

TOXICOLOGICAL PROFILE FOR PROPYLENE GLYCOL

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Agency for Toxic Substances and Disease Registry

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DISCLAIMER

The use of company or product name(s) is for identification only and does not imply endorsement by the Agency for Toxic Substances and Disease Registry.

UPDATE STATEMENT

A Technical Report for propylene glycol was released in May 1993. This edition supersedes any previously released draft or final profile or report.

Toxicological profiles are revised and republished as necessary, but no less than once every three years. For information regarding the update status of previously released profiles, contact ATSDR at:

Agency for Toxic Substances and Disease Registry
Division of Toxicology and Environmental Medicine/Applied Toxicology Branch
1600 Clifton Road NE
Mailstop F-32
Atlanta, Georgia 30333

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FOREWORD

This toxicological profile is prepared in accordance with guidelines* developed by the Agency for Toxic Substances and Disease Registry (ATSDR) and the Environmental Protection Agency (EPA). The original guidelines were published in the *Federal Register* on April 17, 1987. Each profile will be revised and republished as necessary.

The ATSDR toxicological profile succinctly characterizes the toxicologic and adverse health effects information for the hazardous substance described therein. Each peer-reviewed profile identifies and reviews the key literature that describes a hazardous substance's toxicologic properties. Other pertinent literature is also presented, but is described in less detail than the key studies. The profile is not intended to be an exhaustive document; however, more comprehensive sources of specialty information are referenced.

The focus of the profiles is on health and toxicologic information; therefore, each toxicological profile begins with a public health statement that describes, in nontechnical language, a substance's relevant toxicological properties. Following the public health statement is information concerning levels of significant human exposure and, where known, significant health effects. The adequacy of information to determine a substance's health effects is described in a health effects summary. Data needs that are of significance to protection of public health are identified by ATSDR and EPA.

Each profile includes the following:

- (A) The examination, summary, and interpretation of available toxicologic information and epidemiologic evaluations on a hazardous substance to ascertain the levels of significant human exposure for the substance and the associated acute, subacute, and chronic health effects;
- (B) A determination of whether adequate information on the health effects of each substance is available or in the process of development to determine levels of exposure that present a significant risk to human health of acute, subacute, and chronic health effects; and
- (C) Where appropriate, identification of toxicologic testing needed to identify the types or levels of exposure that may present significant risk of adverse health effects in humans.

The principal audiences for the toxicological profiles are health professionals at the Federal, State, and local levels; interested private sector organizations and groups; and members of the public.

This profile reflects ATSDR's assessment of all relevant toxicologic testing and information that has been peer-reviewed. Staff of the Centers for Disease Control and Prevention and other Federal scientists have also reviewed the profile. In addition, this profile has been peer-reviewed by a nongovernmental panel and was made available for public review. Final responsibility for the contents and views expressed in this toxicological profile resides with ATSDR.



David Satcher, M.D., Ph.D.
Administrator
Agency for Toxic Substances and
Disease Registry

*Legislative Background

The toxicological profiles are developed in response to the Superfund Amendments and Reauthorization Act (SARA) of 1986 (Public Law 99-499) which amended the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA or Superfund). Section 211 of SARA also amended Title 10 of the U. S. Code, creating the Defense Environmental Restoration Program. Section 2704(a) of Title 10 of the U. S. Code directs the Secretary of Defense to notify the Secretary of Health and Human Services of not less than 25 of the most commonly found unregulated hazardous substances at defense facilities. Section 2704(b) of Title 10 of the U. S. Code directs the Administrator of the Agency for Toxic Substances and Disease Registry (ATSDR) to prepare a toxicological profile for each substance on the list provided by the Secretary of Defense under subsection (b).

CONTRIBUTORS

CHEMICAL MANAGER(S)/AUTHOR(S):

Ed Murray, Ph.D.
ATSDR, Division of Toxicology and Environmental Medicine, Atlanta, GA

Julia George, Ph.D.
Research Triangle Institute, Research Triangle Park, NC

THE PROFILE HAS UNDERGONE THE FOLLOWING ATSDR INTERNAL REVIEWS:

1. Green Border Review. Green Border review assures consistency with ATSDR policy.
2. Health Effects Review. The Health Effects Review Committee examines the health effects chapter of each profile for consistency and accuracy in interpreting health effects and classifying end points.
3. Minimal Risk Level Review. The Minimal Risk Level Workgroup considers issues relevant to substance-specific minimal risk levels (MRLs), reviews the health effects database of each profile, and makes recommendations for derivation of MRLs.
4. Quality Assurance Review. The Quality Assurance Branch assures that consistency across profiles is maintained, identifies any significant problems in format or content, and establishes that Guidance has been followed.

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PEER REVIEW

A peer review panel was assembled for propylene glycol. The panel consisted of the following members:

1. Dr. Gregory Grauer, Associate Professor, Department of Clinical Sciences, College of Veterinary Medicine and Biomedical Sciences, Colorado State University, Fort Collins, Colorado;
2. Dr. Philip Leber, Private Consultant, Chem-Tox Consulting, Akron, Ohio; and
3. Dr. Kenneth McMartin, Professor, Department of Pharmacology and Therapeutics, Section of Toxicology, Louisiana State University Medical Center, Shreveport, Louisiana.

These experts collectively have knowledge of propylene glycol's physical and chemical properties, toxicokinetics, key health end points, mechanisms of action, human and animal exposure, and quantification of risk to humans. All reviewers were selected in conformity with the conditions for peer review specified in Section 104(I)(13) of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended.

Scientists from the Agency for Toxic Substances and Disease Registry (ATSDR) have reviewed the peer reviewers' comments and determined which comments will be included in the profile. A listing of the peer reviewers' comments not incorporated in the profile, with a brief explanation of the rationale for their exclusion, exists as part of the administrative record for this compound.

The citation of the peer review panel should not be understood to imply its approval of the profile's final content. The responsibility for the content of this profile lies with the ATSDR.

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CONTENTS

DISCLAIMER	ii
UPDATE STATEMENT	iii
FOREWORD	v
CONTRIBUTORS	vii
PEER REVIEW	ix
CONTENTS.....	xi
LIST OF FIGURES	xv
LIST OF TABLES.....	xvii
1. PUBLIC HEALTH STATEMENT.....	1
1.1 WHAT IS PROPYLENE GLYCOL?.....	1
1.2 WHAT HAPPENS TO PROPYLENE GLYCOL WHEN IT ENTERS THE ENVIRONMENT.....	2
1.3 HOW MIGHT I BE EXPOSED TO PROPYLENE GLYCOL?.....	2
1.4 HOW CAN PROPYLENE GLYCOL ENTER AND LEAVE MY BODY?.....	3
1.5 HOW CAN PROPYLENE GLYCOL AFFECT MY HEALTH?.....	3
1.6 ARE THERE MEDICAL TESTS TO DETERMINE WHETHER I HAVE BEEN EXPOSED TO PROPYLENE GLYCOL?.....	3
1.7 WHAT RECOMMENDATIONS HAS THE FEDERAL GOVERNMENT MADE TO PROTECT HUMAN HEALTH?	4
1.8 WHERE CAN I GET MORE INFORMATION?	4
2. HEALTH EFFECTS	7
2.1 INTRODUCTION.....	7
2.2 DISCUSSION OF HEALTH EFFECTS BY ROUTE OF EXPOSURE	7
2.2.1 Inhalation Exposure	9
2.2.1.1 Death.....	9
2.2.1.2 Systemic Effects.....	9
2.2.1.3 Immunological and Lymphoreticular Effects	15
2.2.1.4 Neurological Effects	16
2.2.1.5 Reproductive Effects.....	16
2.2.1.6 Developmental Effects.....	16
2.2.1.7 Genotoxic Effects.....	16
2.2.1.8 Cancer	17
2.2.2 Oral Exposure.....	17
2.2.2.1 Death.....	17
2.2.2.2 Systemic Effects.....	17
2.2.2.3 Immunological and Lymphoreticular Effects	27
2.2.2.4 Neurological Effects	28
2.2.2.5 Reproductive Effects.....	29
2.2.2.6 Developmental Effects.....	29
2.2.2.7 Genotoxic Effects.....	30
2.2.2.8 Cancer	30
2.2.3 Dermal Exposure.....	30
2.2.3.1 Death.....	31
2.2.3.2 Systemic Effects.....	31
2.2.3.3 Immunological and Lymphoreticular Effects	37
2.2.3.4 Neurological Effects	38
2.2.3.5 Reproductive Effects.....	39

2.2.3.6	Developmental Effects.....	39
2.2.3.7	Genotoxic Effects.....	39
2.2.3.8	Cancer	39
2.3	TOXICOKINETICS.....	40
2.3.1	Absorption.....	40
2.3.1.1	Inhalation Exposure	40
2.3.1.2	Oral Exposure	40
2.3.1.3	Dermal Exposure	40
2.3.2	Distribution	41
2.3.2.1	Inhalation Exposure	41
2.3.2.2	Oral Exposure	42
2.3.2.3	Dermal Exposure	42
2.3.3	Metabolism.....	42
2.3.4	Excretion	44
2.3.4.1	Inhalation Exposure	44
2.3.4.2	Oral Exposure	44
2.3.4.3	Dermal Exposure	44
2.3.5	Mechanism of Action.....	44
2.4	RELEVANCE TO PUBLIC HEALTH.....	45
2.5	BIOMARKERS OF EXPOSURE AND EFFECT	51
2.5.1	Biomarkers Used to Identify or Quantify Exposure to Propylene Glycol.....	53
2.5.2	Biomarkers Used to Characterize Effects Caused by Propylene Glycol.....	53
2.6	INTERACTIONS WITH OTHER CHEMICALS	54
2.7	POPULATIONS THAT ARE UNUSUALLY SUSCEPTIBLE	54
2.8	METHODS FOR REDUCING TOXIC EFFECTS.....	55
2.8.1	Reducing Peak Absorption Following Exposure	55
2.8.2	Reducing Body Burden	55
2.8.3	Interfering with the Mechanism of Action for Toxic Effects.....	56
2.9	ADEQUACY OF THE DATABASE	56
2.9.1	Existing Information on Health Effects of Propylene Glycol	56
2.9.2	Identification of Data Needs	58
2.9.3	Ongoing Studies	65
3.	CHEMICAL AND PHYSICAL INFORMATION.....	66
3.1	CHEMICAL IDENTITY.....	67
3.2	PHYSICAL AND CHEMICAL PROPERTIES.....	67
4.	PRODUCTION, IMPORT/EXPORT, USE, AND DISPOSAL	71
4.1	PRODUCTION	71
4.2	IMPORT/EXPORT	71
4.3	USE	72
4.4	DISPOSAL.....	73
5.	POTENTIAL FOR HUMAN EXPOSURE	75
5.1	OVERVIEW	75
5.2	RELEASES TO THE ENVIRONMENT	75
5.2.1	Air	77
5.2.2	Water.....	77
5.2.3	Soil	78
5.3	ENVIRONMENTAL FATE	78
5.3.1	Transport and Partitioning.....	78

5.3.2	Transformation and Degradation	79
5.3.2.1	Air	79
5.3.2.2	Water.....	79
5.3.2.3	Sediment and Soil	80
5.4	LEVELS MONITORED OR ESTIMATED IN THE ENVIRONMENT	80
5.4.1	Air	80
5.4.2	Water	80
5.4.3	Sediment and Soil	81
5.4.4	Other Environmental Media.....	81
5.5	GENERAL POPULATION AND OCCUPATIONAL EXPOSURE	82
5.6	POPULATIONS WITH POTENTIALLY HIGH EXPOSURES	82
5.7	ADEQUACY OF THE DATABASE	82
5.7.1	Identification of Data Needs	83
5.7.2	Ongoing Studies	86
6.	ANALYTICAL METHODS.....	87
6.1	BIOLOGICAL MATERIALS	87
6.2	ENVIRONMENTAL SAMPLES	90
6.3	ADEQUACY OF THE DATABASE	92
6.3.1	Identification of Data Needs	92
6.3.2	Ongoing Studies	93
7.	REGULATIONS AND ADVISORIES	94
8.	REFERENCES	98
9.	GLOSSARY	137
APPENDICES		
A.	ATSDR MINIMAL RISK LEVELS AND WORKSHEETS	A-1
B.	USER’S GUIDE.....	B-1
C.	ACRONYMS, ABBREVIATIONS, AND SYMBOLS.....	C-1

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LIST OF FIGURES

2-1. Levels of Significant Exposure to Propylene Glycol – Inhalation	12
2-2. Levels of Significant Exposure to Propylene Glycol – Oral	22
2-3. Propylene Glycol Metabolism in Mammals	43
2-4. Existing Information on Health Effects of Propylene Glycol.....	57
5-1. Frequency of NPL Sites with Propylene Glycol Comtamination.....	76

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LIST OF TABLES

2-1. Levels of Significant Exposure to Propylene Glycol – Inhalation	10
2-2. Levels of Significant Exposure to Propylene Glycol – Oral	18
2-3. Levels of Significant Exposure to Propylene Glycol – Dermal.....	32
2-4. Genotoxicity of Propylene Glycol <i>In Vitro</i>	52
3-1. Chemical Identity of Propylene Glycol	68
3-2. Physical and Chemical Properties of Propylene Glycol	69
6-1. Analytical Methods for Determining Propylene Glycol in Biological Samples.....	88
6-2. Analytical Methods for Determining Propylene Glycol in Environmental Samples	91
7-1. Regulations and Guidelines Applicable to Propylene Glycol	96