Dichlorodifluoromethane; CASRN 75-71-8

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 Dichlorodifluoromethane

File First On-Line 01/31/1987

<table>
<thead>
<tr>
<th>Category (section)</th>
<th>Assessment Available?</th>
<th>Last Revised</th>
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<tr>
<td>Oral RfD (I.A.)</td>
<td>yes</td>
<td>01/31/1987*</td>
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<tr>
<td>Inhalation RfC (I.B.)</td>
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<tr>
<td>Carcinogenicity Assessment (II.)</td>
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</tr>
</tbody>
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* A comprehensive review of toxicological studies was completed 01/10/05 - please see section I.A.6 for more information.

I. Chronic Health Hazard Assessments for Noncarcinogenic Effects

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

Substance Name — Dichlorodifluoromethane
CASRN — 75-71-8
Last Revised — 01/31/1987

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

<table>
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<tr>
<th>Critical Effect</th>
<th>Experimental Doses*</th>
<th>UF</th>
<th>MF</th>
<th>RfD</th>
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<tbody>
<tr>
<td>Reduced body weight</td>
<td>NOAEL: 300 ppm (converted to 15 mg/kg/day)</td>
<td>100</td>
<td>1</td>
<td>2E-1 mg/kg/day</td>
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<tr>
<td>Rat Chronic Oral Study</td>
<td>LOAEL: 3000 ppm (converted to 150 mg/kg/day)</td>
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</tbody>
</table>

*Conversion Factors -- 1 ppm = 0.05 mg/kg/day (assumed rat food consumption)

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


Haskell Laboratory (Sherman, 1974) conducted feeding studies in which dogs and rats received 300 ppm or 3000 ppm of dichlorodifluoromethane in the diet for 2 years. Additionally, carcinogenic and three-generation reproductive studies were conducted in rats. Clinical biochemical, urine analytical, hematological or histopathological evaluations were performed. Except for decreased weight gain in rats (about 20% in females) receiving 3000 ppm (150 mg/kg/day) dichlorodifluoromethane, no other adverse effects were attributed to this compound in either rats or dogs.

This study is sufficiently complete to derive an RfD for adequate protection against adverse human health effects. The high dose (3000 ppm or 150 mg/kg/day) caused decreased body weights in rats and is therefore considered a LOAEL, whereas the low dose (300 ppm or 15 mg/kg/day)
mg/kg/day) in rats produced no adverse effects attributable to the oral administration of dichlorodifluoromethane, and is the NOAEL.

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

UF — The NOEL from the 2-year rat study (15 mg/kg/day) and an uncertainty factor of 100 (10 for species extrapolation and 10 for sensitive individuals) were used to derive the RfD of 0.2 mg/kg/day, or 10 mg/day for a 70-kg human being.

MF — None

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

None.

I.A.5. Confidence in the Oral RfD

Study — High
Database — Medium
RfD — Medium

The Haskell Laboratory study is a chronic oral study in two species, which incorporated extensive clinical and toxicologic parameters. Therefore, a high level of confidence in the study is appropriate. Confidence in the database is medium because of the lack of teratology and reproductive data. Medium confidence in the RfD follows.

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


This document has undergone a limited Agency Review.

Other EPA Documentation — None


Verification Date — 07/22/1985

A comprehensive review of toxicological studies published through 2004 was conducted. No new health effects data were identified that would be directly useful in the revision of the
existing RfD for Dichlorodifluoromethane and a change in the RfD is not warranted at this time. For more information, IRIS users may contact 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 — Dichlorodifluoromethane
CASRN — 75-71-8

Not available at this time.

II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — Dichlorodifluoromethane
CASRN — 75-71-8

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 — Dichlorodifluoromethane
CASRN — 75-71-8

VI.A. Oral RfD References


VI.B. Inhalation RfC References

None

VI.C. Carcinogenicity Assessment References

None

VII. Revision History

Substance Name — Dichlorodifluoromethane
CASRN — 75-71-8

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<th>Date</th>
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<th>Description</th>
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<td>03/03/2005</td>
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VIII. Synonyms

Substance Name — Dichlorodifluoromethane
CASRN — 75-71-8
Last Revised — 01/31/1987

- 75-71-8
- ALGOFRENE TYPE 2
- ARCTON 6
- Dichlorodifluoromethane
- DIFLUORODICHLOROMETHANE
- DWUCHLORODWUFLUOROMETAN
- ELECTRO-CF 12
- ESKIMON 12
- F 12
- FC 12
- FLUOROCARBON-12
- FREON 12
- FREON F-12
- FRIGEN 12
- GENETRON 12
- HALON
- ISCEON 122
- ISOTRON 12
- KAISER CHEMICALS 12
- LEDON 12
- PROPELLANT 12
- R 12
- RCRA WASTE NUMBER U075
- REFRIGERANT 12
- UCON 12
- UCON 12/HALOCARBON 12
- UN 1028