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

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

12/JUN/2007

MEMORANDUM

Subject: Name of Pesticide Product: GF-1118
EPA Reg. No. /File Symbol: 62719-LTA
DP Barcode: D335725
Decision No.: 372917
PC Code: 005100

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

To: Eugene Wilson, RM Team 23
Herbicide Branch
Registration Division (7505P)

Applicant: Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, IN 46268

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Potassium salt of 2-pyridine carboxylic acid, 4-amino -3, 6-dichloro-	88.8
Inert Ingredient(s):	11.2
Total:	100.0%

Acid equivalent: aminopyralid (2-pyridine carboxylic acid, 4-amino-3, 6-dichloro-) - 75%

ACTION REQUESTED: The Risk Manager requests:

Please review the acute toxicity data submitted in support of this new chemical.

BACKGROUND: Dow AgroSciences LLC has submitted a six pack of acute toxicity studies to support the registration of the proposed product, GF-1118, EPA File Symbol 62719-LTA. The studies were conducted at Product Safety Laboratories, Dayton, New Jersey with assigned MRID numbers 470101-03 to -08. A CSF dated December 1, 2006 for a basic formulation is included in the submission.

RECOMMENDATIONS: The six studies have been reviewed and are classified as acceptable. They do support registration of the proposed product.

The acute toxicity profile for GF-1118, EPA File Symbol 62719-LTA, is as follows:

Acute oral toxicity	IV	Acceptable	MRID 47010103
Acute dermal toxicity	IV	Acceptable	MRID 47010104
Acute inhalation toxicity	IV	Acceptable	MRID 47010105
Primary eye irritation	IV	Acceptable	MRID 47010106
Primary skin irritation	IV	Acceptable	MRID 47010107
Dermal sensitization	Neg.	Acceptable	MRID 47010108

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 #: 062719-00576

PRODUCT NAME: GF-1118

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION (optional)

Hazards to Humans and Domestic Animals:

Wear: Long-sleeved shirt and long pants, socks, shoes, and chemical-resistant gloves (such as Natural Rubber, Selection Category A).

First Aid: No statements are required. Registrant may use Category 3 statements.

Reviewer: Eugenia McAndrew **Date:** June 12, 2007
Risk Manager: 23

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

TEST MATERIAL: GF-1118 (XDE-750 Formulation) [Lot # F0443-151; TSN104131; 89.8% w/w XDE-750 potassium (a.i.) and 75.9% w/w XDE-750 (a.e.); light brown solid granules; pH 4-10; specific gravity - 1.415 g/mL)

CITATION: Merkel, D. (2003) Acute Oral Toxicity Up and Down Procedure in Rats. Product Safety Laboratories, Dayton, New Jersey. Laboratory Study Number 13986. September 18, 2003. MRID 47010103 Unpublished.

SPONSOR: The Dow Chemical Company Midland, MI for Dow AgroSciences LLC, Indianapolis, IN 46268

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 47010103), four female Fischer 344 young adult rats (age: 9 weeks; source: Hilltop Animals, Scottdale, PA; 133-138 g) were given a single oral dose of GF-1118 (XDE-750 Formulation) [Lot # F0443-151; TSN104131; 89.8% w/w XDE-750 potassium (a.i.) and 75.9% w/w XDE-750 (a.e.); light brown solid granules; pH 4-10; specific gravity - 1.415 g/mL) using the Up and Down Procedure. The test substance was administered as a 60% w/w suspension in distilled water. A limit dose of 5000 mg/kg of the test substance was administered to one healthy female rat by oral gavage. This animal survived so two additional females received the same dose level. Due to the mortality of one of these animals, one additional female received the same dose level. Animals were then observed for 14 days.

Oral LD_{50} Females > 5000 mg/kg bw

One animal died by day 2. No toxic signs were noted in the decedent. One of the surviving animals was observed with ano-genital staining but recovered by day 1. All surviving animals gained weight. At necropsy, discoloration of the lungs and gaseous distention of the GI tract were noted in the decedent. No gross abnormalities were noted in the other three animals.

Toxicity based on the calculated LD_{50} with one death at the limit dose. EPA Toxicity Category IV.

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:

Individual animals were dosed as follows:

Limit Test

Dosing Sequence	Animal No.	Dose level (mg/kg)	Short Term Outcome	14 Day Outcome
1	172	5000	S	S
2	189	5000	D	D
3	190	5000	S	S
4	259	5000	S	S

S = survival D = death

A. Mortality - One animal died by day 2.

B. Clinical observations - No toxic signs were noted in the decedent. One of the surviving animals was observed with ano-genital staining but recovered by day 1. All surviving animals gained weight.

C. Gross Necropsy - Discoloration of the lungs and gaseous distention of the GI tract were noted in the decedent. No gross abnormalities were noted in the other three animals.

D. Reviewer's Conclusions: We agree with the study author that the acute oral LD_{50} of GF-1118 (XDE-750 Formulation) is greater than 5000 mg/kg of body weight in female rats.

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

Date/Time: Wednesday, June 06, 2007, 1:12:06 PM
Data file name: GF-1118.dat
Last modified: 6/6/2007 1:12:08 PM

Test/Substance: GF-1118
Test type: Limit Test
Limit dose (mg/kg): 5000
Assumed LD50  (mg/kg): Default
Assumed sigma (mg/kg): 0.5
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DATA:

Test Seq.	Animal ID	Dose (mg/kg)	Short-term Result	Long-term Result
1	172	5000	O	O
2	189	5000	X	X
3	190	5000	O	O
4	259	5000	O	O

(X = Died, O = Survived)

Dose Recommendation: The limit test is complete.

SUMMARY OF LONG-TERM RESULTS:

Dose	O	X	Total
5000	3	1	4
All Doses	3	1	4

Statistical Estimates:

The LD50 is greater than 5000 mg/kg.

Reviewer: Eugenia McAndrew
Risk Manager: 23

Date: June 12, 2007

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

TEST MATERIAL: GF-1118 (XDE-750 Formulation) [Lot # F0443-151; TSN104131; 89.8% w/w XDE-750 potassium (a.i.) and 75.9% w/w XDE-750 (a.e.); light brown solid granules; pH 4-10)

CITATION: Merkel, D. (2003) Acute Dermal Toxicity Study in Rats- Limit Test. Product Safety Laboratories, Dayton, New Jersey. Laboratory Study Number 13987. September 18, 2003. MRID 47010104 Unpublished.

SPONSOR: The Dow Chemical Company Midland, MI for Dow AgroSciences LLC, Indianapolis, IN 46268

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 47010104), 5/sex of Fischer 344 young adult rats (age: 9 weeks; source: Hilltop Animals, Scottdale, PA; 207-215 g males and 135-150 g females) were dermally exposed to GF-1118 (XDE-750 Formulation) [Lot # F0443-151; TSN104131; 89.8% w/w XDE-750 potassium (a.i.) and 75.9% w/w XDE-750 (a.e.); light brown solid granules; pH 4-10). Prior to application, the test substance was moistened with distilled water to achieve a dry paste by preparing a 75% w/w mixture. Five thousand mg/kg of body weight of the test substance was applied to a dose area of approximately 2 inches x 3 inches (approximately 10% of the body surface) and covered with a gauze pad. The gauze pad and entire trunk of each animal was wrapped with tape for a 24 hour period. After 24 hours the pads were removed and the sites were cleansed. Animals were then observed for 14 days.

Dermal LD_{50} Males > 5000 mg/kg bw
Dermal LD_{50} Females > 5000 mg/kg bw
Dermal LD_{50} Combined > 5000 mg/kg bw

All animals survived and gained weight. "There were no signs of gross toxicity, dermal irritation, adverse pharmacologic effects or abnormal behavior." No gross abnormalities were noted at necropsy.

Toxicity based on no deaths at the limit dose. 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 - None

B. Clinical observations - All animals gained weight. "There were no signs of gross toxicity, dermal irritation, adverse pharmacologic effects or abnormal behavior."

C. Gross Necropsy - No gross abnormalities were noted.

D. Reviewer's Conclusions: We agree with the study author that the acute dermal LD_{50} of GF-1118 (XDE-750 Formulation) is greater than 5000 mg/kg bw in male and female rats.

Reviewer: Eugenia McAndrew **Date:** June 12, 2007
Risk Manager: 23

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

TEST MATERIAL: GF-1118 (Lot # F1096-169; TSN104632; 87.9% w/w XDE-750 potassium salt (a.i.) and 74.3% w/w XDE-750 (a.e.); light tan solid granule)

CITATION: Merkel, D. (2004) Acute Inhalation Toxicity Study in Rats- Limit Test. Product Safety Laboratories, Dayton, New Jersey. Laboratory Study Number 15920. December 16, 2004. MRID 47010105 Unpublished.

SPONSOR: The Dow Chemical Company Midland, MI for Dow AgroSciences LLC, Indianapolis, IN 46268

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (MRID 47010105), 5/sex of young adult Fischer 344 young adult rats (age: 9-10 weeks; source: Hilltop Animals, Scottdale, PA; 226-239 g males and 140-151 g females) were exposed (nose only) via the inhalation route to aerosolized GF-1118 (Lot # F1096-169; TSN104632; 87.8% w/w XDE-750 potassium salt (a.i.) and 74.3% w/w XDE-750 (a.e.); light tan solid granule) for 4 hours at a concentration of 5.10 mg/L. Animals were then observed for 14 days.

LC_{50} Males > 5.10 mg/L
LC_{50} Females > 5.10 mg/L
LC_{50} Combined > 5.10 mg/L

All animals survived and gained weight. "There were no signs of gross toxicity, adverse clinical signs or abnormal behavior." No gross abnormalities were noted at necropsy. The gravimetric chamber concentration was 5.10 mg/L and the mass median aerodynamic diameter was estimated to be 3.1 µm with a geometric standard deviation of 1.76.

Toxicity is based on no deaths at the limit dose. 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:

Nominal Conc. (mg/L)	Gravimetric Conc. (mg/L)	MMAD µm	GSD	Mortality/Number Tested		
				Males	Females	Combined
23.18	5.10	3.1	1.76	0/5	0/5	0/10

Test Atmosphere / Chamber Description:

Chamber Volume:	6.7 L
AirFlow:	31.6 LPM
Temperature:	20-21°C
Relative Humidity:	57-68%
Time to Equilibrium T_{99}:	1.0 min.

Test atmosphere concentration - Gravimetric samples were withdrawn at 6 intervals from the breathing zone of the animals. Filter papers were weighed before and after collection to determine the chamber concentration. This value was divided by the total volume of air sampled to determine the chamber concentration.

Particle size determination - Particle size was determined twice during the exposure. The MMAD and geometric standard deviation were determined graphically using the two-cycle logarithmic probit axes.

A. **Mortality** - None

B. **Clinical observations** - All animals survived and gained weight. "There were no signs of gross toxicity, adverse clinical signs or abnormal behavior."

C. **Gross Necropsy** - No gross abnormalities were noted.

D. **Reviewer's Conclusions:** We agree with the study author that the acute inhalation LC_{50} for GF-1118 is greater than 5.10 mg/L in male and female rats.

Reviewer: Eugenia McAndrew
Risk Manager: 23

Date: June 12, 2007

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

TEST MATERIAL: GF-1118 (XDE-750 Formulation) [Lot # F0443-151; TSN104131; 89.8% w/w XDE-750 potassium (a.i.) and 75.9% w/w XDE-750 (a.e.); light brown solid granules; pH 4-10)

CITATION: Merkel, D. (2003) Primary Eye Irritation in Rabbits. Product Safety Laboratories, Dayton, New Jersey. Laboratory Study Number 13988 September 18, 2003. MRID 47010106 Unpublished.

SPONSOR: The Dow Chemical Company Midland, MI for Dow AgroSciences LLC, Indianapolis, IN 46268

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 47010106), GF-1118 (XDE-750 Formulation) [Lot # F0443-151; TSN104131; 89.8% w/w XDE-750 potassium (a.i.) and 75.9% w/w XDE-750 (a.e.); light brown solid granules; pH 4-10) was instilled into the conjunctival sac of the right eye of three male young adult New Zealand albino rabbits (source: Davidson's Mill Farm, South Brunswick, NJ). The left eye served as the control. Prior to instillation, the test substance was ground to a powder. One-tenth of a milliliter (0.05-0.06 g) of the ground test substance was instilled into each eye. Animals were then observed at 1, 24, 48, and 72 hours post-instillation. Irritation was scored by the method of Draize.

Conjunctival redness was noted in 3/3 eyes at the one hour observation. A score of 1 was still noted for conjunctivitis but no positive scores were noted at 24 hours. All eyes were free of irritation by 48 hours.

In this study, the formulation is minimally irritating to the eye. EPA Toxicity Category IV.

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:

	Number "positive"/number tested			
Observations	**Hours**			
	1	24	48	72
Corneal Opacity	0/3	0/3	0/3	0/3
Iritis	0/3	0/3	0/3	0/3
Conjunctivitis*				
Redness*	3/3	0/3	0/3	0/3
Chemosis*	0/3	0/3	0/3	0/3
Discharge*	0/3	0/3	0/3	0/3

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

A. Observations - Conjunctival redness was noted in 3/3 eyes at the one hour observation. A score of 1 was still noted for conjunctivitis but no positive scores were noted at 24 hours. All eyes were free of irritation by 48 hours.

B. Reviewer's Conclusions: We agree with the study author that GF-1118 (XDE-750 Formulation) is minimally irritating to the eye.

Reviewer: Eugenia McAndrew
Risk Manager: 23

Date: June 12, 2007

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

TEST MATERIAL: GF-1118 (XDE-750 Formulation) [Lot # F0443-151; TSN104131; 89.8% w/w XDE-750 potassium (a.i.) and 75.9% w/w XDE-750 (a.e.); light brown solid granules; pH 4-10)

CITATION: Merkel, D. (2003) Primary Skin Irritation in Rabbits. Product Safety Laboratories, Dayton, New Jersey. Laboratory Study Number 13989. September 18, 2003. MRID 47010107 Unpublished.

SPONSOR: The Dow Chemical Company Midland, MI for Dow AgroSciences LLC, Indianapolis, IN 46268

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 47010107), three young adult New Zealand albino rabbits (2 male and 1 female; source: Davidson's Mill Farm, NJ) were dermally exposed to 0.5 mL of GF-1118 (XDE-750 Formulation) [Lot # F0443-151; TSN104131; 89.8% w/w XDE-750 potassium (a.i.) and 75.9% w/w XDE-750 (a.e.); light brown solid granules; pH 4-10). Prior to application, the test substance was ground to a powder and then moistened with distilled water to achieve a dry paste by preparing a 75% w/w mixture. Five-tenths of a gram of the ground test substance (0.67 g of the mixture) was placed on a 1 inch by 1 inch gauze pad and applied to one 6 cm^2 site on the dorsal area of each animal. The pad and entire trunk of each animal was wrapped with semi-occlusive tape. After a four hour exposure period, the pads were removed and the sites were cleansed of residual test substance. Animals were then observed at 1, 24, 48 and 72 hours after patch removal. Irritation was scored by the method of Draize.

Primary Dermal Irritation Index (PDII) = 0.17 Very slight erythema was noted at 2/3 test sites one hour after patch removal. All sites were free of dermal irritation by 24 hours.

In this study, the formulation is slightly irritating. 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 No.	Sex	Hours After Patch Removal			
		1	24	48	72
9978	M	1/0	0/0	0/0	0/0
9979	F	1/0	0/0	0/0	0/0
9980	M	0/0	0/0	0/0	0/0

A. Observations - Very slight erythema was noted at 2/3 test sites one hour after patch removal. All sites were free of dermal irritation by 24 hours.

B. Results - Primary Dermal Irritation Index (PDII) = 0.17

C. Reviewer's Conclusions: We agree with the study author that GF-1118 (XDE-750 Formulation) is slightly irritating to the skin.

Reviewer: Eugenia McAndrew
Risk Manager: 23

Date: June 12, 2007

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

TEST MATERIAL: GF-1118 [Lot # TSN104131; 89.8% w/w XDE-750 potassium (a.i.) and 75.9% w/w XDE-750 (a.e.); light brown solid granules; pH 4-10)

CITATION: Merkel, D. (2003) Dermal Sensitization Study in Guinea Pigs (Magusson-Kligman Method). Product Safety Laboratories, Dayton, New Jersey. Laboratory Study Number 14164. December 1, 2003. MRID 47010108 Unpublished.

SPONSOR: The Dow Chemical Company Midland, MI for Dow AgroSciences LLC, Indianapolis, IN 46268

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID 47010108) with GF-1118 [Lot # TSN104131; 89.8% w/w XDE-750 potassium (a.i.) and 75.9% w/w XDE-750 (a.e.); light brown solid granules; pH 4-10) , 30 Hartley albino male guinea pigs (source: Elm Hill Breeding Labs, Chelmsford, MA; 310-401 g) were tested using the Magnusson-Kligman method. The test substance was a granular material. To enhance skin contact, the test substance was ground to a powder and moistened with distilled water prior to application. The procedures were validated using alpha-Hexylcinnamaldehyde (HCA) in PSL study #13923 as the positive control substance

The animals were induced with intradermal injection and topical application and then challenged by topical application. The animals were placed into two groups - ten control and 20 treatment. Preliminary irritation testing was performed to determine appropriate concentrations of the test substance to be used for induction and challenge.

For the intradermal induction, animals in the two groups were treated with six injections (0.1 mL) each. The treatment group received pairs of injections of the test substance in distilled water, the test substance combined with Complete Freund's Adjuvant and Adjuvant alone. The animals in the control group received pairs of injections of distilled water, distilled water combined with Complete Freund's Adjuvant and Adjuvant alone.

One week later, the topical induction phase was initiated. Twenty-four hours prior to the topical induction, the shoulder area of each test and control animal was treated with sodium lauryl sulfate in order to enhance sensitization. Approximately twenty-five hours after application, readings were made of local reactions. The test sites were cleansed of any residual sodium lauryl sulfate. A gauze patch containing 0.5 g of a 75% w/w mixture of the test substance in distilled water was applied to the intradermal injection sites of the treatment group of animals. After a 48-hour exposure period, the patches were removed and the sites were cleansed. Readings were made for local reactions one hour after patch removal. The control group received the same treatment using 0.5 mL of distilled water for the topical application.

Twenty-one days after test initiation, the challenge phase was initiated. Four-tenths of a gram of a 75% w/w mixture of the test substance in distilled water (highest non-irritating concentration) was applied to a naïve site on each test and control animal for a 24- hour exposure period. After 24 hours, the sites were cleansed of any residual test substance. The skin reactions were

evaluated for a sensitization response in the control and treatment groups at 24 and 48 hours after removal of the test patches.

In this study, formulation is not a dermal sensitizer.

Following the topical induction phase, very faint to faint erythema (0.5-1) was noted at all of the test sites one hour after patch removal. Very faint erythema was noted at 9/10 control animal sites during the induction phase. Following the challenge, very faint erythema (0.5) was noted at 8/20 test animal sites at 24 hours persisting at 5 sites at 48 hours. In the control animals, very faint erythema (0.5) was noted at 5/10 sites at 24 hours persisting at 3 sites at 48 hours. No sensitizing responses were noted in any of the animals.

In this study, the formulation 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) in the Guinea pig.

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

I. PROCEDURE

A. Induction - For the intradermal induction, animals in the two groups were treated with six injections (0.1 mL) each. The treatment group received pairs of injections of the test substance in distilled water, the test substance combined with Complete Freund's Adjuvant and Adjuvant alone. The animals in the control group received pairs of injections of distilled water, distilled water combined with Complete Freund's Adjuvant and Adjuvant alone.

One week later, the topical induction phase was initiated. Twenty-four hours prior to the topical induction, the shoulder area of each test and control animal was treated with sodium lauryl sulfate in order to enhance sensitization. Approximately twenty-five hours after application, readings were made of local reactions. The test sites were cleansed of any residual sodium lauryl sulfate. A gauze patch containing 0.5 g of a 75% w/w mixture of the test substance in distilled water was applied to the intradermal injection sites of the treatment group of animals. After a 48-hour exposure period, the patches were removed and the sites were cleansed. Readings were made for local reactions one hour after patch removal. The control group received the same treatment using 0.5 mL of distilled water for the topical application.

B. Challenge - Twenty-one days after test initiation, the challenge phase was initiated. Four-tenths of a gram of a 75% w/w mixture of the test substance in distilled water (highest non-irritating concentration) was applied to a naïve site on each test and control animal for a 24 hour exposure period. After 24 hours, the sites were cleansed of any residual test substance. The skin reactions were evaluated for a sensitization response in the control and treatment groups at 24 and 48 hours after removal of the test patches.

II. RESULTS and DISCUSSION:

A. Reactions and duration - Following the topical induction phase, very faint to faint erythema (0.5-1) was noted at all of the test sites one hour after patch removal. Very faint erythema was noted at 9/10 control animal sites during the induction phase. Following the challenge, very faint erythema (0.5) was noted at 8/20 test animal sites at 24 hours persisting at 5 sites at 48 hours. In the control animals, very faint erythema (0.5) was noted at 5/10 sites at 24 hours persisting at 3 sites at 48 hours. No sensitizing responses were noted in any of the animals.

B. Positive control - The positive results of the HCA study validate the test system used in this study.

C. Reviewer's Conclusions: We agree with the study author that based on the findings and evaluation system used, GF-1118 is not considered to be a contact sensitizer.

D. Deficiencies: The study author reports that the study protocol requires that the individual body weights of the animals be recorded the day after challenge application. Due to a technician oversight, these body weights were not recorded. This deviation did not affect the outcome of the study.

ACUTE TOX ONE-LINERS

1. **DP BARCODE:** D335725
2. **PC CODE:** 005100
3. **CURRENT DATE** 12/JUN/2007
4. **TEST MATERIAL:** GF-1118 (XDE-750 Formulation) [Lot # F0443-151; TSN104131; 89.8% w/w XDE-750 potassium (a.i.) and 75.9% w/w XDE-750 (a.e.); light brown solid granules; pH 4-10)

* GF-1118 (Lot # F1096-169; TSN104632; 87.9% w/w XDE-750 potassium salt (a.i.) and 74.3% w/w XDE-750 (a.e.); light tan solid granule)

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity / rat Product Safety Lab 13986/9-18-03	47010103	LD_{50} > 5000 mg/kg (females)	IV	A
Acute dermal toxicity / rat Product Safety Lab 13987/9-18-03	47010104	LD_{50} > 5000 mg/kg (males and females)	IV	A
*Acute inhalation toxicity / rat Product Safety Lab 15920/12-16-04	47010105	LC_{50} > 5.10 mg/L (males and females)	IV	A
Primary eye irritation / rabbit Product Safety Lab 13988/9-18-03	47010106	Conjunctivitis in 3/3 eyes at one hour. No positive scores at 24 hours. All eyes free of irritation by 48 hours.	IV	A
Primary dermal irritation / rabbit Product Safety Lab 13989/9-18-03	47010107	PDII = 0.17 Very slight erythema at 2/3 sites at one hour. All sites free of irritation by 24 hours.	IV	A
Dermal sensitization / guinea pig Product Safety Lab 1416412-1-03	47010108	Not a sensitizer	--	A

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