# 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 <u>IRIS assessment</u> <u>development process</u>. 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 <u>guidance documents located</u> <u>on the IRIS website</u>.

#### STATUS OF DATA FOR Maleic hydrazide

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

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

# I. Chronic Health Hazard Assessments for Noncarcinogenic Effects

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

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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

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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
Renal dysfunction	NOEL: none	1000	1	5E-1 mg/kg/day
2-Year Rat Feeding Study	LEL: 1% of diet (500 mg/kg/day)			
Uniroyal Chemical Co. 1981				

\*Conversion Factors and Assumptions — 1 ppm = 0.05 mg/kg/day (assumed rat food consumption)

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

Uniroyal Chemical Co. 1981. Acc. No. 250523. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

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) Teratolgy - 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 <u>hotline.iris@epa.gov</u> 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 <u>hotline.iris@epa.gov</u> (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

Uniroyal Chemical Co. 1981. Acc. No. 250523. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Uniroyal Chemical Co. 1954. MRID No. 00112753; HED Doc. No. 004757. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Uniroyal Chemical Company. 1983a. MRID No. 00128721; HED Doc. No. 004330. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Uniroyal Chemical Co. 1983b. MRID No. 00141358, 00128720; HED Doc. No. 004330. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

#### **VI.B. Inhalation RfD References**

None

VI.C. Carcinogenicity Assessment References

None

#### **VII. Revision History**

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

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

# **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
- REGULOX
- REGULOX 50 W
- REGULOX W
- RETARD
- ROYAL MH-30
- ROYAL SLO-GRO
- SLO-GRO
- SPROUT/OFF
- SPROUT-STOP
- STUNTMAN
- SUCKER-STUFF

- SUPER-DE-SPROUT
- SUPER SPROUT STOP
- SUPER SUCKER-STUFF
- 1,2,3,6-TETRAHYDRO-3,6-DIOXOPYRIDAZINE
- VONDALHYDE
- VONDRAX