

**DRAFT
TOXICOLOGICAL PROFILE FOR
SYNTHETIC VITREOUS FIBERS**

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

September 2002

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

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/Toxicology Information Branch
1600 Clifton Road NE, E-29
Atlanta, Georgia 30333

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. We plan to revise these documents in response to public comments and as additional data become available. Therefore, we encourage comments that will make the toxicological profile series of the greatest use.

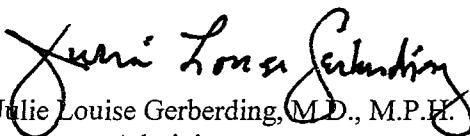
Comments should be sent to:

Agency for Toxic Substances and Disease Registry
Division of Toxicology
1600 Clifton Road, N.E.
Mail Stop E-29
Atlanta, Georgia 30333

Background Information

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). This public law directed ATSDR to prepare toxicological profiles for hazardous substances most commonly found at facilities on the CERCLA National Priorities List and that pose the most significant potential threat to human health, as determined by ATSDR and the EPA. The availability of the revised priority list of 275 hazardous substances was announced in the *Federal Register* on October 25, 2001 (66 FR 54014). For prior versions of the list of substances, see *Federal Register* notices dated April 17, 1987 (52 FR 12866); October 20, 1988 (53 FR 41280); October 26, 1989 (54 FR 43619); October 17, 1990 (55 FR 42067); October 17, 1991 (56 FR 52166); October 28, 1992 (57 FR 48801); February 28, 1994 (59 FR 9486); April 29, 1996 (61 FR 18744); November 17, 1997 (62 FR 61332); and October 21, 1999 (64 FR 56792). Section 104(i)(3) of CERCLA, as amended, directs the Administrator of ATSDR to prepare a toxicological profile for each substance on the list.

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 is being made available for public review. Final responsibility for the contents and views expressed in this toxicological profile resides with ATSDR.



Julie Louise Gerberding, M.D., M.P.H.
Administrator
Agency for Toxic Substances and
Disease Registry

QUICK REFERENCE FOR HEALTH CARE PROVIDERS

Toxicological Profiles are a unique compilation of toxicological information on a given hazardous substance. Each profile reflects a comprehensive and extensive evaluation, summary, and interpretation of available toxicologic and epidemiologic information on a substance. Health care providers treating patients potentially exposed to hazardous substances will find the following information helpful for fast answers to often-asked questions.

Primary Chapters/Sections of Interest

Chapter 1: Public Health Statement: The Public Health Statement can be a useful tool for educating patients about possible exposure to a hazardous substance. It explains a substance's relevant toxicologic properties in a nontechnical, question-and-answer format, and it includes a review of the general health effects observed following exposure.

Chapter 2: Relevance to Public Health: The Relevance to Public Health Section evaluates, interprets, and assesses the significance of toxicity data to human health.

Chapter 3: Health Effects: Specific health effects of a given hazardous compound are reported by *type of health effect* (death, systemic, immunologic, reproductive), by *route of exposure*, and by *length of exposure* (acute, intermediate, and chronic). In addition, both human and animal studies are reported in this section.

NOTE: Not all health effects reported in this section are necessarily observed in the clinical setting. Please refer to the Public Health Statement to identify general health effects observed following exposure.

Pediatrics: Four new sections have been added to each Toxicological Profile to address child health issues:

- Section 1.6** **How Can Synthetic Vitreous Fibers Affect Children?**
 - Section 1.7** **How Can Families Reduce the Risk of Exposure to Synthetic Vitreous Fibers?**
 - Section 3.7** **Children's Susceptibility**
 - Section 6.6** **Exposures of Children**

Other Sections of Interest:

- ## **Section 3.8 Biomarkers of Exposure and Effect**

Section 3.11 Methods for Reducing Toxic Effects

ATSDR Information Center

Phone: 1-888-42-ATSDR or (404) 498-0110 **Fax:** (404) 498-0057
E-mail: atsdric@cdc.gov **Internet:** <http://www.atsdr.cdc.gov>

The following additional material can be ordered through the ATSDR Information Center:

Case Studies in Environmental Medicine: Taking an Exposure History—The importance of taking an exposure history and how to conduct one are described, and an example of a thorough exposure history is provided. Other case studies of interest include *Reproductive and Developmental Hazards; Skin Lesions and Environmental Exposures; Cholinesterase-Inhibiting Pesticide*

Toxicity; and numerous chemical-specific case studies.

Managing Hazardous Materials Incidents is a three-volume set of recommendations for on-scene (prehospital) and hospital medical management of patients exposed during a hazardous materials incident. Volumes I and II are planning guides to assist first responders and hospital emergency department personnel in planning for incidents that involve hazardous materials. Volume III—*Medical Management Guidelines for Acute Chemical Exposures*—is a guide for health care professionals treating patients exposed to hazardous materials.

Fact Sheets (ToxFAQs) provide answers to frequently asked questions about toxic substances.

Other Agencies and Organizations

The National Center for Environmental Health (NCEH) focuses on preventing or controlling disease, injury, and disability related to the interactions between people and their environment outside the workplace. *Contact:* NCEH, Mailstop F-29, 4770 Buford Highway, NE, Atlanta, GA 30341-3724 • Phone: 770-488-7000 • FAX: 770-488-7015.

The National Institute for Occupational Safety and Health (NIOSH) conducts research on occupational diseases and injuries, responds to requests for assistance by investigating problems of health and safety in the workplace, recommends standards to the Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration (MSHA), and trains professionals in occupational safety and health. *Contact:* NIOSH, 200 Independence Avenue, SW, Washington, DC 20201 • Phone: 800-356-4674 or NIOSH Technical Information Branch, Robert A. Taft Laboratory, Mailstop C-19, 4676 Columbia Parkway, Cincinnati, OH 45226-1998 • Phone: 800-35-NIOSH.

The National Institute of Environmental Health Sciences (NIEHS) is the principal federal agency for biomedical research on the effects of chemical, physical, and biologic environmental agents on human health and well-being. *Contact:* NIEHS, PO Box 12233, 104 T.W. Alexander Drive, Research Triangle Park, NC 27709 • Phone: 919-541-3212.

Referrals

The Association of Occupational and Environmental Clinics (AOEC) has developed a network of clinics in the United States to provide expertise in occupational and environmental issues. *Contact:* AOEC, 1010 Vermont Avenue, NW, #513, Washington, DC 20005 • Phone: 202-347-4976 • FAX: 202-347-4950 • e-mail: AOEC@AOEC.ORG • Web Page: <http://www.aoec.org/>.

The American College of Occupational and Environmental Medicine (ACOEM) is an association of physicians and other health care providers specializing in the field of occupational and environmental medicine. *Contact:* ACOEM, 55 West Seegers Road, Arlington Heights, IL 60005 • Phone: 847-818-1800 • FAX: 847-818-9266.

CONTRIBUTORS

CHEMICAL MANAGER(S)/AUTHORS(S):

Malcolm Williams, D.V.M., Ph.D.
ATSDR, Division of Toxicology, Atlanta, GA

Peter R. McClure, Ph.D., D.A.B.T.
Syracuse Research Corporation, North Syracuse, NY

Andrew McDougal, Ph.D.
Syracuse Research Corporation, North Syracuse, NY

Mario J. Citra, Ph.D.
Syracuse Research Corporation, North Syracuse, NY

THE PROFILE HAS UNDERGONE THE FOLLOWING ATSDR INTERNAL REVIEWS:

1. 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.
2. 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.
3. Data Needs Review. The Research Implementation Branch reviews data needs sections to assure consistency across profiles and adherence to instructions in the Guidance.

PEER REVIEW

A peer review panel was assembled for synthetic vitreous fibers. The panel consisted of the following members:

1. Jeffrey I. Everitt, D.V.M.
Senior Scientist
CIIT Centers for Health Research
Research Triangle Park, NC
2. Morton Lippmann, Ph.D.
Professor of Environmental Medicine
New York University School of Medicine
Tuxedo, NY
3. John A. Pickrell, Ph.D., D.V.M.
Associate Professor of Environmental Toxicology
Kansas State University
Diagnostic Medical Pathobiology Department
Manhattan, KS

These experts collectively have knowledge of synthetic vitreous fibers' 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. A list of databases reviewed and a list of unpublished documents cited are also included in the administrative record.

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.

CONTENTS

FOREWORD	v
QUICK REFERENCE FOR HEALTH CARE PROVIDERS	vii
CONTRIBUTORS	ix
PEER REVIEW	xi
LIST OF FIGURES	xvii
LIST OF TABLES	xix
 1. PUBLIC HEALTH STATEMENT	1
1.1 WHAT ARE SYNTHETIC VITREOUS FIBERS?	1
1.2 WHAT HAPPENS TO SYNTHETIC VITREOUS FIBERS WHEN THEY ENTER THE ENVIRONMENT?	2
1.3 HOW MIGHT I BE EXPOSED TO SYNTHETIC VITREOUS FIBERS?	3
1.4 HOW CAN SYNTHETIC VITREOUS FIBERS ENTER AND LEAVE MY BODY?	4
1.5 HOW CAN SYNTHETIC VITREOUS FIBERS AFFECT MY HEALTH?	5
1.6 HOW CAN SYNTHETIC VITREOUS FIBERS AFFECT CHILDREN?	8
1.7 HOW CAN FAMILIES REDUCE THE RISK OF EXPOSURE TO SYNTHETIC VITREOUS FIBERS?	8
1.8 IS THERE A MEDICAL TEST TO DETERMINE WHETHER I HAVE BEEN EXPOSED TO SYNTHETIC VITREOUS FIBERS?	10
1.9 WHAT RECOMMENDATIONS HAS THE FEDERAL GOVERNMENT MADE TO PROTECT HUMAN HEALTH?	10
1.10 WHERE CAN I GET MORE INFORMATION?	11
 2. RELEVANCE TO PUBLIC HEALTH	13
2.1 BACKGROUND AND ENVIRONMENTAL EXPOSURES TO SYNTHETIC VITREOUS FIBERS IN THE UNITED STATES	13
2.2 SUMMARY OF HEALTH EFFECTS	15
2.3 MINIMAL RISK LEVELS	20
 3. HEALTH EFFECTS	25
3.1 INTRODUCTION	25
3.2 DISCUSSION OF HEALTH EFFECTS BY ROUTE OF EXPOSURE	25
3.2.1 Inhalation Exposure	27
3.2.1.1 Death	27
3.2.1.2 Systemic Effects	27
3.2.1.3 Immunological and Lymphoreticular Effects	76
3.2.1.4 Neurological Effects	76
3.2.1.5 Reproductive Effects	76
3.2.1.6 Developmental Effects	76
3.2.1.7 Cancer	76
3.2.2 Oral Exposure	85
3.2.2.1 Death	86
3.2.2.2 Systemic Effects	86

3.2.2.3	Immunological and Lymphoreticular Effects	86
3.2.2.4	Neurological Effects	86
3.2.2.5	Reproductive Effects	86
3.2.2.6	Developmental Effects	86
3.2.2.7	Cancer	86
3.2.3	Dermal Exposure	86
3.2.3.1	Death	86
3.2.3.2	Systemic Effects	86
3.2.3.3	Immunological and Lymphoreticular Effects	87
3.2.3.4	Neurological Effects	87
3.2.3.5	Reproductive Effects	87
3.2.3.6	Developmental Effects	87
3.2.3.7	Cancer	87
3.2.4	Other Routes of Exposure	87
3.3	GENOTOXICITY	88
3.4	TOXICOKINETICS	89
3.4.1	Absorption	89
3.4.1.1	Inhalation Exposure	90
3.4.1.2	Oral Exposure	92
3.4.1.3	Dermal Exposure	93
3.4.2	Distribution	93
3.4.2.1	Inhalation Exposure	93
3.4.2.2	Oral Exposure	99
3.4.2.3	Dermal Exposure	99
3.4.2.4	Other Routes of Exposure	99
3.4.3	Metabolism	100
3.4.3.1	Inhalation Exposure	100
3.4.3.2	Oral Exposure	101
3.4.3.3	Dermal Exposure	101
3.4.4	Elimination and Excretion	101
3.4.4.1	Inhalation Exposure	101
3.4.4.2	Oral Exposure	102
3.4.4.3	Dermal Exposure	102
3.4.4.4	Other Routes of Exposure	102
3.4.5	Physiologically Based Pharmacokinetic (PBPK)/Pharmacodynamic (PD) Models	102
3.5	MECHANISMS OF ACTION	107
3.5.1	Pharmacokinetic Mechanisms	107
3.5.2	Mechanisms of Toxicity	109
3.5.3	Animal-to-Human Extrapolations	111
3.6	TOXICITIES MEDIATED THROUGH THE NEUROENDOCRINE AXIS	113
3.7	CHILDREN'S SUSCEPTIBILITY	114
3.8	BIOMARKERS OF EXPOSURE AND EFFECT	116
3.8.1	Biomarkers Used to Identify or Quantify Exposure to Synthetic Vitreous Fibers	117
3.8.2	Biomarkers Used to Characterize Effects Caused by Synthetic Vitreous Fibers	118
3.9	INTERACTIONS WITH OTHER CHEMICALS	119
3.10	POPULATIONS THAT ARE UNUSUALLY SUSCEPTIBLE	120
3.11	METHODS FOR REDUCING TOXIC EFFECTS	121
3.11.1	Reducing Peak Absorption Following Exposure	121
3.11.2	Reducing Body Burden	122

3.11.3	Interfering with the Mechanism of Action for Toxic Effects	122
3.12	ADEQUACY OF THE DATABASE	122
3.12.1	Existing Information on Health Effects of Synthetic Vitreous Fibers	123
3.12.2	Identification of Data Needs	125
3.12.3	Ongoing Studies	136
4.	CHEMICAL AND PHYSICAL INFORMATION	139
4.1	CHEMICAL IDENTITY	139
4.2	PHYSICAL AND CHEMICAL PROPERTIES	142
5.	PRODUCTION, IMPORT/EXPORT, USE, AND DISPOSAL	147
5.1	PRODUCTION	147
5.2	IMPORT/EXPORT	151
5.3	USE	151
5.4	DISPOSAL	153
6.	POTENTIAL FOR HUMAN EXPOSURE	155
6.1	OVERVIEW	155
6.2	RELEASES TO THE ENVIRONMENT	158
6.2.1	Air	158
6.2.2	Water	158
6.2.3	Soil	159
6.3	ENVIRONMENTAL FATE	159
6.3.1	Transport and Partitioning	159
6.3.2	Transformation and Degradation	159
6.3.2.1	Air	159
6.3.2.2	Water	160
6.3.2.3	Sediment and Soil	160
6.3.2.4	Other Media	160
6.4	LEVELS MONITORED OR ESTIMATED IN THE ENVIRONMENT	160
6.4.1	Air	160
6.4.2	Water	162
6.4.3	Sediment and Soil	164
6.4.4	Other Environmental Media	164
6.5	GENERAL POPULATION AND OCCUPATIONAL EXPOSURE	164
6.6	EXPOSURES OF CHILDREN	171
6.7	POPULATIONS WITH POTENTIALLY HIGH EXPOSURES	172
6.8	ADEQUACY OF THE DATABASE	173
6.8.1	Identification of Data Needs	173
6.8.2	Ongoing Studies	176
7.	ANALYTICAL METHODS	177
7.1	BIOLOGICAL MATERIALS	179
7.2	ENVIRONMENTAL SAMPLES	180
7.3	ADEQUACY OF THE DATABASE	183
7.3.1	Identification of Data Needs	183
7.3.2	Ongoing Studies	185
8.	REGULATIONS AND ADVISORIES	187
9.	REFERENCES	191

10. GLOSSARY 235

APPENDICES

A. ATSDR MINIMAL RISK LEVELS AND WORKSHEETS	A-1
B. USER'S GUIDE	B-1
C. ACRONYMS, ABBREVIATIONS, AND SYMBOLS	C-1
D. INDEX	D-1

LIST OF FIGURES

3-1	Levels of Significant Exposure to Synthetic Vitreous Fibers—Inhalation	64
3-2	Existing Information on Health Effects of Synthetic Vitreous Fibers	124
6-1	Frequency of NPL Sites with Synthetic Vitreous Fiber Contamination	156

LIST OF TABLES

3-1	Levels of Significant Exposure to Synthetic Vitreous Fibers	42
3-2	Lung Clearance of Fibers with Lengths >20 µm in F344 Male Rats Following Nose-only Inhalation Exposure (6 hours/day for 5 days) to 19 Different Synthetic Vitreous Fibers or Two Types of Asbestos	98
3-3	Comparative Human and Rat Anatomical and Physiological Parameters Relevant to Alveolar Retention of Refractory Ceramic Fibers	106
4-1	Chemical Identity of Some Types of Synthetic Vitreous Fibers	140
4-2	Physical Properties of Some Types of Synthetic Vitreous Fibers	144
4-3	Measured Nominal Diameters of Glass Wool, Rock Wool, Slag Wool, Refractory Ceramic Fibers, and a Special Purpose Glass Fiber	146
5-1	Production Volumes of Glass Wool, Rock Wool, and Slag Wool Products in the United States	148
5-2	Continuous Filament Glass Fiber Production in the United States	149
5-3	U.S. Import/Export Volume of Glass Fibers (Including Glass Wool), Mineral Wool and Refractory Ceramic Goods	152
6-1	Airborne Concentrations of Synthetic Vitreous Fibers in Buildings in Denmark	163
6-2	Concentrations (mg/m ³) of Total Suspended Airborne Particulate Matter in 16 Facilities in the United States	167
6-3	Concentrations (fiber(s)/cc) of Total Airborne Fibers in 16 Facilities in the United States	168
6-4	Typical Exposures in the Manufacture and Use of Refractory Ceramic Fibers	169
7-1	Analytical Methods for Determining Synthetic Vitreous Fibers in Biological Samples	181
7-2	Analytical Methods for Determining Synthetic Vitreous Fibers in Environmental Samples	182
8-1	Regulations and Guidelines Applicable to Synthetic Vitreous Fibers	188

