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

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

29/JUN/2007

MEMORANDUM

Subject: Name of Pesticide Product: A14796 Insecticide
EPA Reg. No. /File Symbol: 100-RETG
DP Barcode: 336671
Decision No: 373756
PC Code: 128897 lambda-Cyhalothrin

From: Tracy Keigwin
Technical Review Branch
Registration Division (7505C)

Brant T. Boland 6/29/2007

To: Bonaventure Akinlosotu
Insecticides Branch
Registration Division (7505C)

Applicant: Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Lambda-cyhalothrin	0.5
Inert Ingredient(s):	99.5
Total:	100.00%

ACTION REQUESTED: PM requests review of acute toxicity data for A14796, EPA File Symbol 100-RETG.

BACKGROUND: Syngenta Crop Protection, Inc. has submitted 6 acute toxicity studies (MRIDs 47028703-47028708) in support of the registration of A14796, EPA File Symbol 100-RETG. The product label states that this residential use product is for the control of insects in lawns, vegetables, roses, flowers, trees and shrubs. The 6 submitted acute toxicity studies were conducted at Product Safety Laboratories, Dayton, NJ and Central Toxicology Laboratory, Cheshire, UK.

OF NOTE: Child Resistant Packaging (CRP) is required for this product (on the basis of an oral LD50 $\leq$ 1500 mg/kg) per 40 CFR 157.22, unless it can meet the exemptions as detailed in 40 CFR 157.24.

RECOMMENDATIONS: The studies submitted by Syngenta Crop Protection, Inc. are acceptable. The acute toxicity profile for A14796, EPA File Symbol 100-RETG is as follows:

acute oral toxicity	III	Acceptable	MRID 47028704
acute dermal toxicity	IV	Acceptable	MRID 47028703
acute inhalation toxicity	IV	Acceptable	MRID 47028705
primary eye irritation	III	Acceptable	MRID 47028706
primary skin irritation	IV	Acceptable	MRID 47028707
dermal sensitization	Negative	Acceptable	MRID 47028708

PRECAUTIONARY LANGUAGE.

The Precautionary language for EPA File Symbol Reg. No. 100-RETG is as follows:

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed. Causes moderate eye irritation. 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.

Applicators and other handlers of this product should wear:
-Long sleeve shirt
-Long Pants
-Shoes
-Socks

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 do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

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.

HOT LINE NUMBER
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: Tracy Keigwin June 28, 2007
Review for RM Team 13

STUDY TYPE: Acute Oral Toxicity - rat; OPPTS 870.1100; OECD 425

TEST MATERIAL (% a.i.): Lambda-Cyhalothrin ME (.5), A14796A, FL-450712; Purity: .50%(wt/wt) or 5.1 g/l Lambda-Cyhalothrin, clear colorless liquid, specific gravity = 1.030 g/mL.

CITATION: Moore, G. Lambda-Cyhalothrin ME (.5) (A14796A): Acute Oral Toxicity Up and Down Procedure in Rats. Product Safety Laboratories. PSL Study Number 18384. February 23, 2006. MRID 47028704. Unpublished.

SPONSOR: Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 47028704), 7 female Sprague-Dawley derived , albino rats (source: Ace Animals, Inc., Boyertown, PA; age: 9-10 weeks; weight: 187-210g) were given a single oral dose of Lambda-Cyhalothrin ME (.5), A14796A, FL-450712; Purity: .50%(wt/wt) or 5.1 g/l Lambda-Cyhalothrin, clear colorless liquid, specific gravity = 1.030 g/mL using the Up and Down Procedure. The doses were 175 mg/kg (1 rat), 550 mg/kg (3 rats) and 1750 mg/kg (3 rats). "The test substance was administered via a stainless steel ball-tipped gavage needle attached to an appropriate syringe". Animals were inspected for mortality and clinical abnormalities during the first hours following dosing and at least once a day for up to 14 days thereafter. Bodyweights were obtained prior to dosing and again on days 7 and 14 or after death. A necropsy examination was performed on all test animals.

All animals from the 175 mg/kg dose group (1 animal) and the 550 mg/kg dose group (3 animals) survived and gained weight throughout the study. One rat (1/3) from the 550 mg/kg dose group exhibited hypoactivity from 3-6 hours post-dosing. This was the only clinical abnormality observed at these dose levels. All animals (3/3) from the 1750 mg/kg dose group died within 3 hours of test substance administration. Clinical abnormalities observed prior to death included hypoactivity and/or hunched posture.

No gross abnormalities were observed at necropsy in animals which survived to study termination. Decedents exhibited a discoloration of the intestines at necropsy.

Oral LD_{50} Females is estimated to be 1030 mg/kg; EPA Toxicity Category III.

This acute oral study is classified as acceptable. It does satisfy the guideline requirement for an acute oral study (OPPTS 870.1100; OECD 425) in the rat.

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

RESULTS and DISCUSSION

Main Test

Dosing Sequence	Animal ID	Dose level (mg/kg)	Short Term Outcome	Long Term Outcome
1	5729	175	S	S
2	5736	550	S	S
3	5776	1750	D	D
4	5791	550	S	S
5	5846	1750	D	D
6	5864	550	S	S
7	5878	1750	D	D

S = survival D = Death

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AOT425statpgm (Version: 1.0) Test Results and Recommendations
Acute Oral Toxicity (OECD Test Guideline 425) Statistical Program
Date/Time: Friday, June 29, 2007, 8:59:50 AM
Data file name: work.dat
Last modified: 6/29/2007 8:59:50 AM
Test/Substance: Lambda Cyaholthrin ME (.5)
Test type: Main Test
Limit dose (mg/kg): 5000
Assumed LD50  (mg/kg): Default
Assumed sigma (mg/kg): 0.5

Recommended dose progression: 5000, 1750, 550, 175, 55, 17.5, 5.5,
1.75
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DATA:

Test Seq.	Animal ID	Dose (mg/kg)	Short-term Result	Long-term Result
1	5729	175	O	O
2	5736	550	O	O
3	5776	1750	X	X
4	5791	550	O	O
5	5846	1750	X	X
6	5864	550	O	O
7	5878	1750	X	X

(X = Died, O = Survived)

Dose Recommendation: The main test is complete.

Stopping criteria met: 5 reversals in 6 tests.

SUMMARY OF LONG-TERM RESULTS:

Dose	O	X	Total
175	1	0	1
550	3	0	3
1750	0	3	3
All Doses	4	3	7

Statistical Estimate based on long term outcomes:

Estimated LD50 = 1030 (Based on an assumed sigma of 0.5).
Approximate 95% confidence interval is 550 to 1750.

A. <u>Mortality</u> - As listed above.

B. <u>Clinical observations</u> – All animals from the 175 mg/kg dose group (1 animal) and the 550 mg/kg dose group (3 animals) survived and gained weight throughout the study. One rat (1/3) from the 550 mg/kg dose group exhibited hypoactivity from 3-6 hours post-dosing. This was the only clinical abnormality observed at these dose levels. All animals (3/3) from the 1750 mg/kg dose group died within 3 hours of test substance administration. Clinical abnormalities observed prior to death included hypoactivity and/or hunched posture.

C. Gross Necropsy – No gross abnormalities were observed at necropsy in animals which survived to study termination. Decedents exhibited a discoloration of the intestines at necropsy.

D. Reviewer's Conclusions: TRB agrees with the study author that the test substance has an LD_{50} of 1030 mg/kg.

E. Deficiencies – None.

Reviewer: Tracy Keigwin
Review for RM Team 13

June 28, 2007

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

TEST MATERIAL (% a.i.): Lambda-Cyhalothrin ME (.5), A14796A, FL-450712; Purity: .50%(wt/wt) or 5.1 g/l Lambda-Cyhalothrin, clear colorless liquid.

CITATION: Moore, G. Lambda-Cyhalothrin ME (.5) (A14796A): Acute Dermal Toxicity Study in Rats. Product Safety Laboratories. PSL Study Number 18385. February 23, 2006. MRID 47028703. Unpublished.

SPONSOR: Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 47028703) 5 male and 5 female Sprague-Dawley derived albino rats (source: Ace Animals, Inc., Boyertown, PA; age: 9-10 weeks; weight: males 312-325g, females 220-233g) were dermally exposed to Lambda-Cyhalothrin ME (.5), A14796A, FL-450712; Purity: .50%(wt/wt) or 5.1 g/l Lambda-Cyhalothrin, clear colorless liquid at a dose of 5000 mg/kg bw. On the day prior to study initiation the dorsal and trunk area of test animals was clipped. On the day of study initiation a 5000 mg/kg dose of the test substance was applied to an approximate 2x3 inch dose site (approximately 10% body surface) and covered with a 4-ply gauze pad. "The gauze pad and entire trunk of each animal were then wrapped with 3 inch Durapore tape to avoid dislocation of the pad and minimize loss of the test substance". After 24 hours all binding materials were removed and the test sites washed to remove any residual test substance. Animals were observed for clinical abnormalities and mortality during the first several hours after application and at least once daily thereafter until study termination. Body weights were taken prior to treatment and on days 7 and 14 of the study. A necropsy examination was performed on all test animals.

All animals (5/5 males, 5/5 females) survived and gained weight until study termination. No clinical abnormalities were observed.

No gross abnormalities were observed at necropsy.

Dermal LD_{50} Males > 5000 mg/kg bw (0/5 died)
Dermal LD_{50} Females > 5000 mg/kg bw (0/5 died)
Dermal LD_{50} Combined > 5000 mg/kg bw (0/10 died)

Toxicity based on the lack of mortality observed in both the male and female rat. 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 bw)	Mortality/Number Tested		
	Males	Females	Combined
5000	0 / 5	0 / 5	0 / 10

A. Mortality - as noted in table.

B. Clinical observations – All animals (5/5 males, 5/5 females) survived and gained weight until study termination. No clinical abnormalities were observed.

C. Gross Necropsy - No gross abnormalities were observed at necropsy.

D. Reviewers Conclusions: TRB agrees with the study author that the acute dermal LD_{50} for this product is greater than 5000 mg/kg bw.

E. Deficiencies - None

Reviewer: Tracy Keigwin June 28, 2007
Review for RM Team 13

STUDY TYPE: Acute Inhalation Toxicity - Rat; OPPTS 870.1300; OECD 403

TEST MATERIAL (% a.i.): Lambda-cyhalothrin ME (0.5), (A14796A); Batch Reference Number 450712; Purity: 0.5% (wt/wt) or 5.1 g/l Lambda-cyhalothrin; Density 1013 g/L; clear liquid.

CITATION: Rattray, N. Lambda-Cyhalothrin ME (0.5) (A14796A): 4-Hour Acute Inhalation Toxicity Study in Rats. Central Toxicology Laboratory. Study Number HR2508-REG-R1. April 11, 2006. MRID 47028705. Unpublished.

SPONSOR: Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (MRID 47028705), 5 male and 5 female (and additionally 2 males and 2 females in a preliminary trial exposure) Alpk:AP$_f$SD (Wistar Derived) rats (source: AstraZenca Biological Services Section, Alderley Park, Macclesfield, Cheshire, UK; age: 9-10 weeks; weight: males 399±SD32.9g, females 278.2±SD16.8g) were exposed "nose-only" via the inhalation route to Lambda-cyhalothrin ME (0.5), (A14796A); Batch Reference Number 450712; Purity: 0.5% (wt/wt) or 5.1 g/l Lambda-cyhalothrin; Density 1013 g/L; clear liquid at a total formulation concentration of 6.60 ± 0.91 mg/L. The MMAD was 1.99 and 2.11µm; the GSD was 1.73 and 1.75. Animals were observed for clinical signs frequently during and at the end of exposure and daily until study termination. Bodyweights were recorded on study days -1, 1, 8 and 15. A necropsy examination was performed on all test animals.

All animals survived to study termination. Clinical abnormalities observed during exposure included wet fur and salivation in all animals, with some animals additionally exhibiting chromodacryorrhoea. Immediately following exposure and during the maintenance period animals exhibited abnormal respiratory noise, resolving within 5 days. No other clinical abnormalities were observed. "All animals except 1 female had gained weight by study day 8 and all animals had gained weight by the end of the study".

At necropsy, no macroscopic abnormalities were observed.

LC_{50} Males => Greater than 6.60 ± 0.91 mg/L (0/5 males died)
LC_{50} Females => Greater than 6.60 ± 0.91 mg/L (0/5 females died)
LC_{50} Combined => Greater than 6.60 ± 0.91 mg/L (0/10 died)

Toxicity based on the lack of mortality in the rat. EPA Toxicity Category IV.

This acute inhalation study is classified as Acceptable. It does satisfy the guideline requirement for an acute inhalation study (OPPTS 870.1300; OECD 403) in the rat.

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

RESULTS and DISCUSSION:

Total formulation Concentration (mg/L)	Mortality/Number Tested		
	Males	Females	Combined
6.60 ± 0.91	0 / 5	0 / 5	0 / 10

Total formulation Concentration (mg/L)	Nominal Concentration (mg/L)	MMAD µm	GSD
6.60 ± 0.91	41.7	1.99, 2.11	1.73, 1.75

Test Atmosphere / Chamber Description:

Total formulation Concentration (mg/L)	Chamber Volume (L)	Airflow (LPM)	Temperature (C)	Relative Humidity (%)
6.60 ± 0.91	27.6	17	20.2-20.8	80-83

A. Mortality - as noted in table.

B. Clinical observations - All animals survived to study termination. Clinical abnormalities observed during exposure included wet fur and salivation in all animals, with some animals additionally exhibiting chromodacryorrhoea. Immediately following exposure and during the maintenance period animals exhibited abnormal respiratory noise, resolving within 5 days. No other clinical abnormalities were observed. "All animals except 1 female had gained weight by study day 8 and all animals had gained weight by the end of the study".

C. Gross Necropsy – At necropsy, no macroscopic abnormalities were observed.

D. Reviewers Conclusions: Agree with the study author that the LC_{50} for this product is greater than 6.60 mg/L.

E. Deficiencies – None.

Reviewer: Tracy Keigwin June 28, 2007
Review for RM Team 13

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

TEST MATERIAL (% a.i.): Lambda-Cyhalothrin ME-A (.5), A14796A, FL-050030; Purity: .50%(wt/wt) or 5.1 g/l Lambda-Cyhalothrin, pale yellow liquid.

CITATION: Merkel, D. Primary Eye Irritation Study in Rabbits with Lambda-Cyhalothrin .5 ME-A (A14796A). Product Safety Laboratories. PSL Study Number 16911. May 2, 2005. MRID 47028706. Unpublished.

SPONSOR: Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 47028706), the eyes of 1 male and 2 female New Zealand White rabbits (source: Robinson Services Inc., Clemmons, NC; age: young adult; weight: not provided) were exposed to 0.1 ml of Lambda-Cyhalothrin ME-A (.5), A14796A, FL-050030; Purity: .50%(wt/wt) or 5.1 g/l Lambda-Cyhalothrin, pale yellow liquid. "Prior to instillation, two drops of ocular anaesthetic (Tetracaine Hydrochloride Ophthalmic Solution, 0.5%) were placed into both the treated and control eye of each animal". After anaesthetic instillation, the lower lid of the right eye of each test animal was pulled away from the eyeball and 0.1 mL of the test substance was instilled. After instillation the eyelids were held together for approximately 1 second to limit test article loss. Animals were observed for ocular irritation at 1, 24, 48, and 72 hours post instillation. A fluorescein dye was used at the 24 hour observation and as needed at subsequent intervals to "verify the absence of corneal damage".

No corneal opacity or iritis was observed during the study. Positive signs of conjunctivitis were observed in all animals (3/3) at the 1 and 24 hour observations, resolving in all animals by 48 hours. 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.

R1ESULTS AND DISCUSSION:

	Number "positive"/number tested			
	Hours			
Observations	1	24	48	72
Corneal Opacity	0 / 3	0 / 3	0 / 3	0 / 3
Iritis	0 / 3	0 / 3	0 / 3	0 / 3
Conjunctivae[a]:				
Redness	3 / 3	3 / 3	0 / 3	0 / 3
Chemosis	0 / 3	0 / 3	0 / 3	0 / 3
Discharge	3 / 3	0 / 3[c]	0 / 3	0 / 3

[a] Score of 2 or more required to be considered a positive.

A. Observations – No corneal opacity or iritis was observed during the study. Positive signs of conjunctivitis were observed in all animals (3/3) at the 1 and 24 hour observations, resolving in all animals by 48 hours. Please note that the study does record additional signs of conjunctivitis, however the scores (grade 1) are not considered positive per 870.2400.

B. Reviewers Conclusions: TRB agrees with the results reported by the study author (as listed above), placing this product in Toxicity Category III for primary eye irritation.

C. Deficiencies - None

Reviewer: Tracy Keigwin June 28, 2007
Review for RM Team 13

STUDY TYPE: Primary Dermal Irritation - New Zealand White rabbit; OPPTS 870.2500; OECD 404

TEST MATERIAL (% a.i.): Lambda-Cyhalothrin ME-A (.5), A14796A, FL-050030; Purity: .50%(wt/wt) or 5.1 g/l Lambda-Cyhalothrin, pale yellow liquid.

CITATION: Merkel, D. Primary Skin Irritation Study in Rabbits with Lambda-Cyhalothrin .5 ME-A (.5) (A14796A). Product Safety Laboratories. PSL Study Number 16912. May 2, 2005. MRID 47028707. Unpublished.

SPONSOR: Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 47028707), 1 male and 2 female New Zealand albino rabbits (source: Robinson Services, Inc., Clemmons, NC; age: young adult; weight: not provided) were dermally exposed to Lambda-Cyhalothrin ME (.5), A14796A, FL-450712; Purity: .50%(wt/wt) or 5.1 g/l Lambda-Cyhalothrin, clear colorless liquid. On the day prior to study initiation the dorsal and trunk area of test animals was clipped free of fur. An application of 0.5ml of the test substance was applied to a 6 cm^2 dose site and covered with a 1 inch by 1 inch 4- ply gauze pad. "The gauze pad and the entire trunk of the test animals were then wrapped with semi-occlusive Micropore tape to avoid dislocation of the pad. Elizabethan collars were placed on each rabbit and they were returned to their cages." After 4 hours all binding materials were removed and the test sites washed to remove any residual test substance. Animals were observed for erythema and edema at 30-60 minutes, 24, 48 and 72 hours following patch removal.

Very slight (grade 1) to well defined (grade 2) erythema was observed in all animals (3/3) through the 24 hour observation, resolving within 48 hours. All animals exhibited very slight (grade 1) edema at the 1 hour observation, resolving within 24 hours.

EPA Toxicity Category IV. PDI = 0.9.

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:

		Hours			
		1	24	48	72
13835 Female	Erythema	2	1	0	0
	Edema	1	0	0	0
13836 Male	Erythema	2	1	0	0
	Edema	1	0	0	0
13837 Female	Erythema	1	1	0	0
	Edema	1	0	0	0

[a] desquamation

A. Observations – Very slight (grade 1) to well defined (grade 2) erythema was observed in all animals (3/3) through the 24 hour observation, resolving within 48 hours. All animals exhibited very slight (grade 1) edema at the 1 hour observation, resolving within 24 hours.

B. Results - PDI – 0.9

C. Reviewers Conclusions – Product is category IV for primary dermal irritation.

D. Deficiencies – None

Reviewer: Tracy Keigwin June 28, 2007
Review for RM Team 13

STUDY TYPE: Dermal Sensitization – Guinea Pigs; OPPTS 870.2600; OECD 406

TEST MATERIAL (% a.i.): Lambda-Cyhalothrin ME (.5), A14796A, FL-450712; Purity: .50%(wt/wt) or 5.1 g/l Lambda-Cyhalothrin, clear colorless liquid.

CITATION: Moore, G. Lambda-Cyhalothrin ME (.5) (A14796A): Dermal Sensitization Study in Guinea Pigs (Buehler Method). Product Safety Laboratories. PSL Study Number 18386. February 23, 2006. MRID 47028708. Unpublished.

SPONSOR: Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID 47028708) with Lambda-Cyhalothrin ME (.5), A14796A, FL-450712; Purity: .50%(wt/wt) or 5.1 g/l Lambda-Cyhalothrin, clear colorless liquid, 34 male Hartley albino guinea pigs [preliminary irritation - 4 animals; test group - 20 animals; naive control group (challenge) - 10 animals] were tested using the method of Buehler (source: Elm Hill Breeding Labs, Chelmsford , MA; age: young adult; weight: 324-391g at study initiation). Based on an initial screening with 4 subjects, it was determined that an undiluted test substance would be appropriate for the induction applications and a 75% w/w mixture in distilled water would be appropriate for challenge applications. The test group guinea pigs received a total of 9 (3/week) induction exposures.

All test animals exhibited very faint to faint (grade 0.5 – 1) erythema during induction. Following challenge, 8/20 test animals exhibited very faint (grade 0.5) erythema at 24 hours after challenge, persisting in 2/20 animals at the 48 hour observation. Very faint (grade 0.5) erythema was observed in 3/10 naïve control animals at the 24 hour challenge observation, resolving within 48 hours. None of the 20 previously induced or 10 control guinea pigs gave a positive response following challenge (all scores $\leq$ 0.5).

The procedures were validated within 6 months of this study using undiluted HCA for induction and 75% w/w mixture of HCA in mineral oil at challenge. Following challenge, 3/10 positive control animals exhibited faint to moderate erythema (grade 1.0 – grade 2) at the 24 and 48 hour observation. Two of the 5 naïve control animals exhibited very faint (grade 0.5) erythema at the 24 hour observation, persisting in 1/5 animals at the 48 hour observation.

In this study, the test substance is not a dermal sensitizer.

This study is classified as acceptable. It does satisfy the guideline requirement for a dermal sensitization study (OPPTS 870.2600; OECD 406, 429) in the Guinea pig.

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

I. PROCEDURE

A. Induction – Induction applications were made 3 times each week for 3 weeks. On the day prior to induction fur was removed from the dorsal and flank area with animal clippers. "At study initiation, a dose of 0.4 ml of undiluted test substance was applied to the left side of each test animal using an occlusive 25 mm Hill Top Chamber. The chamber was secured in place and wrapped with non-irritating with adhesive tape to avoid dislocation of the chambers and minimize test substance loss". After 6 hours all binding materials were removed and the test sites cleansed to remove any residual test substance. At 24 and 48 hours after each induction the application sites were scored for signs of erythema.

B. Challenge – "Twenty eight days after the first induction dose, 0.4 ml of an a 75% w/w mixture of the test substance in distilled water was applied to a naive site on the right side of each animal as a challenge dose using the procedures described above". The irritation response was noted at 24 and 48 hours after application.

C. Naive Controls - Ten naive control guinea pigs were treated with 0.4 ml of a 75% w/w mixture of the test substance in distilled water at challenge only in the manner described above.

II. RESULTS and DISCUSSION:

Reactions and duration - During the main test, all test animals exhibited very faint to faint (grade 0.5 – 1) erythema during induction. Following challenge, 8/20 test animals exhibited very faint (grade 0.5) erythema at 24 hours after challenge, persisting in 2/20 animals at the 48 hour observation. Very faint (grade 0.5) erythema was observed in 3/10 naïve control animals at the 24 hour challenge observation, resolving within 48 hours. None of the 20 previously induced or 10 control guinea pigs gave a positive response following challenge (all scores ≤ 0.5).

B. Positive control - Following challenge, 3/10 positive control animals exhibited faint to moderate erythema (grade 1.0 – grade 2) at the 24 and 48 hour observation. Two of the 5 naïve control animals exhibited very faint (grade 0.5) erythema at the 24 hour observation, persisting in 1/5 animals at the 48 hour observation.

C. Reviewers Conclusions: Agree with the study author that this product is not a dermal sensitizer.

D. Deficiencies – None

ACUTE TOX ONE-LINERS
1. DP BARCODE: 336671
2. PC CODES: 128897
3. CURRENT DATE: 28/JUN/2007
4. TEST MATERIAL: Lambda-Cyhalothrin ME (.5), A14796A, FL-450712; Purity: .50% (wt/wt) or 5.1 g/l Lambda-Cyhalothrin, clear colorless liquid - OR - Lambda-cyhalothrin ME (0.5), (A14796A); Batch Reference Number 450712; Purity: 0.5% (wt/wt) or 5.1 g/l Lambda-cyhalothrin; Density 1013 g/L; clear liquid

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity/rat Product Safety Laboratories Lab Study # 18384 Date: February 23, 2006	47028704	LD_{50} =1030 mg/kg	III	A
Acute dermal toxicity/rat Product Safety Laboratories Lab Study # 18385 Date: February 23, 2006	47028703	LD_{50} > 5000 mg/kg	IV	A
Acute inhalation toxicity/rat Product Safety Laboratories Lab Study # HR2508-REG-R1 Date: April 11, 2006	47028705	LC_{50} > 6.60 mg/L	IV	A
Primary eye irritation/rabbit Product Safety Laboratories Lab Study # 16911 Date: May 2, 2005	47028706	Conjunctivitis clearing within 48 hours.	III	A
Primary dermal irritation/rabbit Product Safety Laboratories Lab Study # 16912 Date: May 2, 2005	47028707	PDI = 0.9	IV	A
Dermal sensitization/guinea pig Product Safety Laboratories Lab Study # 18386 Date: February 23, 2006	47028708	Not a Sensitizer	No	A

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