

US EPA ARCHIVE DOCUMENT

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11-6-96

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(S)

MEMORANDUM

Subject: EPA Reg. #: 66550-1
DPBarcode: D228930
Chemical #: 128725
Chemical Name: Methyl anthranilate
Action Code: 305
Type of Data: Toxicology, acute
PRS Bean #: 5633

TO: Robert Forrest, PM # 14 Attn: Dan Peacock
Insecticide/Rodenticide Branch
Registration Division (7505C)

FROM: David Ritter, Toxicologist OLR 11-6-96
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)

Registrant: Bird Shield Repellent Corp.
PO Box 785
Pullman WA 99163-0785

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by Wt.</u>
Methyl anthranilate	26.4%
<u>Inert Ingredient(s):</u>	73.6%
Total	100.0%

Action Requested:

Review eye and skin irritation studies and precautionary labeling.

PRS Response:

The data have been reviewed and the DERs are attached.

The eye irritation study was placed in TOX category II and the skin irritation study was placed in TOX category III. Both studies were classified as acceptable.

The studies are summarized below:

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

<u>Data Required</u>	<u>MRID #</u>	<u>Toxicity Category</u>	<u>Classi- fication</u>
Eye Irr. (§81-4)	440703-02	II	A
Dermal Irr. (§81-5)	" -01	III	A

These data support registration of the product.

Precautionary Labeling Review:

PRS has no information from other acute toxicity studies required to write precautionary labeling. Therefore, the attached label reflects only the results of those studies (eye and dermal irritation) reviewed in this submission.

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DATA EVALUATION RECORD FOR EYE IRRITATION TOXICITY TESTING
 (PM): 14 EPA Reg. No.: 66550-1 Reviewer: D. Ritter
 MRID No.: 440703-02 Lab. No.: 4372
 Testing Laboratory: Product Safety Labs

725 Cranbury Road
 East Brunswick NJ 08816

Title of Report: Primary Eye Irritation
 Date of Report: 6/11/96 Author(s): Gary Wnorowski
 Species: NZW rabbit
 Source: Davidson's Mill Farm, S. Brunswick NJ
 Test Material: Bird Shield Repellant Concentrate
 Dosage: 0.1 ml
 Quality Assurance (40 CFR, Section 160.12): Acceptable

Summary: Corneal effects clearing in 8 - 21 days
 Toxicity Category: II Classification: Acceptable
 Procedure (Deviation From Series 81-4):

Standard laboratory animal husbandry and GLP were observed. Eyes were examined with 2 % sodium fluorescein 24 hours prior to application. 0.1 ml undiluted Test Article was administered as a single instillation into the everted lower eyelid. Observations for effects were made at 1, 24, 48 and 72 hours, and on days 4, 7, 10 and 14. Irritancy scores were made after Kay, et al (1962).

Results:

EYE IRRITATION SCOREBOARD

	No. affected/No. exposed in days								
	1hr	1	2	3	4	7	10	14	
Ocular Effects									
Cornea	1/6	6/6	6/6	5/6	5/6	3/6	2/6	0/6	
Iris	2/6	4/6	4/6	4/6	3/6	1/6	0/6	0/6	
Conjunctivae									
Redness	6/6	6/6	6/6	5/6	5/6	1/6	0/6	0/6	
Chemosis	6/6	6/6	5/6	4/6	0/6	0/6	0/6	0/6	
Discharge	6/6	6/6	4/6	2/6	0/6	0/6	0/6	0/6	

Conclusions:

See summary above.

DATA EVALUATION RECORD DERMAL IRRITATION TOXICITY TESTING §81-5
 (PM): 14 EPA Reg. No.: 66550-1 Reviewer: D. Ritter
 MRID No.: 440703-01 Lab. No.: 4373

Testing Laboratory: Product Safety Labs
 725 Cranbury Road
 East Brunswick NJ 08816

Title Of Report: Primary Skin Irritation
 Date of Report: 6/7/96 Author(s): Gary Wnorowski
 Species: NZW rabbit
 Source: Davidson's Mill Farm, S. Brunswick NJ
 Test Material: Bird Shield Repellant Concentrate
 Dosage: 0.5 ml applied topically
 Quality Assurance (40 CFR, Section 160.12): Acceptable

Summary: Moderate irritation at 72 hours
 Toxicity Category: III Classification: Acceptable
 Procedure (Deviation From Series 81-5):

Standard laboratory animal husbandry and GLP were observed. Fur was clipped from the dorsal trunk one day prior to exposure. Undilute Test Article was administered as a single topical dose of 0.5 ml under a 6 cm² gauze patch which was then secured with semi-occlusive dressings and Elizabethan collars. After 4 hours the dressings were removed and the test sites cleansed.

Observations for dermal irritation were made at 1, 24, 48 and 72 hours, and on days 7, 10 and 14. Dermal irritation was scored after Draize (1944).

Results:

DERMAL IRRITATION SCOREBOARD

Rab.#	Eschar/Erythema											Edema											Score
	OBSERVATION TIMES IN DAYS																						
	1hr	1	2	3	4	5	6	7	10	14	21	1hr	1	2	3	4	5	6	7	10	14	21	
520	1	1	1	1				1	1	0		0	0	0	0				0	0	0		1.00
521	1	0	0	0				0	0	0		0	0	0	0				0	0	0		0.00
522	1	1	1	1				1	0	0		0	0	0	0				0	0	0		1.00
523	1	2	2	2				2	1	1		0	0	0	0				0	0	0		1.75
524	1	2	2	2				1	1	1		2	2	2	2				0	0	0		4.25
525	1	1	2	2				2	1	0		0	0	0	0				1	0	0		1.50

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

PII = Sum of scores/No. animals = 9.5/6 = 1.6
 Slight < 2.0; Moderate 2 - 5; Severe > 5

Conclusions: See summary above.

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ACUTE TOX ONE-LINER

1. PC CODE: 128725; methyl anthranilate
2. CURRENT DATE: 11-6-96
3. TEST MATERIAL: Bird Shield Repellant Concentrate
4. EPA Reg. #: 66550-1

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
Eye irr./rabbit/PSL* /4372/6-11-96	440703-02	Corneal effects clearing in 8 - 21 days	II	A
Skin irr./rabbit/PSL /4373/6-7-96	" -01	Mod. irr. @ 72 hrs	III	A

* Product Safety Labs
725 Cranbury Road
East Brunswick NJ 08816

Core Grade Key:

A = Acceptable
U = Unacceptable
S = Supplementary

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ID #: 066550-00001 BIRD SHIELD REPELLENT

SIGNAL WORD: WARNING

PRECAUTIONARY STATEMENTS:

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Avoid contact with skin. Wear goggles or face shield. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF SWALLOWED: Call a physician or Poison Control Center. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

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

IF IN EYES: Hold eyelids open and flush with steady, gentle stream of water for 15 minutes. Get medical attention.

Probable mucosal damage may contraindicate the use of gastric lavage.