Tridiphane; CASRN 58138-08-2

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 Tridiphane

File First On-Line 01/31/1987

Category (section)	Assessment Available?	Last Revised
Oral RfD (I.A.)	yes	01/31/1987
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 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
Decreased fertility index and depressed body weight of dams **Rat, 2-Generation Reproduction Study** **Dow Chemical, l984**	NOEL: 0.33 mg/kg/day LEL: l.67 mg/kg/day	100	1	3E-3 mg/kg/day

*Dose Conversion Factors & Assumptions: none

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

Dow Chemical. l984. MRID No. 00132088, 00145080; HED Doc. No. 003604, 004594. Available from EPA. Write to FOI, EPA, Washington D.C. 20460.

Rats (30/sex/group) were fed tridiphane at dose levels of 0, l, 5, or 30 mg/kg/day. Females were maintained on these diets throughout the study for the production of Fla and Flb litters, and F2a and F2b litters. However, starting with the F1b litters tridiphane concentrations in the diet were adjusted downward so that lactating dams were receiving l/2 of the original concentration between days 7-l4 of lactation, and l/3 of the original concentration between days l4-28 of lactation. On day 28, the diets were readjusted to the prelactation concentrations. Results of this study indicated that tridiphane decreases the fertility index at the 5 and 30 mg/kg/day dose levels. Thus, the NOEL for reproductive effects was l mg/kg/day. However, since the dose levels were adjusted downward by 67%, the U.S. EPA established the NOEL as 0.33 mg/kg/day and the LEL as l.67 mg/kg/day.

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

UF — The standard UF of 100 was used for extrapolating from animal data to humans accounting for intra- and inter-species variability.

MF — None

I.A.4. Additional Studies/Comments (Oral RfD)

Other studies showed evidence that tridiphane caused liver toxicity.

Data Considered for Establishing the RfD

1) Two-Generation Reproduction - rat: Principal study - see discussion above; core grade supplementary

2) Six-Month Feeding - dog: NOEL=l0 mg/kg/day; LEL=50 mg/kg/day (hepatocellular hypotrophy; increased liver weight); Dose levels tested: 0, l, l0, or 50 mg/kg/day; core grade guideline (Dow Chemical, 1982)

3) Teratology - mice: Teratogenic NOEL=250 mg/kg/day; Fetotoxic NOEL=75 mg/kg/day; LEL=250 mg/kg/day; Dose levels tested: 0, 25, 75, and 250 mg/kg/day; core grade minimum (Dow Chemical, 1978)

4) Teratology - rat: Teratogenic NOEL=200 mg/kg/day; Fetotoxic NOEL=30 mg/kg/day; LEL=l00 mg/kg/day; Dose levels tested: 0, 30, l00, and 200 mg/kg/day; core grade guideline (Dow Chemical, 1980)

5) Two-Year Feeding (Oncogenic) - rat: Systemic NOEL=3 mg/kg/day (M); LEL=30 mg/kg/day (M); Systemic NOEL=5 mg/kg/day (F); LEL=50 mg/kg/day F); Dose levels tested: 0, 0.3, 3, and 30 mg/kg/day (Male); 0, 0.3, 5, and 50 mg/kg/day (Female); core grade minimum (Dow Chemical, 1983)

Data Gap(s): None

I.A.5. Confidence in the Oral RfD

Study — Medium
Database — High
RfD — High

The principal study is of good quality and is given a medium confidence rating. The database is of high quality and complete, thus, resulting in a high confidence rating. High confidence in the RfD follows.

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

Pesticide Registration Files/New Chemical

Agency Work Group Review — 04/22/1986

Verification Date — 04/22/1986

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 Tridiphane 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 — Tridiphane
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Not available at this time.

II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — Tridiphane
CASRN — 58138-08-2

Not available at this time.

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

VI. Bibliography

Substance Name — Tridiphane
CASRN — 58138-08-2

VI.A. Oral RfD References

Dow Chemical. l978. MRID No. 00132090; HED Doc. No. 003605. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Dow Chemical. l980. MRID No. 00132089; HED Doc. No. 003605. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Dow Chemical. l982. MRID No. 00132086, 00165619; HED Doc. No. 004593. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Dow Chemical. l983. MRID No. 00128804, 00132087; HED Doc. No. 003604, 003605. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Dow Chemical. l984. MRID No. 00132088, 00145080; HED Doc. No. 003604, 004594. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

VI.B. Inhalation RfC References

None

VI.C. Carcinogenicity Assessment References

None

VII. Revision History

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

VIII. Synonyms

Substance Name — Tridiphane
CASRN — 58138-08-2
Last Revised — 01/31/1987

- 58138-08-2
- DOWCO 356
- Tandem
- Tridiphane