IMMEDIATELY DANGEROUS TO LIFE OR HEALTH (IDLH) VALUE PROFILE

FOR

PERACETIC ACID

[CAS NO. 79-21-0]

Department of Health and Human Services
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

DRAFT - DO NOT DISTRIBUTE OR CITE

This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the National Institute for Occupational Safety and Health. It does not represent and should not be construed to represent any agency determination or policy.

DISCLAIMER

Mention of any company or product does not constitute endorsement by the National Institute for Occupational Safety and Health (NIOSH). In addition, citations of Web sites external to NIOSH do not constitute NIOSH endorsement of the sponsoring organizations or their programs or products. Furthermore, NIOSH is not responsible for the content of these Web sites.

ORDERING INFORMATION

This document is in the public domain and may be freely copied or reprinted. To receive NIOSH documents or other information about occupational safety and health topics, contact NIOSH at

Telephone: 1-800-CDC-INFO (1-800-232-4636)
TTY: 1-888-232-6348
E-mail: cdcinfo@cdc.gov

or visit the NIOSH Web site at www.cdc.gov/niosh.

DRAFT - DO NOT DISTRIBUTE OR CITE

This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the National Institute for Occupational Safety and Health. It does not represent and should not be construed to represent any agency determination or policy.

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 have the ability to 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 air concentration values (IDLH 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 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. The purpose of this technical report is to present the IDLH value for peracetic acid (CAS # 79-21-0). 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.
Director
National Institute for Occupational Safety and Health

This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the National Institute for Occupational Safety and Health. It does not represent and should not be construed to represent any agency determination or policy.

DRAFT - DO NOT DISTRIBUTE OR CITE

1 Centers for Disease Control and Prevention

DRAFT - DO NOT DISTRIBUTE OR CITE

This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the National Institute for Occupational Safety and Health. It does not represent and should not be construed to represent any agency determination or policy.

Contents

FOREWORD III
ABBREVIATIONS VI
GLOSSARY VII
ACKNOWLEDGMENTS XI
1.0 INTRODUCTION 1
1.1 Overview of IDLH Value for Peracetic Acid 1
1.2 Purpose 1
1.3 General Substance Information 2
2.0 ANIMAL TOXICITY DATA 5
3.0 HUMAN DATA 9
4.0 SUMMARY 9
5.0 REFERENCES 10

DRAFT - DO NOT DISTRIBUTE OR CITE

This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the National Institute for Occupational Safety and Health. It does not represent and should not be construed to represent any agency determination or policy.

Abbreviations

ACGIH	American Conference of Governmental Industrial Hygienists
AEGL	Acute Exposure Guideline Levels
AIHA	American Industrial Hygiene Association
BMC	benchmark concentration
BMCL	benchmark concentration lower confidence limit
C	ceiling
CAS	chemical abstract service
ERPG	Emergency Response Planning Guidelines
IDLH	immediately dangerous to life or health
LC_{50}	median lethal concentration
LC_{Lo}	lowest concentration of a chemical that caused death in humans or animals
LEL	lower explosive limit
LOAEL	lowest observed adverse effect level
mg/m^3	milligram(s) per cubic meter
NAC	National Advisory Committee
NAS	National Academy of Sciences
NIOSH	National Institute for Occupational Safety and Health
NOAEL	no observed adverse effect level
OSHA	Occupational Safety and Health Administration
PEL	permissible exposure limit
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
SCP	Standard Completion Program
STEL	short term exposure limit
TLV	threshold limit value
TWA	time weighted average
UEL	upper explosive limit
WEEL	workplace environmental exposure level

DRAFT - DO NOT DISTRIBUTE OR CITE

This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the National Institute for Occupational Safety and Health. It does not represent and should not be construed to represent any agency determination or policy.

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 [NAS 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 [NAS 2001]. The threshold exposure limits are designed to protect the general population, including the elderly, children or other potentially sensitive groups that are generally not considered in the development of workplace exposure recommendations (additional information available at http://www.epa.gov/oppt/aegl/).

Acute Reference Concentration (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 USEPA noncancer health assessments [USEPA 2014].

Acute Toxicity: Any poisonous effect produced within a short period of time following an exposure, usually 24 to 96 hours.

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 to background [USEPA 2014] (additional information available at http://www.epa.gov/ncea/bmds/).

Benchmark Response (BMR): A predetermined change in response rate of an effect. Common defaults for the BMR are 10% or 5%, reflecting study design, data variability, and sensitivity limits used.

BMCL: A statistical lower confidence limit on the concentration at the BMC [USEPA 2014].

Bolus Exposure: A single, relatively large dose.

Ceiling Value ("C"): U.S. 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 [USEPA 2014].

This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the National Institute for Occupational Safety and Health. It does not represent and should not be construed to represent any agency determination or policy.

DRAFT - DO NOT DISTRIBUTE OR CITE

Dose: The amount of a substance available for interactions with metabolic processes or biologically significant receptors after crossing the outer boundary of an organism [USEPA 2014].

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% (one half) 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 2006].

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 situation 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% (one half) 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% (one half) of the test animals; median lethal concentration.

This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the National Institute for Occupational Safety and Health. It does not represent and should not be construed to represent any agency determination or policy.

DRAFT - DO NOT DISTRIBUTE OR CITE

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

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.

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.

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. Mode of action is distinguished from the more detailed mechanism of action, which 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 non-governmental 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, short-term (STELs), or time-weighted average (TWA) limits.

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

Permissible Exposure Limit (PEL): 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, STEL, 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% (one half) 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, STEL, 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.

This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the National Institute for Occupational Safety and Health. It does not represent and should not be construed to represent any agency determination or policy.

DRAFT - DO NOT DISTRIBUTE OR CITE

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, short-term (STELs), or 8-hr 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 is able to 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 a TWA or ceiling limit.

DRAFT - DO NOT DISTRIBUTE OR CITE

This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the National Institute for Occupational Safety and Health. It does not represent and should not be construed to represent any agency determination or policy.

Acknowledgments

This document was developed by the Education and Information Division (Paul Schulte, Ph.D., Director). G. Scott Dotson, Ph.D., was the project officer and lead NIOSH author for this technical report. The basis for this document was a report contracted by NIOSH and prepared by Andrew Maier, Ph.D., Ann Parker, and Lynn Haber, Ph.D. (Toxicology Excellence for Risk Assessment [TERA]).

Education and Information Division

Devin Baker, M.Ed.
Charles L. Geraci, Ph.D.
Thomas J. Lentz, Ph.D.
Richard Niemeier, Ph.D.
Chris Sofge, Ph.D.

NIOSH would like to acknowledge the contribution of the following subject matter experts for their critical technical review of this report.

Mary A. Fox, Ph.D., Assistant Professor; Co-Director, Risk Sciences and Public Policy Institute; Department of Health Policy and Management, Bloomberg School of Public Health, Johns Hopkins University

Richard B. Schlesinger, Ph.D., Fellow A.T.S., Senior Associate Dean for Academic Affairs and Research Professor of Biology, Dyson College of Arts and Sciences, Pace University

DRAFT - DO NOT DISTRIBUTE OR CITE

This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the National Institute for Occupational Safety and Health. It does not represent and should not be construed to represent any agency determination or policy.

1.0 Introduction

1.1 Overview of IDLH Value for Peracetic Acid

IDLH Value: 1.7 mg/m^3 (0.64 ppm)

Basis for IDLH Value: A human study [Fraser and Thorbinson 1986] reported that exposure to 4.67 mg/m^3 for 12 minutes caused slight to mild irritation, which is classified as a potentially escape- impairing effect, and exposure to 6.23 mg/m^3 for 60 minutes caused extreme discomfort and possibly escape-impairing effects. The threshold for severe irritation lies between these two values. In order to be health protective, 4.67 mg/m^3 is selected as the point of departure. Time adjustment to a 30-minute equivalent concentration yields 5 mg/m^3. Applying a composite uncertainty factor of 3 to account for extrapolation from a concentration that potentially causes escape-impairing effects in humans, results in an IDLH value of **1.7 mg/m^3**.

1.2 Purpose

This *IDLH Value Profile* presents (1) a brief summary of technical data associated with acute inhalation exposures to n-butyl acrylate and (2) the rationale behind the Immediately Dangerous to Life or Health (IDLH) value for peracetic acid. IDLH values are developed based on the 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]. As described in CIB 66, NIOSH performs in-depth literature searches to ensure that all relevant data from human and animal studies with acute exposures to the substance are identified. Information included in CIB 66 on the literature search includes pertinent databases, key terms, and guides for evaluating data quality and relevance for the establishment of an IDLH value. The information that is identified in the in-depth literature search is evaluated with general considerations that include description of studies (i.e., species, study protocol, exposure concentration and duration), health endpoint evaluated, and critical effect levels (e.g., NOAELs, LOAELs, LC_{50} values). For peracetic acid, the in-depth literature search was conducted through February 2014.

DRAFT - DO NOT DISTRIBUTE OR CITE

This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the National Institute for Occupational Safety and Health. It does not represent and should not be construed to represent any agency determination or policy.

1.3 General Substance Information

Chemical: Peracetic acid

CAS No: 79-21-0

Synonyms: Ethaneperoxoic acid; Peroxyacetic acid[*]

Chemical category: Organic peroxides[†]

Structural formula:

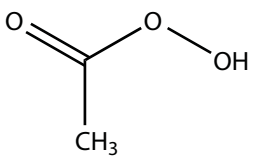

Table 1 highlights selected physiochemical properties of peracetic acid relevant to IDLH conditions. Table 2 provides alternative exposure guidelines for peracetic acid. Table 3 summarizes the Acute Exposure Guidelines Level (AEGL) values for peracetic acid.

Table 1: Physiochemical Properties of Peracetic Acid

Property	Value
Molecular weight	76.05[‡]
Chemical formula	$C_2H_4O_3$
Description	Colorless liquid
Odor	Disagreeable, pungent; Acrid
Odor Threshold	Not available
UEL	Not available
LEL	Not available
Vapor pressure	14.5 mmHg at 25°C (77°F)[‡]
Flash point	40.6°C (105°F)[‡]
Ignition temperature	200°C (392°F)[‡]
Solubility	Mixable in water[†]

Abbreviation: C° – Celsius; °F – Fahrenheit; mmHg – millimeter mercury; LEL – lower explosive limit; UEL – upper explosive limit
[*] NLM [2014]
[†] IFA [2014]
[‡] HSDB [2014]

DRAFT - DO NOT DISTRIBUTE OR CITE

This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the National Institute for Occupational Safety and Health. It does not represent and should not be construed to represent any agency determination or policy.

Table 2: Alternative Exposure Guidelines for Peracetic Acid

Organization	Value
Original (SCP) IDLH value	None
NIOSH REL	Not available
OSHA PEL [2014]	Not available
ACGIH TLV [2014]	Not available
AIHA ERPG [2010]	Not available
AIHA WEEL [2010]	Not available

Abbreviation: ACGIH – American Conference of Governmental Industrial Hygienists; AIHA – American Industrial Hygiene Association; ERPG – Emergency Response Preparedness Guidelines; IDLH – immediately dangerous to life or health; NIOSH – National Institute for Occupational Safety and Health; OSHA – Occupational Safety and Health Administration; PEL – permissible exposure limit; REL – recommended exposure limit; SCP – Standards Completion Program; WEEL – workplace environmental exposure level

DRAFT - DO NOT DISTRIBUTE OR CITE

This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the National Institute for Occupational Safety and Health. It does not represent and should not be construed to represent any agency determination or policy.

Table 3: AEGL Values for Peracetic Acid

Classification	10-min	30-min	1-hour	4-hour	8-hour	Endpoint [reference]
AEGL-1	0.17 ppm 0.52 mg/m^3	0.17 ppm 0.52 mg/m^3	0.17 ppm 0.52 mg/m^3	0.17 ppm 0.52 mg/m^3	0.17 ppm 0.52 mg/m^3	Threshold for irritation [Fraser and Thorbinson 1986; McDonagh 1997]
AEGL-2	0.51 ppm 1.6 mg/m^3	0.51 ppm 1.6 mg/m^3	0.51 ppm 1.6 mg/m^3	0.51 ppm 1.6 mg/m^3	0.51 ppm 1.6 mg/m^3	Mild irritation [Fraser and Thorbinson 1986]
AEGL-3	19.2 ppm 60.0 mg/m^3	9.6 ppm 30.0 mg/m^3	4.8 ppm 15.0 mg/m^3	2.0 ppm 6.3 mg/m^3	1.3 ppm 4.1 mg/m^3	Highest concentration causing no deaths [Janssen 1989a]

Abbreviation: AEGL – acute exposure guideline levels; mg/m^3 – milligrams per cubic meter; min – minute; ppm – parts per million
*__References__: NAS [2010]

DRAFT - DO NOT DISTRIBUTE OR CITE

This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the National Institute for Occupational Safety and Health. It does not represent and should not be construed to represent any agency determination or policy.

2.0 Animal Toxicity Data

No exposure data are available for pure peracetic acid. Technical or commercial peracetic acid products contain peracetic acid, acetic acid, hydrogen peroxide, and small amounts of sulfuric acid. Peracetic acid is unstable and decomposes to sulfuric acid, acetic acid, and hydrogen peroxide. Peracetic acid is extremely irritating to the respiratory tract of animals. Janssen [1989a] exposed male CPB-WU Wistar rats (nose-only) to Proxitane 1507® (15% peracetic acid, ~28% acetic acid, 14% hydrogen peroxide, ~1% stabilizer, and ~43% water) at 320 mg peracetic acid/m^3 for 15 or 30 minutes, 390 mg peracetic acid /m^3 for 60 minutes, or 1450 mg peracetic acid/m^3 for 60 minutes. Janssen [1989b] performed a second study exposing male CPB-WU Wistar rats (nose-only) to Proxitane 1507® at 499 mg peracetic acid/m^3 for 15 minutes, 304 or 578 mg peracetic acid/m^3 for 30 minutes, 329 or 589 mg peracetic acid/m^3 for 60 minutes, or 172 or 355 mg peracetic acid /m^3 for 90 minutes Reduced respiratory rate, respiratory difficulties, blood around the nose and mouth, sneezing, and rubbing the nose were observed at all concentrations except the control, with the severity increasing from slight to severe as the exposure concentration increased. In a preliminary study, Janssen [1989c] exposed rats to Proxitane 1507® containing varying ratios of peracetic acid and hydrogen peroxide. There was no clear concentration-related trend, and the estimated RD_{50} (50% depression in respiratory rates) values ranged from 21.5 to 24.1 mg peracetic acid/m^3, depending on which groups were included in the calculation. In a follow-up study conducted with higher concentrations of Proxitane 1507® (components same as for Janssen 1989a), peracetic acid concentrations ranging from 221 to 461.5 mg peracetic acid/m^3 caused 71-74% decreases in respiratory rate during a 25-minute exposure [Janssen 1990]. Another rat study [Janssen and Van Doorn 1994] exposed male and female rats (nose only) to 87, 163, 185, or 267 mg/m^3 of Proxitane AHC® (4.7-5.4% (~5%) peracetic acid, 19% (minimum) hydrogen peroxide, 10% acetic acid, water, and 1% surfactant) for 4 hours. Clinical signs including apathy, respiratory difficulties, reduced respiratory rate, noisy breathing, drooping upper eyelids, twitching, hypothermia, abnormal gait and posture, crusts on nose, and blood under cage were observed in the 87 mg/m^3 exposure group; the higher exposure groups had the same signs, with the addition of cyanosis, lacrimation, and salivation.

Merka and Urban [1978] exposed mice for 60 minutes to 150, 300, 450, 600, 800, 1,000, 1,300, or 1,600 mg peracetic acid/m^3 as laboratory peracetic acid (made from acetic acid and hydrogen with sulfuric acid as the catalyst, but containing no sulfuric acid) or Persteril® (commercial product containing 40% peracetic acid). Similar LC_{50} values of 524 mg peracetic acid/m^3 and 512 mg peracetic acid/m^3 were obtained for laboratory peracetic acid and for Persteril, respectively, indicating that the small amount of sulfuric acid in Persteril had no

DRAFT - DO NOT DISTRIBUTE OR CITE

This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the National Institute for Occupational Safety and Health. It does not represent and should not be construed to represent any agency determination or policy.

effect on lethality in the mouse. Clinical signs were similar to the ones seen in rats: eye and nasal discharge with nose rubbing, respiratory distress, gasping, increased respiration, restlessness, bristling fur, and red swollen drooping eyelids. Histological examination revealed lung lesions with concentration-related severity.

Table 4 summarizes the LC data identified in animal studies and provides 30-minute equivalent derived values for peracetic acid. Table 5 provides non-lethal data reported in animal studies with 30-minute equivalent derived values. Information in these tables includes species of test animals, toxicological metrics (i.e., LC, NOAEL, LOAEL), adjusted 30-minute concentration, and the justification for the composite uncertainty factors applied to calculate the derived values.

DRAFT - DO NOT DISTRIBUTE OR CITE

This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the National Institute for Occupational Safety and Health. It does not represent and should not be construed to represent any agency determination or policy.

Table 4: Lethal Concentration Data for Peracetic Acid

Reference	Species	LC_{50} (mg/m^3)	LC_{Lo} (mg/m^3)	Time (min)	Adjusted 30-min Concentration* (mg/m^3)	Composite Uncertainty Factor	Derived Value (mg/m^3)†
Merka and Urban [1978]	Mice	524	--	60	660	30‡	22
Janssen [1989a]	Rat	476	--	30	476	30‡	16
Janssen and Van Doorn [1994]	Rat	204	--	240	748	30‡	25

Abbreviation: LC – lethal concentration; LC_{50} – median lethal concentration; LC_{Lo} – lowest concentration of a chemical that caused death in humans or animals; min – minute; ppm – parts per million

* For exposures other than 30 minutes the ten Berge et al. [1986] relationship is used for duration adjustment ($C^n \times t = k$). NAS [2008] empirically estimated n = 1.6 for rats; no time scaling was used for the human studies, based on the absence of increased irritation with exposure duration. The default value of n = 3 was used for mice, since the study duration was >30 minutes and no data were available supporting a species-specific value.

†The derived value is the result of the adjusted 30-minute LC value divided by the composite uncertainty factor.

‡Composite uncertainty factor to account for adjustment of LC_{50} values to LC_{01} values, use of lethal concentration threshold in animals, interspecies differences and human variability.

DRAFT - DO NOT DISTRIBUTE OR CITE

This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the National Institute for Occupational Safety and Health. It does not represent and should not be construed to represent any agency determination or policy.

Table 5: Non-lethal Concentration Data for Peracetic Acid

Reference	Species	NOAEL (mg/m^3)	LOAEL (mg/m^3)	Time (min)	Adjusted 30-min Concentration*	Composite Uncertainty Factor	Derived Value † (mg/m^3)
Fraser and Thorbinson [1986]	Human	--	15.6	7	16	3‡	5.3
Fraser and Thorbinson [1986]	Human	--	9.4	20	9	3‡	3
Fraser and Thorbinson [1986]	Human	--	6.2	60	6	3‡	2
Fraser and Thorbinson [1986]	Human	--	4.7	12	5	3‡	1.7

Abbreviation: NOAEL – no observed adverse effect level; min – minute; LOAEL – lowest observed adverse effect level; ppm – parts per million

* For exposures other than 30 minutes the ten Berge et al. [1986] relationship is used for duration adjustment ($C^n \times t = k$). NAS [2008] empirically estimated n = 1.6 for rats; no time scaling was used for the human studies, based on the absence of increased irritation with exposure duration. The default value of n = 3 was used for mice, since the study duration was >30 minutes and no data were available supporting a species-specific value.

†The derived value is the result of the adjusted 30-min value divided by the composite uncertainty factor. The composite uncertainty factor used varies for each study based on the nature and severity of the endpoint observed.

‡Composite uncertainty factor assigned to account for human variability.

DRAFT - DO NOT DISTRIBUTE OR CITE

This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the National Institute for Occupational Safety and Health. It does not represent and should not be construed to represent any agency determination or policy.

3.0 Human Data

No human lethality studies for peracetic acid were located. Peracetic acid is highly irritating to the human eye and nasal mucous membranes [Bock et al. 1975]. A case study [McDonagh 1997] reported that concentrations of 1.56-1.87 mg/m^3 (0.5-0.6 ppm) were not immediately irritating but that this concentration range was considered "unpleasant for an extended period of time." Fraser and Thorbinson [1986] exposed volunteers (number of subjects not reported) to fogged Peratol diluted 1:20 (5% peracetic acid, corresponding to 1904 mg/L in the liquid formulation) for about 2 hours of continuous fogging, followed by 45 minutes of monitoring after the fogger was turned off. Exposure and effects were measured at various time points during the study and at various distances from the fogger; exposure levels tended to decrease with time. The authors reported lacrimation at 15.6 mg peracetic acid/m^3, extreme discomfort and mucous membrane irritation at 6.23 mg peracetic acid/m^3, slight to mild discomfort at 1.56-4.67 mg peracetic acid/m^3, and no discomfort at <1.56 mg peracetic acid/m^3. Because of the nature of the exposure protocol, these concentrations may not reflect continuous exposures at these concentrations.

4.0 Summary

Both animal and human data exist for peracetic acid. Although an appropriate animal study exists for derivation of an IDLH, exposures were 2 orders of magnitude higher than those causing possible escape impairing effects in humans. Fraser and Thorbinson [1986] reported that exposure to 4.67 mg/m^3 for 12 minutes caused slight to mild irritation, and exposure to 6.23 mg/m^3 for 60 minutes caused extreme discomfort and possibly escape impairing effects. These effects are can be classified as potentially escape impairing. The threshold for severe irritation lies between these two values. In order to be health protective 4.67 mg/m^3 is selected as the point of departure. Time adjustment to a 30-minute equivalent concentration yields 5 mg/m^3. Applying an uncertainty factor of 3 to account for human variability results in an IDLH value of 1.7 mg/m^3.

DRAFT - DO NOT DISTRIBUTE OR CITE

This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the National Institute for Occupational Safety and Health. It does not represent and should not be construed to represent any agency determination or policy.

5.0 References

ACGIH (American Conference of Governmental Industrial Hygienists) [2014]. Annual TLVs® (Threshold Limit Values) and BEIs® (Biological Exposure Indices) booklet. Cincinnati, OH: ACGIH Signature Publications.

AIHA (American Industrial Hygiene Association) [2009]. AIHA Emergency Response Planning (ERP) Committee procedures and responsibilities. Fairfax, VA: American Industrial Hygiene Association.

AIHA (American Industrial Hygiene Association) [2010]. Emergency response planning guidelines (ERPG) and workplace environmental exposure levels (WEEL) handbook. Fairfax, VA: American Industrial Hygiene Association Press.

Bock FG, Meyers HK, Fox HW [1975]. Cocarcinogenic activity of peroxy compounds. J Nat Cancer Inst *55*:1359–1361.

Fraser JAL, Thorbinson A [1986]. Fogging trials with Tenneco Organics Limited (30th June, 1986) at Collards Farm.

HSDB [2014]. Hazardous Substances Data Bank [http://toxnet.nlm.nih.gov/cgi-bin/sis/search2/f?./temp/~tfkhc8:1] Peracetic Acid - CAS No. 79-21-0. Date accessed: August 1, 2014.

IFA (Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung) [2014]. GESTIS: database on hazardous substances. [http://gestis-en.itrust.de/nxt/gateway.dll?f=templates&fn=default.htm&vid=gestiseng:sdbeng]. Date accessed: March 17, 2014.

Janssen PJM [1989a]. Acute inhalation toxicity studies of Proxitane 1507 in male rats (I). Report No. S. 8906, Int. Doc. No. 56645/25/89.

Janssen PJM [1989b]. Acute inhalation toxicity studies of Proxitane 1507 in male rats (II). Report No. S. 8908, Int. Doc. No. 56645/34/89.

Janssen PJM [1989c]. Acute inhalation study to investigate the respiratory irritating properties of Proxitane 1507 in male rats. Duphar B.V., Report No. S. 8912, Int. Doc. No. 56645/40/89.

Janssen PJM [1990]. Preliminary acute inhalation study to investigate the respiratory irritating properties of Proxitane 1507 in male rats. Duphar B.V. Report No. S.9003, Int. Doc. No. 56645/33/90.

Janssen PJM, van Doorn WM [1994]. Acute inhalation toxicity study with Proxitane AHC in male and female rats. Solvay Duphar B.V., Report No. S. 9408, Int. Doc. No. 56345/48/94.

Merka V, Urban R [1978]. Study of inhalation toxicity of performic, peracetic and perpropionic acid in mice. J Hyg Epidemiol Microbiol Immunol *20*:54–63.

DRAFT - DO NOT DISTRIBUTE OR CITE

This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the National Institute for Occupational Safety and Health. It does not represent and should not be construed to represent any agency determination or policy.

McDonagh J [1997]. Atmospheric monitoring of peracetic acid on the existing caprolactone plant distillation houses A & B B assessment of results. Solvay Interox, Warrington, Reference No. EE970192.M01, Memorandum to R.A. Haffenden et al. dated 30 April 1997.

NAS (National Academy of Science) [2001]. Standing operating procedures for developing Acute Exposure Guidelines Levels for hazardous chemicals. NAS, National Research Council (NRC), Committee on Toxicology, Subcommittee on Acute Exposure Guideline Levels. National Academy Press: Washington, DC. IBSN: 0-309-07553-X. [http://www.epa.gov/oppt/aegl/pubs/sop.pdf]. Date accessed: March 17, 2014.

NAS (National Academies of Science) [2010]. Acute Exposure Guideline Levels (AEGLs) for selected airborne chemicals - Volume: 8. Peracetic acid (CAS Reg. No. 79-21-0). NAS, National Research Council, Committee on Toxicology, Subcommittee on Acute Exposure Guideline Levels National Academy Press: Washington, DC. [http://www.epa.gov/oppt/aegl/pubs/results80.htm]. Data accessed: August 1, 2014.

NIOSH (National Institute for Occupational Safety and Health) [2004]. NIOSH respirator selection logic. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2005-100. [http://www.cdc.gov/niosh/docs/2005-100/pdfs/2005-100.pdf]. Date accessed: March 17, 2014.

NIOSH [2013]. NIOSH Current Intelligence Bulletin 66: Derivation of Immediately Dangerous to Life or Health (IDLH) Values. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2014-100.
[http://www.cdc.gov/niosh/docs/2014-100/pdfs/2014-100.pdf]. Date accessed: March 17, 2014.

NIOSH [2014]. NIOSH pocket guide to chemical hazards. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2005-149. [http://www.cdc.gov/niosh/npg/]. Date accessed: March 17, 2014.

NLM (National Library of Medicine) [2014]. ChemIDplus lite [http://chem.sis.nlm.nih.gov/chemidplus/]. Date accessed: August 1, 2014.

OSHA (Occupational Safety and Health Administration) [2014]. Occupational Safety and Health Standards. 29 CFR 1910. Subpart Z -- Toxic and Hazardous Substances. OSHA; Washington, DC [http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=9992]. Date accessed: August 1, 2014.

ten Berge WF, Zwart A, Appelman LM [1986]. Concentration-time mortality response relationship of irritant and systematically acting vapors and gases. J Haz Mat *13*:301–309.

USEPA (U.S. Environmental Protection Agency) [2014]. Integrated Risk Information System (IRIS). [http://www.epa.gov/iris/]. Date accessed: March 17, 2014.

DRAFT. DO NOT DISTRIBUTE OR CITE

This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the National Institute for Occupational Safety and Health. It does not represent and should not be construed to represent any agency determination or policy.