12-12-93

426356-01
-02

MEMORANDUM:

Subject: EPA Reg. No.: 28293-11

From: Mark J. Perry, Biologist
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

MJP 2-12-93

To: Richard Mountfort, PM 10
Insecticide-Rodenticide Branch
Registration Division (H7505C)

E 2/12/93

Thru: Thomas C. Ellwanger, Section Head
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

Applicant: Unicorn Laboratories
1002 118th Ave. North
St. Petersburg, FL 33716

FORMULATION FROM LABEL:

	% by wt.
Active Ingredient(s):	
Pyrethrins	0.150
Piperonly Butoxide, Tech	1.500
N-Octyl bicycloheptene dicarboximide	0.333
Inert Ingredient(s):	98.017
Total:	100%

057001

BACKGROUND

Unicorn Laboratories submitted primary eye and skin irritation studies for the product Unicorn Liquid Pet Spray. The eye irritation study was submitted as 6(a)(2), adverse data since one animal exhibited corneal opacity and irritation on day 21 of the study. The current precautionary labeling for this product includes the signal word "caution."

Unicorn Liquid Pet Spray contains the active ingredients Pyrethrins (0.150%), Piperonly Butoxide, Tech (1.500%) and N-Octyl bicycloheptene dicarboximide (0.333%). Both studies were performed by Biosearch Incorporated and the MRID numbers are 426356-01 and 426356-02.

RECOMMENDATION

The primary eye and dermal irritation studies are acceptable as core guideline data.

LABELING

1. The appropriate signal word is "DANGER."

2. The Precautionary Statements should include the following prior to any additional statements:

Corrosive, causes irreversible eye damage. Do not get in eyes or on clothing. Wear goggles or face shield when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

3. The Statements of Practical Treatment should include the following prior to any additional statements:

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes.
IF SWALLOWED: Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol. Do not induce vomiting.
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

NOTE TO PM: Due to eye irritation, this product meets the criteria for restricted use classification. The PM should decide if the label contains sufficient alternative labeling language to offset the hazard and the need for this classification.

NOTE TO PM: Due to eye irritation, this product meets the criteria for child-resistant packaging.

NOTE TO PM: The above precautionary labeling requirements are based on the results of the submitted eye and skin irritation studies. Other precautionary labeling currently on the product label cannot be reviewed for acceptabliity since additional supporting acute data is unavailable.

DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager: 10
MRID No.: 426356-01
Testing Laboratory: Biosearch
Author(s): George E. Moore
Species: Rabbit
Sex: NA
Weight: NA
Source: Buckshire Corp.
Dosage: 0.1 ml
Test Material: Unicorn Liquid Pet Spray
Quality Assurance (40 CFR §160.12): Present

Reviewer: M. Perry
Report Date: 8/13/92
Report No.: 92-7576A

Summary:

1. **Toxicity Category:** I

2. **Classification:** Guideline

Procedure: A 0.1 ml dose of the test material was placed into one conjunctival sac of each animal and the eyelids were held together for approximately one second to prevent loss of the test material. All test eyes were evaluated at 1, 24, 48, 72 and 96 hours and at 7 days. Some animals required evaluation at 14 and 21 days.

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Cornea Opacity	1/6	6/6	4/6	4/6	3/6	2/6	1/2	1/1
Iris	0/6	0/6	0/6	0/6	1/6	0/6	0/2	0/1
Conjunctivae								
Redness	6/6	6/6	4/6	3/6	3/6	1/6	1/2	1/1
Chemosis	6/6	6/6	3/6	3/6	3/6	1/6	1/2	1/1
Discharge*	6/6	6/6	3/6	2/6	2/6	1/6	1/2	1/1

* Not considered "positive"

Comments: Fluorescein dye results were considered in the above opacity scores. Due to the presence of corneal opacity and irritation at 21 days, this test material is in category I for eye irritation.

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5)

Product Manager:10
MRID No.:426356-02
Testing Laboratory: Biosearch
Author(s): George E. Moore
Species: Rabbit
Age: Not provided
Sex:NA
Weight:NA
Dosage:0.5 ml
Test Material: Unicorn Liquid Pet Spray
Quality Assurance (40 CFR §160.12): Present

Reviewer:M. Perry
Report Date:8/10/92
Report No.:92-7576A

Summary:

1. **The Primary Irritation Index = --**

2. **Toxicity Category:**IV

3. **Classification:**Guideline

Procedure: A 0.5 ml dose of test material was applied to clipped exposure sites and occluded for a period of four hours. Dermal evaluations were performed at 30-60 minutes and at 24, 48, and 72 hours.

Results: No dermal irritation was observed during the evaluations.

UNICORN

LIQUID PET SPRAY

FOR CATS * KITTENS * DOGS * PUPPIES

KILLS: FLEAS, LICE, TICKS, and EAR MITES

ALSO KILLS EAR MITES ON RABBITS

Repels Temporarily Gnats, Flies, Mosquitoes

ACTIVE INGREDIENTS:

Pyrethrins	0.150%
Piperonyl Butoxide, Technical*	1.500%
N-Octyl bicycloheptene dicarboximide	0.333%
INERT INGREDIENTS:	98.017%
	100.000%

* Equivalent to 1.20% of (butylcarbityl) (6-propylpiperonyl) ether and 0.3% of related compounds.

Keep Out of Reach of Children

CAUTION

See Side/Back Panel for Precautionary Statements

NET CONTENTS: 1 PINT

ACCEPTED
DEC 13 1991
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 28293-11

MANUFACTURED BY:

Unicorn Laboratories
1002 118th Avenue North
St. Petersburg, Florida 33716

EPA REG. NO. 28293-11(E:9/18/91) EPA EST. NO. 28293-FL-1

6

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

AUTION: Harmful if swallowed or inhaled. Avoid contact with eyes. In case f contact immediately flush eyes with plenty of water. Get medical ttention if irritation persists. Avoid breathing mist. Avoid contamination f food. Wash hands with soap and water after using. Avoid treatment of ursing kittens and puppies. If treatment is necessary, spray on tips of ingers and rub into coat. Remove birds and cover fish aquariums before reatment.

Statement of Practical Treatment

SWALLOWED: Call a physician or Poison Control Center. Give milk or water. Do not induce vomiting because of aspiration hazard.

IN EYES: Flush with plenty of water. Get medical attention.

ON SKIN: Wash off with soap and water.

Environmental Hazards

is product is toxic to fish.

Physical or Chemical Hazards

AMMABLE: Keep away from heat and open flames.

DIRECTIONS FOR USE

is a violation of Federal law to use this product in a manner inconsistent th its labeling.

ls and Dogs: Remove cap and insert trigger sprayer. Cover animals eyes th hand and with a firm fast stroke, to get a proper spray mist, spray ad, ears and chest until damp. With finger tips rub into face around uth, nose and eyes. Then spray neck, middle and hind quarters, finishing gs last. For best penetration of spray to skin, direct spray against the tural lay of the hair. On long haired dogs rub your hand against the lay the hair, spraying the ruffles hair directly behind the hand. Make sure ray thoroughly wets ticks. Repeat treatment as needed.

ppies and Kittens: Treat same as cats and dogs except nursing puppies and ttens, spray only along back or on your finger tips and rub in with your nger tips.

r Mites: While holding pet firmly, fill each ear canal half full of spray d massage base of ear to insure that insecticidal action penetrates ear x. Repeat treatment every other day until condition is relieved. provement is usually noted after two applications.

t Sleeping Quarters: Spray around baseboards, windows, door frames, wall acks and local area of floors. If mosquitoes, gnats or lice are present, ray lightly into the air. Repeat as needed. The bedding should be sprayed d then replaced with fresh bedding for best results.

Horses: To control Stable flies, horse flies, deer flies and face flies, apply to face, legs, flanks topline and other body areas commonly attacked by these flies. Repeat treatment as needed.

Goats: To repel flies and gnats, and to kill lice, ticks and keds; wipe-on face with towel and spray flanks, topline, legs. Repeat treatment as needed.

STORAGE AND DISPOSAL

STORAGE: Store in original container in cool, locked storage area.

CONTAINER DISPOSAL: Securely wrap original container in several layers of newspaper and discard in trash. Do not reuse container. Rinse thoroughly before discarding in trash.

FOR CONTAINERS 1 GALLON AND OVER: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, by other procedures pproved by state and local authorities.