

Toxicological Profile for N-Nitrosodimethylamine (NDMA)

April 2023



NDMA

DISCLAIMER

Use of trade names is for identification only and does not imply endorsement by the Agency for Toxic Substances and Disease Registry, the Public Health Service, or the U.S. Department of Health and Human Services.

NDMA iii

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 these toxic substances described therein. Each peer-reviewed profile identifies and reviews the key literature that describes a 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 relevance to public health discussion which would allow a public health professional to make a real-time determination of whether the presence of a particular substance in the environment poses a potential threat to human health. 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 the protection of public health are identified by ATSDR.

Each profile includes the following:

- (A) The examination, summary, and interpretation of available toxicologic information and epidemiologic evaluations on a toxic substance to ascertain the levels of significant human exposure for the substance due to associated acute, intermediate, and chronic exposures;
- (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, intermediate, 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. Staffs 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.

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*Legislative Background

The toxicological profiles are developed under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA or Superfund). CERCLA section 104(i)(1) directs the Administrator of ATSDR to "...effectuate and implement the health related authorities" of the statute. This includes the preparation of toxicological profiles for hazardous substances most commonly found at facilities on the CERCLA National Priorities List (NPL) and that pose the most significant potential threat to human health, as determined by ATSDR and the EPA. Section 104(i)(3) of CERCLA, as amended, directs the Administrator of ATSDR to prepare a toxicological profile for each substance on the list. In addition, ATSDR has the authority to prepare toxicological profiles for substances not found at sites on the NPL, in an effort to "...establish and maintain inventory of literature, research, and studies on the health effects of toxic substances" under CERCLA Section 104(i)(1)(B), to respond to requests for consultation under section 104(i)(4), and as otherwise necessary to support the site-specific response actions conducted by ATSDR.

NDMA v

VERSION HISTORY

Date	Description
April 2023	Final toxicological profile released
January 2022	Draft for public comment toxicological profile released
December 1989	Final toxicological profile released

NDMA vi

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These experts collectively have knowledge of toxicology, chemistry, and/or health effects. All reviewers were selected in conformity with Section 104(I)(13) of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended.

ATSDR scientists review peer reviewers' comments and determine whether changes will be made to the profile based on comments. The peer reviewers' comments and responses to these comments are part of the administrative record for this compound.

The listing of peer reviewers should not be understood to imply their approval of the profile's final content. The responsibility for the content of this profile lies with ATSDR.

CONTENTS

DISCLAIMER	ii
FOREWORD	iii
VERSION HISTORY	v
CONTRIBUTORS & REVIEWERS	vi
CONTENTS	vii
LIST OF FIGURES	ix
LIST OF TABLES	X
CHAPTER 1. RELEVANCE TO PUBLIC HEALTH	1
1.1 OVERVIEW AND U.S. EXPOSURES	
1.2 SUMMARY OF HEALTH EFFECTS	
1.3 MINIMAL RISK LEVELS (MRLs)	
CHAPTER 2. HEALTH EFFECTS	
2.1 INTRODUCTION	
2.2 DEATH	
2.3 BODY WEIGHT	
2.4 RESPIRATORY	
2.5 CARDIOVASCULAR	
2.6 GASTROINTESTINAL	
2.7 HEMATOLOGICAL	
2.8 MUSCULOSKELETAL	
2.9 HEPATIC	
2.10 RENAL	
2.11 DERMAL	
2.12 OCULAR	
2.13 ENDOCRINE	
2.14 IMMUNOLOGICAL	
2.15 NEUROLOGICAL	
2.16 REPRODUCTIVE	
2.17 DEVELOPMENTAL	
2.18 OTHER NONCANCER	
2.19 CANCER	
2.20 GENOTOXICITY	70
CHAPTER 3. TOXICOKINETICS, SUSCEPTIBLE POPULATIONS, BIOMARKERS, CHEMICAL	Ĺ
INTERACTIONS	
3.1 TOXICOKINETICS	79
3.1.1 Absorption	80
3.1.2 Distribution	82
3.1.3 Metabolism	85
3.1.4 Excretion	88
3.1.5 Physiologically Based Pharmacokinetic (PBPK)/Pharmacodynamic (PD) Models	90
3.1.6 Animal-to-Human Extrapolations	
3.2 CHILDREN AND OTHER POPULATIONS THAT ARE UNUSUALLY SUSCEPTIBLE	
3.3 BIOMARKERS OF EXPOSURE AND EFFECT	
3.3.1 Biomarkers of Exposure	

3.3.2 Biomarkers of Effect	
3.4 INTERACTIONS WITH OTHER CHEMICALS	98
CHAPTER 4. CHEMICAL AND PHYSICAL INFORMATION	102
4.1 CHEMICAL IDENTITY	102
4.2 PHYSICAL AND CHEMICAL PROPERTIES	102
CHAPTER 5. POTENTIAL FOR HUMAN EXPOSURE	104
5.1 OVERVIEW	
5.2 PRODUCTION, IMPORT/EXPORT, USE, AND DISPOSAL	105
5.2.1 Production	105
5.2.2 Import/Export	106
5.2.3 Use	
5.2.4 Disposal	107
5.3 RELEASES TO THE ENVIRONMENT	
5.3.1 Air	
5.3.2 Water	
5.3.3 Soil	
5.4 ENVIRONMENTAL FATE	
5.4.1 Transport and Partitioning	
5.4.2 Transformation and Degradation	
5.5 LEVELS IN THE ENVIRONMENT	
5.5.1 Air	
5.5.2 Water	
5.5.3 Sediment and Soil	
5.5.4 Other Media	
5.6 GENERAL POPULATION EXPOSURE	
5.7 POPULATIONS WITH POTENTIALLY HIGH EXPOSURES	
CHAPTER 6. ADEQUACY OF THE DATABASE	131
6.1 INFORMATION ON HEALTH EFFECTS	131
6.2 IDENTIFICATION OF DATA NEEDS	
6.3 ONGOING STUDIES	138
CHAPTER 7. REGULATIONS AND GUIDELINES	139
CHAPTER 8. REFERENCES	
CHAI IER 6. REI EREIVEES	171
APPENDICES APPENDIX A. ATSDR MINIMAL RISK LEVEL WORKSHEETS	Λ 1
APPENDIX B. LITERATURE SEARCH FRAMEWORK FOR NDMA	
APPENDIX C. USER'S GUIDE	
APPENDIX D. QUICK REFERENCE FOR HEALTH CARE PROVIDERS	D ₋ 1
APPENDIX E. GLOSSARY	
APPENDIX F. ACRONYMS, ABBREVIATIONS, AND SYMBOLS	
,	

NDMA ix

LIST OF FIGURES

1-1.	Health Effects Found in Animals Following Oral Exposure to N-Nitrosodimethylamine (NDMA)	3
1-2.	Summary of Sensitive Targets of N-Nitrosodimethylamine (NDMA) – Oral	6
2-1.	Overview of the Number of Studies Examining N-Nitrosodimethylamine (NDMA) Health Effects	11
2-2.	Levels of Significant Exposure to N-Nitrosodimethylamine – Inhalation	14
2-3.	Levels of Significant Exposure to N-Nitrosodimethylamine – Oral	30
3-1.	Metabolism of N-Nitrosodimethylamine	86
5-1.	Number of NPL Sites with NDMA Contamination	104
6-1.	Summary of Existing Health Effects Studies on N-Nitrosodimethylamine (NDMA) by Route and Endpoint	132

NDMA S

LIST OF TABLES

1-1.	Minimal Risk Levels (MRLs) for N-Nitrosodimethylamine (NDMA)	7
2-1.	Levels of Significant Exposure to N-Nitrosodimethylamine – Inhalation	12
2-2.	Levels of Significant Exposure to N-Nitrosodimethylamine – Oral	16
2-3.	Overview of Epidemiological Studies of Ranitidine Use and Cancers	56
2-4.	Overview of Epidemiological Studies of N-Nitrosodimethylamine Dietary Intake and Cancers.	59
2-5.	Genotoxicity of N-Nitrosodimethylamine In Vitro	70
2-6.	Genotoxicity of N-Nitrosodimethylamine In Vivo	74
3-1.	Maximum Blood Concentration and Time to Maximum in Animals Exposed to N-Nitroso- dimethylamine (NDMA) by Oral Administration	81
3-2.	Species Differences in Steady-State Volume of Distribution for Unmetabolized N-Nitroso-dimethylamine (NDMA) (V_{ss}) after Intravenous Exposure	83
4-1.	Chemical Identity of N-Nitrosodimethylamine	102
4-2.	Physical and Chemical Properties of N-Nitrosodimethylamine	102
5-1.	Facilities that Produce, Process, or Use N-Nitrosodimethylamine	106
5-2.	Releases to the Environment from Facilities that Produce, Process, or Use N-Nitrosodimethylamine	108
5-3.	Emissions of N-Nitrosodimethylamine (NDMA) to Air Reported to the National Emissions Inventory	109
5-4.	Lowest Limit of Detection Based on Standards	114
5-5.	N-Nitrosodimethylamine (NDMA) Levels in Water, Soil, and Air of National Priorities List (NPL) Sites	114
5-6.	Detection of N-Nitrosodimethylamine in Foods and Beverages	120
5-7.	Estimates of Daily Intake of N-Nitrosodimethylamine (NDMA) from Endogenous and Exogenous Sources for Selected Age Groups (ng/kg Body Weight/Day)	128
7-1	Regulations and Guidelines Applicable to N-Nitrosodimethylamine (NDMA)	139