Picloram; CASRN 1918-02-1

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 assessment</u> <u>development process</u>. 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>guidance documents located</u> <u>on the IRIS website</u>.

STATUS OF DATA FOR Picloram

File First On-Line 09/30/1987

| Category (section) | Assessment Available? | Last Revised |
|----------------------------------|-----------------------|--------------|
| Oral RfD (I.A.) | yes | 09/30/1987 |
| Inhalation RfC (I.B.) | not evaluated | |
| Carcinogenicity Assessment (II.) | not evaluated | |

I. Chronic Health Hazard Assessments for Noncarcinogenic Effects

I.A. Reference Dose for Chronic Oral Exposure (RfD)

Substance Name — Picloram CASRN — 1918-02-1 Last Revised — 09/30/1987

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

1

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 |
|------------------------------|-----------------------------------|-----|----|-------------------|
| Increased liver weights | NOEL: 7 mg/kg/day | 100 | 1 | 7E-2 mg/kg/day |
| 6-Month Dog Feeding Study | LEL: 35 mg/kg/day (males only) | | | |
| Dow Chemical, 1982a | | | | |

*Conversion Factors and Assumptions --- none

I.A.2. Principal and Supporting Studies (Oral RfD)

Dow Chemical Company. 1982a. MRID No. 000110534, 00110535; HED Doc. No. 003954. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Male and female dogs (6/sex/group) were fed diets containing 0, 7, 35, or 175 mg/kg/day of picloram. The observed effects included reduced food consumption and body weight at 175 mg/kg/day for male and female dogs. Also, liver effects were experienced at 35 mg/kg/day for males (increased absolute and relative liver weights) and at 175 mg/kg/day for both males and females (increased absolute and relative liver weights and elevated serum alkaline phosphatase).

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.

MF — None

I.A.4. Additional Studies/Comments (Oral RfD)

Data Considered for Establishing the RfD:

1) 6-Month Feeding - dog: Principal study - see previous description; core grade minimum

2) 2-Year Feeding - rat: NOEL=20 mg/kg/day; LEL=60 mg/kg/day (toxic changes in liver (histopathology); core grade guideline (Dow Chemical, 1986)

3) 90-Day Feeding - rat: NOEL=1000 ppm (50 mg/kg/day); LEL=3000 ppm (150 mg/kg/day)(liver histopathology, necrosis, and bile duct proliferation); core grade minimum (Dow Chemical, 1962)

4) 3-Generation Reproduction - rat: NOEL=1000 ppm (50 mg/kg/day); LEL=3000 ppm (150 mg/kg/day) (reduced fertility); core grade supplementary (Dow Chemical, 1967)

5) Teratology - rat: Teratagenic NOEL=1000 mg/kg/day (HDT); LEL=none; Fetotoxic NOEL=none; core grade minimum (Dow Chemical, 1972)

Other Data Reviewed:

1) 13-Week Feeding - rat: NOEL=50 mg/kg/day (liver effects at 150, 300 or 500 mg/kg/day, slight kidney enlargement at 300 or 500 mg/kg/day); core grade minimum (Dow Chemical, 1982b)

Data Gap(s): Rabbit Teratology Study

I.A.5. Confidence in the Oral RfD

Study — Medium Database — Medium RfD — Medium

The principal study appears to be of fair quality and, therefore, is given a medium confidence rating. The database is of fair to good quality with one data gap and is given a medium confidence rating. Medium confidence in the RfD follows.

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

Pesticide Registration Standard, February, 1984

Agency Work Group Review — 05/30/1986, 04/15/1987

Verification Date — 04/15/1987

Screening-Level Literature Review Findings — A screening-level review conducted by an EPA contractor of the more recent toxicology literature pertinent to the RfD for Picloram conducted in September 2002 identified one or more significant new studies. IRIS users may request the references for those studies from the IRIS Hotline at <u>hotline.iris@epa.gov</u> or (202)566-1676.

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 <u>hotline.iris@epa.gov</u> (internet address).

I.B. Reference Concentration for Chronic Inhalation Exposure (RfC)

Substance Name — Picloram CASRN — 1918-02-1

Not available at this time.

II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — Picloram CASRN — 1918-02-1

Not available at this time.

III. [reserved]IV. [reserved]V. [reserved]

VI. Bibliography

Substance Name — Picloram CASRN — 1918-02-1

VI.A. Oral RfD References

Dow Chemical Company. 1962. MRID No. 00041093, 00069969, 00072318, 00072320; HED Doc. No. 003954. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Dow Chemical Company. 1967. MRID No. 000410984; HED Doc. No. 003954. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Dow Chemical Company. 1972. MRID No. 00059417; HED Doc. No. 003177, 003954. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Dow Chemical Company. 1982a. MRID No. 000110534, 00110535; HED Doc. No. 003954. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Dow Chemical Company. 1982b. MRID No. 000110537; HED Doc. No. 003954. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Dow Chemical U.S.A. 1986. MRID No. 00155940. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

VI.B. Inhalation RfD References

None

VI.C. Carcinogenicity Assessment References

None

VII. Revision History

Substance Name — Picloram CASRN — 1918-02-1

| Date | Section | Description |
|------------|---------|--------------------------------------------------------------------|
| 12/03/2002 | I.A.6. | Screening-Level Literature Review Findings message has been added. |

VIII. Synonyms

Substance Name — Picloram CASRN — 1918-02-1 Last Revised — 09/30/1987

- 1918-02-1
- AMDON GRAZON
- 4-AMINO-3,5,6-TRICHLOROPICOLINIC ACID
- 4-AMINO-3,5,6-TRICHLORO-2-PICOLINIC ACID
- 4-AMINO-3,5,6-TRICHLORPICOLINSAEURE
- ATCP
- BOROLIN
- CHLORAMP
- K-PIN
- NCI-C00237
- Picloram
- PICOLINIC ACID, 4-AMINO-3,5,6-TRICHLORO-
- TORDON 10K
- TORDON 22K
- 3,5,6-TRICHLORO-4-AMINOPICOLINIC ACID