This IRIS Summary has been removed from the IRIS database and is available for historical reference purposes. (July 2016)

Dodine; CASRN 2439-10-3

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 Dodine

File First On-Line 09/30/1987

<table>
<thead>
<tr>
<th>Category (section)</th>
<th>Assessment Available?</th>
<th>Last Revised</th>
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<tbody>
<tr>
<td>Oral RfD (I.A.)</td>
<td>yes</td>
<td>09/30/1987</td>
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<tr>
<td>Inhalation RfC (I.B.)</td>
<td>not evaluated</td>
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<tr>
<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 — Dodine
CASRN — 2439-10-3
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

<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>Thyroid toxicity</td>
<td>NOEL: 50 ppm diet (1.25 mg/kg/day)</td>
<td>300</td>
<td>1</td>
<td>4E-3 mg/kg/day</td>
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<tr>
<td>1-Year Dog Feeding Study</td>
<td>LEL: 200 ppm diet (5.0 mg/kg/day)</td>
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<tr>
<td>American Cyanamid, 1958</td>
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*Conversion Factors -- 1 ppm = 0.025 mg/kg/day (assumed dog food consumption)

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


Two beagle dogs/sex were exposed in the diet to 0, 50, 200, or 800 ppm of technical dodine for 1 year. Exposure related effects, at 800 ppm, were changes in the shape of follicular epithelial cells of the thyroid from squamous to cuboidal and low columnar in 4/4 dogs; increased vascularity; and partially filled follicles that stained less intensely. Milder changes of the same kind in 1 dog of 4 given 200 ppm were seen, and thus 50 ppm is considered the NOEL. The study was rated core grade supplementary for chronic nonrodent feeding study because of the small number of dogs.

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

UF — An uncertainty factor of 100 was used to account for inter- and intraspecies differences. An additional UF of 3 was used to allow for the uncertainty caused by existing data gaps in teratogenicity, the supplementary dog study, and the inadequate histopathology in the chronic rat study.

MF — None
I.A.4. Additional Studies/Comments (Oral RfD)

Data Considered for Establishing the RfD:

1) 1-Year Feeding - dog: Principal study - see previous description; core grade supplementary

2) 2-Year Feeding - rat: NOEL=200 ppm (7-10 mg/kg/day); LEL=800 ppm (29-45 mg/kg/day) (decreased weight gain in males, females; reduced food consumption in males); core grade supplementary (American Cyanamid Co., 1959)

3) 3-Generation Reproduction - mouse: Fetotoxic NOEL=none; LEL=(74-89 mg/kg/day) (LDT; decreased viability and lactation indices in two matings of the third generation); Reproductive and Parental NOEL=800 ppm (120 mg/kg/day) (HDT); Reproductive and Parental LEL=none; core grade supplementary (American Cyanamid, 1967)

4) 2-Generation Reproduction - rat: Reproductive NOEL=800 ppm (40 mg/kg/day) (ODT); LEL=none; Fetotoxic LEL=800 ppm (reduced number pups/litter); Parental NOEL=none; Parental LEL=800 ppm (40 mg/kg/day) (decreased weight gain, decreased food consumption); core grade supplementary (American Cyanamid, 1958b)

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

I.A.5. Confidence in the Oral RfD

Study — Low
Database — Low
RfD — Low

The principal study is valid but of low sensitivity because of a small number of animals. It is given a low confidence rating. The database on chronic toxicity is likewise incomplete, thus, it is given a low confidence rating. Low confidence in the RfD follows.

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

Pesticide Registration Standard, 1986

Pesticide Registration Files

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 Dodine conducted in November 2001 identified one or more significant new studies. IRIS users may request the references for those studies from 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 — Dodine
CASRN — 2439-10-3

Not available at this time.

II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — Dodine
CASRN — 2439-10-3

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 — Dodine
CASRN — 2439-10-3

VI.A. Oral RfD References


VI.B. Inhalation RfD References

None

VI.C. Carcinogenicity Assessment References

None
VII. Revision History

Substance Name — Dodine
CASRN — 2439-10-3

<table>
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<th>Section</th>
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VIII. Synonyms

Substance Name — Dodine
CASRN — 2439-10-3
Last Revised — 09/30/1987

- 2439-10-3
- AC 5223
- APADODINE
- CARPENE
- CURITAN
- CYPREX
- CYPREX 65W
- DODECYLGUANIDINE ACETATE
- n-DODECYLGUANIDINE ACETATE
- DODIN
- Dodine
- DODINE ACETATE
- DOGUADINE
- DOQUADINE
- ENT 16,436
- GUANIDINE, DODECYL-, ACETATE
- LAURYLGUANIDINE ACETATE
- MELPREX
- MILPREX
- N-DODECYLGUANIDINACETAT
- SYLLIT
- TSITREX
- VENTUROL
- VONDODINE