US EPA ARCHIVE DOCUMENT

12-30-92

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MEMORANDUM:

Subject: EPA File Symbol/EPA Reg. No.: 241-268 Prowl
241-338 Pentagon
241-340 Stomp

From: Mark J. Perry, Biologist
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)
MJP 12-22-92

To: Robert J. Taylor, PM 25
Fungicide-Herbicide Branch
Registration Division (H7505C)

Thru: Thomas C. Ellwanger, Section Head
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)
E 12/30/92

Applicant: American Cyanamid Company
P.O. Box 400
Princeton, NJ 08543

FORMULATION FROM LABEL:

	% by wt.
Active Ingredient(s): pendimethalin, N-(1-ethyl-propyl)-3,4-dimethyl-2,6-dinitrobenzenamine	60.0
Inert Ingredient(s):	40.0
Total:	100%

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BACKGROUND

The American Cyanamid Company submitted an eye irritation study flagged as 6(a)(2) data. Following a SWAT team review it was decided that this submission should be expedited since it indicated the presence of an increased hazard. According to the Registrant, the study was performed on a formulation which represents Prowl (60) WDG, Pentagon (60) WDG and Stomp (60) DG. The Registrant has also stated that other companies have similar products registered which are supported by the same data base as these American Cyanamid products. Further, the Registrant has included several points as to why the current labeling for the subject product is adequate. The study was performed by American Cyanamid and the MRID number is 425535-02.

RECOMMENDATION

1. The eye irritation study is acceptable as core guideline data. Due to the presence of corneal opacity at 21 days, the test material has been placed in category I for eye irritation.

2. PRS has reviewed the Registrants objections (outlined in the 11/10/92 letter, MRID# 425535-00) to using the results of this study to determine the precautionary labeling for the subject product. The Registrant stated that "5 different formulations with similar ingredients" resulted in less eye irritation than the subject study. PRS, however, is concerned only with the formulation under evaluation or formulations determined to be substantially similar by the Agency.

Another point addressed involves the requirement for grinding the test material prior to administration. The Registrant claims that exposure to the powder test article, rather than to the large granules which actually compose the product, results in significantly more irritation. However, PRS believes that even though the subject product is composed of large granules, some or part of the granules may break down into a fine dust or powder upon transport and subsequent handling. As a result, the possibility of ocular exposure to the "reduced" product does exist. This situation and the fact that the Agency tests for the worst-case scenario, explains why the test material is reduced to a powder for eye irritancy testing.

3. PRS considers EPA Reg. Nos. 241-268, 241-338 and 241-340 to be substantially similar formulations. Thus, labeling requirements apply to all three products.

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LABELING

1. The appropriate signal word is "DANGER."

2. The Precautionary Statements should read as follows:

Corrosive. Causes irreversible eye damage. Harmful if absorbed through skin. Do not get in eyes or on clothing. Wear goggles or face shield when handling. Avoid contact with skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

3. The Statements of Practical Treatment should read as follows:

IF IN EYES: Hold eyelids open and flush with 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, large quantities of water. Note To Physician: Probable mucosal damage may contra-indicate the use of gastric lavage.
IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

4. Label revisions may be required following the submission of requested acute data (see below).

NOTE TO PM: The above labeling recommendations are based on the precautionary labeling on the most recently accepted labels of these products. However, acute inhalation and dermal sensitization studies performed with the formulation stated in the CSFs of EPA Reg. No. 241-268, 241-338 and 241-340 could not be found. Studies cited in support of this requirement were apparently performed with technical pendimethalin. Therefore, inhalation and sensitization studies performed with the subject formulation should be submitted to the Agency since they are necessary to determine the proper precautionary labeling language for these products.

NOTE TO PM: The statement "Do not apply directly to water or wetlands" appears on the labels of 241-268 and 241-338. This statement should be replaced with "Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark."

NOTE TO PM: Due to eye irritation, these products meet 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.

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ACUTE TOXICITY PROFILE

Acute Oral*	Category IV/G
Acute Dermal*	Category III/G
Acute Inhalation	Requested
Eye Irritation	Category I/G
Dermal Irritation*	Category IV/G
Dermal Sensitization	Requested

* See 1/27/83 D. Graham review

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

Product Manager:25
MRID No.:425535-02
Testing Laboratory: American Cyanamid
Author(s):C. Lowe
Species: Rabbit
Sex: Male
Weight:NA
Source: Skippack Farms
Dosage:0.1 ml
Test Material: AC 92,553 WDG Formulation (Stomp WDG)
Quality Assurance (40 CFR §160.12): Present

Reviewer:M. Perry
Report Date:1/31/92
Report No.:T-0389

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 one second. The test eyes were examined as indicated below.

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	5	7	14	21
Cornea Opacity	0/6	5/6	5/6	2/6	2/6	2/4	1/1	1/1
Iris	0/6	1/6	0/6	0/6	0/6	0/4	0/1	0/1
Conjunctivae								
Redness	2/6	2/6	2/6	1/6	0/6	0/4	0/1	0/1
Chemosis	3/6	0/6	0/6	0/6	0/6	0/4	0/1	0/1
Discharge*	6/6	2/6	0/6	0/6	0/6	0/4	0/1	0/1

* Not considered positive

Comments: Due to opacity at 21 days, the test material has been placed in category I.

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