

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Mallolm

September 3, 2010

MEMORANDUM

Subject: Name of Pesticide Product: M920 INSECTICIDE

 EPA File Symbol:
 11556-RLG

 DP Barcode:
 377087

 Decision No.:
 431842

 Action Code:
 R310

 PC Code:
 129099

From: Princess Campbell, DVM

Risk Integration, Minor Use and Emergency Response Branch

Registration Division (7505P)

Through: Masih Hashim, Team Leader-Toxicology

Technical Review Branch Registration Division

To: Venus Eagle/Dani Daniel, RM Team 01

Insecticide Branch

Registration Division (7505P)

Applicant: Bayer Healthcare LLC

Shawnee Mission, KS 66201-0390

FORMULATION FROM LABEL:

Active Ingredient(s):% by wtImidacloprid21.4Other Ingredient(s):78.6

Total: 100.0%

ACTION REQUESTED: The Risk Manager requests a review of the acute toxicology 6 pack (MRIDs 48060203-08) submitted to support an application for a new product which is claiming similarity to EPA Reg. No. 11556-RLG.

BACKGROUND: Bayer HealthCare, LLC has submitted a six pack of toxicity studies to support the registration of M920 Insecticide (EPA File Symbol 11556-RLG). The toxicity studies were conducted at Eurofins Product Safety Laboratories, Dayton, NJ.

COMMENTS AND RECOMMENDATIONS:

- 1. The six studies have been reviewed and are classified as Acceptable.
- 2. The acute toxicity profile for #11556-RLG is as follows:

Acute oral toxicity	III	acceptable	MRID 48060203
Acute dermal toxicity	II1	acceptable	MRID 48060204
Acute inhalation toxicity	III	acceptable	MRID 48060205
Primary eye irritation	111	acceptable	MRID 48060206
Primary skin irritation	IV	acceptable	MRID 48060207
Dermal sensitization	Sensitizing	acceptable	MRID 48060208

3. 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:

Lebel

PRODUCT ID #: 011556-00153

PRODUCT NAME: M920 INSECTICIDE

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if absorbed through skin. Harmful if inhaled. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water, after handling and before eating, drinking, chewing gum, or using tobacco. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Remove and wash contaminated clothing before reuse. Avoid breathing spray mist. Avoid contact with eyes or clothing. Wear protective eyewear.

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

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.

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 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 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.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

Reviewer: Princess Campbell, DVM Date: August 25, 2010

Risk Manager (EPA): 01

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

TEST MATERIAL: Imidacloprid 2; Lot # 2008-002241; off white liquid; pH 9.80

SYNONYMS: M 920 Insecticide

CITATION: Durando, Jennifer (2008) Imidacloprid 2— Acute oral toxicity in Rats. Study Number 24858. Eurofins Product Safety Laboratories. June 2, 2008. MRID 48060203.

SPONSOR: Makhteshim Agan of North America, INC.

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 48060203), six female Sprague Dawley rats, (source: Ace Animals Inc, Boyertown, PA), 10-11 weeks old and weighing from 180 to 225 g, were given a single oral dose of lmidacloprid 2 at dose level of either 350 mg/kg or 1,110 mg/kg bw. Animals were then observed for 14 days. The statistical program (Weststat, version I.0, May 2001) was used for all data analyses.

All three females dosed at the 1,110 mg level died within one day of test substance administration.

Prior to death the three females were hypoactive and exhibited hunched or prone posture, tremors and/or piloerection. The surviving animals gained body weight and appeared active and healthy during the study.

Gross necropsy of the three decedents revealed red intestines. No gross abnormalities were noted for any of the surviving animals when necropsied at the end of the 14-day observation period.

Oral LD₅₀ Females > 623.3 mg/kg bw

Based on the Oral LD₅₀ in females, Imidacloprid 2 is classified as 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.

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

Date/Time: Thursday, August 19, 2010, 3:37:31 PM

Data file name: imidacloprid.dat Last modified: 8/19/2010 3:37:29 PM

Test/Substance: Acute oral up and down-Imidacloprid 2

Test type: Main Test Limit dose (mg/kg): 2000

Assumed LD50 (mg/kg): Default Assumed sigma (mg/kg): 0.5

Recommended dose progression: 2000, 550, 175, 55, 17.5, 5.5, 1.75

DATA:

Test	Anima	al Dose	Short-ter	m Long-term	
Seq.	Œ	(mg/kg)	Result	Result	
1	3101	1110	Х	X	
2	3102	350	0	0	
3	3103	1110	Х	X	
4	3104	350	0	0	
5	3105	1110	X	X	
6	3106	350	0	0	

(X = Died, O = Survived)

Dose Recommendation: The main test is complete.

WARNING:

Please review the data for accuracy.

Starting the Main Test above the likely LD50 will induce bias toward the starting dose. See OECD Guideline 425.

Stopping criteria met: 5 reversals in 6 tests. LR criterion.

SUMMARY OF LONG-TERM RESULTS:

	Dose	0	Х	Total	
-	350 1110	-	0 3	3 3	
A	Doses	3	3	6	

Statistical Estimate based on long term outcomes:

Estimated LD50 = 623.3 (Based on an assumed sigma of 0.5). Approximate 95% confidence interval is 350 to 1110.

- A. <u>Mortality</u>: All three females dosed at the 1,110 mg level died within one day of test substance administration.
- **B.** <u>Clinical observations</u>: Prior to death the three females were hypoactive and exhibited hunched or prone posture, tremors and/or piloerection. The surviving animals gained body weight and appeared active and healthy during the study.
- C. <u>Gross Necropsy</u>: Gross necropsy of the three decedents revealed red intestines. No gross abnormalities were noted for any of the surviving animals when necropsied at the end of the 14-day observation period.
- **D.** Reviewer's Conclusions: This reviewer agrees with the study author's conclusions. Based on the LD₅₀ in females, the test material is classified as EPA Toxicity Category III.
- E. Deficiencies: None.

Reviewer: Princess Campbell, DVM

Risk Manager (EPA):01

Date: August 25, 2010

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

TEST MATERIAL: Imidacloprid 2; Lot # 2008-002241; off white liquid; pH 9.80

SYNONYMS: M920 Insecticide

<u>CITATION</u>: Durando, Jennifer. (2008) Imidacloprid 2 – Acute dermal toxicity in Rats. Study Number 24859. Eurofins Product Safety Laboratories. June 3, 2008. MRID 48060204.

SPONSOR: Bayer Environmental Science

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 48060204), two groups (5/sex/group) of Sprague Dawley rats (source: Ace Animals Inc, Boyertown, PA), 8-9 weeks old, weighing from: males 254-271 g; females 200-232 g, were dermally exposed to Imidacloprid 2 at a dose level of 2000 mg/kg bw over an area approximately 2 inch x 3 inch (approximately 10% of the body surface) and covered with a 2 inch x 3 inch, 4- ply gauze pad. The gauze pad and entire trunk of each animal were wrapped with a 3-inch Durapore tape for 24 hours. After 24 hours the test sites were gently cleansed with a soap solution and animals were then observed for 14 days.

There were no deaths in rats.: All animals gained body weight, and appeared active and healthy during the study. There were signs of, dermal irritation, at five dose site between Days 1 and Day 5. Three females (3206, 3208, 3209) showed erythema between Days 1-3, one female (3207) showed erythema from Day 1-3 and desquamation on Day 4; one female (3210) showed erythema from Day 1-3 and desquamation from Day 4-5. No other clinical findings were recorded.

No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14- day observation period.

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

Based on the LD₅₀, Imidacloprid 2 is classified as EPA Toxicity Category III.

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.

	Mortality/Number Tested					
Dose (mg/kg bw)	Males	Females	Combined			
2000	0/5	0/5	0/10			

- A. Mortality: There were no deaths in rats.
- B. Clinical observations: All animals gained body weight, and appeared active and healthy during the study. There were signs of, dermal irritation, at five dose site between Days I and Day 5. Three females (3206, 3208, 3209) showed erythema between Days I-3, one female (3207) showed erythema from Day 1-3 and desquamation on Day 4; one female (3210) showed erythema from Day I-3 and desquamation from Day 4-5. No other clinical findings were recorded.
- C. <u>Gross Necropsy</u>: No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the I4- day observation period.
- **D.** Reviewer's Conclusions: This reviewer agrees with the study author's conclusions. Based on the LD₅₀, the test material is classified as EPA Toxicity Category III.
- E. <u>Deficiencies</u>: None.

Reviewer: Princess Campbell Risk Manager (EPA):01

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

Date: August 25, 2010

TEST MATERIAL: Imidacloprid 2; Lot # 2008-002241; off white liquid; pH 9.80

SYNONYMS: M920 Insecticide

<u>CITATION</u>: Durando, Jennifer. (2008) Imidacloprid 2— Acute inhalation toxicity in Rats. Study Number 24860. Eurofins Product Safety Laboratories. June 13, 2008. MRID 48060205.

SPONSOR: Bayer Environmental Science.

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (MRID 48060205), three groups (5/sex/group) of Sprague Dawley rats (source: Ace Animals Inc, Boyertown, PA); age: 8 – 10 weeks, weight: males 225-307 g; females 189-241 g) were selected. Animals were exposed (nose only) via the inhalation route to Imidacloprid 2 for four hours at concentrations of 0.05, 0.5, and 2.0 mg/L. Animals were then observed for any effects for 14 days.

All animals survived exposure to the test atmosphere at the 0.05 exposure level. Two male rats died within one day after exposure to the test atmosphere at the 0.5 exposure level. Three male and four female rats died within one day of exposure to the test atmosphere at the 2.05 exposure level. Following exposure to Imidacloprid 2 at the 0.5, and 2.05 exposure levels, most animals were hypoactive, exhibited hunched posture, abnormal respiration and dry rales. Surviving animals recovered by Day 2 and appeared active and healthy for the remainder of the study. Upon necropsy abnormalities were noted for the animals from the 0.05, and 0.5 test exposure levels or the euthanized animals from the 2.05 exposure levels when necropsied following the 14-day observation period. Gross necropsy of the descedents from the 2.05 test atmosphere exposure groups revealed discoloured, edematous lungs.

LC₅₀ Males > 1.0977 mg/L LC₅₀ Females > 0.51- 2.05 mg/L

Based on the LC50, Imidacloprid 2 is classified as EPA Toxicity Category III.

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.

	Actual Conc.			Mortality/Number Tested			
Nominal Conc. (mg/L)	(Gravimetric/ Analytical) (mg/L)	MMAD	GSD	Males	Females	Combined	
5.38	0.053	3.1	2.08	0/5	-	0/5	
48.61	0.51	3.4	2.07	2/5	0/5	2/10	
240,28	2.05	3.6	2.11	3/5	4/5	5/10	

Test Atmosphere / Chamber Description:

Gravimetric Conc. (mg/L):	0.05	0.51	2.05
Chamber Volume (L):	6.7	6.7	6.7
Total Airflow (L/min):	25.7	25.7	25.7
Temperature	21-22 (°C)	21	20-21
Relative Humidity (%):	55-58	52-53	50-56
Time to Equilibrium (min):	1.0	1.0	1.0

Test atmosphere concentration: 0.05, 0.5, and 2.0 mg/l

Particle size determination: Particle size was determined by using an eight stage Anderson Cascade Impactor.

<u>Statistics</u>: Probit analysis was used for all data analyses including LC₅₀ and confidence limit calculations.

- **A. Mortality:** All animals survived exposure to the test atmosphere at the 0.05 exposure level. Two male rats died within one day after exposure to the test atmosphere at the 0.5 exposure level. Three male and four female rats died within one day of exposure to the test atmosphere at the 2.05 exposure level.
- **B.** Clinical observations: Following exposure to Imidacloprid 2 at the 0.5, and 2.05 exposure levels, most animals were hypoactive, exhibited hunched posture, abnormal respiration and dry rales. Surviving animals recovered by Day 2 and appeared active and healthy for the remainder of the study.
- C. <u>Gross Necropsy</u>: No gross abnormalities were noted for any of the animals from the 0.05, and 0.5 test atmosphere exposure levels or the euthanized animals from the 2.05 exposure levels when necropsied following the 14-day observation period. Gross necropsy of the descedents from the 2.05 test atmosphere exposure groups revealed discoloured, edematous lungs.

D. Reviewer's Conclusions: This reviewer agrees with the study author regarding the acute inhalation LC_{50} . The test material is classified as EPA Toxicity Category III.

E. Deficiencies: None.

Reviewer: Princess Campbell

Risk Manager (EPA): RM 01

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

TEST MATERIAL: Imidacloprid 2; Lot # 2008-002241; off white liquid; pH 9.80

SYNONYMS: M 920 Insecticide

<u>CITATION</u>: Durando, Jennifer (2008) Mefenoxam 2AQ – Acute Eye Irritation in Rabbits. Study Number 24861. Eurofins Product Safety Laboratories, Dayton, NJ. June 3, 2008. MRID 48060206.

Date: August 25, 2010

SPONSOR: Bayer Environmental Science.

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 48060206) 0.1 ml of Imidacloprid 2 was instilled into the conjunctival sac of the right eye of three rabbits. The untreated left eye of each rabbit served as the control. Animals were then observed for 72 hours. Eye irritation was scored by the method of Draize et al for 17 days post instillation (see table next page).

One hour after test substance instillation all eyes exhibited positive iritis and positive conjunctivitis. All animals were free of ocular irritation by 72 hours. The maximum mean total score was 15.7, recorded 24 hours after test material instillation.

In this study, Imidacloprid 2 is mildly irritating to the eyes of rabbits. Imidacloprid 2 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.

	Numbe	Number "positive"/number tested					
	Hours						
Observations	1	24	48	72			
Corneal Opacity	0/3	1/3	0/3	0/3			
Iritis	3/3	0/3	0/3	0/3			
Conjunctivae:	Conjunctivae:						
Redness*	3/3	0/3	0/3	0/3			
Chemosis*	3/3	0/3	0/3	0/3			
Discharge*	3/3	0/3	0/3	0/3			
Severity of Irritation – Mean Score	15.7	7.0	3.3	0			

^{*}Score of 2 or more required to be considered "positive."

A. Observations: See the table above.

B. Results: Imidacloprid 2 mildly irritating to the eyes of rabbits. The maximum mean total score was 15.7, recorded 24 hours after test material instillation.

C. <u>Reviewer's Conclusions</u>: This reviewer agrees with the study author's conclusions. Imidacloprid 2 is classified as EPA Toxicity Category III.

D. <u>Deficiencies</u>: None.

Reviewer: Princess Campbell

Risk Manager (EPA):01

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

TEST MATERIAL: Imidacloprid 2; Lot # 2008-002241; off white liquid; pH 9.80.

SYNONYMS: M920 Insecticide

<u>CITATION</u>: Durando, Jennifer (2008) Imidacloprid 2-Dermal Irritation in Rabbits. Study Number 24862. Eurofins Product Safety Laboratories. October 20, 2008. MRID 48060207

Date: August 25, 2010

SPONSOR: Bayer Environmental Science

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 48060207), three male New Zealand White rabbits (source: Robinson Services, Inc, Clemmons, NC) were dermally exposed to 0.5 ml of undiluted Imidacloprid 2, for four hours on a 6 cm² area of the clipped skin of the dorsal area of the trunk. Test sites were covered with a 1 inch x 1 inch 4-ply gauze pad. The pad and entire trunk of each animal were then wrapped with semi-occlusive 3 inch Micropore tape. Elizabethan collars were placed on each rabbit. Animals were then observed for three days for skin irritation and scored by the method of Draize et al.

All the irritation subsided within 24 hours. In this study, Imidacloprid 2 is slightly irritating. Primary Dermal Irritation Index (PDII) = 1.0.

Based on the results, the test material 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.

INDIVIDUAL SKIN IRRITATION SCORES

ERYTHEMA/EDEMA

		Hours After Patch Removal					
Animal No.	Sex	30-60 minutes	24	48	72		
I	M	2/1	1/0	0/0	0/0		
2	M	2/1	1/0	0/0	0/0		
3	М	2/1	1/0	0/0	0/0		
Severity of Irritation - Mean Score		2.0/1.0	1.0/0	0	0		

A. Observations: See table above.

B. Results: Primary Dermal Irritation Index (PDII) = 1.0.

C. <u>Reviewer's Conclusions</u>: TRB agrees with the study author's conclusions. Based on the results, the test material is classified as EPA Toxicity Category IV.

D. Deficiencies: None.

Reviewer: Princess Campbell

Risk Manager (EPA):01

STUDY TYPE: Dermal Sensitization - Guinea Pig; OPPTS 870.2600; OECD 406, 429

Date: August 25, 2010

TEST MATERIAL: Imidacloprid 2; Lot # 2008-002241; off white liquid; pH 9.8

SYNONYMS: M 920 Insecticide

<u>CITATION</u>: Durando, Jennifer (2008) Imidacloprid 2— Dermal Sensitization in Guinea Pigs. Study Number 24863. Eurofins Product Safety Laboratories. October 21, 2008. MRID 48060208

SPONSOR: Bayer Healthcare LLC.

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID 43060208) with Imidacloprid 2, 30 Guinea pigs, Hartley, species (source: Elm Hill Breeding Labs, Chelmsford, MA; weight females 328-399 g) were tested using the Buehler method. Based on the screening test, once each week for three weeks, 0.4 mL of the undiluted test substance was applied to the left side of each test animal using a 1 inch x 1 inch, 4-ply gauze patch. The sites were then covered with a strip of plastic film and then wrapped with non-allergenic Durapore adhesive tape. After a 6-hour exposure period the patches were removed and the test sites were cleansed of any residual test substance. Animal were challenged after 27 days (with 100% HNIC). Additional 10 guinea pigs were treated with 0.4 mL of the test substance (100% HNIC), topically applied to a naive site on the right side of each animal (naive controls).

There was no dermal irritation observed at any naïve control test site 24 or 48 hours after challenge. Three of twenty animals exhibited signs of a sensitization response (faint erythema) 24 hours after challenge. Very faint erythema was observed at these test sites at 48 hours. Very faint erythema (0.5) was noted for most other sites.

The report included the results of a positive HCA study conducted within six months of the current study; July 10, 2008. The results were appropriate.

Based on the results of this study, Imidacloprid 2 is 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.

I. PROCEDURE:

- A. Induction: In a dermal sensitization study with Imidacloprid 2, 30 Guinea pigs were tested using the Buehler method. Once each week for three weeks, 0.4 mL of the undiluted test substance was applied to the left side of each test animal using an occlusive 25 mm Hil Top Chamber. The chambers were secured with non-allergenic Durapore adhesive tape. After a 6-hour exposure period the chambers were removed and the test sites were cleansed of any residual test substance.
- **B.** Challenge: Twenty seven days after the first induction, 0.4 mL of the test substance (25% HNIC) was topically applied to a naive site on the right side of each animal. Sites were evaluated approximately 24 and 48 hours after the challenge.
- C. <u>Naive Controls</u>: At challenge, an additional 10 guinea pigs were treated with 0.4 mL of the test substance (25% HNlC), topically applied to a naive site on the right side of each animal. Sites were evaluated approximately 24 and 48 hours after the challenge.

<u>Rechallenge Phase</u>: Due to ambiguous results for the test animals following the challenge phase, it was necessary to conduct a rechallenge using the same concentration of the test material seven days after the primary challenge.

II. RESULTS and DISCUSSION:

- A. <u>Reactions and duration</u>: There was no dermal irritation observed at any naïve control test site 24 or 48 hours after challenge. Three of twenty animals exhibited signs of a sensitization response (faint erythema) 24 hours after challenge. Very faint erythema was observed at these test sites at 48 hours. Very faint erythema (0.5) was noted for most other sites.
- **B.** <u>Positive control</u>: The report included the results of a positive HCA study conducted within six months of the current study; July 10, 2008.
- C. <u>Reviewer's Conclusions</u>: This reviewer agrees with the study author that the test material is a dermal sensitizer.
- D. Deficiencies: None.

ACUTE TOX ONE-LINERS

1. DP BARCODE: 377087 **2. PC CODE:** 129099

3. CURRENT DATE: August 25, 2010,

4. TEST MATERIAL: Imidacloprid 2; Lot # 2008-002241; off white liquid; pH 9.8

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grad e
Acute oral toxicity / rat Eurofins Product Safety Laboratories, Dayton, NJ. 24858/June 2, 2008	48060203	LD ₅₀ > 623.3 mg/kg (females)	III	A
Acute dermal toxicity / rat Eurofins Product Safety Laboratories, Dayton, NJ 24859/ June 3, 2008	48060204	LD ₅₀ >2000 mg/kg (males and females)	Ш	A
Acute inhalation toxicity / rat Eurofins Product Safety Laboratories, Dayton, NJ 24860/ June 13, 2008	48060205	LC ₅₀ > 1.0977 mg/L (males); 0.51 -2.05 mg/L (females)	III	A
Primary eye irritation / rabbit Eurofins Product Safety Laboratories, Dayton, NJ 24861/ June 3, 2008	48060206	Mild irritation	III	A
Primary dermal irritation / rabbit Eurofins Product Safety Laboratories, Dayton, NJ 24862/ October 20, 2008	48060207	Slightly irritating	IV	A
Dermal sensitization / guinea pig Eurofins Product Safety Laboratories, Dayton, NJ 24863/October 21, 2008	48060208	Sensitizing	-	A

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