

US EPA ARCHIVE DOCUMENT



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

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

02/DEC/2008

MEMORANDUM

Subject: Name of Pesticide Product: Chaparral
EPA Reg. No.: 62719-597
DP Barcode: D357041
Decision No.: 400238
Action Code: R340
PC Code: 122010 (metsulfuron),
005219 (potassium salt of aminopyralid)

From: Eugenia McAndrew, Biologist
Technical Review Branch
Registration Division (7505P) *E. McAndrew*
A. Whistler

To: Michael Walsh, RM Team 23
Herbicide Branch
Registration Division (7505P)

Applicant: Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, IN 46268-1054

FORMULATION FROM LABEL:

| | |
|---|-----------------|
| <u>Active Ingredient(s):</u> | <u>% by wt.</u> |
| Potassium salt of 2-pyridine carboxylic acid, 4-amino-3, 6-dichloro | 62.13 |
| Metsulfuron methyl | 9.45 |
| <u>Inert Ingredient(s):</u> | <u>28.42</u> |
| Total: | 100.00% |

ACTION REQUESTED: The Risk Manager requests: Please review dermal sensitization study for 62719-597.

US EPA ARCHIVE DOCUMENT

BACKGROUND: Dow AgroSciences LLC has submitted a dermal sensitization study (MRID 47534601) to support the registration of Chaparral, EPA Reg. No. 62719-597. This product was conditionally registered pending the submission of a guinea pig study to replace the unacceptable Local Lymph Node Assay study (MRID 47328608) submitted originally. This guinea pig study was conducted at Eurofins/Product Safety Laboratories, Inc. The acute oral, acute dermal, acute inhalation, primary eye irritation and primary skin irritation studies were reviewed and classified as acceptable in a prior TRB memo (McAndrew; D350118; 08/JUL/2008).

Note: Dow changed the name of this product from “GF-2050” to “Chaparral.”

RECOMMENDATIONS: The skin sensitization study is classified as acceptable.

The acute toxicity profile for Chaparral, EPA Reg. No. 62719-597, is as follows:

| | | | |
|---------------------------|----------|------------|---------------|
| Acute oral toxicity | IV | Acceptable | MRID 47328603 |
| Acute dermal toxicity | IV | Acceptable | MRID 47328604 |
| Acute inhalation toxicity | IV | Acceptable | MRID 47328605 |
| Primary eye irritation | III | Acceptable | MRID 47328606 |
| Primary skin irritation | III | Acceptable | MRID 47328607 |
| Dermal sensitization | Negative | Acceptable | MRID 47534601 |

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 #: 062719-00597

PRODUCT NAME: Chaparral

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Avoid contact with skin, eyes or clothing. Causes moderate eye irritation. 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. [Wear protective eyewear.]*

*[Protective eyewear may be specified, if appropriate.]

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 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. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Reviewer: Eugenia McAndrew
Risk Manager (EPA): 23

Date: December 2, 2008

STUDY TYPE: Dermal Sensitization – guinea pig; OPPTS 870.2600; OECD 406

TEST MATERIAL: Chaparral [GF-2050; Lot No. E2350-46, TSN 106390; 9.3% w/w metsulfuron-methyl, 52.8% w/w aminopyralid (a.e.), 62.5% aminopyralid potassium (a.i.); beige solid]

CITATION: Durando, J. (2008) GF-2050 – Dermal Sensitization Study in Guinea Pigs (Buehler Method). Study Number 25210. Eurofins/Product Safety Laboratories, 2394 US Highway 130, Dayton, NJ 08810. August 4, 2008. MRID 47534601.

SPONSOR: Woodstream Corporation, 69 North Locust Street, Lititz, PA 17543

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID 47534601) with Chaparral [GF-2050; Lot No. E2350-46, TSN 106390; 9.3% w/w metsulfuron-methyl, 52.8% w/w aminopyralid (a.e.), 62.5% aminopyralid potassium (a.i.); beige solid], 30 male young adult Hartley albino guinea pigs (body weight: 354-441 g; source: Elm Hill Breeding Labs, Chelmsford, MA) were tested using the Buehler Method. The test animals were induced with 0.4 gram of a 75% w/w mixture of the test material in distilled water for six hours using occlusive 25 mm Hill Top Chambers that were secured and wrapped with non-allergenic adhesive tape. The procedure was repeated once each week for three consecutive weeks. Twenty-seven days after the first induction, the test animals were challenged with 0.4 gram of a 38% w/w mixture in distilled water under occlusion to naive sites. The naive control animals were treated with 0.4 gram of a 38% w/w mixture of the test material in distilled water under occlusion at challenge. Reactions were scored 24 and 48 hours after test material applications.

After three consecutive weekly inductions, no positive dermal reactions were noted from any animal after challenge.

Based on the results of this study, GF-2050 was 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 animals were induced and challenged according to the Buehler method. The dorsal and flank areas of 20 test guinea pigs were clipped prior to each treatment. For induction, 0.4 gram of a 75% w/w mixture of the test material in distilled water was applied to the animal using an occlusive 25 mm Hill Top Chamber and secured with non-allergenic adhesive tape. The chamber was removed after six hours and excess test material removed. The procedure was repeated once each week for three consecutive weeks. Reactions were scored 24 and 48 hours after the induction applications.
- B. **Challenge**: Twenty-seven days after the first induction, the test animals were challenged with 0.4 gram of a 38% w/w mixture of the test material in distilled water under occlusion to naive sites for 6 hours. Reactions were scored 24 and 48 hours after challenge application.
- C. **Naive control**: The dorsal and flank areas of 10 naive control animals were clipped prior to treatment. At challenge, the naive control group was treated with 0.4 gram of a 38% w/w mixture of the test material in distilled water for 6 hours. Reactions were scored 24 and 48 hours following challenge application.

RESULTS and DISCUSSION:

- A. **Reactions and durations**: Very faint to faint erythema (0.5-1) was noted on 19/20 test animals over the course of three inductions. Very faint erythema was noted on 11/20 test animals at 24 hours and on 9/20 test animals at 48 hours after challenge. Very faint usually non-confluent erythema was noted on 6/10 naive control animals 24 hours and on three sites at 48 hours. The test material was not a dermal sensitizer.
- B. **Positive control**: The report included the results of a positive control (alpha-hexylcinnamaldehyde) study # 25331 conducted within six months of the current study; the results were appropriate.
- C. **Reviewer's conclusion**: This reviewer agrees with the study author that the test material was not a dermal sensitizer.

1. **DP BARCODE:** DP357041
2. **PC CODES:** 122010, 005219
3. **CURRENT DATE:** December 2, 2008
4. **TEST MATERIAL:** Chaparral [GF-2050; Lot No. E2350-46, TSN 106390; 9.3% w/w metsulfuron-methyl, 52.8% w/w aminopyralid (a.e.), 62.5% aminopyralid potassium (a.i.); beige solid]

| Study/Species/Lab Study # / Date | MRID | Results | Tox. Cat. | Core Grade |
|--|-------------|-----------------|----------------------|-----------------------|
| Dermal sensitization/guinea pig Eurofins.Product Safety Labs 25210/August4, 2008 | 47534601 | Not sensitizing | - | A |

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