

US EPA ARCHIVE DOCUMENT



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

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

OCT
06/SEPT/2004

MEMORANDUM

Subject: Name of Pesticide Product: GF-871
EPA File Symbol: 62719-LRO
DP Barcode: 306167
Decision #: 341122
PC Code: 005209 Triisopropanolamine salt of aminopyralid

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

Byron T. B...
10-06-04

To: Eugene Wilson, PM 23
Herbicide Branch
Registration Division (7505C)

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

Byron T. B...
Rec'd.
10-06-04

FORMULATION from the Label:

Active Ingredient(s): % by wt.
Triisopropanolamine salt of aminopyralid 40.6

Inert Ingredient(s): 59.4

Total: 100.0%

ACTION REQUESTED: PM requests review of acute toxicity in support of GF-871, EPA File Symbol: 62719-LRO.

BACKGROUND: Dow AgroSciences LLC has submitted 6 acute toxicity studies (MRIDs 46235604, 46235606, 46235608, 46235610, 46235612, and 46235614) in support of the registration of GF-871, EPA File Symbol: 62719-LRO. This end use herbicide contains the triisopropanolamine salt of aminopyralid and will be used to control annual and perennial broadleaf weeds in wheat, on rangeland, permanent pastures, CRP acres, non cropland areas, and other labeled areas. The studies were conducted at the Toxicology and Environmental Research and Consulting (Dow Chemical) and Springborn Laboratories, Inc.

RECOMMENDATIONS: The studies submitted by Dow AgroSciences LLC are acceptable. The acute toxicity for EPA File Symbol 62719-LRO:

acute oral toxicity (rat)	IV	Acceptable	MRID 46235604 *
acute dermal toxicity	IV	Acceptable	MRID 46235606
acute inhalation toxicity	IV	Acceptable	MRID 46235608
primary eye irritation	IV	Acceptable	MRID 46235610
primary skin irritation	IV	Acceptable	MRID 46235612
dermal sensitization	Neg	Acceptable	MRID 46235614

*The incorrect protocol (OECD 401: Acute Oral LD50) was used for this test. Although, we accepted the study in this case, our guidance is that OECD 401 is an unacceptable protocol. Please inform the Registrant that the preferred protocol is OECD 425: Acute Oral Toxicity-Up-and-Down Procedure.

PRECAUTIONARY LANGUAGE: Note that the registrant has included toxicity category III labeling for eye irritation ("causes moderate eye irritation"). This is voluntary labeling and is acceptable with a first aid statement. We have rewritten it slightly to reflect category III precautionary labeling for the eye, as detailed in the label review manual (3rd edition)

Hazards to Humans and Domestic Animals

CAUTION

Causes moderate eye irritation. Do not get in eyes or on 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.

Personal Protective Equipment (PPE)

Applicators and Handlers of this product must wear:

Long-sleeve shirt and long pants

Socks and Shoes

Reentry workers of this product must wear

Coveralls

Socks + Shoes

(PPE for reentry workers should appear in the agricultural use requirements box)

USER SAFETY REQUIREMENTS

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS.

IMPORTANT: when reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.

USER SAFETY RECOMMENDATIONS

Wash thoroughly with soap and water after handling. Wash hands before eating, drinking chewing gum, using tobacco or using the toilet.

Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes. Call a poison control center 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

September 28, 2004

Product Manager (EPA): 23

STUDY TYPE: Acute Oral Toxicity - rat; OPPTS 870.1100; OECD 401

TEST MATERIAL (% a.i.): GF-871, 41.9% XDE-750 Triisopropanolammonium, (calculated from XDE-750 21.8%), Lot/Reference # TSN103622/E-1175-52, pH 7.35, dark brown liquid

CITATION: Wilson, D.M., Brooks, K.J. and Radtke, B.J. GF-871: Acute Oral Toxicity Study in Fischer 344 Rats. Toxicology and Environmental Research and Consulting, Midland, Michigan. Laboratory Project Study ID: 021096. December 2, 2002. MRID 46235604. Unpublished.

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

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 46235604), 5 male and 5 female Fischer 344 rats [(Source: Charles River Laboratories, Inc.; Age: approximately 7 weeks (both sexes); Weight: males 136.2-137.2g, females 91.6-94.4g) were given an oral dose of undiluted GF-871, 41.9% XDE-750 Triisopropanolammonium, (calculated from XDE-750 21.8%), Lot/Reference # TSN103622/E-1175-52, pH 7.35, dark brown liquid at a dose level of 5000 mg/kg. Animals were observed for signs of toxicity or clinical abnormalities minimally twice a day on the first day and daily thereafter (including weekends and holidays) until study termination. Bodyweights were taken prestudy, on the day of test substance administration, and on study days 2, 8 and 15. A necropsy examination was performed on all test animals.

Oral LD₅₀ males is greater than 5000 mg/kg (0/5 died)

Oral LD₅₀ females is greater than 5000 mg/kg (0/5 died)

Toxicity based on the lack of mortality in the male and female rat. 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 401) in the rat.

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

RESULTS and DISCUSSION:

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

A. **Mortality** - as noted in table.

B. **Clinical observations** - All animals (5/5 males, 5/5 females) survived to study termination. "Clinical observations included bilateral cloudy eyes in all animals on test day 1, lacrimation, watery or soft feces, and soiling of periocular and /or perineal regions. All symptoms were resolved by study day 4. All animals gained weight throughout the study.

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

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

E. **Deficiencies** - None

Reviewer: Tracy Keigwin

September 28th, 2004

Product Manager (EPA): 23

STUDY TYPE: Acute Dermal Toxicity - rat; OPPTS 870.1200

TEST MATERIAL (% a.i.): GF-871, 41.9% XDE-750 Triisopropanolammonium, (calculated from XDE-750 21.8%), Lot/Reference # TSN103622/E-1175-52, pH 7.35, dark brown liquid

CITATION: Wilson, D.M., Brooks, K.J. and Radtke, B.J. GF-871: Acute Dermal Toxicity Study in Fischer 344 Rats. Toxicology and Environmental Research and Consulting, Midland, Michigan. Laboratory Project Study ID: 021097. December 2, 2002. MRID 46235606. Unpublished.

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

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 46235606), 5 male and 5 female Fischer 344 rats (Source: Charles River Laboratories, Inc.; Age: 7 weeks (both sexes); Weight: males 148.3-160.3g, females 101.0-106.9g) were dermally exposed to GF-871, 41.9% XDE-750 Triisopropanolammonium, (calculated from XDE-750 21.8%), Lot/Reference # TSN103622/E-1175-52, pH 7.35, dark brown liquid to the clipped dorsal trunk region of test animals at a dose level of 5000 mg/kg. The test substance was covered with a 6 x 6 cm gauze which was held in place with elastic tape and wrap. After 24 hours all binding materials were removed and the test areas were wiped with a disposable towel moistened with water. Animals were observed for clinical abnormalities twice on the day of treatment and daily thereafter (including weekends and holidays). Bodyweights were taken pre-study, the day of treatment and again on days 2, 8 and 15.

Dermal LD₅₀ > 5000 mg/kg bw (both sexes)

Toxicity based on the lack of mortality observed at the 5000 mg/kg dose level. 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** - No mortality was observed during the study. Treatment related abnormalities included perineal soiling in one male rat (1/5) and a reddening of the skin on the dermal test site in 2 male rats, the reddening resolving by day 3 or 6. Both sexes lost weight by study day 2, but regained weight during the study.

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

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

E. **Deficiencies:** None.

DATA EVALUATION RECORD

STUDY TYPE: ACUTE INHALATION TOXICITY TESTING (870.1300 formerly §81-3)

Product Manager: 23

Reviewer: Tracy Keigwin

TEST MATERIAL (% a.i.): GF-871 (Lot E-1175-52), 41.9% XDE-750
Triisopropanolammonium by weight.

CITATION: Landry, T.D., Krieger, S.M. GF-871: Acute Liquid Aerosol Inhalation Toxicity Study in Fischer 344 Rats. Toxicology and Environmental Research and Consulting, Midland, Michigan. Laboratory Project Study ID: 021061. June 13, 2002. MRID 46235608. Unpublished.

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

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (MRID 46235608), 5 male and 5 female Fischer - 344 rats (Source: Charles River Laboratories; Age: 7 weeks (both sexes) ; Weight: males 171.7 - 179.9g , females 125.9-128.7g on the day of exposure) were exposed via the "nose only" inhalation route to GF-871 (Lot E-1175-52), 41.9% XDE-750 Triisopropanolammonium by weight for 4 hours at 5.79 mg/L. Animals were observed for exposure related effects every 30 minutes during the exposure. Clinical observations were performed daily . Animals were observed for morbidity and mortality twice daily. Bodyweights were taken on test days 2, 4, 8, 11 and 15. A necropsy examination was performed on all test animals.

Inhalation LC₅₀ Males = > 5.79 mg/L
Inhalation LC₅₀ Females = > 5.79 mg/L
Inhalation LC₅₀ Combined = > 5.79 mg/L

Toxicity based on the lack of mortality at an exposure of 5.79 mg/L. EPA Toxicity Category IV.

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

RESULTS and DISCUSSION:

Dose (mg/L)	Mortality/Number Tested		
	Males	Females	Combined
5.79	0/5	0/5	0/10

Chamber atmosphere

Gravimetric Concentration (mg/L)*	MMAD (μm)	GSD
5.79	2.9	1.675

*Nominal concentration for exposure 14.95 mg/L

Chamber Environment

Chamber volume (L)	42
Air supply (Lpm)	30
Temperature (C)	21.7 \pm 0.36
Relative Humidity(%)	25.1 \pm 9.44

OBSERVATIONS

A. **Mortality** - as noted in table.

B. **Clinical observations** - No mortality was observed during the study. The only clinical effect observed during exposure was soiling of the haircoat in 3/5 males and 5/5 females. "Post exposure effects included perioral, periocular, perinasal, perineal and/or extensive body soiling.", all effects resolving by study day 4. A mean body weight loss of 3.4% in males and 4.5% in females was observed on study day 2, however both sexes exceeded pre exposure mean values by test day 4 (males) and test day 8 (females).

[PC Codes 005209]

EPA Reg. Number 62719-LRO

C. Gross Necropsy - No test substance related abnormalities were observed at necropsy.

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

E. Deficiencies: None

Reviewer: Tracy Keigwin

Date: October 4, 2004

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

Product Manager (EPA): 23

TEST MATERIAL (% a.i.): GF-871, 41.9% XDE-750 Triisopropanolammonium, (calculated from XDE-750 21.8%), Lot/Reference # TSN103622/E-1175-52, pH 7.35, dark brown liquid

CITATION: Brooks, K.J, Radtke, B.J. GF-871: Acute Eye Irritation Study in New Zealand White Rabbits. Toxicology and Environmental Research and Consulting, Midland, Michigan. Laboratory Project Study ID: 021098. December 2, 2002. MRID 46235610. Unpublished.

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

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 46235610), 0.1 ml of GF-871, 41.9% XDE-750 Triisopropanolammonium, (calculated from XDE-750 21.8%), Lot/Reference # TSN103622/E-1175-52, pH 7.35, dark brown liquid was instilled into the conjunctival sac of the right eye of 1 male and 2 female New Zealand White rabbits (source: Covance Research products, Inc.; Age: approximately 16 weeks; Weight: 2.537-2.579 g). The left eye was untreated to serve as a control. Animals were observed at 1, 24, 48 and 72 hours following instillation. Bodyweights were taken on the day of treatment and at study termination.

In this study, GF-871 is not an eye irritant. 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:

Observations	Number "positive"/number tested			
	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 ^a	0/3	0/3	0/3	0/3
Chemosis ^a	0/3	0/3	0/3	0/3
Discharge ^a	0/3	0/3	0/3	0/3

^aScore of 2 or more required to be considered "positive."

A. Observations - No corneal opacity, iritis or conjunctivitis was observed at any time during the study. Please note that the study does record signs of conjunctivitis in test animals, however the scores (grade 1) are not considered positive per 870.2400.

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

C. Deficiencies - In the results section of the study it is stated that "one hour after dosing, the male rabbit and one female rabbit had slight (grade 1) conjunctival redness (in the right eye resolving by test day 2", but Table 1 only shows grade 1 conjunctival redness at the 1 hour observation, and a grade of "0" thereafter. This discrepancy does not effect the toxicity categorization of the study since grade 1 is not considered a positive affect per 870.2400.

Reviewer: Tracy Keigwin

October 4, 2004

Product Manager (EPA): 23

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

TEST MATERIAL (% a.i.): GF-871, 41.9% XDE-750 Triisopropanolammonium, (calculated from XDE-750 21.8%), Lot/Reference # TSN103622/E-1175-52, pH 7.35, dark brown liquid

CITATION: Brooks, K.J, Radtke, B.J. GF-871: Acute Dermal Irritation Study in New Zealand White Rabbits. Toxicology and Environmental Research and Consulting, Midland, Michigan. Laboratory Project Study ID: 021099. December 2, 2002. MRID 46235612. Unpublished.

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

EXECUTIVE SUMMARY: In a primary skin irritation study (MRID 46235612), 1 male and 2 female New Zealand White Rabbits (source: Covance Research Products; Age: approximately 4 -6 months; Weight: 2.833-3.551 kg) were dermally exposed to GF-871, 41.9% XDE-750 Triisopropanolammonium, (calculated from XDE-750 21.8%), Lot/Reference # TSN103622/E-1175-52, pH 7.35, dark brown liquid. On the day prior to study initiation, a 10 cm x 10 cm area on the back of each animal with animal clippers. On day 1 a "0.5ml aliquot of the test material was applied to the back of each rabbit". The test substance was covered with a gauze patch ("semi-occlusive dressing, 6 x 6 cm") with cotton backing. An elastic jacket held the patch in place. After 4 hours all binding materials were removed and the back was wiped with a "damp disposable towel to remove any remaining test substance". Test sites were observed for erythema and edema at 30 minutes, and 24 , 48 and 72 hours and 6 days after test substance removal. "Animals were weighed on the day of treatment and at study termination".

In this study, GF-871 is considered to be slightly irritating to the skin. EPA Toxicity Category IV. PDI = 0.33.

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:

Rabbit	Observations	Within 60 Minutes	Hours			Day
			24	48	72	
02A1676/F	Erythema	0	1	0	1	0
	Edema	0	0	0	0	0
02A1677/F	Erythema	0	1	0	1	0
	Edema	0	0	0	0	0
02A1678/M	Erythema	0	0	0	0	NA
	Edema	0	0	0	0	NA

A. Observations - "The 2 female rabbits had very slight erythema 24 and 72 hours after unwrapping, which resolved by test day 7. The male rabbit had no signs of irritation throughout the duration of the study. The male and the female rabbit were removed from the study on test day 4 and test day 7." No edema was observed in any of the test animals during the study.

B. Results - PDII - 0.33

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

D. Deficiencies - The table in the study does not match the written study results. The table records erythema in the 2 females at 48 hours, rather than the written 24. We have placed the values in the table above based on the written comments in the study, rather than from the respective table in the study.

Reviewer: Tracy Keigwin

October 5, 2004

Product Manager (EPA): 23

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

TEST MATERIAL (% a.i.): GF-871, Lot Number E-1175-52, 21.8% XDE-750 by weight as the active ingredient, amber liquid via pipet (wine colored in bulk)

CITATION: Wilson, C. W. GF-871: A Dermal Sensitization Study in Hartley Albino Guinea Pigs - Maximization Design. Springborn Laboratories, Inc. Spencerville, Ohio. SLI Study Number 3504.250. June 18, 2002. MRID 46235614. Unpublished.

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

EXECUTIVE SUMMARY: In a dermal sensitization study using the maximization method (MRID 46235614) the sensitization potential of GF-871, Lot Number E-1175-52, 21.8% XDE-750 by weight as the active ingredient, amber liquid via pipet (wine colored in bulk) was determined in 34 Hartley derived albino guinea pigs (4 range finding animals, 20 test animals, 10 challenge control animals; Source: Hilltop Lab Animals; Range finding males 7 weeks, 379-414g, Range finding females 9-10 weeks, 393-465g; Sensitization study males 7 weeks, 357-448g, sensitization females 8 weeks, 360-436g). The intradermal inductions (0.1 mL/site) were Freund's Complete Adjuvant emulsion; 0.1 mL of 1.0 % w/v GF-871/deionized water; and 0.1 mL of 1.0% w/v GF-871/FCA emulsion. The topical induction was 0.8 ml of GF-871 (100% concentration). Challenge was 0.3 mL undiluted GF-871 using a 25 mm Hilltop Chamber. Following challenge all scores were zero in both previously exposed guinea pigs and their negative controls. The procedures were validated within 6 months of this study with 2 separate maximization tests utilizing HCA and DNCB as the test substances. The HCA test utilized 5% w/v HCA in propylene glycol for both the intradermal and topical induction and 0.5% and 1% w/v HCA w/v HCA in propylene glycol at challenge. The DNCB test utilized 0.1% w/v DNCB in acetone/propylene glycol for both the intradermal and topical induction and 0.05% and 0.1% w/v DNCB in acetone/propylene glycol for challenge.

In this study, GF-871 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 - Hair was removed from the scapular area of test animals with animal clippers on the day prior to the intradermal induction (study day -1). The following day 3 pairs of intradermal injections were made in an approximate 2 x 4 cm area of the test site with one row of 3 injections on each side of the back. The injections for the test animals were as follows: Injection pair A: 0.1 mL of FCA emulsion; Injection pair B: 0.1 mL of 1.0% w/v GF-871/deionized water; Injection pair C: 0.1 mL of 1.0% w/v GF-871/FCA emulsion. On study day 5 hair was removed from the scapular area with animal clippers. "A 0.5 mL of 10% w/w sodium lauryl sulfate in petrolatum was spread over the intradermal injection sites of test animals". On study day 6 any residual sodium lauryl sulfate was removed with a dry gauze. An application of 0.8 ml of GF-871 was applied to a 2 x 4 cm modified Webril patch and placed over the injections sites (occlusive patch). "The trunk of each animal was wrapped with elastic wrap which was secured with adhesive tape to prevent removal of the patch. After 48 hours all binding materials were removed and the test sites were wiped with gauze moistened with deionized water to remove any residual test substance".

B. Challenge - On the day prior to challenge application (study day 22) hair was removed from the right side of test and challenge control animals with animal clippers. On the day of challenge application both test and challenge control animals received a 0.3 ml application of 100% GF-871 applied using a 25 mm Hilltop chamber and occlusive patch and applied to the test area. "The trunk of each animal was wrapped with elastic wrap which was secured with adhesive tape to prevent removal of the chamber". Challenge sites were scored for dermal irritation at approximately 24 and 48 hours after chamber removal.

C. Naive Controls - Ten control guinea pigs were treated in the same manner as the test animals as detailed, above with the exception that the intradermal injection pairs were 0.1 ML of FCA emulsion, 0.1 mL of deionized water and 0.1 mL of 1.0% w/v deionized water/FCA emulsion. For the topical induction only 0.8 mL of deionized water was applied to the Webril patches.

II. RESULTS and DISCUSSION:

A. Reactions and duration - No irritation or positive responses (grade 0) were observed in the test or naive control animals at challenge. The test substance did not affect bodyweight gain.

B. Positive control - Test animals treated with HCA or DNCB showed appropriate responses (17/20 positive in HCA assay; 10/10 positive in DNCB assay).

C. Reviewer's Conclusions: Agree with study author

D. Deficiencies - None

[PC Codes 005209]

EPA Reg. No. 62719-LRO

ACUTE TOX ONE-LINERS

1. DP BARCODE: 306167

2. PC CODES: 005209

3. CURRENT DATE: 06/OCT/2004

4. TEST MATERIAL(s): GF-871, 41.9% XDE-750 Triisopropanolammonium, (calculated from XDE-750 21.8%), Lot/Reference # TSN103622/E-1175-52, pH 7.35, dark brown liquid; GF-871 (Lot E-1175-52), 41.9% XDE-750 Triisopropanolammonium by weight; GF-871, Lot Number E-1175-52, 21.8% XDE-750 by weight as the active ingredient, amber liquid via pipet (wine colored in bulk)

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity/rat Toxicology and Environmental Research and Consulting 021097/12-2-2002	46235604	Oral LD ₅₀ > 5000 mg/kg (both sexes)	IV	A
Acute dermal toxicity/rabbit Toxicology and Environmental Research and Consulting 021061/6-13-2002	46235606	LD ₅₀ > 5000 mg/kg (both sexes)	IV	A
Acute inhalation toxicity/rat Toxicology and Environmental Research and Consulting 021098/12-2-2002	46235608	LC ₅₀ > 5.79 mg/L (both sexes)	IV	A
Primary eye irritation/rabbit Toxicology and Environmental Research and Consulting 021099/12-2-2002	46235610	No positive signs of corneal opacity, iritis or conjunctivitis observed.	IV	A
Primary dermal irritation/rabbit Toxicology and Environmental Research and Consulting 021099/12-2-2002	46235612	Slight erythema observed at 24 and 72 hours, resolving by study day 7.	IV	A
Dermal sensitization/Guinea Pig Springborn Laboratories, Inc. 3504.250/6-18-2002	46235614	Not a sensitizer	No	A

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