

US EPA ARCHIVE DOCUMENT

EPA #241-ELU, Prowl 10G, herbicide, N-(1-ethyl-  
propyl)-3,4-dimethyl-2,6-dinitrobenzenamine.  
Caswell No: 454BB

August 16, 1977

Toxicology Branch, Spencer, H.W.

PM#25, Taylor, R.

Registration of Pesticide Conclusion:

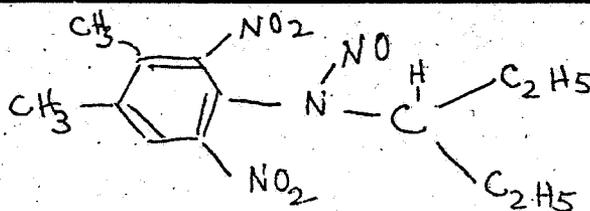
1. T.B. objects to registration of the above material because of the N-nitroso contamination.
2. The teratology study in support of registration is lacking and must be rectified by either: (a) repeat of the study or (b) submission of standard deviations or standard errors for the mean values seen in the study.
3. Label: T.B. suggests the following label changes:
  - a. Place the "First Aid Statement" immediately after the precautionary statements and before Environmental Hazards section.
  - b. Place "avoid inhalation of dust" after caution statement.

Chemical Formula:

Prowl:

Formulation: Prowl 10G  
Active Ingredients % w/w  
Prowl (Technical, commercial) 10.85

Inert Ingredients



**Review:**

The following toxicological studies referenced as support for this registration have been reviewed by R. Engler, Ph.D., Tox. Br. consequent to Reg. #241-EXP-X dtd. 2/22/75 and excepting where noted are considered core minimum studies.

**Technical:**

1. Acute Oral Toxicity (98.7% Technical)

LD<sub>50</sub> 12050 mg/kg; rat, male (95% C.L. 560-2780 mg/kg)

LD<sub>50</sub> 1050 mg/kg; rat, female (95% C.L. 310-360 mg/kg)

LD<sub>50</sub> 1620 mg/kg; mouse, male (95% C.L. 860-2070 mg/kg)

LD<sub>50</sub> 1340 mg/kg; mouse, female (95% C.L. 950-1880 mg/kg)

LD<sub>50</sub> > 5000 mg/kg, dog, beagle male & female

Studies by American Cyanamid. dtd 6/1/72

Report A-72-4, Book I, Section A-C

Reference: Pet # 5F1556

(93% Technical, commercial)

LD<sub>50</sub> 2140 mg/kg rat, male (95% C.L. 1330 - 4430 mg/kg)

LD<sub>50</sub> > 5000 mg/kg rabbit, male

Studies by American Cyanamid dtd. 11/28/73

Report A-73-133 pp 269

Reference: Pet. 35F1556.

2. Acute Skin Irritation, rabbit

no irritation noted

Study by American Cyanamid dtd 6/1/72

Report No. A-72-4 pp 270 dtd 11/28/73

Reference Pet. #5F1556

3. Acute Eye Irritation, rabbit

Slight conjunctival irritation

Study by American Cyanamid dtd 6/1/72

Report No. A-72-4 pp270 dtd 11/28/73

Reference: Pet. #5F1556

4. Acute Inhalation - rat

15% aqueous solution fog.

LC<sub>50</sub> > 320 mg/L (nominal concentration)

Study by Affiliated Medical Research, Inc.  
dtd 10/24/73 Contract N. 122-1968-43

Reference Pet. # 5F1556

5. Subacute Dermal Toxicity (technical)

21 day study - rabbit - NEL < 500 mg/kg  
minimal erythema and edema - no toxicity noted.

Study by Food and Drug Research Labs, Inc.  
dtd 8/24/73 Lab No. 1613

Reference: Reg. #241-EXP-X dtd 2/22/75

6. Carcinogenicity Study: (Technical)

18 month-mouse-no increase tumors or cancers was noted in data presented. Increased adrenal and thyroid weights in treated animals were noted by R.P. Schmidt.

Reference: Pet# 4G1451 dtd 1/30/74  
Study by Bio/dynamics Inc. Project No. 72R-747.

7. Carcinogenicity Study (technical)

24 month-rat-increased liver weights were noted by 3 months. Hepatocyte and bile duct hyperplasia was noted. Thyroid glands exhibited increases in weight in both sexes. No significant increases in tumors or cancers were noted in this study by Bio/dynamics, Inc. Project No. 72R-746, dtd. 8/21/74.

Study reviewed by R. Engler, Ph.D. Reg. # 241-EXP-X

8. Mutagenic index's: control 2.97, 500 ppm, 2.37, 2500 ppm, 1.82 indicates a slight though not statistically significant change. A core minimum study by Food lab No. 2006 and Drug Research Labs. dtd 10/5/73.
9. Mutogenicity Tests of Prowl Herbicide and of Minor components, CL 94269 (N-nitroso contaminant). Study by American Cyanamid dtd 6/10/77, a core-minimum study.

Three typical Prowl preparations were used in this testing, Lots #C 1984-79-3 and AC 2318-141-3 prepared [redacted] prepared using [redacted]

The minor component (n-nitroso contaminant), CL94269, lot numbers AC 2911-2 and AC2096-44 were also tested. Results of all types of tests, Ames plates, Ames discs, and host-mediated assays were negative. The controls, 2AF (2-aminofluorene), MNNG (N-methyl-N'-nitro-nitrosoguanidine), DMNA (diethyl nitrosamine) and 9AA (9-aminoacridine) exhibited good positive results in the individual tests. Discrepancy in Tables VII concerning test material. Report submitted by American Cyanamid 6/10/77 and is considered a core-minimum study.

10. Teratogenicity Study - rat.

Dosages of 0, 500, 1000 mg/kg of the technical material were used ( $LD_{50} = 1250$  mg/kg)

No terata were reported. Study is incomplete and maybe rectified with submission of either standard deviations or standard errors for mean values presented in Study. IBT Study No. 2324 dtd. 12/12/72.

11. Cataract Study

17 day study - white leghorn chick. No cataracts were reported at 1000, 3000 ppm. No positive controls were used.

IBT Study No. 8580-08771 dtd. 1/5/77. Ref. Pet. #6F1704 dtd 2/8/77.

Formulation: Prowl 10G.

Reviewed by R. Engler in regard to Reg. # 241-EYP-63G dtd 6/9/75. The following studies on the 10G formulation are considered to be core minimum data.

1. Acute Oral Toxicity

$LD_{50} > 5$ g/kg rat, male

$LD_{50} > 5$ g/kg mouse, female

2. Acute Dermal Toxicity

$LD_{50} > 5$ g/kg

3. Skin Irritation - rabbit

combined draize score of 0.33 due to slight erythema.

4. Eye Irritation - rabbit.

Sores at 24 hr., 12.7; 48 hr., 5.0; 72 hr., 1.7; due to conjunctival irritation. No corneal involvement noted.

H.W. Spencer