2-26-96

MEMORANDUM

Subject: EPA Reg. #: 10163-EEU

To: George Larocca, PM # 13 Attn: Linda Deluise
Insecticide-Rodenticide Branch
Registration Division (7505C)

FROM: David L. Ritter, Toxicologist
Registration Support Branch
Precautionary Review Section
Registration Division (7505W)

2-26-96 D 102

Registrant: Gowan Company
PO Box 5569
Yuma AZ 85366

FORMULATION FROM LABEL:

Active Ingredient(s):	% by Wt.
Permethrin	0.5%
Inert Ingredient(s):	99.5%
Total	100.0%

Action Requested:

Review acute toxicity studies and precautionary labeling.

Review request for waiver of acute inhalation toxicity study.

PRS Response:

The studies have been reviewed and the DERs are attached. The acute oral and skin irritation studies were placed in TOX category IV. The acute dermal and eye irritation studies were placed in TOX category III. The dermal sensitization study was negative for sensitizing potential. The studies were found to be Acceptable.

The inhalation study is being waived based on the following considerations: The request is based on the registrant's proposition that no solvents or clays are used, and that dust generation would be negligible.

PRS also notes that the product contains a small amount of [redacted] and a large amount of [redacted].

It would be virtually impossible to generate a satisfactory aerosol using a product containing these inert ingredients. We would expect that the aerosol nozzles would become plugged even if a satisfactory dust could be milled; however, based on the amount of [redacted] present and on the amount of [redacted], the result would be a useless mess.

Accordingly, PRS recommends that the requirement be waived.

The data are summarized below:

Acute Toxicity Data Requirements (40 CFR §158.340). Pesticide Assessment Guidelines, Subdivision F. Hazard Evaluation: Human and Domestic Animals. (1982; revised 1984).

Data Required	MRID #	Toxicity Category	Classification
Acute Oral (§81-1)	437592-01	IV	A
Acute Dermal (81-2)	" -02	III	A
Acute Inhal. (81-3)	Requirement waived		
Eye Irr. (§81-4)	" -03	III	A
Dermal Irr. (§81-5)	" -04	IV	A
Dermal Sens. (§81-6)	" -05	non-sens.	A

These data are complete and will support registration of this product.

Precautionary Labeling Review:

See the attached LRS sheet.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

DATA EVALUATION RECORD FOR ACUTE ORAL TOXICITY TESTING §81-1

Product Manager (PM): 13 EPA Reg. No.: 10163-EEU

Reviewer: David L. Ritter, Toxicologist

MRID No.: 437592-01

Testing Laboratory:
Hazleton Wisconsin Inc.
3301 Kinsman Blvd.
Madison WI 53704

Title Of Report: Acute Oral Toxicity Study of Ambush 0.5% Bait in Rats

Date of Report: 3/18/94

Lab. No.: HWI 31000514

Author(s): Steven Glaza

Species: Albino rat Sex: 5/sex Wt.: 209 - 299 gm

Source: Charles River Labs.

Test Material: Ambush 0.5% bait

Dosage: 5000 mg/kg

Quality Assurance (40 CFR, Section 160.12): Acceptable

Summary: LD_{50} M + F > 5000 mg/kg

TOX Category: IV Classification: Acceptable

Procedure (Deviation From Series 81-1):

Standard laboratory animal husbandry and GLP were observed.

Animals were weighed initially, on day 7 and at termination.

Test Article was administered as a single dose by gavage of 5000 mg/kg.

Observations for effects and mortality were made three times on day one, then twice daily thereafter for 14 days.

Animals dying during the observation period and those surviving to termination were subjected to gross necropsy.

Results:

Clinical signs were not present.

Body weight gain was not affected.

There was no mortality.

REPORTED MORTALITY

	No. Killed/No. Exposed		
Dose mg/kg	Males	Females	Combined
5000 mg/kg	0/5	0/5	0/10

Conclusions:

LD_{50} M + F > 5000 mg/kg

TOX Category: IV Classification: Acceptable

DATA EVALUATION RECORD ACUTE DERMAL TOXICITY TESTING §81-2

Product Manager (PM): 13 EPA Reg. No.: 10163-EEU

Reviewer: David L. Ritter, Toxicologist

MRID No.: 437592-02

Testing Laboratory:
Hazleton Wisconsin Inc.
3301 Kinsman Blvd.
Madison WI 53704

Title Of Report: Acute Dermal Toxicity Study of Ambush 0.5% Bait in Rabbits

Date of Report: 3/18/94

Lab. No.: HWI 31000515

Author(s): Steven Glaza

Species: Albino rabbit Sex: 5/sex Wt.: 2348 - 2872 gm

Source: Hazleton Wisconsin

Test Material: Ambush 0.5% Bait

Dosage: 2000 mg moistened with NS applied topically

Quality Assurance (40 CFR, Section 160.12): Acceptable

Summary: LD_{50} M + F > 2000 mg/kg

TOX Category: III Classification: Acceptable

Procedure (Deviation From Series 81-1):

Standard laboratory animal husbandry and GLP were observed.

Animals were clipped free of fur over 10% of body surface are 24 hours prior to exposure.

Test Article administered as a single topical dose of 2000 mg moistened with NS was applied to a 10 cm^2 gauze patch which was then secured with occlusive dressings. After 24 hours the dressings were removed and the test sites cleansed.

Observations for effects and mortality were made three times on day one, then twice daily thereafter for 14 days.

Animals dying during the observation period and those surviving to termination were subjected to gross necropsy.

Results:

Clinical signs were absent.

Body weight gain was not affected.

There was no mortality.

REPORTED MORTALITY

	No. Killed/No. Exposed		
Dose mg/kg	Males	Females	Combined
2000 mg/kg	0/5	0/5	0/10

Conclusions:

LD_{50} M + F > 2000 mg/kg

TOX Category: III Classification: Acceptable

DATA EVALUATION RECORD FOR EYE IRRITATION TOXICITY TESTING §81-4

Product Manager (PM): 13 EPA Reg. No.: 10163-EEU

Reviewer: David L. Ritter, Toxicologist

MRID No.: 437592-03

Testing Laboratory:
Hazleton Wisconsin Inc.
3301 Kinsman Blvd.
Madison WI 53704

Title Of Report: Primary Eye Irritation Study of Ambush 0.5% Bait in Rabbits

Date of Report: 3/18/94

Lab. No.: HWI 31000517

Author(s): Steven Glaza

Species: Albino rabbit Sex: 3/sex Wt.: 2499 - 2874 gm

Source: HRP, Inc.

Test Material: Ambush 0.5% Bait

Dosage: 0.03 gm in lower eyelid

Quality Assurance (40 CFR, Section 160.12): Acceptable

Summary: Irritation clearing in less than 7 days

Toxicity Category: III Classification: Acceptable

Procedure (Deviation From Series 81-1):

Standard laboratory animal husbandry and GLP were observed.

Eyes were examined with sodium fluorescein 24 hours prior to application.

0.03 gm of Test Article was administered as a single instillation into the everted lower eyelid. [This is equivalent to 0.1 ml of the Test Article with a bulk density of only 0.26 gm/ml, meaning that the tested powder was only ca one third as dense as water].

Observations for effects were made at 1, 24, 48 and 72 hours.

Irritancy scores were made after Draize (1959).

Results:

EYE IRRITATION SCOREBOARD

	No. affected/No. exposed in days								
Ocular Effects	hr	1	2	3	4				
Cornea	0/6	0/6	0/6	0/6					
Iris	0/6	0/6	0/6	0/6					
Conjunctivae									
Redness	6/6	4/6	0/6	0/6					
Chemosis	3/6	1/6	0/6	0/6					
Discharge	4/6	1/6	0/6	0/6					

Conclusions: Irritation clearing in less than 7 days

TOX Category: III Classification: Acceptable.

DATA EVALUATION RECORD DERMAL IRRITATION TOXICITY TESTING §81-5

Product Manager (PM): 13 EPA Reg. No.: 10163-EEU

Reviewer: David L. Ritter, Toxicologist

MRID No.: 437592-04

Testing Laboratory:
Hazleton Wisconsin Inc.
3301 Kinsman Blvd.
Madison WI 53704

Title Of Report: Primary ~~Eye~~ Dermal Irritation Study of Ambush 0.5% Bait in Rabbits

Date of Report: 3/18/94

Lab. No.: HWI 31000516

Author(s): Steven Glaza

Species: Albino rabbit Sex: 3/sex Wt.: 2771 - 3014 gm

Source: HRP, Inc.

Test Material: Ambush 0.5% Bait

Dosage: 0.5 gm Test Article moistened with NS

Quality Assurance (40 CFR, Section 160.12): Acceptable

Summary: IV based on mild or slight irritation.

Procedure (Deviation From Series 81-1):

Standard laboratory animal husbandry and GLP were observed.

0.5 gm Test Article moistened with NS was administered as a single topical dose under a 6 cm^2 gauze patch which was then secured with semi-occlusive dressings.

After 4 hours the dressings were removed and the test sites cleansed.

Observations for dermal irritation were made on days 1, 24, 48 and 72 hours.

Animals dying during the observation period and those surviving to termination were subjected to gross necropsy.

Results:

DERMAL IRRITATION SCOREBOARD

Rab.#	Eschar/Erythema											Edema										Score
	OBSERVATION TIMES IN DAYS																					
	30m	1	2	3	4	5	6	7	10	14	21	30m	1	2	3	4	5	6	7	10	14	21	
52	1	0	0	0								0	0	0	0								0.25
53	1	1	0	0								1	0	0	0								0.75
54	1	1	1	0								0	0	0	0								0.75
55	1	1	1	0								1	0	0	0								1.00
56	1	0	0	0								0	0	0	0								0.25
57	1	0	0	0								1	0	0	0								0.50

Score = sum of numerical grades/no. observation periods at 1, 24, 48 and 72 hours.

PII = Sum of scores/No. animals = 3.50/6 = 0.6

Slight < 2.0; Moderate 2 - 5; Severe > 5

Conclusions:

TOX Category: IV based on mild or slight irritation.

Classification: Acceptable

DATA EVALUATION RECORD DERMAL SENSITIZATION TESTING §81-6

Product Manager (PM): 13 EPA Reg. No.: 10163-EEU

Reviewer: David L. Ritter, Toxicologist

MRID No.: 437592-05

Testing Laboratory:
Hazleton Wisconsin Inc.
3301 Kinsman Blvd.
Madison WI 53704

Title Of Report: Dermal Sensitization Study of Ambush 0.5% Bait in Guinea Pigs - Closed Patch Technique

Date of Report: 3/18/94

Lab. No.: HWI 31000516

Author(s): Steven Glaza

Species: Albino guinea pig

Source: Charles River Labs.

Test Material: Ambush 0.5% Bait

Dosage:

Quality Assurance (40 CFR, Section 160.12): Acceptable

Summary:

Classification:

Procedure (Deviation From Series 81-1):

Standard laboratory animal husbandry and GLP were observed.

Animals were weighed initially, on day 7 and at termination.

Test Article was administered as a single 0.4 gm dose under a Hilltop chamber which was then secured for 6 hours.

The dressings were then removed and the dermal irritation was determined at 24 nd 48 hours after the method of Buehler (1980)

Screening Phase:

Doses tested:

Induction Phase:

10 pigs were exposed as noted above to a dose of 0.2 gm. a second naive control group received no treatment. 4 pigs were exposed to 0.4 ml of a 0.3% solution of DNCB in 80% EtOH and served as a positive control group.

Exposure was repeated at two further weekly intervals for a total of three exposures.

Observations were made as described above.

Challenge Phase:

After 2 weeks animals were exposed to Test Article at 0.2 gm at virgin test sites and evaluated as above. 10 control pigs were likewise exposed.

Positive control animals received o.1 % DNCB in acetone.

Results:

Induction Phase:

No Test Article group animals showed any dermal response. Positive control animals showed +3 responses at 48 hours.

Challenge Phase:

No Test Article group animals showed any dermal response. Naive control animals showed no response.

Positive control animals showed 2/4 had +3 responses and 2/4 had +2 responses at 48 hours.

Conclusions:

Product is not a dermal sensitizer in this assay.

Classification: Acceptable

1. PC CODE:109701; Permethrin

2. CURRENT DATE: 2/9/96

3. TEST MATERIAL: Ambush 0.5% Bait

4. EPA Reg. #: 10163-EEU

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
Acute oral/rat/HWI*/ HWI 21000514/3-18-94	437592-01	LD_{50} M+F > 5000 mg/kg	IV	A
Acute dermal/rabbit/ HWI/HWI 21000515/3-18-94	" -02	LD_{50} M+F > 2000 mg/kg	III	A
Eye irr./rabbit/HWI/ HWI 21000517/3-18-94	" -03	Irr. cleared in less than 7 days	III	A
Skin irr./rabbit/HWI /HWI 21000517/3-18-94	" -04	Mild or slight irr.	IV	A
Skin sens./guinea pig/HWI/HWI 21000517/3-18-94	" -05	Non-sensitizing	---	A

* Hazleton Wisconsin Inc.
3301 Kinsman Blvd.
Madison WI 53704

Core Grade Key:

A = Acceptable
U = Unacceptable
S = Supplementary

ID #: 010163-00224 AMBUSH 0.5% BAIT

AGRICULTURAL USE REQUIREMENTS:

DIRECTIONS FOR USE:

For early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, wear: coveralls over long-sleeved shirt and long pants, socks and chemical resistant footwear and waterproof gloves.

SIGNAL WORD: **CAUTION**

PRECAUTIONARY STATEMENTS:

Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wear long-sleeved shirt and long pants, socks and shoes and waterproof gloves. Wash thoroughly with soap and water after handling.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.