Maleic hydrazide; CASRN 123-33-1

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 Maleic hydrazide

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>
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<td>03/31/1987</td>
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<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 — Maleic hydrazide
CASRN — 123-33-1
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

<table>
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<tr>
<th>Critical Effect</th>
<th>Experimental Doses*</th>
<th>UF</th>
<th>MF</th>
<th>RfD</th>
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<tr>
<td>Renal dysfunction</td>
<td>NOEL: none</td>
<td>1000</td>
<td>1</td>
<td>5E-1 mg/kg/day</td>
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<tr>
<td>2-Year Rat Feeding Study</td>
<td>LEL: 1% of diet (500 mg/kg/day)</td>
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<td></td>
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<tr>
<td>Uniroyal Chemical Co. 1981</td>
<td></td>
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*Conversion Factors and Assumptions — 1 ppm = 0.05 mg/kg/day (assumed rat food consumption)

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


Twenty-five male and 50 female SPF Wistar rats were fed 0, 1 or 2% maleic hydrazide (MH) in their diet during the 1-week premating period and the 1-week mating period. At weaning, F1 offspring males and females were taken at random from the three experimental groups for the 28-month carcinogenicity study. The same levels of MH were administered in the diet. Group 1 consisted of 65 female and 65 male rats (2%); group 2 consisted of 55 animals from each sex (1%); and group 3 consisted of 55 control animals (diet only) from each sex. Observations included renal dysfunction.

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 to account for the fact that a LEL was used as a basis for the RfD instead of a NOEL.
MF — None

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) Teratology - Rabbit: NOEL=100 mg/kg/day; LEL=300 mg/kg/day; (malformed scapulae); core grade minimum (Uniroyal Chemical Co., 1983a)
3) 2-Generation Reproduction - Rat: NOEL=500 mg/kg/day; LEL=1500 mg/kg/day; (postnatal decrease in body weight); core grade minimum (Uniroyal Chemical Co., 1983b)
4) 1-Year Feeding - Dog: NOEL=600 mg/kg/day (HDT); no core grade (Uniroyal Chemical Co., 1954)

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

I.A.5. Confidence in the Oral RfD

Study — Low
Database — Medium
RfD — Medium

The critical study appears to be of low to medium quality and is given a low confidence rating. The database is given medium confidence since it is incomplete. Medium confidence in the RfD follows.

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

Pesticide Registration Files

Agency Work Group Review — 07/22/1986

Verification Date — 07/22/1986

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 Maleic hydrazide conducted in September 2002 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 — Maleic hydrazide
CASRN — 123-33-1

Not available at this time.

II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — Maleic hydrazide
CASRN — 123-33-1

Not available at this time.

III. [reserved]
IV. [reserved]
V. [reserved]

VI. Bibliography

Substance Name — Maleic hydrazide
CASRN — 123-33-1

VI.A. Oral RfD References


VI.B. Inhalation RfD References

None

VI.C. Carcinogenicity Assessment References

None

VII. Revision History

Substance Name — Maleic hydrazide
CASRN — 123-33-1

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<th>Section</th>
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<td>Screening-Level Literature Review Findings message has been added.</td>
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VIII. Synonyms
Substance Name — Maleic hydrazide
CASRN — 123-33-1
Last Revised — 03/31/1987

- 123-33-1
- BURTOLIN
- CHEMFORM
- DE-CUT
- DE-SPROUT
- 1,2-DIHYDRO-3,6-PYRADIZINEDIONE
- 1,2-DIHYDROPYRIDAZINE-3,6-DIONE
- DREXEL-SUPER P
- ENT 18,870
- FAIR 30
- FAIR PS
- 6-HYDROXY-3(2H)-PYRIDAZINONE
- KMH
- MAH
- MAINTAIN 3
- MALAZIDE
- MALEIC ACID HYDRAZIDE
- Maleic Hydrazide
- MALEIC HYDRAZIDE 30%
- MALEIC HYDRAZINE
- MALEIN 30
- MALEINSAEUREHYDRAZID
- MH
- MH 30
- MH 36 BAYER
- MH-40
- N,N-MALEOYLHYDRAZINE
- 3,6-PYRIDAZINEDIONE, 1,2-DIHYDRO-
- RCRA WASTE NUMBER U148
- REGUOX
- REGUOX 50 W
- REGUOX W
- RETARD
- ROYAL MH-30
- ROYAL SLO-GRO
- SLO-GRO
- SPROUT/OFF
- SPROUT-STOP
- STUMTMAN
- SUCKER-STUFF
• SUPER-DE-SPROUT
• SUPER SPROUT STOP
• SUPER SUCKER-STUFF
• 1,2,3,6-TETRAHYDRO-3,6-DIOXOPYRIDAZINE
• VONDALHYDE
• VONDRAK