4/8/86

REFERENCE DOSE FOR CHRONIC ORAL EXPOSURE (RfD)

Substance Name: Baythroid
CASRN: 68359-37-5

128831 = CYFLUTHRIN

The Reference Dose (RfD) is based on the assumption that thresholds exist for certain toxic effects such as cellular necrosis, but may not exist for other toxic effects such as carcinogenicity. 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 Oral RfD Background Document for an elaboration of these concepts. RfDs can also be derived for the noncarcinogenic health effects of compounds which 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 the Carcinogenicity Assessment Section of this file when a review of that evaluation is completed.

RfD ASSESSMENT SUMMARY TABLE

Crit. Dose: 2.5 mg/kg-day [Study 1 NOAEL(adj)]
UF: 100 MF: 1 RfD: 2.5E-2 mg/kg-day Confidence: High

Crit Effect: (1) Decreased body weights in males, inflammatory foci in kidneys of females

	NOAEL (Study 1)	LOAEL (Study 1)
Reported	50 ppm	150 ppm
ADJ	2.5 mg/kg-day	7.5 mg/kg-day
Study Type	2-Year Rat Study, Dietary	2-Year Rat Study, Dietary
Reference	Mobay Chemical, 1983a	Mobay Chemical, 1983a

1) Mobay Chemical, 1983a
2-Year Rat Study, Dietary

Critical Effect: Decreased body weights in males, inflammatory foci in kidneys of females

Defined Dose Levels:
NOAEL= 50 ppm
NOAEL(ADJ)= 2.5 mg/kg-day
LOAEL= 150 ppm
LOAEL(ADJ)= 7.5 mg/kg-day

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

DISCUSSION OF PRINCIPAL AND SUPPORTING STUDIES

Mobay Chemical Corporation. 1983a. MRID No. 00137303. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

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Sixty-five male and 65 female Wistar SPF rats, 5-6 weeks of age, were assigned to four groups which were fed diets containing 0, 50, 150, and 450 ppm of baythroid. Animals were observed for clinical signs twice daily and once daily on weekends and holidays. Individual body weights and group food consumption were determined weekly for the first 26 weeks, biweekly during week 27 through 74, and then weekly until termination. Hematology, clinical chemistry, and urinalysis were performed on 10 rats/sex/group at 6, 12, 18, and 24 months of study. Observed results included decreased body weights in males and inflammatory foci in kidneys of females.

UNCERTAINTY AND MODIFYING FACTORS

UNCERTAINTY FACTORS:

A 100-fold UF has been used to compensate for both the interspecies differences in extrapolating from the human, and the expected intrahuman variability to the toxicity of this chemical.

ADDITIONAL COMMENTS / STUDIES

Data Considered for Establishing the RfD:

1) 2-Year Feeding - rat: Principal study - see previous description; core grade minimum

2) 1-Year Feeding - dog: NOEL=160 ppm (4 mg/kg/day); LEL=640 ppm (16 mg/kg/day) (slight ataxia in two dogs, one occasion each; increased vomiting; increased pasty-to-liquid feces; decreased body weights in males); core grade minimum (Mobay Chemical, 1983b)

3) 3-Generation Reproduction - rat: Systemic NOEL=50 ppm (2.5 mg/kg/day); Systemic LEL=150 ppm (7.5 mg/kg/day) (body weight decrease in the pups); Reproductive NOEL=50 ppm; Reproductive LEL=150 ppm (decreased viability index); core grade minimum (Mobay Chemical, 1983c)

4) Teratology - rat: Maternal NOEL=3 mg/kg/day; Maternal LEL=10\mg/kg/day (behavioral changes in gait and coordination); Teratogenic NOEL=30 mg/kg/day (HDT); Fetotoxic NOEL=30 mg/kg/day (HDT); core grade minimum (Mobay Chemical, 1982)

5) Teratology - rabbit: Maternal NOEL=15 mg/kg/day, Maternal LEL=45\mg/kg/day (abortion and resorption); Teratogenic NOEL=45 mg/kg/day (HDT); Fetotoxic NOEL=45 mg/kg/day (HDT); core grade minimum (Mobay Chemical, 1983d)

Other Data Reviewed:

1) 23-Month Feeding (oncogenic) - mice: Systemic NOEL=none; Systemic LEL=50 ppm (7.5 mg/kg/day) (LDT) (increased alkaline phosphatase activity in males); core grade supplementary (Mobay Chemical, 1983e)

Data Gap(s): None

REFERENCE DOSE FOR CHRONIC ORAL EXPOSURE (RfD)

CONFIDENCE IN THE RfD

Study: High Data Base: High RfD: High

The principal study appears to be of good quality and is given a high rating. Since there are no data gaps existing for baythroid and additional studies are also of good quality, the data base is given a high confidence. High confidence in the RfD follows.

EPA DOCUMENTATION AND REVIEW

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

Other EPA Documention: Pesticide Registration Files

Agency Work Group Review: 04/08/86

Verification Date: 04/08/86

EPA CONTACTS

William Burnam / OPP -- (703)305-7491

George Ghali / OPP -- (703)305-7490

BIBLIOGRAPHY

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Mobay Chemical Corporation. 1983b. MRID No. 00151358. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Mobay Chemical Corporation. 1983c. MRID No. 00131532, 00137545, 00149597. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Mobay Chemical Corporation. 1983d. MRID No. 00131534. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Mobay Chemical Corporation. 1983e. MRID No. 00137304. Available from EPA. Write to FOI, EPA, Washington, DC 20460.