Ethyl acetate; CASRN 141-78-6

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 Ethyl acetate

File First On-Line 03/01/1987

<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>
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<td>03/01/1987</td>
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<tr>
<td>Inhalation RfC (I.B.)</td>
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<td>Carcinogenicity Assessment (II.)</td>
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I. Chronic Health Hazard Assessments for Noncarcinogenic Effects

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

Substance Name — Ethyl acetate
CASRN — 141-78-6
Last Revised — 03/01/1987

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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<tr>
<td>Mortality and body weight loss</td>
<td>NOEL: 900 mg/kg/day</td>
<td>1000</td>
<td>1</td>
<td>9E-1 mg/kg/day</td>
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<tr>
<td></td>
<td>LOAEL: 3600 mg/kg/day</td>
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<tr>
<td>Rat Oral Subchronic Study</td>
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<td>U.S. EPA, 1986</td>
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*Conversion Factors -- none

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


Ethyl acetate is fairly nontoxic [LD50 orally in rats: 11.3 g/kg, (Smyth et al., 1962)] and because of its characteristic fruity odor and pleasant taste when diluted, it is primarily used as fruit essences. Pertinent information regarding the mutagenicity, teratogenicity and carcinogenicity of ethyl acetate could not be located in the available literature. Therefore, the U.S. EPA, Office of Solid Waste, under the RCRA Land Disposal Ban, sponsored the 90-day subchronic study of ethyl acetate with rats. Four groups of rats (30/sex/group) were gavaged daily with 0, 300, 900 and 3600 mg/kg/day of ethyl acetate. Six weeks after the initial dosing, 10 rats/sex were subjected to interim sacrifice while the remaining rats continued on the dosing regimen until the final sacrifice (90 days). This study generated data on weekly body weights and food consumption, clinical signs of toxicity, ophthalmological evaluations, moribundity, mortality, blood and urine chemistry and gross and histopathologic evaluations of target organs. Evaluation of the data indicated that male rats exposed to the high dose (3600 mg/kg/day) of ethyl acetate showed significant toxic effects, which resulted in depressed body and organ weights, and depressed food consumption. Female rats exposed to the high dose showed slight but nonsignificant depression of above parameters compared with controls. The next lower dose
(900 mg/kg/day) did not produce any adverse effects in either male or female rats and is, therefore, considered a NOEL. By applying an uncertainty factor of 1000 to this NOEL of 900 mg/kg/day, an RfD of 0.9 mg/kg/day or 63 mg/day for a 70-kg person can be recommended.

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

UF — An uncertainty factor of 1000 is applied: 10 for intra- and 10 for interspecies extrapolation, and 10 to extrapolate subchronic to chronic exposure.

MF — None

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

None.

I.A.5. Confidence in the Oral RfD

Study — High
Database — Low
RfD — Low

The principal study is a well-designed oral study that includes several toxicologic endpoints; high confidence in the study is recommended. The data base did not provide information on additional subchronic/chronic or reproductive toxicity studies; therefore, low confidence is recommended. Confidence in the RfD can be considered low to medium.

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


Other EPA Documentation — U.S. EPA, 1986

Agency Work Group Review — 06/11/1986

Verification Date — 06/11/1986

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 Ethyl acetate conducted in November 2001 did not identify any critical new studies. IRIS users who know of
important new studies may provide that information to 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 — Ethyl acetate
CASRN — 141-78-6

Not available at this time.

II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — Ethyl acetate
CASRN — 141-78-6

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 — Ethyl acetate
CASRN — 141-78-6
VI.A. Oral RfD References


VI.B. Inhalation RfD References

None

VI.C. Carcinogenicity Assessment References

None

VII. Revision History

Substance Name — Ethyl acetate
CASRN — 141-78-6

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<tr>
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VIII. Synonyms
Substance Name — Ethyl acetate
CASRN — 141-78-6
Last Revised — 03/31/1987

- 141-78-6
- ACETIC ACID, ETHYL ESTER
- ACETIC ETHER
- ACETIDIN
- ACETOXYETHANE
- AETHYLACETAT
- ESSIGESTER
- ETHYLACETAAT
- Ethyl Acetate
- ETHYL ACETIC ESTER
- ETHYLE (ACETATE D’)
- ETHYL ETHANOATE
- ETILE (ACETATO DI)
- OCTAN ETYLU
- RCRA WASTE NUMBER U112
- UN 1173
- VINEGAR NAPHTHA