topical application of test substance in a 35% w/v suspension in sterile water to both the test and control guinea pigs, which were left in place for 24 hours. 24 and 48 hours after patch removal the animals were scored for dermal irritation.

The procedures were validated using hexyl cinnamic aldehyde (HCA) as the positive control substance.

All animals survived and gained weight during the study. During the induction phase, no irritation was noted in either the test and control groups receiving the test substance or sterile water. Necrosis

was noted at sites receiving Freund's Complete Adjuvant. At challenge there was no dermal irritation noted in either the test or control animals.

Based on the results of this study, Abamectin Technical **does have to be labeled as a dermal sensitzer.**

This study is classified as acceptable. It does satisfy the guideline requirement for a primary dermal sensitization study (OPPTS 870.2600; OECD 406) in the Guinea pig .

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. PROCEDURE

A. Preliminary Testing - During the preliminary testing phase, appropriate concentrations of the test substance to be used were determined for the intradermal induction (test substance in a 5% w/v suspension in sterile water), topical induction (test substance in a 65% w/v suspension in sterile water), and topical challenge (test substance in a 65% w/v and 35% w/v suspension in sterile water).

B. Induction - The first induction phase involved 3, 0.1 mL intradermal paired injections into 10 guinea pigs of the test substance (test substance in a 5% w/v suspension in sterile water), test substance and Freund's Adjuvant (test substance in a 5% w/v suspension in a 50/50 mixture of Freund's Complete Adjuvant and sterile water), and Adjuvant alone (Freund's Complete Adjuvant at 50% v/v in sterile water). Dermal irritation was noted 24 hours following the injections.

A second induction phase was then conducted consisting of a 0.4 mL topical application of the test substance in a 65% w/v suspension in sterile water applied directly to the dose site of the test animals, which was then left in place for 48 hours. The day before this second induction animals were treated with 0.5 mL of 10% w/w sodium lauryl sulphate in petrolatum. Dermal irritation was noted immediately following removal of the bandages.

C. Challenge - Two weeks after the topical application of the induction phase the challenge phase was conducted by applying 0.2 mL of a topical application of test substance in a 65% w/v and 0.2 mL of a topical application of test substance in a 35% w/v suspension in sterile water to the test guinea pigs, which were left in place for 24 hours. 24 and 48 hours after patch removal the animals were scored for dermal irritation.

D. Naive Controls - During the first induction phases, paired injections were administered to 5 naive control guinea pigs under the same conditions as in the treated group except that the test substance was omitted.

At the second induction phase, the control group treated was under the same conditions as in the treated group, except that the test substance was omitted.

At challenge, the naive controls received 0.2 mL of a topical application of test substance in a 65%

w/v and 0.2 mL of a topical application of test substance in a 35% w/v suspension in sterile water, which were left in place for 24 hours. 24 and 48 hours after patch removal the animals were scored for dermal irritation.

II. RESULTS and DISCUSSION:

A. Reactions and duration - All animals survived and gained weight during the study. During the induction phase, no irritation was noted in either the test and control groups receiving the test substance or sterile water. Necrosis was noted at sites receiving Freund's Complete Adjuvant. At challenge there was no dermal irritation noted in either the test or control animals.

B. Positive control - Results were appropriate with a HCA study to validate test procedures. The most recent validation of this procedure was performed in November 2001. The test on Abamectin Technical was performed in February 2002.

C. Reviewer's Conclusions: Agree with study author.

1. DP BARCODE: D310857
2. PC CODE: 122804
3. CURRENT DATE: 17/DEC/2004
4. TEST MATERIAL:
[a] Abamectin Technical (Avermectin b1a: 80%, Avermectin B1b: 20%; Batch# 625d; off white powder)
[b] Abamectin Technical (Avermectin b1a: 80%, Avermectin B1b: 20%; Batch# 625c; off white powder)

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade

Acute oral toxicity/rat [a] Huntingdon Life Sciences Ltd. LDA/042 03/19/2002	46385006	LD_{50} < 50 mg/kg (females)	I	A
Acute dermal toxicity/rat [a] Huntingdon Life Sciences Ltd. LDA/043 03/19/2002	46385007	LD_{50} > 5,000 mg/kg (males, females combined)	IV	A
Primary eye irritation/rabbit [a] Huntingdon Life Sciences Ltd. LDA/045 03/19/2002	46385008	no corneal opacity or iritis noted. Mild conjuncitivis (score 2) noted through day 1.	III	A
Primary dermal irritation/rabbit [a] Huntingdon Life Sciences Ltd. LDA/044 03/19/2002	46385009	slight irritation	IV	A
Dermal sensitization/guinea pig [b] Huntingdon Life Sciences Ltd. LDA/046 03/25/2002	46385010	is not a sensitizer	–	A

Core Grade Key: **A =Acceptable, S = Supplementary, U = Unacceptable, W = Waived**