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# Pendimethalin (CASRN 40487-42-1)

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#### Pendimethalin; CASRN 40487-42-1

Human health assessment information on a chemical substance is included in the IRIS database only after a comprehensive review of toxicity data, as outlined in the <u>IRIS</u> assessment development process. Sections I (Health Hazard Assessments for Noncarcinogenic Effects) and II (Carcinogenicity Assessment for Lifetime Exposure) present the conclusions that were reached during the assessment development process. Supporting information and explanations of the methods used to derive the values given in IRIS are provided in the <u>quidance documents located on the IRIS website</u>.

STATUS OF DATA FOR Pendimethalin

#### File First On-Line 06/30/1988

| Category (section)               | Status  | Last Revised |  |
|----------------------------------|---------|--------------|--|
| Oral RfD Assessment (I.A.)       | on-line | 02/01/1991   |  |
| Inhalation RfC Assessment (I.B.) | no data |              |  |
| Carcinogenicity Assessment (II.) | no data |              |  |

# \_I. Chronic Health Hazard Assessments for Noncarcinogenic Effects

## \_I.A. Reference Dose for Chronic Oral Exposure (RfD)

Substance Name — Pendimethalin CASRN — 40487-42-1 Primary Synonym — Prowl Last Revised — 02/01/1991

The oral Reference Dose (RfD) is based on the assumption that thresholds exist for certain

toxic effects such as cellular necrosis. It is expressed in units of mg/kg-day. In general, the RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. Please refer to the Background Document for an elaboration of these concepts. RfDs can also be derived for the noncarcinogenic health effects of substances that are also carcinogens. Therefore, it is essential to refer to other sources of information concerning the carcinogenicity of this substance. If the U.S. EPA has evaluated this substance for potential human carcinogenicity, a summary of that evaluation will be contained in Section II of this file.

## \_\_I.A.1. Oral RfD Summary

| Critical Effect  | Experimental Doses*  | UF  | MF | RfD       |
|--|----------------------|-----|----|-----------|
|  | NOEL: 12.5 mg/kg/day | 300 | 1  | 4E-2      |
| Increase in serum alkaline phosphatase and liver weight, and hepatic lesions | LEL: 50 mg/kg/day    |     |    | mg/kg/day |
| 2-Year Dog Feeding<br>Study  |                      |     |    |           |
| American Cyanamid,<br>1979   |                      |     |    |           |

<sup>\*</sup>Conversion Factors and Assumptions — none

#### \_\_I.A.2. Principal and Supporting Studies (Oral RfD)

American Cyanamid Co. 1979. MRID No. 00058657. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Purebred beagle dogs, 4/sex/dose, were fed pendimethalin 7 days a week by gelatin capsule at 0, 12.5, 50, and 200 mg/kg/day. Clinical chemistry findings were considered within normal limits for all dose levels however, serum alkaline phosphatase (SAP) was increased at the mid- and high-dose levels. Liver weights were increased and the liver showed lesions consisting of inflammation and hemosiderosis at the mid- and high-dose levels. The NOEL and LEL for systemic toxicity are 12.5 and 50 mg/kg/day, respectively, based on hepatic lesions and an increase in SAP and liver weights.

#### \_\_I.A.3. Uncertainty and Modifying Factors (Oral RfD)

UF — An uncertainty factor of 100 was used to account for the inter- and intraspecies differences. An additional UF of 3 was used to account for the lack of an acceptable long term study in a second species. A factor of 3 was chosen rather than 10 since the studies at hand, although of insufficient quality, indicate that the dog is the more sensitive species, and since there is no significant difference in subchronic and chronic effects for this chemical.

MF - None

#### \_\_I.A.4. Additional Studies/Comments (Oral RfD)

Data Considered for Establishing the RfD:

- 1) 2-Year Feeding dog: Principal study see previous description; core grade minimum (American Cyanamid Co., 1979a)
- 2) 3-Generation Reproduction rat: Reproductive NOEL=500 ppm (25 mg/kg/day); Reproductive LEL=5000 ppm (250 mg/kg/day) (HDT; reduced litter size, survival index, and pup weight); core grade minimum (American Cyanamid Co., 1974a)
- 3) Teratology rat: Fetotoxic and Teratogenic NOEL=500 mg/kg/day (HDT); core grade guideline (American Cyanamid Co., 1979b)
- 4) Teratology rabbit: NOEL=60 mg/kg/day (HDT); core grade minimum (American Cyanamid Co., 1982)

Other Data Reviewed:

- 1) 90-Day Feeding rat: NOEL=500 ppm (25 mg/kg/day); LEL=5000 ppm (250 mg/kg/day) (decrease in hematocint and hemoglobin in males, decreased body weight and food consumption, hypertrophy of the liver accompanied by increased liver weights); core grade guideline (American Cyanamid Co., 1974b)
- 2) 90-Day Feeding dog: NOEL=2500 ppm (62.5 mg/kg/day) (by gavage); no core grade (American Cyanamid Co., 1973)

Data Gap(s): Chronic Rat Feeding Study

#### I.A.5. Confidence in the Oral RfD

Study — Medium Database — Medium RfD — Medium

The critical study appears to be of good quality and is given a medium confidence rating. Since the database on chronic toxcity is supportive but incomplete, the database is given a medium confidence rating. Medium confidence in the RfD follows.

#### I.A.6. EPA Documentation and Review of the Oral RfD

Source Document — This assessment is not presented in any existing U.S. EPA document.

Other EPA Documentation — Pesticide Registration Standard, September 1984; Pesticide Registration Files

Agency Work Group Review — 08/19/1986, 09/16/1987

Verification Date — 09/16/1987

#### \_\_I.A.7. EPA Contacts (Oral RfD)

Please contact the IRIS Hotline for all questions concerning this assessment or IRIS, in

general, at (202)566-1676 (phone), (202)566-1749 (FAX) or <a href="mailto:hotline.iris@epa.gov">hotline.iris@epa.gov</a> (internet address).

## \_I.B. Reference Concentration for Chronic Inhalation Exposure (RfC)

Substance Name — Pendimethalin CASRN — 40487-42-1 Primary Synonym — Prowl

Not available at this time.

# \_II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — Pendimethalin CASRN — 40487-42-1 Primary Synonym — Prowl

This substance/agent has not undergone a complete evaluation and determination under US EPA's IRIS program for evidence of human carcinogenic potential.

\_III. [reserved] \_IV. [reserved] \_V. [reserved]

# \_VI. Bibliography

Substance Name — Pendimethalin CASRN — 40487-42-1 Primary Synonym — Prowl Last Revised — 02/01/1991

#### \_VI.A. Oral RfD References

American Cyanamid Company. 1973. MRID No. 00026672, 00040305, 00106763. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

American Cyanamid Company. 1974a. MRID No. 00026671, 00059470, 00106762. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

American Cyanamid Company. 1974b. MRID No. 00026667, 00026668, 00040302. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

American Cyanamid Company. 1979a. MRID No. 00058657. Available from EPA. Write to FOI,

EPA, Washington, DC 20460.

American Cyanamid Company. 1979b. MRID No. 00025752. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

American Cyanamid Company. 1982. MRID No. 00117444. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

## \_VI.B. Inhalation RfC References

None

#### \_VI.C. Carcinogenicity Assessment References

None

## \_VII. Revision History

Substance Name — Pendimethalin CASRN — 40487-42-1 Primary Synonym — Prowl

| Date       | Section          | Description  |
|------------|------------------|--|
| 02/01/1991 | I.A.             | Text edited  |
| 02/01/1991 | VI.              | Bibliography on-line   |
| 01/01/1992 | IV.              | Regulatory Action section on-line  |
| 04/01/1997 | III., IV.,<br>V. | Drinking Water Health Advisories, EPA Regulatory Actions, and Supplementary Data were removed from IRIS on or before April 1997. IRIS users were directed to the appropriate EPA Program Offices for this information. |
| 12/10/1998 | I.A., II.        | This chemical is being reassessed under the IRIS Program.  |
| 02/09/2004 | I.A., II.        | This chemical is no longer being reassessed under the IRIS Program. See Federal Register February 9, 2004 (Volume 69, Number 26).  |

# \_VIII. Synonyms

Substance Name — Pendimethalin CASRN — 40487-42-1

Primary Synonym — Prowl Last Revised — 06/30/1988

- 40487-42-1
- AC 92553
- ANILINE, 3,4-DIMETHYL-2,6-DINITRO-N-(1-ETHYLPROPYL)-
- BENZENAMINE, 3,4-DIMETHYL-2,6-DINITRO-N-(1-ETHYLPROPYL)-
- BENZENAMINE, N-(1-ETHYLPROPYL)-3,4-DIMETHYL-2,6-DINITRO-
- HERBADOX
- HORBADOX
- N-(1-AETHYLPROPYL)-3,4-DIMETHYL-2,6-DINITROANILIN
- N-(1-AETHYLPROPYL)-2,6-DINITRO-3,4-XYLIDIN
- N-(1-ETHYLPROPYL)-3,4-DIMETHYL-2,6-DINITRO- BENZENAMINE
- N-(3-PENTYL)-3,4-DIMETHYL-2,6-DINITROANILINE
- PAY-OFF
- Pendimethalin
- PENDIMETHALINE
- PENOXALIN
- PENOXALINE
- PENOXYN
- PHENOXALIN
- Prowl
- STOMP
- STOMP 330D
- STOMP 330E
- TENDIMETHALIN
- 3,4-XYLIDINE, 2,6-DINITRO-N-(1-ETHYLPROPYL)-

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- Additional Studies/Comments
- Confidence in the Oral RfD
- EPA
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Reference Concentration for Chronic Inhalation Exposure (RfC)

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Carcinogenicity
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Quantitative
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