# Fluometuron; CASRN 2164-17-2

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 IRIS 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 guidance documents located on the IRIS website.

STATUS OF DATA FOR Fluometuron

**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 — Fluometuron
CASRN — 2164-17-2
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

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 |
|---|---|---|---|---|
| **No adverse effects**<br><br>**103-Week Rat Feeding Study**<br><br>**NCI, 1980** | NOAEL: 250 ppm diet (12.5 mg/kg/day)<br><br>LEL: None | 1000 | 1 | 1.3E-2 mg/kg/day |

*Conversion Factors: 1 ppm = 0.05 mg/kg/day (assumed rat food consumption)

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

NCI (National Cancer Institute). 1980. Bioassay of Fluometuron for Possible Carcinogenicity, CAS No. 2164-17-2, NCI-CG-TR-195, NTP-80-11, NIH Publ. No. 80-1751. National Institute of Health, Bethesda, MD.

Groups of rats (50/sex/dose) were fed diets containing 0, 125, or 250 ppm of fluometuron for 103 weeks. All surviving animals were killed at 103 to 105 weeks. Mean body weights and survival of the dosed groups of male and female rats were essentially the same as those of the corresponding control group. No observed effects were seen at the highest dose tested, 250 ppm (12.5 mg/kg/day), which was the NOAEL for this study.

### I.A.3. Uncertainty and Modifying Factors (Oral RfD)

UF — An uncertainty factor of 1000 was used to account for the inter- and intraspecies differences and for the fact that the database on toxicity is incomplete (e.g., lacking a mammalian reproductive study). Furthermore, the available supporting studies are of low quality.

MF — None

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

Data Considered for Establishing the RfD:

1) 103-Week Feeding - rat: Principal study - see previous description; no core grade

2) 90-Day Feeding - rat: NOEL=7.5 mg/kg/day; LEL=75 mg/kg/day (decrease in body weight and enlarged spleens); no core grade (Ciba Agrochemical, 1965a)

3) 90-Day Feeding - dog: NOEL=10 mg/kg/day; LEL=100 mg/kg/day (inflammatory reaction in kidney and liver); no core grade (Ciba Agrochemical, 1965b)

4) Teratology - rabbit: Maternal and Fetotoxic NOEL not established; LEL=50 mg/kg/day; minimum for teratogenicity otherwise supplementary (Ciba-Geigy, 1984)

5) 103-Week Feeding - mouse: NOEL=500 ppm (75 mg/kg/day); LEL=1000 ppm (150 mg/kg/day) (marginal increase in liver tumors); no core grade (NCI, 1980)

Data Gap(s): Chronic Rat Feeding Study; Chronic Dog Feeding Study; Rat Reproduction Study; Rat Teratology Study; Rabbit Teratology Study

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

Study — Low
Database — Low
RfD — Low

The principal study appears to be of low quality and is given a low confidence rating. Since the database on toxicity is incomplete and of apparently low quality, the database is given a low confidence rating. Low 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, 1985; Pesticide Registration Files

Agency Work Group Review — 07/08/1986, 03/18/1987

Verification Date — 03/18/1987

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 Fluometuron conducted in August 2003 did not identify any critical new studies. IRIS users who know of important new studies may provide that information to the IRIS Hotline at hotline.iris@epa.gov 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 hotline.iris@epa.gov (internet address).

---

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

Substance Name — Fluometuron
CASRN — 2164-17-2

Not available at this time.

---

## II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — Fluometuron
CASRN — 2164-17-2

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 — Fluometuron
CASRN — 2164-17-2

## VI.A. Oral RfD References

Ciba Agrochemical Company. 1965a. MRID No. 00019034. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Ciba Agrochemical Company. 1965b. MRID No. 00019035. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Ciba-Geigy Corporation. 1984. MRID No. 00147554. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

NCI (National Cancer Institute). 1980. Bioassay of Fluometuron for Possible Carcinogenicity, CAS No. 2164-17-2, NCI-CG-TR-195, NTP-80-11, NIH Publ. No. 80-1751. National Institute of Health, Bethesda, MD.

## VI.B. Inhalation RfC References

None

## VI.C. Carcinogenicity Assessment References

None

## VII. Revision History

Substance Name — Fluometuron
CASRN — 2164-17-2

| Date | Section | Description |
|---|---|---|
| **10/28/2003** | I.A.6. | Screening-Level Literature Review Findings message has been added. |

## VIII. Synonyms

Substance Name — Fluometuron
CASRN — 2164-17-2
Last Revised — 09/30/1987

- 2164-17-2
- C 2059
- CIBA 2059
- COTORAN MULTI 50WP
- COTTONEX
- 1,1-DIMETHYL-3-(3-TRIFLUOROMETHYLPHENYL)UREA
- 1,1-DIMETHYL-3-(alpha,alpha,alpha-TRIFLUORO-m-TOLYL) UREA
- Fluometuron
- HERBICIDE C-2059
- LANEX
- NCI-C08695
- N-(3-TRIFLUOROMETHYLPHENYL)-N'-N'-DIMETHYLUREA
- N-(m-TRIFLUOROMETHYLPHENYL)-N',N'-DIMETHYLUREA
- PAKHTARAN
- 3-(5-TRIFLUORMETHYLPHENYL)-1,1-DIMETHYLHARNSTOFF
- 3-(m-TRIFLUOROMETHYLPHENYL)-1,1-DIMETHYLUREA
- UREA, 1,1-DIMETHYL-3-(alpha,alpha,alpha-TRIFLUORO-m-TOLYL)-
- UREA, N,N-DIMETHYL-N'-(3-(TRIFLUOROMETHYL)PHENYL)-