Iprodione; CASRN 36734-19-7

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 Iprodione

File First On-Line 06/30/1988

Category (section)	Assessment Available?	Last Revised
Oral RfD (I.A.)	yes	06/30/1988
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)

Substance Name — Iprodione CASRN — 36734-19-7 Primary Synonym — Rovral Last Revised — 06/30/1988

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
Increased RBC Heinz boies; decreased prostate weight	NOEL: 100 ppm (4.2 mg/kg/day)	100	1	4E-2 mg/kg/day
1-Year Dog Feeding Study	LEL: 600 ppm (15 mg/kg/day)			
Rhone-Poulenc, 1984				

^{*}Conversion Factors -- Dose conversions based on actual food consumption data

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

Rhone-Poulenc, Inc. 1984. MRID No. 00144391, 41327001. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Beagle dogs (6/sex/dose) (Balbeggie Kennels, Fife, Scotland) were administered 0, 4.2, 15, and 90 mg/kg/day Iprodione Technical (96.5% pure) for 52 weeks, starting at 15 to 17 weeks of age (bw 2.7 to 6.8 kg). At 15 and 90 mg/kg/day effects noted in males were decreased prostate weight, increased RBC Heinz bodies. At 90 mg/kg/day increased absolute and relative adrenal weight and increased absolute and relative liver weight were observed in males. The effects noted in females at 90 mg/kg/day were increased absolute and relative adrenal weight, slight decrease in uterus weight, and increased liver weight. Increased RBC Heinz bodies at 15 and 90 mg/kg/day. The dose of 4.2 mg/kg/day was considered a NOEL in both sexes.

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

UF — An uncertainty factor of 100 was used to account for inter- and intraspecies differences.

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 minimum
- 2) 3-Generation Reproduction rat: NOEL=500 ppm (25 mg/kg/day); LEL=2000 ppm (100 mg/kg/day) (lower kidney weights in F3 females; core grade minimum (Rhone-Poulenc, 1976a)
- 3) 24-Month Feeding (oncogenic) rat: NOEL=1000 ppm (HDT; 50 mg/kg/day); core grade minimum (Rhone-Poulenc, 1978a)
- 4) 18-Month Feeding (oncogenic) mouse: NOEL=12,500 ppm (HDT; approximately 1870 mg/kg/day); core grade minimum (Rhone-Poulenc, 1978b)
- 5) Developmental toxicity rabbit: Maternal toxicity NOEL=20 mg/kg/day; LEL=60 mg/kg/day (increased abortions, body weight loss, lowered food consumption); Developmental toxicity NOEL=60 mg/kg/day; LEL=200 mg/kg/day (skeletal variations [13th full rib, sternebrae malaligned], delayed ossification); core grade minimum (Rhone-Poulenc, 1985)

Other Data Reviewed:

- 1) 90-Day Feeding dog: NOEL=2400 ppm; LEL=7200 ppm (liver hypertrophy, increased SAP [serum alkaline phosphatase]; core grade minimum (Rhone-Poulenc, 1976b)
- 2) 5-Month Feeding rat: NOEL=1000 ppm (HDT); core grade minimum (Rhone- Poulenc, 1973)

Data Gap(s): Developmental toxicity - Rat; Study under review

I.A.5. Confidence in the Oral RfD

Study — Medium Database — High RfD — High

The critical study is of adequate quality and is given a medium confidence rating. The database on chronic toxicity is of adequate quality; therefore, the database is given a high confidence rating. High confidence in the RfD follows.

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 — 07/15/1987

Verification Date — 07/15/1987

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 Iprodione 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 — Iprodione CASRN — 36734-19-7 Primary Synonym — Rovral

Not available at this time.

II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — Iprodione CASRN — 36734-19-7 Primary Synonym — Rovral

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 — Iprodione CASRN — 36734-19-7 Primary Synonym — Rovral

VI.A. Oral RfD References

Rhone-Poulenc, Inc. 1973. MRID No. 00157376. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Rhone-Poulenc, Inc. 1976a. MRID No. 00071927. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Rhone-Poulenc, Inc. 1976b. MRID No. 00157377, 00157378. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Rhone-Poulenc, Inc. 1978a. MRID No. 00071997. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Rhone-Poulenc, Inc. 1978b. MRID No. 00070963, 00112530. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Rhone-Poulenc, Inc. 1984. MRID No. 00144391, 41327001. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Rhone-Poulenc, Inc. 1985. MRID No. 00155469. 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 — Iprodione CASRN — 36734-19-7 Primary Synonym — Rovral

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

VIII. Synonyms

Substance Name — Iprodione CASRN — 36734-19-7 Primary Synonym — Rovral Last Revised — 06/30/1988

- 36734-19-7
- CHIPCO 26019
- 3-(3,5-DICHLOROPHENYL)-N-(1-METHYLETHYL)-2,4-DIOXO-1-IMIDAZOLIDINECARBOXAMIDE
- FA 2071
- GLYCOPHEN
- GLYCOPHENE
- 1-IMIDAZOLIDINECARBOXAMIDE, 3-(3,5-DICHLOROPHENYL)-N-(1-METHYL-ETHYL)-2,4-DIOXO-
- Iprodione
- 1-ISOPROPYL CARBAMOYL-3-(3,5-DICHLOROPHENYL)-HYDANTOIN
- LFA 2043
- MRC 910
- NRC 910

- PROMIDIONE
- ROP 500 F
- Rovral
- RP 26019