

EEE BRANCH REVIEW

DATE: IN 1/13 OUT 6/5/78 IN \_\_\_\_\_ OUT \_\_\_\_\_  
FISH & WILDLIFE ENVIRONMENTAL CHEMISTRY EFFICACY

FILE OR REG. NO. 100-542

PETITION OR EXP. PERMIT NO. \_\_\_\_\_

DATE DIV. RECEIVED 12/29/77

DATE OF SUBMISSION \_\_\_\_\_

DATE SUBMISSION ACCEPTED \_\_\_\_\_

TYPE PRODUCTS(S): I, D, H, F, N, R, S \_\_\_\_\_

DATA ACCESSION NO(S). 232551

PRODUCT MGR. NO. 25 R. Taylor

PRODUCT NAME(S) Prometryn

COMPANY NAME Ciba-Geigy

SUBMISSION PURPOSE Data submission

CHEMICAL & FORMULATION 2,4 - Bis (isopropylamino)-6-(methylthio)-s-  
triazine

100.0 Pesticide use:

Prometryne is the active ingredient for the herbicide Caparol 80W which is used for selective weed control in soybeans (post-emergence directly sprayed to weeds).

The primary purpose of this review is to evaluate data.

101.0 Chemical and Physical Properties:

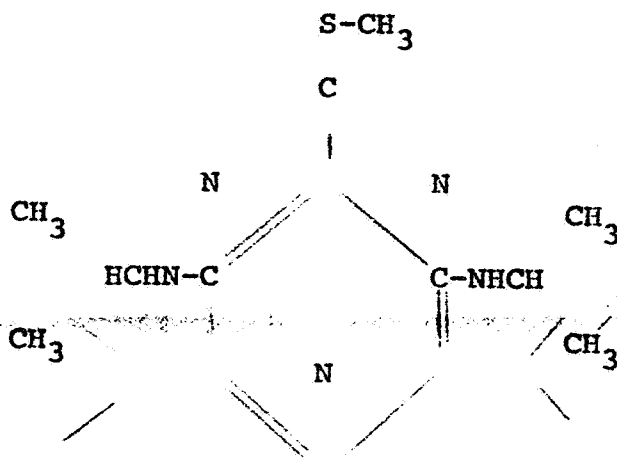
Chemical name:

2,4 - bis (isopropylamino)-6-methylthio-s-triazine

Common name:

Prometryne, principal commercial formulation is Caparol 80W. Technical also referred to as G-34161.

Structural formula:



Molecular formula: C<sub>10</sub> H<sub>19</sub> N<sub>5</sub> S

Molecular weight: 241.4

Physical properties: White, crystalline, non-combustible and non-corrosive

102.0 Behavior in the Environment

Not applicable.

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103.0 Toxicological Properties

The following fish and wildlife studies were submitted to update agency files for technical Prometryn, EPA Reg. No. 100-542. A summary of all studies and an evaluation of each study follows.

SUMMARY OF STUDIES: PROMETRYN

SPECIES	STUDY	RESULTS(95% conf.limits)	REVIEW NUMBER	VALIDATION
Bobwhite quail	Avian dietary	LC <sub>50</sub> - 20,000ppm (10,255 - 39,220)	ES-D-1	Supplemental
Mallard duck	Avian dietary	LC <sub>50</sub> = 48,000ppm (25,000 - 93,160)	ES-E-1	Core Supplemental
Rainbow Trout	96 hr. fish a acute	LC <sub>50</sub> = 2.5ppm (1.6 - 4.0)	ES-G-1	Core
Sunfish	96 hr. fish acute	LC <sub>50</sub> = 10ppm (6.2 - 14.0)	ES-F-1	Core
Goldfish	96 hr. fish acute	LC <sub>50</sub> = 3.5ppm (0.53 - 6.6)	ES-F-2	Supplemental
Mallard duck	Avian acute oral	LD <sub>50</sub> 4640 mg/kg	ES-C-1	Core
<u>Daphnia magna</u>	Aquatic invertebrate acute toxicity	48 hr. LC <sub>50</sub> - 18.9 mg/l (16.0 - 22.2)	ES-H-1	core
Oyster	Shell Deposition	No affect at 1 ppm	ES-H-1	Supplemental

DATA REVIEW NUMBER: ES-D-1

TEST: Avian subacute dietary LC<sub>50</sub>

SPECIES: Bobwhite quail

RESULTS/ABSTRACT:

LC<sub>50</sub> = 20,000ppm (95% C.L. - 10,255 - 39,220 ppm).

Six to eight week old birds were acclimated for 7 days then divided into a negative control group, three treatment groups and five positive control groups (DDT). Mortality occurred at the 10,000 ppm level (3 of 10 birds) and at the 20,000 ppm level (5 of 10 birds). No mortality occurred at 5,000 ppm. The LC<sub>50</sub> (and 95% confidence limites) were statistically determined using the method of Litchfield and Wilcoxon (1949). Bird weights indicated a significant lack of body-weight gain in treatment groups at the 10,000 and 20,000 ppm levels.

CHEMICAL: Prometryne 80W (80% a.i.)

TITLE: Safety evaluation on fish and wildlife  
Bobwhite quail, mallard duck, rainbow trout, sunfish,  
goldfish

ACCESSION NO: 232551 (report 1)

STUDY DATE: April 1965

RESEARCHER: Woodard Research Corp.

REGISTRANT: Ciba-Geigy Corp.

VALIDATION CATEGORY: Supplemental

CATEGORY REPAIRABILITY: None

The study does not meet "core" requirements for an avian test because the formulated product and 6-8 week old birds were used to conduct the study.

DATA REVIEW NUMBER: ES-E-1

TEST: Avian subacute dietary LC<sub>50</sub>

SPECIES: Mallard duck

RESULTS:

LC<sub>50</sub> = 48,000 ppm (95% C.L. - 25,000 - 93,160 ppm)

One day old birds were acclimated for 5 days then divided into a negative control group, four treatment groups and six positive control groups. The ducks (10/cage) were housed in brooders measuring 13" x 36" with the temperature maintained at 90°F. The ducks were fed diets containing an appropriate amount of toxicant for 5 days and then returned to the basal diet for 3 days. Mortality occurred at the 32,000 ppm level (3 of 10 birds) and the 18,000 ppm level (1 of 10 birds) with no mortality at 10,000 and 5,600 ppm levels. The data was examined by the method of Litchfield and Wilcoxon (1949) which yielded the above results. The birds at all dose levels except 5,600 ppm exhibited reduced body weight gain. Gross necropsy of animals receiving 18,000 and 10,000 ppm revealed no visible lesions.

CHEMICAL: Prometryne 80W (80.7% a.i.)

TITLE: Safety evaluation on fish and wildlife; Bobwhite quail, mallard duck, rainbow trout, sunfish, goldfish

ACCESSION NO: 232551 (Report 1)

STUDY DATE: April 1965

RESEARCHER: Woodard Research Corp.

REGISTRANT: Ciba-Geigy Corp.

VALIDATION CATEGORY: Supplemental *Cov 2*

CATEGORY REPAIRABILITY: ~~Yes, if a bird study testing the toxicity of the formulated product is necessary.~~

The study is a good study but it failed to use the technical material. *IT will be considered Cov due to the high toxicity value attained.* *J.*

DATA REVIEW NUMBER: ES-G-1

TEST: Fish acute 96 hr. LC<sub>50</sub>

SPECIES: Rainbow trout (Salmo gairdneri)

RESULTS:

96 hr. LC<sub>50</sub> = 2.5ppm (95% conf. limites = 1.6 - 4.0 ppm)

Tests followed recommended protocol with one exception. The temperature was allowed to fluctuate between 55° and 63°F. during the course of the experiment. LC<sub>50</sub> value was determined by the method of Litchfield and Wilcoxon (1949).

CHEMICAL: Prometryne (99% a.i.) Lot No. FL-1839 ARS 428A-65

TITLE: Safety evaluation on fish and wildlife; Bobwhite quail, mallard duck, rainbow trout, sunfish, goldfish.

ACCESSION NO: 232551 (Report 1)

STUDY DATE: 1965

RESEARCHER: Woodward Research Corp.

REGISTRANT: Ciba-Geigy Corp.

VALIDATION CATEGORY: Core

CATEGORY RATIONALE:

The study was validated as core because the only variation from recommended protocol was the fluctuation of the temperature. This could only work against the registrant in that it acted as an additional stress placed on the fish.

DATA REVIEW NUMBER: ES-F-1

TEST: Fish acute 96 hr. LC<sub>50</sub>

SPECIES: Sunfish (Lepomis macrochirus)

RESULTS:

96 hr. LC<sub>50</sub> = 10 ppm (95% Conf. Limites = 6.2 - 14ppm)

Tests followed recommended protocol with one exception. The temperature was allowed to fluctuate between 64° and 74°F during the course of the experiment. LC<sub>50</sub> value and 95% confidence limites were determined by the method of Litchfield and Wilcoxon (1949).

CHEMICAL: Prometryne (99% a.i.) Lot No. FL-1839 ARS 428A-65

TITLE: Safety evaluation on fish and wildlife; bobwhite quail, mallard duck, rainbow trout, sunfish and goldfish.

ACCESSION NO; 232551 (Report 1)

STUDY DATE: 1965

RESEARCHER: Woodard Research Corp.

REGISTRANT: Ciba-Geigy Corp.

VALIDATION CATEGROY: Core

CATEGORY RATIONALE:

The study was validated as core because the only variation from recommended protocol was the fluctuation of the temperature. This could only work against the registrant in that the variation acted as additional stress on the fish.



DATA REVIEW NUMBER: ES-F-2

TEST: Fish acute 96 hr. LC<sub>50</sub> (warmwater)

SPECIES: Goldfish (Garrassius auratus)

RESULTS:

96 hr. LC<sub>50</sub> = 3.5 ppm (95% conf. limites = 0.53 - 6.6 ppm)

The test primarily followed recommended protocol but varied in two areas. First the species use is not a recommended species. Secondly, the water temperature was lower than recommended and was variable. The temperature fluctuated between 15.5°C - 18.8°C (60° - 66°F).

The results of the treatments - (positive control with DDT and Prometryne) were analyzed and 95% confidence limites were determined by the method of Litchfield and Wilcoxon (1949).

CHEMICAL: Prometryne (99% a.i.) Lot No. FL-1839 ARS 428A-65

TITLE: Safety evaluation on fish and wildlife; bobwhite quail, mallard duck, rainbow trout, sunfish, goldfish.

ACCESSION No. 232551 (Report 1)

STUDY DATE: 1965

Researcher: Woodard Research Corp.

REGISTRANT: Ciba-Geigy Corp.

VALIDATION CATEGORY: Supplemental

CATEGORY RATIONALE:

The study failed to use an approved species and tested at a temperature lower than recommended.

DATA REVIEW NUMBER: ES-H-1

TEST: Aquatic Invertebrate Acute Toxicity

SPECIES: Daphnia magna straus

RESULTS:

48 hr.  $LC_{50} = 18.9$  mg/l. (95% conf. limites = 16.0 -  
22.2 mg/l)

Study follows recommended protocol - using soft lake water  
@ 17.0°C + 1°, 50 mg/l hardner as  $CaCO_3$ , at a pH of 7.21.  
 $LD_{50}$  and 95% conf. limits were determined using the  
Spearman-Karber Estimator in Finney, 1971.

CHEMICAL: Prometryn FL-761355 (98.9% a.i.)

TITLE: Acute toxicity of Prometryn - F1-761355 to the water  
flea Daphnia magna staus.

ACCESSION NO: 232551

STUDY DATE: June 6, 1977

RESEARCHER: Union Carbide Environmental Services

REGISTRANT: Ciba-Geigy Corp.

VALIDATION CATEGORY: Core

DATA REVIEW NUMBER: ES-U-1

TEST: Shell deposition (marine mollusk)

SPECIES: Oysters (Ostrea virginica)

RESULTS:

Oysters (Ostrea virginica) were exposed to a concentration of 1.0ppm (flow through) of Prometryne Technical 99.0% (FL-1839 ARS 428A-65). One negative control using acetone, and four positive controls using DOT were tested along with 1 concentration (1ppm) of Test material. Ten oysters were placed in each two-gallon aquaria, resulting in loading of one oyster per 0.75 l of water. Flow rate was 2 l/min. Oysters weighing 16 - 29g were acclimated for one week, and those not increasing in shell weight by 50 mg were discarded. Test organisms were exposed for one week. Shell deposition was based on an increase in weight, measured in sea water (body has some density as sea water). The percentage gain during the test week was compared to gain during the acclimation week to determine deposition. Data was examined using the White modification of the Wilcoxon technique (Snedecor, 1956) and it indicated that the control and treatment group were not significantly different (P 0.05).

CHEMICAL: Prometryne Technical (99.0% active, FL-1839 ARS 428A-65)

TITLE: Prometryne the effect on shell growth in oysters.

ACCESSION NO: ~~23255~~ Dec. 14, 1966

STUDY DATE: circe Dec. 16, 1966

RESEARCHER: Woodard Research Corp.

REGISTRANT: Ciba-Geigy Corp.

VALIDATION CATEGORY: Supplemental

CATEGORY REPAIRABILITY: None

The test was conducted at one concentration 1.0ppm. An EC<sub>50</sub> or LC<sub>50</sub> was not produced as is specified in the protocol.

The method of weighing (submerged weight) instead of measuring to determine growth is a scientifically sound practice that may be more precise than measuring depending on the skill of the technician. The drawback is that

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the two methods of weighing and measuring shell growth may not be comparable. Each is measuring shell growth per se, however, there is no evidence that the results (EC<sub>50</sub> or LC<sub>50</sub>) of the two methods would be the same.

DATA REVIEW NO: ES-1

TEST: Avian acute Oral LD<sub>50</sub>

SPECIES: Mallard duck

RESULTS:

LD<sub>50</sub> 4640 mg/kg

No mortality was observed in the control or test group at the dose levels used, 0, 215 - 4640 ppm.

The study followed protocol with the following exceptions:

- a) 14 day old birds were used
- b) the design of the cages and environmental parameters were not specified
- c) birds were not fasted prior to testing.

CHEMICAL: Prometryn "Technical" (98.8% a.i.)

TITLE: Acute oral LD<sub>50</sub> - mallard duck - Prometryn technical - Final report.

ACCESSION No; 232551

STUDY DATE: June 14, 1977

RESEARCHER: Robert Fink, Wildlife International, Ltd.

REGISTRANT: Ciba Geigy

VALIDATION CATEGORY: Core

CATEGORY RATIONALE:

The rationale for allowing 14 day old birds to be used is found in the memo by J. Ackerman dated March 13, 1978.

104.0 Hazard Assessment:

No hazard assessment is necessary - data submission only.

104.1.3 Adequacy of toxicity data:

The following studies have been evaluated and found adequate to support registration.

- a) Safety Evaluation on Fish and wildlife (rainbow trout and sunfish), Woodard Research Corp., Nov. 3, 1965. Note: This title also included other fish and bird studies however they either fulfill requirements for conditional studies or test an introduced species (i.e. goldfish).
- b) Acute oral LD<sub>50</sub> - Mallard Duck - Prometryn technical, Final Report, Wildlife International Ltd. Project No. 108-131, June 14, 1977.
- c) Acute Toxicity of Prometryn - FL-761355 - To the Water Flea Daphnia Magna Straus. Aquatics Environmental Sciences. USEC Proj. No. 11506-04-04. June 6, 1977.

d) Safety Evaluation on fish and wildlife (mallard duck only) →

The following studies will support registration if avian dietary studies on the formulated product (Prometryn 80W) are necessary.

- a) Safety Evaluation on fish and wildlife (Bobwhite quail ~~and mallard duck~~).

The following studies will not support registration for the reasons listed.

- a) Safety evaluation on fish and wildlife (goldfish). The species tested is not a recommended species.
- b) Prometryn: The effect of shell growth in Oysters: Woodard Research Corporation. December 16, 1966. The EC<sub>50</sub> or LC<sub>50</sub> was not determined.

107.0 Conclusions:

The following fish and wildlife studies can be used

as data to support registration:

- a) Safety evaluation on fish and wildlife - (Rainbow trout and sunfish only.) Woodward Research Corp. Nov. 3, 1965.
- b) Acute oral LD<sub>50</sub> - Mallard Duck - Prometryn technical, Final Report, Wildlife International Ltd. Project No. 108-131. June 14, 1977.
- c) Acute toxicity of Prometryn - F1-761355 - to the water flea Daphnia magna Straus. Aquatics Environmental Services, ISEC. Proj. No. 11506-04-04. June 6, 1977.

Safety evaluation on fish and wildlife (Mallard duck only).

If avian dietary studies, using the formulated product, are necessary the following studies may be used:

- a) Safety evaluation on fish and wildlife (Bobwhite quail <sup>only</sup> and ~~mallard duck~~); Woodward Research Corp. Nov. 3, 1965.

The following data/studies cannot be used to support registration for the reasons listed.

- a) Safety evaluation on fish and wildlife (goldfish) Woodward Research Corp. Nov. 3, 1965. The goldfish is not a recommended species.
- b) Prometryn: The effect of shell growth in Oysters. Woodward Research Corp. Dec. 16, 1966. Current protocol calls for the determination of a 96 hr. LC<sub>50</sub> value.

107.5

Data requests:

This review is only concerned with the data supplied. No attempt was made to search EPA files to find other studies.

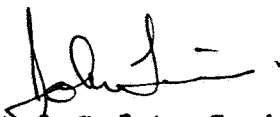
If registration of this product depended only on the data presented, the following studies would have to be submitted or referenced.

A dietary LC<sub>50</sub> for ~~one species of waterfowl (mallard duck)~~ and one species of upland game bird (bobwhite quail or ring-necked pheasant);

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in each case the active ingredient must be tested.

John Tice  
Environmental Safety Section  
EEEEB-RD WH-567  
6/5/78



HTC