Dicamba; CASRN 1918-00-9

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> on the IRIS website.

STATUS OF DATA FOR Dicamba

File First On-Line 09/30/1987

Category (section)	Assessment Available?	Last Revised
Oral RfD (I.A.)	yes	08/22/1988
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 — Dicamba CASRN — 1918-00-9 Primary Synonym — Banvel Last Revised — 08/22/1988

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

1

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
Maternal and fetal	NOEL: 3 mg/kg/day	100	1	3E-2 mg/kg/day
toxicity	LEL: 10 mg/kg/day			iiig/kg/uay
Rabbit Developmental Study				
Velsicol Chemical, 1978				

*Conversion Factors: none

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

Velsicol Chemical Corporation. 1978. MRID No. 00028236. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Five groups of female rabbits (31 to 35/group) were dosed with 0.5% methyl cellulose at 1 mg/kg/day containing doses of 0, 1.0, 3.0, or 10.0 mg/kg/day of dicamba (Banvel technical). A positive control group was treated with 3 mg/kg/day of 6-aminonicotinamide on day 9 of gestation only. Dicamba was administered on days 6 through 18 of gestation. Because of an insufficient number of pregnancies in the initial phases of the experiment, additional rabbits were added to each group at a later starting time. Rabbits receiving 10 mg/kg/day (HDT) had a slightly lower net weight gain. Also, there were slightly reduced fetal body weights and increased post implantation loss in the 10 mg/kg/day group. A NOEL was observed for maternal and fetotoxicity at 3 mg/kg/day.

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)

Data Considered for Establishing the RfD

1) Developmental - rabbit: Principal study - see previous description; core grade minimum

2) 1-Year Feeding - dog: NOEL=2500 ppm (52 mg/kg/day) (HDT); core grade minimum (Sandoz Crop Protection, 1986)

3) 2-Year Feeding (oncogenic) - rat: Systemic NOEL=2500 ppm (125 mg/kg/day); LEL=none; core grade minimum (Velsicol Chemical, 1985)

4) 3-Generation Reproduction - rat: NOEL=500 ppm (25 mg/kg/day) (HDT); LEL=none; core grade minimum (Velsicol Chemical, 1966)

5) Developmental - rat: Maternal NOEL=160 mg/kg/day; Maternal LEL=400 mg/kg/day (ataxia, salivation, decreased motor activity, mortality, decreased body weight); Fetotoxic NOEL=400 mg/kg/day (HDT); Fetotoxic LEL=none; core grade minimum; Teratogenic NOEL=requires clarification because of the occurrence of skeletal malformations at all dosage levels, which are not statistically significant (Velsicol Chemical, 1981a)

Other Data Reviewed:

1) 2-Year Feeding - dog: NOEL=5 ppm (0.125 mg/kg/day); LEL=25 ppm (0.625 mg/kg/day) (decrease in body weight); core grade supplementary (No observations of pharmacologic effects were presented, no gross pathology was done, there was no clinical chemistry data and scant histopathology presented) (Velsicol Chemical, 1962a)

2) 2-Year Feeding (oncogenic) - rat: Systemic NOEL=500 ppm (25 mg/kg/day) (HDT); core grade supplementary (Velsicol Chemical, 1962b)

3) 90-Day Feeding - rat: NOEL=5000 ppm (250 mg/kg/day); LEL=10,000 ppm (500 mg/kg/day) (slight decrease in body weight and food consumption; reduction of cytoplasmic vacuolation of

hepatocytes); core grade minimum (Velsicol Chemical, 1981b)

Data Gap(s): None

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. Additional studies are supportive and 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 — 05/30/1986, 02/18/1987, 06/22/1988

Verification Date — 06/22/1988

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 Dicamba 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 — Dicamba CASRN — 1918-00-9 Primary Synonym — Banvel

Not available at this time.

II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — Dicamba CASRN — 1918-00-9 Primary Synonym — Banvel

Not available at this time.

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

VI. Bibliography

Substance Name — Dicamba CASRN — 1918-00-9 Primary Synonym — Banvel

VI.A. Oral RfD References

Sandoz Crop Protection Corporation. 1986. MRID No. 40321102. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Velsicol Chemical Corporation. 1962a. MRID No. 00028248, 00028260, 00050492. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Velsicol Chemical Corporation. 1962b. MRID No. 00028248, 00028260. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Velsicol Chemical Corporation. 1966. MRID No. 00028249. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Velsicol Chemical Corporation. 1978. MRID No. 00028236. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Velsicol Chemical Corporation. 1981b. MRID No. 00128093. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Velsicol Chemical Corporation. 1981a. MRID No. 00084024. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Velsicol Chemical Corporation. 1985. MRID No. 00125333. 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 — Dicamba CASRN — 1918-00-9 Primary Synonym — Banvel

Date	Section	Description
08/22/1988	I.A.	Oral RfD summary replaced; new basis for RfD
12/03/2002	I.A.6.	Screening-Level Literature Review Findings message has been added.

VIII. Synonyms

Substance Name — Dicamba CASRN — 1918-00-9 Primary Synonym — Banvel Last Revised — 09/30/1987

- 1918-00-9
- ACIDO (3,6-DICLORO-2-METOSSI)-BENZOICO
- o-ANISIC ACID, 3,6-DICHLORO-
- BANEX
- BANLEN
- Banvel
- BANVEL 4S
- BANVEL 4WS
- BANVEL CST
- BANVEL D
- BENZOIC ACID, 3,6-DICHLORO-2-METHOXY-
- BRUSH BUSTER
- DIANAT
- DIANATE
- Dicamba
- DICAMBE
- 3,6-DICHLOOR-2-METHOXY-BENZOEIZUUR
- 3,6-DICHLOR-3-METHOXY-BENZOESAEURE
- 3,6-DICHLORO-o-ANISIC ACID

- 2,5-DICHLORO-6-METHOXYBENZOIC ACID
- 3,6-DICHLORO-2-METHOXYBENZOIC ACID
- MDBA
- MEDIBEN
- 2-METHOXY-3,6-DICHLOROBENZOIC ACID
- NA 2769
- VELSICOL 58-CS-11