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## Imazalil; CASRN 35554-44-0

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 Imazalil

**File First On-Line 03/31/1987**

Category (section)	Assessment Available?	Last Revised
<b>Oral RfD (I.A.)</b>	yes	03/31/1987
<b>Inhalation RfC (I.B.)</b>	not evaluated	
<b>Carcinogenicity Assessment (II.)</b>	not evaluated	

## I. Chronic Health Hazard Assessments for Noncarcinogenic Effects

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

Substance Name — Imazalil

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Last Revised — 03/31/1987

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
<b>Decreased body weight gain</b>	NOEL: 1.25 mg/kg/day LEL: 5.0 mg/kg/day	100	1	1.3E-2 mg/kg/day
<b>2-Year Dog Feeding Study</b>				
<b>Penwalt Corp., 1977</b>				

\*Conversion Factors: none

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

Penwalt Corporation. 1977. MRID No. 00069941, 00069949, 00069951, 00081172, 00084659, 00084660. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Twenty-four young beagle dogs, aged 189 to 212 days, were divided into four groups of six animals each (3M and 3F) and fed 0, 1.25, 5.0, or 20 mg/kg bw/day of Imazalil base (R23979) for 2 years. Signs of toxicity were limited to decreased body weight gains at doses of 5 mg/kg bw/day and higher.

### 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)

None.

Data Considered for Establishing the RfD:

- 1) 2-Year Feeding - dog: Principal study - see previous description; core grade minimum
- 2) 2-Year Feeding (oncogenic) - rat: Systemic NOEL=10 mg/kg/day; Systemic LEL=40 mg/kg (relative liver and kidney weight increase in females) (HDT); core grade supplementary (Janssen R & D, Inc., 1967)
- 3) Teratology - rat: NOEL=10 mg/kg/day; LEL=40 mg/kg/day (increased maternal mortality, decreased food consumption, decreased litter size, increased number of dead fetuses); core grade minimum (Chevron Chemical, 1975)
- 4) 3-Generation Reproduction - rat: NOEL=40 mg/kg/day (HDT); LEL=none; core grade minimum (Penwalt Corp., 1975)

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

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

Study — Medium  
Database — Medium  
RfD — Medium

The principal study appears to be of medium quality and is given a medium confidence rating. Several other studies are moderately supportive; therefore, confidence in the database can be considered medium to high. Confidence in the RfD can also be considered medium to high.

**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 Files

Agency Work Group Review — 09/02/1986

Verification Date — 09/02/1986

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 Imazalil 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](mailto: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](mailto:hotline.iris@epa.gov) (internet address).

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

Substance Name — Imazalil  
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Not available at this time.

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### **II. Carcinogenicity Assessment for Lifetime Exposure**

Substance Name — Imazalil  
CASRN — 35554-44-0

This substance/agent has not undergone a complete evaluation and determination under US EPA's IRIS program for evidence of human carcinogenic potential.

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**III. [reserved]**

**IV. [reserved]**

**V. [reserved]**

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### **VI. Bibliography**

Substance Name — Imazalil  
CASRN — 35554-44-0

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### VI.A. Oral RfD References

Chevron Chemical Company. 1975. MRID No. 00081171. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Janssen R & D, Inc. 1967. MRID No. 00031597. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Penwalt Corporation. 1975. MRID No. 00069944, 00081162. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Penwalt Corporation. 1977. MRID No. 00069941, 00069949, 00069951, 00081172, 00084659, 00084660. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

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### VI.B. Inhalation RfC References

None

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### VI.C. Carcinogenicity Assessment References

None

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## VII. Revision History

Substance Name — Imazalil  
CASRN — 35554-44-0

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

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## VIII. Synonyms

Substance Name — Imazalil

CASRN — 35554-44-0

Last Revised — 03/31/1987

- 35554-44-0
- (+-)-1-(beta-(ALLYLOXY)-2,4-DICHLOROPHENETHYL)IMIDAZOLE
- 1-(2-(2,4-DICHLOROPHENYL)-2-(2-PROPENYLOXY)ETHYL)-1H-IMIDAZOLE
- 1-(2-(2,4-DICHLOROPHENYL)-2-PROPENYLOXY)AETHYL)-1H-IMIDAZOL
- ENILOCONAZOL
- FUNGAFLOL
- Imazalil
- 1H-IMIDAZOLE, 1-(2-(2,4-DICHLOROPHENYL)-2-(2-PROPENYLOXY)ETHYL)-
- R 23979