

## Butylphthalyl butylglycolate (BPBG); CASRN 85-70-1

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 BPBG

**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 — Butylphthalyl butylglycolate (BPBG)

CASRN — 85-70-1

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>No adverse effect</b>	NOEL: 20,000 ppm of diet (estimated as 1000 mg/kg/day)	1000	1	1E+0 mg/kg/day
<b>Rat, Chronic Oral Bioassay</b>	LOAEL: none			
<b>B.F. Goodrich Co., 1950</b>				

\*Conversion Factors: 20,000 mg/kg of diet x 0.05 kg/diet/kg bw/day = 1000 mg/kg bw/day

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

B.F. Goodrich Company. 1950. A study on the toxicity of butylphthalyl butylglycolate (Santicizer B-16). Report to Monsanto, St. Louis, MO.

Twenty Sherman rats received either 200, 2000, or 20,000 ppm butylphthalyl butylglycolate (BPBG) in the diet for 2 years. A control group of 40 rats received only the stock diet. Since there was a transient depression of growth during treatment weeks 5-15, a second set of experimental animals was treated. These rats were maintained on diets containing 20, 200, or 2000 ppm for 1 year. There were no significant effects of treatment on the following: behavior, body weight, mortality, tumor incidence, hematology, and gross pathology (with special attention given to the endocrine system).

Two mongrel dogs treated for 2 years with 140 mg BPBG/day in capsule form likewise showed no evidence of a toxic response.

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

UF — An uncertainty factor of 10 was used to account for interspecies variation, and a second 10-fold factor was used to protect sensitive human subpopulations. An additional 10-fold factor was applied to account for the uncertainty as to whether the chosen effect level was a LOAEL (histopathology was not evaluated in the principal study).

MF — None

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

The minimum oral lethal dose was determined in this study to be 2.1-3.2 g/kg bw for rabbits and 3.2-4.7 g/kg bw for rats.

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

Study — Medium

Database — Low

RfD — Low

This study employed a sufficient number of animals and was of chronic duration and is, therefore, rated medium. Since this is the only long-term treatment study reported for BPBG, confidence in the database is rated low. Low confidence in the RfD follows.

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

Source Document — U.S. EPA, 1980

The RfD in the 1980 Ambient Water Quality Criteria for Phthalate Esters has received extensive peer and public review.

Other EPA Documentation — None

Agency Work Group Review — 01/22/1986

Verification Date — 01/22/1986

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 Butylphthalyl butylglycolate 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)**

Substance Name — Butylphthalyl butylglycolate (BPBG)  
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Not available at this time.

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

Substance Name — Butylphthalyl butylglycolate (BPBG)  
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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 — Butylphthalyl butylglycolate (BPBG)  
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### **VI.A. Oral RfD References**

B.F. Goodrich Company. 1950. A study on the toxicity of butylphthalyl butylglycolate (Santicizer B-16). Report to Monsanto, St. Louis, MO.

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 — Butylphthalyl butylglycolate (BPBG)  
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Date	Section	Description
10/28/2003	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 — Butylphthalyl butylglycolate (BPBG)  
CASRN — 85-70-1  
Last Revised — 01/31/1987

- 85-70-1
- BPBG

- BUTYL CARBOBUTOXYMETHYL PHTHALATE
- BUTYL GLYCOLYL BUTYL PHTHALATE
- BUTYL PHTHALATE BUTYL GLYCOLATE
- Butylphthalyl Butylglycolate
- DIBUTYL o-CARBOXYBENZOYLOXYACETATE
- DIBUTYL O-(o-CARBOXYBENZOYL) GLYCOLATE
- GLYCOLIC ACID, BUTYL ESTER, BUTYL PHTHALATE
- GLYCOLIC ACID, PHTHALATE, DIBUTYL ESTER
- PHTHALIC ACID, BUTOXYCARBONYLMETHYL BUTYL ESTER
- PHTHALIC ACID, BUTYL ESTER, BUTYL GLYCOLATE
- SANTICIZER B-16