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

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

12/JAN/2010

MEMORANDUM

Subject:	Name of Pesticide Product:	ARY-0454-105
	EPA Reg. No. /File Symbol:	66330-GOR
	DP Barcode:	D368761
	Decision No.:	417327
	Action Code:	R310
	PC Code:	114009 (flucarbazone-sodium)
From:	Eugenia McAndrew, Biologist Technical Review Branch Registration Division (7505P)	E. McAndrew M Haslin
To:	Erik Kraft, RM Team 25 Herbicide Branch Registration Division (7505P)	
Applicant:	Arysta LifeScience North America, LLC 15401 Weston Parkway, Suite 150 Cary, NC 27513	

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Flucarbazone-sodium	35.0
Inert Ingredient(s):	65.0
Total:	100.0%

ACTION REQUESTED: The Risk Manager requests: "review the attached tox studies and determine precautionary language."

BACKGROUND: Arysta LifeScience North America, LLC has submitted a six pack of acute toxicity studies to support the proposed product, ARY-0454-105, EPA Reg. No. 66330-GOR. The studies were conducted at Eurofins/Product Safety Laboratories, Dayton, New Jersey and were assigned MRID numbers 478071-03 to -08. A basic CSF dated August 11, 2009 for the proposed formulation is included in the submission. An Agency contractor, Oak Ridge National Laboratory, conducted the primary review of the studies. TRB performed the secondary review and made changes as necessary.

RECOMMENDATIONS: The six studies have been reviewed and are classified as acceptable.

The acute toxicity profile for ARY-0454-105, EPA Reg. No. 66330-GOR, is as follows:

Acute oral toxicity	IV	Acceptable	MRID 47807103
Acute dermal toxicity	III	Acceptable	MRID 47807104
Acute inhalation toxicity	IV	Acceptable	MRID 47807105
Primary eye irritation	IV	Acceptable	MRID 47807106
Primary skin irritation	IV	Acceptable	MRID 47807107
Dermal sensitization	Negative	Acceptable	MRID 47807108

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 #: 066330-00391

PRODUCT NAME: ARY 0454-105

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wear long-sleeved shirt and long pants, socks, shoes, and chemical-resistant gloves (such as Natural Rubber, Selection Category A).

First Aid:

If on skin:
-Take off contaminated clothing.
-Rinse skin immediately with plenty of water for 15-20 minutes.
-Call a poison control center or doctor for treatment 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.

User Safety Recommendations:

Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

DATA EVALUATION RECORD

FLUCARBAZONE-SODIUM [ARY#0454-105]

STUDY TYPE: ACUTE ORAL TOXICITY - RAT [OPPTS 870.1100; OECD 425]
ACUTE DERMAL TOXICITY - RAT [OPPTS 870.1200; OECD 402]
ACUTE INHALATION TOXICITY - RAT [OPPTS 870.1300; OECD 403]
ACUTE EYE IRRITATION - RABBIT [OPPTS 870.2400; OECD 405]
ACUTE DERMAL IRRITATION - RABBIT [OPPTS 870.2500; OECD 404]
DERMAL SENSITIZATION - GUINEA PIG [OPPTS 870.2600; OECD 406]
MRID: 47807103, 47807104, 47807105, 47807106, 47807107, and 47807108

Prepared for

Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
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Prepared by

Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 1-33

Primary Reviewer:
Donna L. Fefee, D.V.M.

Signature: Robert H. Ross for D. L. Fefee
Date: DEC 18 2009

Secondary Reviewers:
Dana F. Glass, D.V.M.

Signature: Robert H. Ross
Date: DEC 18 2009

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: DEC 18 2009

Quality Assurance:
Dana F. Glass, D.V.M.

Signature: Robert H. Ross
Date: DEC 18 2009

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

Reviewer: Eugenia McAndrew **Date:** January 12, 2010
Risk Manager (EPA): 25

STUDY TYPE: Acute Oral Toxicity – Rat; OPPTS 870.1100; OECD 425

TEST MATERIAL: ARY#0454-105; 35.0% Flucarbazone-sodium technical; Lot No. 905601; off-white liquid; pH: 6.90; expiration date: February 25, 2011; expected to be stable for the duration of testing; stored at room temperature

CITATION: Oley, S. (2009) ARY#0454-105: Acute oral toxicity up and down procedure in rats. Study Number 27242. Unpublished study prepared by Eurofins | Product Safety Laboratories, Dayton, New Jersey. June 17, 2009. MRID 47807103.

SPONSOR: Arysta LifeScience North America, LLC, 15401 Weston Parkway, Suite 150, Cary, North Carolina

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 47807103), six fasted, female Sprague-Dawley derived rats were given single oral gavage doses of undiluted ARY#0454-105 (35.0% Flucarbazone-sodium technical; Lot No. 905601; pH 6.90) at dose levels of 175 mg/kg bw (1 animal), 550 mg/kg bw (1 animal), 1750 mg/kg bw (1 animal), or 5000 mg/kg bw mg/kg bw (3 animals) and observed for up to 14 days. Dosing was conducted according to AOT425statpgm. The animals were 9-10 weeks old, weighed 174-198 g, and were supplied by Ace Animals, Inc., Boyertown, Pennsylvania.

There were no deaths and all of the animals gained weight during both weeks of the study. Two of the animals dosed at 5000 mg/kg had abnormal clinical signs: one had reduced fecal volume on day 1, and the other had ano-genital staining on days 1-2. No abnormal gross necropsy findings were noted.

LD_{50} Females > 5000 mg/kg bw

Based on the acute oral LD_{50}, ARY#0454-105 is in EPA Toxicity Category IV.

This study is classified as acceptable. It does satisfy the guideline requirements 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:

AOT425statpgm (Version: 1.0) Test Results and Recommendations
Acute Oral Toxicity (OECD Test Guideline 425) Statistical Program

Date/Time: Tuesday, December 15, 2009, 1:34:39 PM
Data file name: Flucarbazone-sodium.dat
Last modified: 12/15/2009 1:34:36 PM

Test/Substance: ARY#0454-105 (35.0% Flucarbazone-sodium technical)
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

DATA:

Test Seq.	Animal ID	Dose (mg/kg)	Short-term Result	Long-term Result
1	3101	175	O	O
2	3102	550	O	O
3	3103	1750	O	O
4	3104	5000	O	O
5	3105	5000	O	O
6	3106	5000	O	O

(X = Died, O = Survived)

Dose Recommendation: The main test is complete.
Stopping criteria met: 3 at Limit Dose.

SUMMARY OF LONG-TERM RESULTS:

Dose	O	X	Total
175	1	0	1
550	1	0	1
1750	1	0	1
5000	3	0	3
All Doses	6	0	6

Statistical Estimate based on long term outcomes:
The LD50 is greater than 5000 mg/kg.

A. Mortality: There were no deaths.

B. Clinical observations: One of the three animals dosed at 5000 mg/kg had reduced fecal volume on day 1, and a different 5000 mg/kg animal had ano-genital staining on days 1-2. No other abnormal clinical signs were noted for these or any of the other animals. All of the animals gained weight during both weeks of the study.

C. Gross necropsy: There were no abnormal findings.

D. Reviewer's conclusions: In agreement with the study author, the acute oral LD_{50} for females is greater than 5000 mg/kg. This places the test material in EPA Toxicity Category IV.

Reviewer: Eugenia McAndrew **Date:** January 12, 2010
Risk Manager (EPA): 25

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

TEST MATERIAL: ARY#0454-105; 35.0% Flucarbazone-sodium technical; Lot No. 905601; off-white liquid; pH: 6.90; expiration date: February 25, 2011; expected to be stable for the duration of testing; stored at room temperature

CITATION: Oley, S. (2009) ARY#0454-105: Acute dermal toxicity study in rats. Study Number 27243. Unpublished study prepared by Eurofins | Product Safety Laboratories, Dayton, New Jersey. June 17, 2009. MRID 47807104.

SPONSOR: Arysta LifeScience North America, LLC, 15401 Weston Parkway, Suite 150, Cary, North Carolina

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 47807104), a group of five male and five female Sprague-Dawley derived albino rats was dermally exposed to undiluted ARY#0454-105 (35.0% Flucarbazone-sodium technical; Lot No. 905601; pH 6.90) at a dose of 2000 mg/kg bw (limit dose) for 24 hours. The doses were applied to clipped application sites on the dorsal trunk, measuring approximately 2 inches by 3 inches (~10% of the body surface area), using a 4-ply gauze pad secured with 3-inch Durapore tape wrapped around the trunk. The animals were then observed for 14 days, including observation and scoring of the dose sites for dermal irritation. The animals were approximately 8-9 weeks old (males: 243-265 g, females: 186-204 g) and supplied by Ace Animals, Inc., Boyertown, Pennsylvania.

There were no deaths, abnormal systemic clinical signs, or abnormal gross necropsy findings, and all of the animals gained weight during both weeks of the study. Erythema was noted on the dose sites of all males and two females on days 1-3 or 1-4.

LD_{50} Males > 2000 mg/kg bw
LD_{50} Females > 2000 mg/kg bw
LD_{50} Combined > 2000 mg/kg bw

Based on the acute dermal LD_{50}, ARY#0454-105 is in EPA Toxicity Category III.

This study is classified as acceptable. It does satisfy the guideline requirements 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
2000	0/5	0/5	0/10

A. Mortality: There were no deaths.

B. Clinical observations: No abnormal systemic clinical signs were seen, and all of the animals gained weight during both weeks of the study. Erythema was noted on the dose sites of all males and two females on days 1-3 or 1-4.

C. Gross necropsy: There were no abnormal findings.

D. Reviewer's conclusions: In agreement with the study author, the acute dermal LD_{50} for males, females, and the combined sexes is greater than 2000 mg/kg bw. This places the test material in EPA Toxicity Category III.

Reviewer: Eugenia McAndrew **Date:** January 12, 2010
Risk Manager (EPA): 25

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

TEST MATERIAL: ARY#0454-105; 35.0% Flucarbazone-sodium technical; Lot No. 905601; off-white liquid; pH: 6.90; expiration date: February 25, 2011; expected to be stable for the duration of testing; stored at room temperature

CITATION: Oley, S. (2009) ARY#0454-105: Acute inhalation toxicity study in rats. Study Number 27244. Unpublished study prepared by Eurofins | Product Safety Laboratories, Dayton, New Jersey. June 17, 2009. MRID 47807105.

SPONSOR: Arysta LifeScience North America, LLC, 15401 Weston Parkway, Suite 150, Cary, North Carolina

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (MRID 47807105), a group of five male and five female Sprague-Dawley derived rats was exposed by nose-only inhalation for 4 hours to aerosolized ARY#0454-105 (35.0% Flucarbazone-sodium technical; Lot No. 905601) with mean gravimetric concentration of 2.08 mg/L, mass median aerodynamic diameter (MMAD) of 3.3 µm and geometric standard deviation (GSD) of 1.99. Exposure was on day 0, and the animals were observed for 14 days. The animals were 8-9 weeks old (males: 221-235 g; females: 169-188 g) and supplied by Ace Animals, Inc., Boyertown, Pennsylvania.

There were no deaths or abnormal gross necropsy findings, and all of the animals gained weight during both weeks of the study. Upon removal from the exposure tube, all males and three females exhibited hypoactivity, and one male also had irregular respiration. The hypoactivity resolved by day 1 (females) or day 2 (males), and the irregular respiration resolved by day 3.

LC_{50} Males > 2.08 mg/L
LC_{50} Females > 2.08 mg/L
LC_{50} Combined > 2.08 mg/L

Based on the four-hour inhalation exposure LC_{50}, ARY#0454-105 is in EPA Toxicity Category IV.

This study is classified as acceptable. It does satisfy the guideline requirements 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:

Nominal conc. (mg/L)	Mean gravimetric conc. (mg/L)	MMAD (µm)	GSD	Mortality/Number tested		
				Males	Females	Combined
261.25	2.08	3.3	1.91-2.06	0/5	0/5	0/10

Test atmosphere / Chamber description: The exposure atmosphere was generated by using a peristaltic pump to meter the test material to a 1/4-inch JCO atomizer supplied with filtered compressed air at 30 psi and approximately 28.4 L/minute. Additional compressed air was introduced into the chamber at 3.3 L/minute, in order to create a vortex at the chamber inlet to more uniformly distribute the test atmosphere. The nose-only inhalation chamber (Nose-Only Inhalation Chamber, ADG Developments, Ltd.) had an internal volume of approximately 28 L.

Gravimetric Conc. (mg/L)	2.08±0.23 (range:1.74-2.39)
Chamber Volume (L)	28
Total Airflow (L/min)	31.6-31.8
Temperature (° C)	20-21
Relative Humidity (%)	40-46
Time to equilibrium (minutes)	4.1

Test atmosphere concentration: Gravimetric samples were collected from the breathing zone of the animals at 6 intervals during exposure, using a vacuum pump and pre-weighed glass fiber filters. Collections were carried out for 3 minutes at airflows of 4 L/min. The mass collected was then divided by the total volume of air sampled.

Particle size determination: Two samples withdrawn from the breathing zone of the animals were analyzed using an eight-stage Andersen cascade impactor to determine the particle size distribution of the test atmosphere. The mass median aerodynamic diameter (MMAD) and geometric standard deviation (GSD) were determined graphically, using two-cycle logarithmic probit axes, and are given above.

A. **Mortality:** There were no deaths.

B. **Clinical observations:** Upon removal from the exposure tube, all males and three females exhibited hypoactivity, and one male also had irregular respiration. The hypoactivity resolved by day 1 (females) or day 2 (males), and the irregular respiration resolved by day 3. All of the animals gained weight during both weeks of the study.

C. Gross necropsy: There were no gross abnormal findings.

D. Reviewer's conclusions: In agreement with the study author, the four-hour inhalation exposure LC_{50} for males, females, and the combined sexes is greater than 2.08 mg/L. This places the test material in EPA Toxicity Category IV.

Reviewer: Eugenia McAndrew **Date:** January 12, 2010
Risk Manager (EPA): 25

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

TEST MATERIAL: ARY#0454-105; 35.0% Flucarbazone-sodium technical; Lot No. 905601; off-white liquid; pH: 6.90; expiration date: February 25, 2011; expected to be stable for the duration of testing; stored at room temperature

CITATION: Oley, S. (2009) ARY#0454-105: Primary eye irritation study in rabbits. Study Number 27245. Unpublished study prepared by Eurofins | Product Safety Laboratories, Dayton, New Jersey. June 17, 2009. MRID 47807106.

SPONSOR: Arysta LifeScience North America, LLC, 15401 Weston Parkway, Suite 150, Cary, North Carolina

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 47807106), 0.1 mL of undiluted ARY#0454-105 (35.0% Flucarbazone-sodium technical; Lot No. 905601; pH 6.90) was instilled into the conjunctival sac of the anesthetized right eye of three male, young adult New Zealand albino rabbits, and the upper and lower lids were held shut for approximately one second. Eyes were scored for ocular irritation according to the Draize method 1, 24, 48, and 72 hours after instillation. The anesthetized but otherwise untreated left eye of each animal served as a control, and all eyes were rinsed following fluorescein staining at the 24-hour observation. The animals were supplied by Robinson Services Inc., Clemmons, North Carolina.

There were no observations of corneal opacity or iritis. No positive scores were noted for conjunctival redness or chemosis but a score of 1 was noted for redness in 2/3 eyes through 48 hours. All eyes were free of irritation by 72 hours.

In this study, the formulation is minimally irritating. ARY#0454-105 is classified as EPA Toxicity Category IV for primary eye irritation.

This study is classified as acceptable. It does satisfy the guideline requirements 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:

Observations	Number "positive"/Number treated			
	Hours			
	1	24	48	72
Corneal Opacity	0/3	0/3	0/3	0/3
Iritis	0/3	0/3	0/3	0/3
Conjunctivae:				
Redness*	0/3	0/3	0/3	0/3
Chemosis*	0/3	0/3	0/3	0/3
Discharge**	3/3	0/3	0/3	0/3

* Score of 2 or more required to be considered "positive"
** Discharge does not indicate a positive effect according to the grading scale

A. **Observations:** There were no observations of corneal opacity or iritis. No positive scores were noted for conjunctival redness or chemosis but a score of 1 was noted for redness in 2/3 eyes through 48 hours. All eyes were free of irritation by 72 hours.

B. **Results:** The Maximum Mean Total Score (MMTS) was 6.0, recorded 1 hour after instillation of the test material.

C. **Reviewer's conclusions:** The test material is minimally irritating to the eye and is classified as EPA Toxicity Category IV for ocular effects.

Reviewer: Eugenia McAndrew **Date:** January 12, 2010
Risk Manager (EPA): 25

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

TEST MATERIAL: ARY#0454-105; 35.0% Flucarbazone-sodium technical; Lot No. 905601; off-white liquid; pH: 6.90; expiration date: February 25, 2011; expected to be stable for the duration of testing; stored at room temperature

CITATION: Oley, S. (2009) ARY#0454-105: primary skin irritation study in rabbits. Study Number 27246. Unpublished study prepared by Eurofins | Product Safety Laboratories, Dayton, New Jersey. June 18, 2009. MRID 47807107.

SPONSOR: Arysta LifeScience North America, LLC, 15401 Weston Parkway, Suite 150, Cary, North Carolina

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 47807107), three female young adult New Zealand albino rabbits were dermally exposed to 0.5 mL of ARY#0454-105 (35.0% Flucarbazone-sodium technical; Lot No. 905601; pH 6.90) for 4 hours. The doses were applied to intact, clipped, 6-cm^2 application sites on the trunk, and covered by a 4-ply gauze pad secured with semi-occlusive 3-inch Micropore tape wrapped around the trunk. The animals were observed at 30-60 minutes and 24, 48, and 72 hours after patch removal, and any irritation at the dose sites was scored according to Draize. The animals were supplied by Robinson Services Inc., Clemmons, North Carolina.

There were no observations of edema. Barely perceptible erythema (grade 1) was present on all three of the dose sites 30-60 minutes after patch removal, and all dose sites were normal by 24 hours. There were no other treatment-related clinical signs.

In this study, the formulation is a slight irritant. ARY#0454-105 is classified as EPA Toxicity Category IV for primary dermal irritation.

This study is classified as acceptable. It does satisfy the guideline requirements 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:

Animal number	Sex	Hours			
		0.5-1	24	48	72
3501	Female	1/0[a]	0/0	0/0	0/0
3502	Female	1/0	0/0	0/0	0/0
3503	Female	1/0	0/0	0/0	0/0
Severity of Irritation: Mean Score		1.0/0.0	0.0/0.0	0.0/0.0	0.0/0.0

[a] Erythema/Edema

A. Observations: There were no observations of edema. Barely perceptible erythema (grade 1) was present on all three of the dose sites 30-60 minutes after patch removal, with all dose sites normal by 24 hours. There were no other treatment-related clinical signs.

B. Results: The Primary Irritation Index (PII) was 0.25.

C. Reviewer's conclusions: The test material is a slight irritant and is classified as EPA Toxicity Category IV.

Reviewer: Eugenia McAndrew **Date:** January 12, 2010
Risk Manager (EPA): 25

STUDY TYPE: Dermal Sensitization – Guinea Pig; OPPTS 870.2600; OECD 404

TEST MATERIAL: ARY#0454-105; 35.0% Flucarbazone-sodium technical; Lot No. 905601; off-white liquid; pH: 6.90; expiration date: February 25, 2011; expected to be stable for the duration of testing; stored at room temperature

CITATION: Oley, S. (2009) ARY#0454-105: Dermal sensitization study in guinea pigs (Buehler method). Study Number 27247. Unpublished study prepared by Eurofins | Product Safety Laboratories, Dayton, New Jersey. June 18, 2009. MRID 47807108.

SPONSOR: Arysta LifeScience North America, LLC, 15401 Weston Parkway, Suite 150, Cary, North Carolina

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID 47807108), twenty young adult female Hartley albino guinea pigs were tested with undiluted ARY#0454-105 (35.0% Flucarbazone-sodium technical; Lot No. 905601; pH 6.90) using the Buehler method. The animals were supplied by Elm Hill Breeding Labs, Chelmsford, Massachusetts and weighed 331-419 g.

No positive dermal reactions were noted following challenge with 0.4 mL of undiluted test material.

Based on the results of this study, ARY#0454-105 is *not* a dermal sensitizer.

This study is classified as acceptable. It does satisfy the guideline requirements for a 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.

PROCEDURE:

A. Induction: The dorsal area and flanks of the animals were clipped one day prior to each treatment. For each of three successive weekly inductions, 0.4 mL of the undiluted test material was applied to the left side of each animal using an occlusive 25 mm Hill Top Chamber® and secured in place with adhesive tape wrappings for six hours. For the third induction, the test material was applied to adjacent naïve sites in cases where irritation was noted at the previously used dose site. Reactions were scored 24 and 48 hours post application.

B. Challenge: Twenty-seven days after the first induction, the animals were challenged with 0.4 mL of the undiluted test material, applied to naïve sites on the right side of each animal for 6 hours using the same procedure. Reactions were scored 24 and 48 hours post application.

C. Naïve controls: At challenge, a separate "naïve" group of ten previously untreated animals was also treated with 0.4 mL of the undiluted test material. Reactions were scored 24 and 48 hours post application.

RESULTS and DISCUSSION:

A. Reactions and durations: Following the first induction, very faint erythema (score=0.5) was noted on 5/20 and 2/20 application sites at 24 and 48 hours, respectively. Following the second induction, very faint erythema was noted on 1 application site at 24 hours, only. Following the third induction, very faint erythema was noted on 2 application sites at 24 hours, only. Following challenge, very faint erythema was noted on 3/20 and 1/20 treated animals and on 2/10 naïve controls at 24 and 48 hours, respectively, and very faint erythema was noted on 2/10 naïve controls at 24 hours, only.

B. Positive control: The study report included the results from a positive control study with alpha-Hexylcinnamaldehyde Technical. The study was conducted within six months of the submitted study, and the study author stated that the induction and challenge procedures used in both studies were similar. The reviewer considers the results to be appropriate.

C. Reviewer's conclusion: In agreement with the study author, the test material is *not* a sensitizer.

1. **DP BARCODE:** D368761
2. **PC CODE:** 114009
3. **CURRENT DATE:** January 12, 2010
4. **TEST MATERIAL:** ARY#0454-105; 35.0% Flucarbazone-sodium technical; Lot No. 905601; off-white liquid; pH: 6.90; expiration date: February 25, 2011; expected to be stable for the duration of testing; stored at room temperature

Study/Species/Lab Study # / Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity/rat Eurofins | Product Safety Laboratories Study #27242/June 17, 2009	47807103	LD_{50} > 5000 mg/kg bw females	IV	A
Acute dermal toxicity/rat Eurofins | Product Safety Laboratories Study #27243/June 17, 2009	47807104	LD_{50} > 2000 mg/kg bw males, females combibed	III	A
Acute inhalation toxicity/rat Eurofins | Product Safety Laboratories Study #27244/June 17, 2009	47807105	LC_{50} > 2.08 mg/L males, females combined	IV	A
Primary eye irritation/rabbit Eurofins | Product Safety Laboratories Study #27245/June 17, 2009	47807106	Minimally irritating	IV	A
Primary dermal irritation/ rabbit Eurofins | Product Safety Laboratories Study #27246/June 18, 2009	47807107	Slightly irritating	IV	A
Dermal sensitization/guinea pig Eurofins | Product Safety Laboratories Study #27247/June 18, 2009	47807108	*Not* a sensitizer	--	A

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