Baythroid; CASRN 68359-37-5

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 Baythroid

File First On-Line 03/31/1987

<table>
<thead>
<tr>
<th>Category (section)</th>
<th>Assessment Available?</th>
<th>Last Revised</th>
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<tr>
<td>Oral RfD (I.A.)</td>
<td>yes</td>
<td>03/31/1987</td>
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<tr>
<td>Inhalation RfC (I.B.)</td>
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<td>Carcinogenicity Assessment (II.)</td>
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I. Chronic Health Hazard Assessments for Noncarcinogenic Effects

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

Substance Name — Baythroid
CASRN — 68359-37-5
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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

<table>
<thead>
<tr>
<th>Critical Effect</th>
<th>Experimental Doses*</th>
<th>UF</th>
<th>MF</th>
<th>RfD</th>
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<tr>
<td>Decreased body weights in males, inflammatory foci in kidneys of females</td>
<td>NOEL: 50 ppm (2.5 mg/kg/day)</td>
<td>100</td>
<td>1</td>
<td>2.5E-2 mg/kg/day</td>
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<tr>
<td>2-Year Rat Study, Dietary</td>
<td>LEL: 150 ppm (7.5 mg/kg/day)</td>
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</table>

Mobay Chemical, 1983a

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

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


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.

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

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

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

I.A.5. Confidence in the Oral RfD

Study — High
Database — 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 database is given a high confidence. High confidence in the RfD follows.

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

Pesticide Registration Files

Agency Work Group Review — 04/08/1986

Verification Date — 04/08/1986

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 Baythroid conducted in September 2002 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).

**II. Carcinogenicity Assessment for Lifetime Exposure**

Substance Name — Baythroid
CASRN — 68359-37-5

Not available at this time.
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 — Baythroid
CASRN — 68359-37-5

VI.A. Oral RfD References


VI.B. Inhalation RfC References

None

VI.C. Carcinogenicity Assessment References

None

VII. Revision History

Substance Name — Baythroid
CASRN — 68359-37-5

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<tr>
<th>Date</th>
<th>Section</th>
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<td>I.A.6.</td>
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VIII. Synonyms

Substance Name — Baythroid
CASRN — 68359-37-5
Last Revised — 03/31/1987

- 68359-37-5
- BAY FCR 1272
- Baythroid
- BAYTHROID H
- CYFLUTHRIN