

## Ethylphthalyl ethylglycolate (EPEG); CASRN 84-72-0

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 [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 EPEG

**File First On-Line 01/31/1987**

Category (section)	Assessment Available?	Last Revised
<b>Oral RfD (I.A.)</b>	yes	01/31/1987*
<b>Inhalation RfC (I.B.)</b>	not evaluated	
<b>Carcinogenicity Assessment (II.)</b>	not evaluated	

\*A comprehensive review of toxicological studies was completed (2004) - 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 — Ethylphthalyl ethylglycolate (EPEG)

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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

Critical Effect	Experimental Doses*	UF	MF	RfD
<b>Kidney damage and reduced lifespan</b>	NOEL: 0.5% of diet or 250 mg/kg/day	100	1	3E+0 mg/kg/day
<b>Rat, Chronic Oral Bioassay</b>	LOAEL: 5% of diet or 2500 mg/kg/day			
<b>Hodge et al., 1953</b>				

\*Conversion Factors -- It is assumed that a rat eats 5% of its body weight/day; thus, 5000 mg/kg diet (i.e., 0.5% of diet) x 0.05 kg diet/kg bw/day = 250 mg/kg bw/day

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

Hodge, H.C., E.A. Maynard, H.J. Blanchett, R.E. Hyatt, V.K. Rowe and H.C. Spencer. 1953. Chronic oral toxicity of ethylphthalyl ethyl glycolate in rats and dogs. Arch. Ind. Hyg. Occup. Med. 8: 289-295.

Groups of 25 male and 25 female rats were administered either 0, 0.05, 0.5 or 5% ethylphthalyl ethyl glycolate (EPEG) in the diet for 2 years. Over the 2- year period, seven blood samples were taken for hematology, and urinalyses were performed at the same time; gross histopathology was examined at the end of the study. No effects were observed in the low-dose groups, but the 5% group experienced decreased growth and survival. Kidneys of this group were granular, sometimes swollen and of a pale yellow color. The renal pelvis was dilated, and there were deposits of crystalline calcium oxalate in renal tubules.

Paired groups of dogs received doses of 0.01, 0.05 or 0.25 g EPEG/kg/day for 1 year. No effects of the test compounds were seen.

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

UF — The 100-fold factor represents two 10-fold subunits; one each for the expected intrahuman and interspecies variability of the toxicity of this chemical in lieu of specific data.

MF — None

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

There are no published data regarding reproductive effects of EPEG.

### **I.A.5. Confidence in the Oral RfD**

Study — Medium

Database — Low

RfD — Low

Confidence in this study is rated medium since there were sufficient numbers of rats, several endpoints were measured, and there were comparative studies on two species. This was, however, the only study of a chronic or subchronic nature referred to in the 1980 Ambient Water Quality Criteria Document. Confidence in the database is, therefore, rated low. Confidence in the RfD can be considered low to medium.

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

Source Document — U.S. EPA, 1980

The ADI in the 1980 Ambient Water Quality Criteria document was extensively reviewed by the Agency and was reviewed by the public.

Other EPA Documentation — None

Agency Work Group Review — 11/06/1985

Verification Date — 11/06/1985

A comprehensive review of toxicological studies published prior to 2004 was conducted. No new health effects data were identified that would be directly useful in the revision of the existing RfD for Ethylphthalyl ethylglycolate and a change in the RfD is not warranted at this time.

### **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](mailto:hotline.iris@epa.gov) (internet address).

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

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Not available at this time.

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## **II. Carcinogenicity Assessment for Lifetime Exposure**

Substance Name — Ethylphthalyl ethylglycolate (EPEG)  
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This substance/agent has not undergone a complete evaluation and determination under US EPA's IRIS program for evidence of human carcinogenic potential.

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**III. [reserved]**

**IV. [reserved]**

**V. [reserved]**

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## **VI. Bibliography**

Substance Name — Ethylphthalyl ethylglycolate (EPEG)  
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### VI.A. Oral RfD References

Hodge, H.C., E.A. Maynard, H.J. Blanchett, R.E. Hyatt, V.K. Rowe and H.C. Spencer. 1953. Chronic oral toxicity of ethylphthalyl ethyl glycolate in rats and dogs. Arch. Ind. Hyg. Occup. Med. 8: 289-295.

U.S. EPA. 1980. Ambient Water Quality Criteria for Phthalate Esters. Prepared by the Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, Cincinnati, OH for the Office of Water Regulations and Standards, Washington, DC. EPA 440/5-80-067. NTIS PB 81- 117780.

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### VI.B. Inhalation RfC References

None

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### VI.C. Carcinogenicity Assessment References

None

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## VII. Revision History

Substance Name — Ethylphthalyl ethylglycolate (EPEG)  
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Date	Section	Description
12/03/2002	I.A.6.	Screening-Level Literature Review Findings message has been added.
09/29/2004	I.A.6.	Screening-Level Literature Review Findings message has been removed and replaced by comprehensive literature review conclusions.

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## VIII. Synonyms

Substance Name — Ethylphthalyl ethylglycolate (EPEG)

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Last Revised — 01/31/1987

- 84-72-0
- 1,2-BENZENEDICARBOXYLIC ACID, 2-ETHOXY-2-OXOETHYL-,ETHYL ESTER
- CARBETHOXYMETHYL ETHYL PHTHALATE
- DIETHYL o-CARBOXYBENZOYLOXYACETATE
- EPEG
- ETHYL CARBETHOXYMETHYL PHTHALATE
- Ethylphthalyl Ethylglycolate
- SANTICIZER E-15