UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

16 Release

DATE: August 24, 1978

SUBJECT: Atratol 8P (Active Ingredients: Atrazine, sodium chlorate, sodium metaborate) - Addition of Data to Files. EPA Reg. No. 100-475
Caswell Nos. 63, 753, 779AA Shaughnessy Nos. 073301, 011104, 080803

FROM: Toxicology Branch
Hazard Evaluation Division

TO: Robert Taylor
Product Manager #25

Atrazine / Review #30, 8.24.78 / 5 pages

Recommendations

Acute oral LD 50, acute dermal LD 50, acute inhalation LC 50, eye irritation, and skin irritation studies are adequate. The label proposed by the registrant must be revised as follows:

DANGER: Keep Out of Reach of Children. Corrosive, Causes eye damage and skin irritation. Do not get in eyes, on skin or on clothing. Avoid breathing dust. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. Avoid contamination of food or feed.

FIRST AID: In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash contaminated clothing before reuse.

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. Call a physician immediately.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsions may be needed.

* No RPAR criteria have been exceeded. Although the formulation contains Atrazine, a memo from the Fungicide-Herbicide Branch Chief (2/23/78) states that Atrazine is no longer being held due to possible nitrosamine contamination and that products containing Atrazine may be processed.

** The formulation is a candidate for the Restricted Use classification due to corneal opacity formation which was not reversed within 7 days post-treatment.

Review

A. Acute Oral LD 50 Study of Atratol 8P in Rats (Food and Drug Research Laboratories, Inc., 11/23/77, submitted by Ciba-Geigy Corp., 7/21/78, Acc. No. 234490).

1. Procedure

Ninety BLU: Long Evans rats were divided into 9 groups of 10 animals each (5 males and 5 females) which were administered 0.5, 1.0, 2.0, 3.0, 3.5, 4.0, 5.0, 6.0 or 15.0 g/kg of test material by gavage. Observations of mortality and toxic signs were continued over 14 days post-treatment. Necropsies were done.

2. Results

a. Mortality: LD 50 = 3.1 ± 0.3 g/kg

b. Toxic Signs: Ataxia, abnormal activity, facial muscle spasms, exophthalmia, salivation, urinary incontinence, piloerection, rales, nasal discharge, diarrhea, incoordination

c. Necropsy: Lungs, liver, kidneys, spleen-pale and mottled; skin, stomach-vascularized; stomach, gastrointestinal tract-distended; granular spleen; fluid-filled uterus.

3. Conclusions

a. Classification: Core Minimum Data
i) Body weights in conjunction with food intake were not determined daily.

b. TOX. Cat. : III

B. Acute Dermal LD 50 Study in Rabbits (Food and Drug Research Laboratories, Inc., Lab. No. 5608 b, 6/22/78, submitted by Ciba-Geigy Corp. 7/21/78, Acc. No. 234490),.

1. Procedure

Twenty four New Zealand White Rabbits, 2.2-3.9 kg, were separated into 6 groups of 4 animals each (2 males and 2 females) which received dermal applications of 0.2, 2.0, 5.0, 10.0, 15.0, or 20.0 g/kg of test compound under occlusive dressing. The skin of 1 animal/sex/dosage level was abraded before treatment. Dressing was removed at 24 hours following application. Animals were observed for mortality, toxic signs, and body weight changes during 14 days post-treatment. Necropsies were performed.

2. Results

a. Mortality: None LD 50 >20 g/kg

b. Toxic Signs: Redness and lacerations at test sites, diarrhea.

c. Necropsy: Kidneys, liver, lungs-mottled; pinkish-grey lungs; granular and pitted spleen.

d) Body Weight Changes: Unremarkable

3. Conclusions

a). Classification: Core Minimum Data

i) Only 1 rabbit/sex/dosage level with either intact or abraded skin was used; however, the relative toxicity of the test material is considered to be adequately defined.

ii) Body weights in conjunction with food intake were not determined daily.

b) TOX Cat.: IV

C. Acute Inhalation LC 50 Study of Atratol 8P in Rats (International Research and Development Corp., 2/27/78, submitted by Ciba-Geigy Corp., Acc. No. 234490).

1. Procedure

Twelve (6 males and 6 females) Charles River CD rats, 210-300, were placed into a 160 L inhalation chamber and were exposed for 4 hours to a nominal concentration of 11.2 mg/L of test material generated as a dust during an airflow of 45 L/min. Gravimetric determinations indicated an analytical concentration of 2.18 ± 0.16 mg/L of test substance. The diameter of 93% of the dust particles was ≤ 16μ. Observations of mortality toxic signs and body weight changes were done during 14 days post-exposure. Necropsies were done.

2. Results

a) Mortality: None LC 50 > 11.21 mg/L (4 hours)

b) Body Weight Changes: Unremarkable

c) Toxic Signs: Preening, nasal discharge

d) Necropsy: Unremarkable

3. Conclusions

a) Classification: Core Minimum Data

i) Although only 1 concentration was used, the relative inhalation toxicity of the test material is concluded to be adequately defined.

b) TOX. Cat.: III

D. Eye Irritation Study of Atratol 8P in Rabbits (Food and Drug Research Laboratories, Inc., 10/7/77, submitted by Ciba-Geigy Corp., 7/21/78, Acc. No. 234490).

1. Procedure

Nine New Zealand White rabbits, 2.0-4.0 kg, were used. Into 1 eye of each rabbit was introduced 100 mg of test material. Untreated eyes served as controls. Eyes of 3 rabbits were flushed with water for 1 minute at 30 seconds post-treatment. Injuries were scored at 24, 48, and 72 hours and 7 and 14 days after exposure according to the method of Draize et al. (1944). Examinations with sodium fluorescein were done concurrently at 72 hours and 7 and 14 days.

2. Results

Eye Injuries: Unwashed eyes- corneal opacities, iritis, and conjunctivitis throughout 14 days post-treatment; washed eyes-corneal opacity during 72 hours and conjunctivitis during 7 days post-treatment in 1 rabbit, conjunctivitis during 72 hours post-treatment in 2 rabbits.

3. Conclusions

a) Classification: Core Guidelines

b) TOX. Cat.: I

E. Skin Irritation Study of Artatol 8P in Rabbits (Food and Drug Research Laboratories, Inc., Lab. No. 5608, 9/27/77, submitted by Ciba-Geigy Corp., 7/21/78, Acc. No. 234490).

1. Procedure

Six adult albino rabbits, weights unspecified, were used. Onto both intact and abraded test sites was applied 0.5 g of test material under occlusive dressing. Dressing was removed at 24 hours following treatment. Irritation was scored according to the method of Draize et al. (1944) at 24 and 72 hours post-treatment.

2. Results

P.I. Index = 0.79/8.0

3. Conclusions

a) Classification: Core Guidelines

b) TOX. Cat.: IV

F. Final Conclusions

Use of the label signal word DANGER proposed by the registrant is supported by the following hazard indicators:

Hazard Indicator	TOX. CAT.
Acute oral LD 50	III
Acute dermal LD 50	IV
Acute inhalation LC 50	III
Eye irritation	I
Skin irritation	IV

RD inital:RE:8/21/78:lf

9/5/78