IMMEDIATELY DANGEROUS to LIFE or HEALTH

IDLH

VALUE PROFILE

Ethylene Dibromide
CAS® No. 106-93-4

Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

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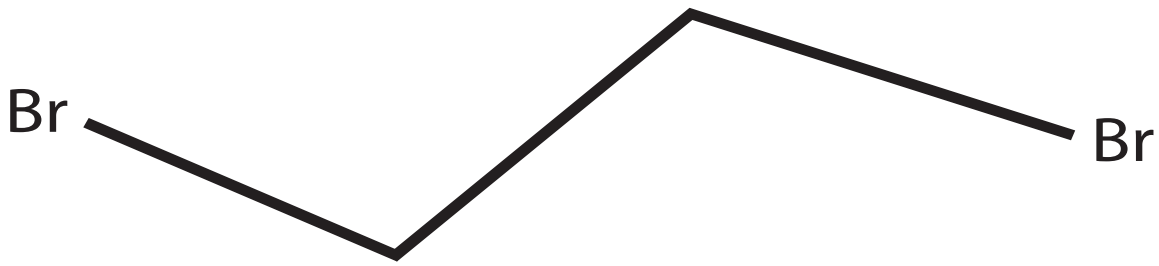
Immediately Dangerous to Life or Health (IDLH) Value Profile

Ethylene Dibromide

[CAS® No. 106-93-4]



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

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July 2020

Foreword

Chemicals are a ubiquitous component of the modern workplace. Occupational exposures to chemicals have the potential to adversely affect the health and lives of workers. Acute or short-term exposures to high concentrations of some airborne chemicals can quickly overwhelm workers, resulting in a spectrum of undesirable health outcomes that may inhibit the ability to escape from the exposure environment (e.g., irritation of the eyes and respiratory tract or cognitive impairment), cause severe irreversible effects (e.g., damage to the respiratory tract or reproductive toxicity), and in extreme cases, cause death. Airborne concentrations of chemicals capable of causing such adverse health effects or of impeding escape from high-risk conditions may arise from a variety of non-routine workplace situations, including special work procedures (e.g., in confined spaces), industrial accidents (e.g., chemical spills or explosions), and chemical releases into the community (e.g., during transportation incidents or other uncontrolled-release scenarios).

The immediately dangerous to life or health (IDLH) air concentration values developed by the National Institute for Occupational Safety and Health (NIOSH) characterize these high-risk exposure concentrations and conditions [NIOSH 2013]. IDLH values are based on a 30-minute exposure duration and have traditionally served as a key component of the decision logic for the selection of respiratory protection devices [NIOSH 2004].

Occupational health professionals have employed these values beyond their initial purpose as a component of the *NIOSH Respirator Selection Logic* to assist in developing risk management plans for non-routine work practices governing operations in high-risk environments (e.g., confined spaces) and the development of emergency preparedness plans.

The approach used to derive IDLH values for high-priority chemicals is outlined in the *NIOSH Current Intelligence Bulletin (CIB) 66: Derivation of Immediately Dangerous to Life or Health (IDLH) Values* [NIOSH 2013]. CIB 66 provides (1) an update on the scientific basis and risk assessment methodology used to derive IDLH values, (2) the rationale and derivation process for IDLH values, and (3) a demonstration of the derivation of scientifically credible IDLH values, using available data resources.

This technical report presents the IDLH value for Ethylene Dibromide (CAS® No. 106-93-4). The scientific basis, toxicologic data, and risk assessment approach used to derive the IDLH value are summarized to ensure transparency and scientific credibility.

John Howard, M.D.
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Contents

Abbreviations

ACGIH®	American Conference of Governmental Industrial Hygienists
AEGLs	Acute Exposure Guideline Levels
AIHA®	American Industrial Hygiene Association
BMC	benchmark concentration
BMD	benchmark dose
BMCL	benchmark concentration lower confidence limit
BMR	benchmark response
C	ceiling value
°C	degrees Celsius
Ca	carcinogen
CAS®	Chemical Abstracts Service, a division of the American Chemical Society
CIB	Current Intelligence Bulletin
ECt_{50}	median effect vapor concentration
ERPGs™	Emergency Response Planning Guidelines
°F	degrees Fahrenheit
g	grams
IDLH	immediately dangerous to life or health
IFA	Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (Institute for Occupational Safety and Health of the German Social Accident Insurance)
L	liter
LC	lethal concentration
LC_{50}	median lethal concentration
LCt_{50}	median lethal time
LC_{LO}	lowest concentration that caused death in humans or animals
LD_{50}	lethal dose
LD_{LO}	lowest dose that caused death in humans or animals
LEL	lower explosive limit
LOAEL	lowest observed adverse effect level
mg	milligrams
mg/m^3	milligram(s) per cubic meter
min	minutes
mL	milliliters
mmHg	millimeter(s) of mercury
NAS	National Academy of Sciences
NIOSH	National Institute for Occupational Safety and Health
NLM	National Library of Medicine
NOAEL	no observed adverse effect level

NRC	National Research Council
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
PBPK	physiologically based pharmacokinetic
PEL	permissible exposure limit
POD	point of departure
ppm	parts per million
RD_{50}	concentration of a chemical in the air that is estimated to cause a 50% decrease in the respiratory rate
REL	recommended exposure limit
STEL	short-term exposure limit
TLV®	Threshold Limit Value
TWA	time-weighted average
UEL	upper explosive limit
UF	uncertainty factor
WEELs®	Workplace Environmental Exposure Levels

Glossary

Acute exposure: Exposure by the oral, dermal, or inhalation route for 24 hours or less.

Acute Exposure Guideline Levels (AEGLs): Threshold exposure limits for the general public, applicable to emergency exposure periods ranging from 10 minutes to 8 hours. AEGL-1, AEGL 2, and AEGL-3 are developed for five exposure periods (10 and 30 minutes, 1 hour, 4 hours, and 8 hours) and are distinguished by varying degrees of severity of toxic effects, ranging from transient, reversible effects to life-threatening effects [NRC 2001]. AEGLs are intended to be guideline levels used during rare events or single once-in-a lifetime exposures to airborne concentrations of acutely toxic, high-priority chemicals [NRC 2001]. The threshold exposure limits are designed to protect the general population, including the elderly, children, and other potentially sensitive groups that are generally not considered in the development of workplace exposure recommendations (additional information available at https://www.epa.gov/oppt/aegl/).

Acute reference concentration (Acute RfC): An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure for an acute duration (24 hours or less) of the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark concentration, with uncertainty factors (UFs) generally applied to reflect limitations of the data used. Generally used in U.S. EPA noncancer health assessments [EPA 2019].

Acute toxicity: Any poisonous effect produced within a short period of time following an exposure, usually 24 to 96 hours [EPA 2019].

Adverse effect: A substance-related biochemical change, functional impairment, or pathologic lesion that affects the performance of an organ or system or alters the ability to respond to additional environmental challenges.

Benchmark dose/concentration (BMD/BMC): A dose or concentration that produces a predetermined change in response rate of an effect (called the benchmark response, or BMR) compared with background [EPA 2019] (additional information available at https://www.epa.gov/ncea/bmds/).

Benchmark response (BMR): An adverse effect, used to define a benchmark dose from which a reference dose or concentration can be developed. The change in response rate over background of the BMR is usually in the range of 5% to 10%, which is the limit of responses typically observed in well-conducted animal experiments [EPA 2019].

Benchmark concentration lower confidence limit (BMCL): A statistical lower confidence limit on the concentration at the BMC [EPA 2019].

Bolus exposure: A single, relatively large dose.

Ceiling value ("C"): Term in occupational exposure indicating the airborne concentration of a potentially toxic substance that should never be exceeded in a worker's breathing zone.

Chronic exposure: Repeated exposure for an extended period of time. Typically, exposures are more than approximately 10% of life span for humans and >90 days to 2 years for laboratory species.

Critical study: The study that contributes most significantly to the qualitative and quantitative assessment of risk [EPA 2019].

Dose: The amount of a substance available for interactions with metabolic processes or biologically significant receptors after crossing the outer boundary of an organism [EPA 2019].

ECt_{50}: A combination of the effective concentration of a substance in the air and the exposure duration that is predicted to cause an effect in 50% of the experimental test subjects.

Emergency Response Planning Guidelines (ERPGs™): Maximum airborne concentrations below which nearly all individuals can be exposed without experiencing health effects for 1-hour exposure. ERPGs are presented in a tiered fashion, with health effects ranging from mild or transient to serious, irreversible, or life threatening (depending on the tier). ERPGs are developed by the American Industrial Hygiene Association [AIHA 2016].

Endpoint: An observable or measurable biological event or sign of toxicity, ranging from biomarkers of initial response to gross manifestations of clinical toxicity.

Exposure: Contact made between a chemical, physical, or biological agent and the outer boundary of an organism. Exposure is quantified as the amount of an agent available at the exchange boundaries of the organism (e.g., skin, lungs, gut).

Extrapolation: An estimate of the response at a point outside the range of the experimental data, generally through the use of a mathematical model, although qualitative extrapolation may also be conducted. The model may then be used to extrapolate to response levels that cannot be directly observed.

Hazard: A potential source of harm. Hazard is distinguished from risk, which is the probability of harm under specific exposure conditions.

Immediately dangerous to life or health (IDLH) condition: A condition that poses a threat of exposure to airborne contaminants when that exposure is likely to cause death or immediate or delayed permanent adverse health effects or prevent escape from such an environment [NIOSH 2004, 2013].

IDLH value: A maximum (airborne concentration) level above which only a highly reliable breathing apparatus providing maximum worker protection is permitted [NIOSH 2004, 2013]. IDLH values are based on a 30-minute exposure duration.

LC_{01}: The statistically determined concentration of a substance in the air that is estimated to cause death in 1% of the test animals.

LC_{50}: The statistically determined concentration of a substance in the air that is estimated to cause death in 50% of the test animals; median lethal concentration.

LC_{LO}: The lowest lethal concentration of a substance in the air reported to cause death, usually for a small percentage of the test animals.

LD_{50}: The statistically determined lethal dose of a substance that is estimated to cause death in 50% of the test animals; median lethal concentration.

LD_{LO}: The lowest dose of a substance that causes death, usually for a small percentage of the test animals.

Lethality: Pertaining to or causing death; fatal; referring to the deaths resulting from acute toxicity studies. May also be used in lethality threshold to describe the point of sufficient substance concentration to begin to cause death.

LEL: The minimum concentration of a gas or vapor in air, below which propagation of a flame does not occur in the presence of an ignition source.

Lowest observed adverse effect level (LOAEL): The lowest tested dose or concentration of a substance that has been reported to cause harmful (adverse) health effects in people or animals.

Mode of action: The sequence of significant events and processes that describes how a substance causes a toxic outcome. By contrast, the term mechanism of action implies a more detailed understanding on a molecular level.

No observed adverse effect level (NOAEL): The highest tested dose or concentration of a substance that has been reported to cause no harmful (adverse) health effects in people or animals.

Occupational exposure limit (OEL): Workplace exposure recommendations developed by governmental agencies and nongovernmental organizations. OELs are intended to represent the maximum airborne concentrations of a chemical substance below which workplace exposures should not cause adverse health effects. OELs may apply to ceiling limits, STELs, or TWA limits.

Peak concentration: Highest concentration of a substance recorded during a certain period of observation.

Permissible exposure limits (PELs): Occupational exposure limits developed by OSHA (29 CFR 1910.1000) or MSHA (30 CFR 57.5001) for allowable occupational airborne exposure concentrations. PELs are legally enforceable and may be designated as ceiling limits, STELs, or TWA limits.

Point of departure (POD): The point on the dose-response curve from which dose extrapolation is initiated. This point can be the lower bound on dose for an estimated incidence or a change in response level from a concentration-response model (BMC), or it can be a NOAEL or LOAEL for an observed effect selected from a dose evaluated in a health effects or toxicology study.

RD_{50}: The statistically determined concentration of a substance in the air that is estimated to cause a 50% decrease in the respiratory rate.

Recommended exposure limit (REL): Recommended maximum exposure limit to prevent adverse health effects, based on human and animal studies and established for occupational (up to 10-hour shift, 40-hour week) inhalation exposure by NIOSH. RELs may be designated as ceiling limits, STELs, or TWA limits.

Short-term exposure limit (STEL): A worker's 15-minute time-weighted average exposure concentration that shall not be exceeded at any time during a work day.

Target organ: Organ in which the toxic injury manifests in terms of dysfunction or overt disease.

Threshold Limit Values (TLVs®): Recommended guidelines for occupational exposure to airborne contaminants, published by the American Conference of Governmental Industrial Hygienists (ACGIH®). TLVs refer to airborne concentrations of chemical substances and represent conditions under which it is believed that nearly all workers may be repeatedly exposed, day after day, over a working lifetime, without adverse effects. TLVs may be designated as ceiling limits, STELs, or 8-hour TWA limits.

Time-weighted average (TWA): A worker's 8-hour (or up to 10-hour) time-weighted average exposure concentration that shall not be exceeded during an 8-hour (or up to 10-hour) work shift of a 40-hour week. The average concentration is weighted to take into account the duration of different exposure concentrations.

Toxicity: The degree to which a substance can cause an adverse effect on an exposed organism.

Uncertainty factors (UFs): Mathematical adjustments applied to the POD when developing IDLH values. The UFs for IDLH value derivation are determined by considering the study and effect used for the POD, with further modification based on the overall database.

Workplace Environmental Exposure Levels (WEELs®): Exposure levels developed by the American Industrial Hygiene Association (AIHA®) that provide guidance for protecting most workers from adverse health effects related to occupational chemical exposures, expressed as TWA or ceiling limits.

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1 Introduction

1.1 Overview of the IDLH Value for Ethylene Dibromide

IDLH Value: 46 ppm (354 mg/m^3)

Basis for IDLH Value: The immediately dangerous to life or health (IDLH) value for ethylene dibromide is based on a 36-minute no observed adverse effect level (NOAEL) for lethality value of 400 ppm in rats [Rowe et al. 1952]. The duration-adjusted value for a 30-minute exposure is 456 ppm. An uncertainty factor (UF) of 10 was applied (1 to account for interspecies variability [animal to human] and 10 to account for human variability). This resulted in a point of departure (POD) of 456 ppm, divided by a UF of 10 or an IDLH of 46 ppm.

1.2 Purpose

This *IDLH Value Profile* presents a brief summary of technical data associated with acute inhalation exposures to ethylene dibromide and the rationale behind the IDLH value for ethylene dibromide. IDLH values are developed on the basis of scientific rationale and logic outlined in the *NIOSH Current Intelligence Bulletin (CIB) 66: Derivation of Immediately Dangerous to Life or Health (IDLH) Values* [NIOSH 2013].

1.3 Literature Search Strategy and Data Evaluation

As described in CIB 66, NIOSH performed in-depth literature searches to ensure that all relevant data from human and animal studies with acute exposures to the substance were identified. See Appendix A for further information about the literature search strategy and data evaluation methods.

1.4 General Substance Information

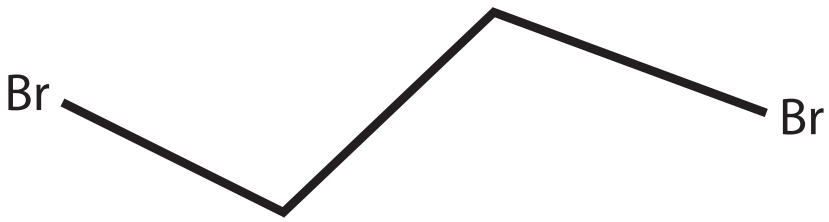
Chemical: Ethylene dibromide

CAS No: 106-93-4

Synonyms*†: 1,2-Dibromoethane; dibromoethane; EDB

Chemical category†: Aliphatic, saturated halogenated hydrocarbons; Organic bromine compounds

Structural formula‡:



References: *EPA [2008],†IFA [2019];‡NLM [2019]

Table 1 highlights selected physiochemical properties of ethylene dibromide relevant to IDLH conditions. Table 2 provides a summary of existing exposure guidelines for ethylene dibromide. Table 3 summarizes the Acute Exposure Guideline Level (AEGL) values for ethylene dibromide.

Table 1. Physiochemical Properties of Ethylene Dibromide*

Property	Value
Molecular weight	187.9†
Chemical formula	$BrCH_2CH_2Br$*
Description	Colorless liquid or solid (below 50°F) with a sweet odor [fumigant]†
Odor	Sweet odor†
Odor threshold	Low: 76.9 mg/m^3 (10 ppm)*
UEL	Not applicable (noncombustible liquid)†
LEL	Not applicable (noncombustible liquid)†
Vapor pressure	11 mmHg@25°C (77°F)†; 17.4 mmHG@30°C (86°F)*
Flash point	Not applicable (noncombustible liquid)†
Ignition temperature	Not applicable (noncombustible liquid)†
Solubility	0.43 g/100 ml water; soluble in ethanol and ethyl ether; miscible with most solvents and thinners*

*EPA [2008]; †NIOSH [2019]

Table 2. Alternative Exposure Values for Ethylene Dibromide

Organization	Value
Revised (1994) IDLH value*	100 ppm
NIOSH REL†	0.045 ppm, TWA [Ca]; 0.13 ppm, 15-minute ceiling
OSHA PEL‡	20 ppm, TWA; 30 ppm, ceiling; 50 ppm, 5-minute maximum peak during an 8-hour shift
ACGIH® TLV§	Skin; A3 (Not classifiable as human carcinogen)
AIHA® ERPGs™¶	Not available
AIHA® WEELs® **	Not available

References: *NIOSH [1994]; †NIOSH [2019]; ‡OSHA [2019]; §ACGIH [2019]; ¶AIHA [2016]; **TERA [2014]

Table 3. Interim AEGL Values for Ethylene Dibromide*

Classification	10-min	30-min	1-hour	4-hour	8-hour	Endpoint/ Reference
AEGL-1 (Nondisabling)	52 ppm 400 mg/m^3	26 ppm 200 mg/m^3	17 ppm 131 mg/m^3	7.1 ppm 55 mg/m^3	4.6 ppm 35 mg/m^3	NOAEL for liver toxicity [Rowe 1952]
AEGL-2 (Disabling)	73 ppm 562 mg/m^3	37 ppm 285 mg/m^3	24 ppm 185 mg/m^3	10 ppm 77 mg/m^3	6.5 ppm 50 mg/m^3	Slight histopathological changes in the liver; no effect-level for irreversible toxicity [Rowe 1952]
AEGL-3 (Lethal)	170 ppm 1,308 mg/m^3	76 ppm 585 mg/m^3	46 ppm 354 mg/m^3	17 ppm 131 mg/m^3	10 ppm 77 mg/m^3	No effect level for lethality [Rowe 1952]

*Reference: EPA [2008]

2 Human Data

There were two limited reports available regarding human lethality from exposure to ethylene dibromide. Letz et al. [1984] reported death from acute liver and renal failure in two workers exposed via inhalation and dermal contact while working in a tank used to store fertilizer mixtures containing 0.1% to 0.3% ethylene dibromide. Air samples collected 20 hours after the incident contained 15 to 41 ppm (average = 28 ppm) in air. The first worker was exposed for approximately 45 minutes and the second worker was exposed for 20 to 30 minutes, while attempting to rescue the first worker. The first worker collapsed within the first 5 minutes of exposure. Other effects included vomiting, eye and respiratory irritation, central nervous system effects, and diarrhea, resulting in an intermittent comatose state.

Ott et al. [1980] reported that a strong odor and respiratory irritation occur when ethylene dibromide concentrations reach 75 ppm, and that gastrointestinal discomfort and vomiting may also occur during acute exposure. No other details were reported.

A few studies have evaluated the potential effects of ethylene dibromide on male fertility following occupational exposure [Wong et al. 1979a; Ratcliffe et al. 1987; Schrader et al. 1987, 1988]. Though all three of these studies suggested reproductive effects following exposure to ethylene dibromide, it is unclear whether these effects would occur as a result of an acute exposure. In addition, these study reports noted confounding factors that may have contributed to the reproductive effects observed, including tobacco and substance use, age, ethnicity, and history of urogenital disorders and other illnesses [Ratcliffe et al. 1987; Schrader et al. 1987, 1988]. These data were not adequate for the derivation of an IDLH value.

The weight of evidence suggests that irritative and toxic effects occur with human exposure to ethylene dibromide; however, quantitative data to determine a POD for derivation of an IDLH value on human data were not identified.

3 Animal Toxicity Data

Lethality studies on ethylene dibromide are limited. In a dog study [Merzbach 1929], one dog for each concentration was exposed to 1, 2, or 5 mL of vaporized ethylene dibromide in a 100-L bell jar for 1 hour. These values are equivalent to 30-minute adjusted exposure concentrations of 4,697 ppm, 9,396 ppm, and 23,485 ppm. All exposed dogs died, although the one exposed to the lowest concentration died 3 weeks post-exposure. Effects seen at the lowest concentration included signs of restlessness, eye irritation, labored respiration, and increased respiration rate during exposure. More severe effects, such as lung, heart, and liver damage, occurred at higher concentrations. No information was provided on whether or not control animals were included in this study.

In the only available acute study conducted according to modern methods, Rowe et al. [1952] exposed groups of four to 30 rats to 100, 200, 400, 800, 1,000, 3,000, 5,000, or 10,000 ppm of ethylene dibromide vapor. Exposure durations ranged from 1.2 minutes to 16 hours. Rat deaths varied over the concentrations and duration tested. NOAELs for lethality are presented in Table 4. The 30-minute adjusted concentration values ranged from 456 to 1,189 ppm. Additionally, on the basis

of the duration response at each concentration, NIOSH [1977] calculated LC_{50} values at each concentration. These values can also be interpreted as the LC_{50} at each respective lethal time and are presented in Table 5. The 30-minute adjusted concentrations for the LC_{50} values ranged from 1,069 to 1,642 ppm.

Deaths at the high concentrations were attributed to cardiac and respiratory failure. Deaths seen in groups with <50% mortality occurred several days post-exposure and were caused by pneumonia secondary to pulmonary damage. Prior to death, effects included weight loss, rough and unkempt appearance, irritability, and bloody discharge from the nose. Increased liver weight and slight histopathologic changes in the liver (not further described) were estimated to be associated with the following concentration/time combinations: 800 ppm for 9 minutes, 200 ppm for 1 hour, and 100 ppm for 4 hours. These liver effects were not considered escape-impairing or severe, and they appeared to be reversible, although there is some uncertainty in the absence of additional description of the effects. However, as noted in the next paragraph, there were no liver lesions at 75 ppm in a subchronic study [NTP 1982]. In a repeated-exposure study, Nitschke et al. [1981] reported signs of nose and eye irritation during the first 6-hour exposure to 40 ppm, but the severity of these effects was not described. Irritation was not observed at lower concentrations or after repeated exposures. Another study in rats determined that the LC_{50} of ethylene dibromide was 1,862 ppm, and 100% mortality occurred at 2,902 ppm with 30-minute exposures [Bakhishev 1973]. No details on the experimental design were provided in the Russian-translated publication.

Another study exposed rats (n = 12) to ethylene dibromide vapors at 1,660 ppm for 1, 3, and 6 hours [Koptagel and Bulut 1998]. Tracheal tissues were harvested at the end of the exposure period, and tissue damage was semi-quantitatively scored. At 1 hour of exposure, mild lymphocyte infiltration and hyperemia were reported, as were moderate vascular dilation and lumen hemorrhage. All of these effects were reported as mild to severe in the 3-hour and 6-hour exposure groups. No epithelial damage was noted at 1 hour of exposure, but moderate damage was reported at 3 and 6 hours of exposure.

Another study exposed white rats to 1,000 ppm of ethylene dibromide [Akamine 1952]. Results were reported as the time required to kill animals, based on weight (190–604 grams), but the number of animals in each weight group was not provided. The time for lethality ranged from 60 to 105 minutes. Visible signs of ethylene dibromide poisoning were reported, including nasal bleeding and mucous membrane reddening, weight and appetite loss, and excessive salivation.

Groups of guinea pigs were also exposed to ethylene dibromide, including 20 animals exposed to vapors at 400 ppm for 7 hours, 5 hours, or 2 hours; 10 animals exposed to 400 ppm for 3 hours; and 15 animals exposed to 200 ppm for 7 hours [Rowe et al. 1952]. Of the animals exposed to 400 ppm, 20/20 died in the 7-hour exposure group, 18/20 died in the 5-hour exposure group, and 5/10 died in the 3-hour exposure group. No animals died at the 400-ppm exposure for 2 hours or 200-ppm exposure for 7 hours. Descriptions of clinical signs or necropsy results were not provided [Rowe et al. 1952].

Rowe et al. [1952] also exposed two monkeys to 50 ppm of ethylene dibromide for 70 days (7 hours/day, 5 days/week). Animals appeared ill, unkempt, and nervous and lost 5% of body weight over the course of the experiment. At the end of the experiment, it was determined that the animals had "very slight" central fatty degeneration and increased lipid values in the liver, as well as a slight increase in kidney weights. No other significant effects were noted. In a similar study, two monkeys were exposed to 25 ppm

of ethylene dibromide for 156 exposure periods in 220 days (no other exposure details were provided) [Rowe et al. 1952]. No adverse effects from these exposures were reported by the authors.

Table 5 summarizes the LC data identified in animal studies and provides 30-minute-equivalent derived values for ethylene dibromide. Information in this table includes species of test animals, LC_{50} values, and the adjusted 30-minute concentrations.

Nasal lesions were reported to occur in rats and mice exposed subchronically (6 hours/day, 5 days/week, for up to 13 weeks) to non-lethal concentrations of ethylene dibromide in two studies, at concentrations of 10 ppm and higher [Reznik et al. 1980; Nitschke et al. 1981]. In the Nitschke et al. [1981] study, it was also observed that rats exposed to 40 ppm for 5 days experienced "eye and nasal irritation during the first exposure period." No other information on these irritative effects was provided. It was also reported that these irritative effects were not observed in other animals. Relative liver weights were slightly increased in male rats exposed to 40 ppm for 6 or 13 weeks and in female rats exposed to 10 ppm (relative liver weight) and 40 ppm (absolute and relative liver weights). Two female rats showed microscopic evidence of slight fatty vacuolation in the liver at 40 ppm. No other liver adverse effects were noted [Nitschke et al. 1981]. In the Resnik et al. [1980] study, rats and mice showed severe effects in the nasal cavity, including necrosis and atrophy of the nasal epithelium at 75 ppm; effects were mild at the lower doses (3 ppm and 15 ppm). Kidney and liver lesions were not observed in rats or mice exposed to concentrations up to 75 ppm for 6 hours/day, 5 days/week, for 13 weeks [NTP 1982]. The National Toxicology Program (NTP) [1982] conducted a carcinogenesis assay of ethylene dibromide in rats and mice; neoplasms were reported in the nasal cavity and lungs, blood vessels, adrenal gland, and mammary gland of both species and in the tunica vaginalis in rats. Ethylene dibromide is metabolized to reactive metabolites that bind to DNA and cause gene mutations and other genotoxicity [EPA 2008]. These data were not appropriate for derivation of an IDLH value.

Two active metabolic pathways are associated with exposure to ethylene dibromide. These include (1) microsomal oxidation of ethylene dibromide to bromoacetaldehyde via the cytochrome P450 pathway, followed by a glutathione conjugation reaction, leading to the eventual formation of mercapturic acid; and (2) a glutathione conjugation reaction with ethylene dibromide via the glutathione-S-transferase pathway to form S-2-bromoethylglutathione, leading to the eventual formation of mercapturic acid [Sipes et al. 1986; Ploemen et al. 1997]. The microsomal oxidation pathway is thought to be responsible for the acute cytotoxic effects of ethylene dibromide via the formation of bromoacetaldehyde, leading to bromine release during oxidative metabolism, which initiates cellular lipid peroxidation [IARC 1999]. Physiologically based pharmacokinetic (PBPK) modeling suggests that rats produce approximately 4 to 5 times more of the microsomal oxidation pathway metabolites than do the most sensitive humans [Ploemen et al. 1997].

It has also been suggested that both ethanol exposure and the use of disulfiram, a medication used to treat alcohol abuse in humans, may exacerbate ethylene dibromide toxicity. Chiarpotto et al. [1995] found that oral pre-treatment of ethanol in rats potentiated the effect of hepatocyte damage caused by ethylene dibromide, including increased lipid peroxidation formation, depletion of total glutathione, and inactivation of hepatocyte total glutathione-transferase. This finding was confirmed in another study by Aragno et al. [1996], in which rats pre-treated with ethanol showed higher levels of liver cytolysis and lipid peroxidation. The authors also found that pre-treatment with ethanol also inhibited glutathione-s-transferase activity, which likely shifted metabolism of ethylene dibromide

to the microsomal oxidation pathway and led to these increased acute effects. Additionally, pre-treatment with disulfiram has been associated with increased acute and chronic liver toxicity with ethylene dibromide exposure [Aragno et al. 1996; NIOSH 1978; Wong 1979b]. Aragno et al. [1996] found that the acute effects observed (liver cytolysis and lipid peroxidation) were likely due to disulfiram's inhibition of aldehyde dehydrogenase, leading to an increased concentration of the intermediate aldehyde metabolites.

The weight of evidence suggests that the 30-minute time-adjusted NOAELs for lethality for ethylene dibromide in two animal species ranged from 456 to 1,317 ppm. The LC_{50} values of ethylene dibromide in two animal species ranged from 727 to 1,861 ppm for 30-minute time-adjusted concentrations. Irritative effects were noted in some studies; however, these effects were not well described and could not be used to determine a POD to derive an IDLH value. Other repeated-dose studies showed similar kidney, liver, and nasal effects in multiple animal species at similar concentrations, suggesting a similar sensitivity to ethylene dibromide across species. For the metabolites responsible for acute toxicity associated with ethylene dibromide, PBPK modeling results suggest the metabolites are 4 to 5 times higher in rats than in the most sensitive humans [Ploemen et al. 1997]. Additionally, three rodent studies suggested that the liver toxicity associated with ethylene dibromide exposure may be potentiated by pre-exposures to either ethanol or disulfiram [Aragno et al. 1996; Chiarpotto et al. 1995; NIOSH 1978; Wong 1979b]. These co-exposures are an important consideration in human exposures to ethylene dibromide. The most sensitive species appeared to be rats (n = 20), in which a NOAEL for lethality was described at 400 ppm of exposure for 36 minutes, resulting in a 30-minute time-adjusted concentration of 456 ppm [Rowe 1952]. This endpoint was selected as the POD for the derivation of the IDLH value. This endpoint was selected both because it was the lowest NOAEL for lethality and because it closely matched the 30-minute time point used for IDLH derivation. An alternative approach for the derivation of this IDLH value would have been based on a 45-minute LC_{50} value of 800 ppm in rats (30-minute concentration-time-adjusted value, 1,069 ppm) [Rowe et al. 1952]. However, the use of this POD value would have required the application of additional UFs to further account for the derivation from an LC_{50} value. The resultant IDLH value derived from this POD would have been similar to the chosen IDLH value.

See section 4 for information regarding the derivation of the IDLH value for ethylene dibromide, including additional information on the study selected as the POD and the UFs applied to derive a final IDLH value.

Table 4. NOAEL (No Observed Adverse Effect Level) Values or Lethality for Ethylene Dibromide

Reference	Species	Number of animals	NOAEL (lethality) (ppm)	Other non-lethal effects	Time (min)	Adjusted 30-min Concentration* (ppm)
Rowe et al. [1952]	Rat	20	10000	—	1.2	1003
		20	5000	—	2.4	823
		20	3000	—	6.0	950
		30	1000	—	12	520
		20	**400**	**—**	**36**	**456‡**
		5	200	—	120	538
		20	100	—	960	1189
	Guinea pig	15	200	—	420	1317
		20	400	—	120	1077
Koptagel and Bulut [1998]	Rat	4	—	1660	60	2724

* For exposures other than 30 minutes, the ten Berge et al. [1986] relationship ($C^n \times t = k$) is used for duration adjustment, where C = concentration, t = time, k = constant, n = time scaling value; EPA [2008] provided an empirically estimated *n* of 1.4 for all time-scaling. Additional information on the calculation of duration-adjusted concentrations can be found in NIOSH [2013].

‡ Bolded data are the primary bases of the IDLH value for ethylene dibromide.

Table 5. Lethal Concentration Data for Ethylene Dibromide

Reference	Species	Number of animals	100% Mortality (ppm)	LC_{50} (ppm)	Time (min)	Adjusted 30-min Concentration* (ppm)
Rowe et al. [1952]	Rat	74	—	10000	2.4	1642
—	—	85	—	5000	5.4	1469
—	—	30	—	3000	10.8	1446
—	—	80	—	1000	18	1111
—	—	80	—	800	45	1069
—	—	170	—	400	120	1077
—	—	122	—	200	720	1077
—	—	60	—	100	ND	—
Bakhishev [1973]	Rat	ND	—	1861	30	1861
—	—	—	2902	—	30	2902
Rowe et al. [1952]	Guinea pig	ND	—	400	180	727
Merzbach [1929]	Dog	3	2863–14317	—	60	4697–23485
Rowe et al. [1952]	Guinea pig	**20**	**400**	—	**420**	**2635**
Akamine [1952]	Rat	ND	1000	—	60–105	1641–2447

*For exposures other than 30 minutes, the ten Berge et al. [1986] relationship ($C^n \times t = k$) is used for duration adjustment, where C = concentration, t = time, k = constant, n = time scaling value; EPA [2008] provided an empirically estimated *n* of 1.4 for all time-scaling. Additional information on the calculation of duration-adjusted concentrations can be found in NIOSH [2013].

ND = not determined or no data.

4 Summary

Lethality studies were the only reliable endpoint available on which to base the IDLH value for ethylene dibromide. As described above, the critical endpoint was determined to be the NOAEL for lethality after a 36-minute exposure of rats in the Rowe [1952] study. For the metabolites responsible for acute toxicity associated with ethylene dibromide, PBPK modeling results suggest the metabolites are 4 to 5 times higher in rats than in the most sensitive humans [Ploemen et al. 1997]. Additionally, rat studies suggested that increased toxicity to ethylene dibromide may occur with pretreatment with ethanol or the alcohol treatment medication disulfiram, which could be an important consideration in human exposures [Chiarpotto et al. 1995; Aragno et al. 1996; Wong 1979b]. Limited human data indicate that potentially escape-impairing effects (vomiting and respiratory discomfort) occur following exposure to approximately 75 ppm ethylene dibromide during acute exposures [Ott 1980]. However, these data were not sufficient to serve as a POD for an IDLH value. The derived IDLH value should also be protective of these severe and non-lethal, escape-impairing effects. An adjusted 30-minute concentration was calculated from 36 minutes of exposure in a NOAEL for lethality in rats [Rowe et al. 1952] with a time-adjusted POD of 456 ppm. A composite UF of 10 was applied. This was composed of a factor of 1 to account for extrapolation from interspecies variability (animal to human) and a factor of 10 to account for human variability, resulting in a POD of 456 ppm divided by a UF of 10 or an IDLH value of 46 ppm. The justifications for the underlying component UFs are as follows:

- **Interspecies UF (=1)**

  Similar acute effects were seen across rats and guinea pigs at similar concentrations. For the metabolites responsible for acute toxicity associated with ethylene dibromide, PBPK modeling results suggest the metabolites are 4 to 5 times higher in rats than in the most sensitive humans; therefore, setting the UF to 1 errs on the side of protecting workers.

- **Intraspecies UF (=10)**

  This value was selected to account for the variability among humans exposed to ethylene dibromide. Since the acute toxicity associated with ethylene dibromide may be increased with co-exposure to ethanol or disulfiram (a medication used to treat alcoholism in humans), and the distribution of these exposures in worker populations is unknown, a 10-fold UF is reasonable to account for increased sensitivity to ethylene dibromide toxicity in some workers.

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Appendix A. Literature Search Strategy and Data Evaluation

As described in CIB 66 [NIOSH 2013], NIOSH performed in-depth literature searches to identify all relevant data from human and animal studies with acute exposures to the substance. For ethylene dibromide, this process included reviewing toxicity summaries and acute exposure guidelines during an initial screening approach, including the AEGL documentation [EPA 2008], ACGIH TLV® documentation [ACGIH 2020], and NIOSH 1994 IDLH documentation [NIOSH 1994]. Studies were identified from these summaries, and additional database queries were conducted in the databases listed in Table A-1. Search terms used in these databases are provided in Table A-2. For ethylene dibromide, the chemical identifiers used in the database searches were "ethylene dibromide," "dibromoethane," "EDB," and "CAS Registry Number: 106-93-4." An in-depth literature search was conducted through June 2019. The information identified in this search was evaluated with general considerations that included description of studies (i.e., species, study protocol, exposure concentration and duration), health endpoint evaluated, and critical effect levels (e.g., NOAELs, LOAELs, and LC_{50} values). Fifty-nine primary and secondary references were identified in the literature search and 17 primary references were cited in the IDLH document. These references included both peer reviewed literature and scientific reports. The references that were not cited did not provide primary or relevant secondary data on ethylene dibromide.

Table A–1. Literature search sources

Database	Link
Centers for Disease Control and Prevention (CDC)/Agency for Toxic Substances and Disease Registry (ATSDR) ToxProfiles	https://www.atsdr.cdc.gov/toxprofiledocs/index.html
ChemIDplus	https://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp
EU, European INventory of Existing Commercial chemical Substances (EINECS)	https://ihcp.jrc.ec.europa.eu/our_labs/predictive_toxicology/information-sources/ec_inventory
EMBASE	https://www.embase.com/
Hazardous Substances Data Bank (HSDB)	https://www.nlm.nih.gov/databases/download/hsdb.html
Haz-map	https://haz-map.com/
National Library of Medicine (NLB)	https://pubchem.ncbi.nlm.nih.gov/
International Agency for Research on Cancer (IARC)	https://www.iarc.fr/
Environmental Protection Agency (EPA) Toxic Substance Control Act (TSCA) Section 8(e) Notices	https://www.epa.gov/chemicals-under-tsca
World Health Organization (WHO)/IPCS International Chemical Safety Card (ICSC)	https://www.ilo.org/safework/lang--en/index.htm
International Toxicity Estimates for Risk (ITER)	https://tera.org/iter/
New Jersey Hazardous Substance Fact Sheets (NJ-HSFS)	https://web.doh.state.nj.us/rtkhsfs/indexfs.aspx
NIOSHTIC-2	https://www2a.cdc.gov/nioshtic-2/default.asp
NLM, PUBMED	https://pubmed.ncbi.nlm.nih.gov/
National Institute for Occupational Safety and Health (NIOSH)/Registry of Toxic Effects of Chemical Substances (RTECS)	https://www.cdc.gov/niosh/rtecs/
NLM, Toxicology Literature Online (TOXLINE)	https://pubmed.ncbi.nlm.nih.gov/?term=tox%20[subset]%20AND
Scopus	https://www.scopus.com/search/form.uri?display=basic

Table A–2. Literature search key words

Search terms		
Acute	Fatal	Threshold
Inhalation	Fatality	Case study
Lethal	Irritation	Poisoning
Lethal concentration	Respiratory	Chemical identifiers
LC	RD	

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