Dalapon, sodium salt; CASRN 75-99-0

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 Dalapon, sodium salt

File First On-Line 01/31/1987

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 — Dalapon, sodium salt CASRN — 75-99-0 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 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
Increased kidney body weight ratio	NOEL: 15 mg/kg/day converted to 8.45 mg/kg/day	300	1	3E-2 mg/kg/day
2-Year Rat Study				
Oral Exposure (diet)	LEL: 50 mg/kg/day converted to			
Paynter et al., 1960	28.17 mg/kg/day			

*Conversion Factors: [15 or 50 mg/kg/day x 0.65 mg dalapon- Na/mg of com- mercial product x (143 g dalapon/165 g dalapon-Na)] = 8.45 or 28.17 mg/kg/day, respectively

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

Paynter, O.E., T.W. Tusing, D.D. McCollister and V.K. Rowe. 1960. Toxicology of Dalapon Sodium (2,2-dichloropropoionic acid, sodium salt). J. Agriculture Food Chemicals. 8: 47-51.

Albino Carworth rats (24 male, 24 female/group) were fed diets providing 0, 5, 15, or 50 mg commerial dalapon sodium salt/kg bw/day for 2 years. Hematological parameters were examined at timed intervals and histopathology was performed at 104 weeks. A statistically significant (p<0.05) increase over controls was observed in the kidney-to-body weight ratios of male rats receiving 50 mg/kg/day. No differences from controls were observed. Kidney lesions were not observed.

Paynter et al. (1960) reported that the commercial-grade dalapon sodium contained 65% of the pure sodium salt of dalapon. The dose is further adjusted to pure dalapon by multiplying by the ratio of the molecular weight of dalapon (143) to its sodium salt (165).

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. An additional UF of 3 was used to account for the incomplete database on chronic toxicity.

MF — None

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

Although the database for Dalapon was judged not to be acceptable for OPP's regulatory requirements by current standards, the existing database does provide useful information to derive an RfD.

Data Considered for Establishing the RfD

1) 2-Year Feeding - rat: Principal study - see previous description; no core grade (Paynter et al., 1960)

2) Teratology - rat: Maternal Toxicity NOEL=none; Maternal Toxicity LEL=500 mg/kg/day (LDT; decreased weight gain in all doses); Fetal Toxicity NOEL=none; Fetal Toxicity LEL=500 mg/kg/day (LDT; decreased and delayed ossification of sternebrae hyoids and sacral arches at all doses); No teratogenic reponses; core grade supplementary (Dow Chemical, 1971)

3) 2-Year Feeding - dog: The Paynter et al. (1960) study is not considered reliable.

4) Multi-generation Reproduction - rat: The Paynter et al. (1960) study is not considered reliable.

Data Gap(s): Chronic Rat Feeding Study, Chronic Dog Feeding Study, Rat Reproduction Study, Rat Teratology Study, Rabbit Teratology Study

I.A.5. Confidence in the Oral RfD

Study — Low Database — Low RfD — Low

The critical study is given a low confidence rating for the following reasons: 1) Hematology was performed on only 3 males and 3 females, 2) clinical chemistry was not performed, 3) histology was performed on only half of the survivers at each dose, and 4) only a limited number of tissues

were examined. Since there are extensive data gaps existing for dalapon, the data base is given a low confidence rating. Low 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 Standard, January 1987; Pesticide Registration Files

Agency Work Group Review — 10/09/1985, 07/22/1986, 07/15/1987, 08/12/1987, 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 Dalapon, sodium salt, conducted in September 2002 did not identify any critical new studies. IRIS users who know of important new studies may provide that information to 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 hotline.iris@epa.gov (internet address).

I.B. Reference Concentration for Chronic Inhalation Exposure (RfC)

Substance Name — Dalapon, sodium salt CASRN — 75-99-0

Not available at this time.

II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — Dalapon, sodium salt CASRN — 75-99-0 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 — Dalapon, sodium salt CASRN — 75-99-0

VI.A. Oral RfD References

Dow Chemical Company. 1971. MRID No. 00082692. Available from EPA. Write to FOI, EPA, Washington, DC 20460.

Paynter, O.E., T.W. Tusing, D.D. McCollister and V.K. Rowe. 1960. Toxicology of Dalapon Sodium (2,2-dichloropropoionic acid, sodium salt). J. Agriculture Food Chemicals. 8: 47-51.

VI.B. Inhalation RfC References

None

VI.C. Carcinogenicity Assessment References

None

VII. Revision History

Substance Name — Dalapon, sodium salt CASRN — 75-99-0

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

VIII. Synonyms

Substance Name — Dalapon, sodium salt CASRN — 75-99-0 Last Revised — 01/31/1987

- 75-99-0
- basfapon B
- CASRN 127-20-8
- dalapon
- dalapon sodium
- Dalapon, sodium salt
- 2,2-dichloropropionic acid
- alpha-alpha-dichloropropionic acid
- 2,2-dichlorpropionsaeure natrium
- Dowpon
- 2,2-DPA
- gramevin
- propionic acid, 2,2-dichloro-
- radapon
- sodium dalapon
- sodium 2,2-dichloropropionate
- sodium alpha, alpha-dichloropropionate
- unipon