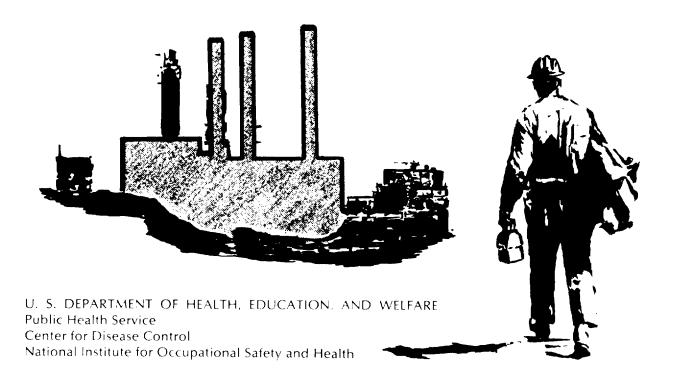


CRITERIA FOR A RECOMMENDED STANDARD....

OCCUPATIONAL EXPOSURE TO

KETONES



criteria for a recommended standard....

OCCUPATIONAL EXPOSURE TO

KETONES



U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE Public Health Service Center for Disease Control National Institute for Occupational Safety and Health

June 1978

For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402

DISCLAIMER

Mention of company names or products does not constitute endorsement by the National Institute for Occupational Safety and Health.

DHEW (NIOSH) Publication No. 78-173

PREFACE

The Occupational Safety and Health Act of 1970 emphasizes the need for standards to protect the health and provide for the safety of workers occupationally exposed to an ever-increasing number of potential hazards. The National Institute for Occupational Safety and Health (NIOSH) evaluates all available research data and criteria and recommends standards for occupational exposure. The Secretary of Labor will weigh these recommendations along with other considerations, such as feasibility and means of implementation, in promulgating regulatory standards.

NIOSH will periodically review the recommended standards to ensure continuing protection of workers and will make successive reports as new research and epidemiologic studies are completed and as sampling and analytical methods are developed.

The contributions to this document on ketones by NIOSH staff, other Federal agencies or departments, the review consultants, the reviewers selected by the American Academy of Industrial Hygiene, and Robert B. O'Connor, M.D., NIOSH consultant in occupational medicine, are gratefully acknowledged.

The views and conclusions expressed in this document, together with the recommendations for a standard, are those of NIOSH. They are not necessarily those of the consultants, the reviewers selected by professional societies, or other Federal agencies. However, all comments, whether or not incorporated, were considered carefully and were sent with the criteria document to the Occupational Safety and Health Administration for consideration in setting the standard. The review consultants and the Federal agencies which received the document for review appear on pages v and vi.

J. Michael Lane, M.D. Acting Director, National Institute for Occupational Safety and Health

The Division of Criteria Documentation and Standards Development, National Institute for Occupational Safety and Health, had primary responsibility for the development of the criteria and recommended standard for ketones. Burt J. Cooper of this Division served as criteria manager. SRI International developed the basic information for consideration by NIOSH staff and consultants under contract CDC-99-74-31.

The Division review of this document was provided by Keith H. Jacobson, Ph.D. (Chairman), Jon R. May, Ph.D., Barry L. Johnson, Ph.D. (Division of Biomedical and Behavioral Science), P.G. Rentos, Ph.D. (Division of Training and Manpower Development), Harold Resnick, Ph.D. (Division of Respiratory Disease Studies), Theodore Thoburn, M.D. (Division of Surveillance, Hazard Evaluations, and Field Studies), and Clara H. Williams, Ph.D.

REVIEW CONSULTANTS

Norman Allen, M.D. Professor of Neurológy Director, Division of Neurology Ohio State University College of Medicine Columbus, Ohio 43210

Roy L. Barnes Secretary-Treasurer, Local 4-367 Oil, Chemical, and Atomic Workers International Union Pasadena, Texas 77502

Donald J. Billmaier, M.D. Assistant Medical Director Owens Corning Fiberglas Corporation Toledo, Ohio 43659

Robert S. Brookman, Ph.D. Manager, Research, Development, and Technical Service Firestone Plastics Company Pottstown, Pennsylvania 19464

Daniel Couri, Ph.D. Professor of Pharmacology Ohio State University College of Medicine Columbus, Ohio 43210

George D. DiVincenzo, Ph.D. Technical Associate, Health, Safety, and Human Factors Laboratory Eastman Kodak Company Rochester, New York 14650

James D. MacEwen, Ph.D. Director, Toxic Hazards Research Unit University of California, Irvine Dayton, Ohio 45431

Leonard D. Pagnotto Chief of Chemical Services Massachusetts Dept of Labor and Industries Division of Occupational Hygiene Boston, Massachusetts 02116

FEDERAL AGENCIES

Department of Defense Office of Assistant Secretary of Defense Energy and Environmental Safety Department of the Army Army Environmental Hygiene Agency Department of the Navy Bureau of Medicine and Surgery Navy Environmental Health Center Department of the Air Force Office of the Surgeon General Occupational and Environmental Health Laboratories Inspection and Safety Center Department of Energy Division of Operational and Environmental Safety Department of Health, Education, and Welfare National Institutes of Health National Institute of Neurological and Communicative Disorders and Stroke Department of Treasury Bureau of Engraving and Printing Environmental Protection Agency Office of Assistant Administrator for Research and Development National Environmental Research Laboratory Health Effects Research Laboratory

National Aeronautics and Space Administration

CONTENTS

		Page
PREFACE		iii
REVIEW C	CONSULTANTS	v
FEDERAL	AGENCIES	vi
I.	RECOMMENDATIONS FOR A KETONES STANDARD	1
	Section 1 - Environmental (Workplace Air)	2
	Section 2 - Medical	2
	Section 3 - Labeling and Posting	5
	Section 4 - Personal Protective Equipment and Clothing Section 5 - Informing Employees of Hazards from	8
	Ketones	12
	Section 6 - Work Practices	13
	Section 7 - Sanitation	16
	Section 8 - Monitoring and Recordkeeping Requirements	17
II.	INTRODUCTION	20
III.	BIOLOGIC EFFECTS OF EXPOSURE	22
	Extent of Exposure	22
	Effects on Humans	28
	Epidemiologic Studies	66
	Animal Toxicity	72
	Correlation of Exposure and Effect	124
	Carcinogenicity, Mutagenicity, Teratogenicity, and	
	Effects on Reproduction	134
	Summary Tables of Exposure and Effect	135
IV.	ENVIRONMENTAL DATA	140
	Sampling	140
	Analysis	144
	Environmental Data	148
	Engineering Controls	150
v.	WORK PRACTICES	153
VI.	DEVELOPMENT OF STANDARD	162
	Basis for Previous Standards	162
	Basis for the Recommended Standard	177

CONTENTS (CONTINUED)

۰. ۱

VII.	RESEARCH NEEDS	194
VIII.	REFERENCES	196
IX.	APPENDIX I - Sampling and Analysis for Selected Ketones	212
x.	APPENDIX II - Material Safety Data Sheet	228
XI.	TABLES AND FIGURE	238

I. RECOMMENDATIONS FOR A KETONES STANDARD

NIOSH recommends that employee exposure to ketones in the workplace be controlled by adherence to the following sections. The standard is designed to protect the health and provide for the safety of employees for up to a 10-hour workshift, 40-hour workweek, over a working lifetime. Compliance with all sections of the standard should prevent adverse effects of ketones on the health of employees and provide for their safety. The standard is measurable by techniques that are valid, reproducible, and available to industry and government agencies. Sufficient technology exists to permit compliance with the recommended standard. Although NIOSH considers the workplace environmental limits to be safe levels based on information, the employer should regard them as the upper current boundaries of exposure and make every effort to maintain the exposure as low as is technically feasible. The criteria and standard will be subject to review and revision as necessary.

These criteria and the recommended standard apply to exposure of employees in the workplace to acetone, (2-propanone), methyl ethyl ketone (2-butanone), methyl n-propyl ketone (2-pentanone), methyl n-butyl ketone (2-hexanone), methyl n-amyl ketone (2-heptanone), methyl isobutyl ketone (4-methyl-2-pentanone), methyl isoamyl ketone (5-methyl-2-hexanone), diisobutyl ketone (2,6-dimethyl-4-heptanone), cyclohexanone, mesityl oxide (4-methyl-3-penten-2-one), diacetone alcohol (4-hydroxy-4-methyl-2pentanone), and isophorone (3,5,5-trimethyl-2-cyclohexan-1-one), referred to as "ketones" in this document.

Ketones have many industrial uses as chemical intermediates, solvents, and components in formulations, including inks, adhesives, and dyes. Exposure to ketones can cause local effects (irritation of eyes, upper respiratory tract, and skin) and systemic effects, the most important of which is peripheral neuropathy from methyl n-butyl ketone.

The action level is defined as half the time-weighted average (TWA) concentration environmental limit of each ketone. "Occupational exposure to ketones" is defined as exposure to ketones at a TWA concentration greater than the action level. Exposure at lower concentrations will not require adherence to the following sections, except for Sections 3(a), 4, 5, 6(b-e), 7, and 8(a).

Section 1 - Environmental (Workplace Air)

(a) Concentration

Occupational exposure to ketones shall be controlled so that employees are not exposed at concentrations greater than the limits, in milligrams per cubic meter (mg/cu m) of air, in Table I-1 as TWA concentrations for up to a 10-hour workshift, 40-hour workweek.

(b) Sampling and Analysis

Workroom air samples shall be collected and analyzed for ketones by the methods described in Appendix I or by methods that are at least equivalent in precision, sensitivity, and accuracy.

Section 2 - Medical

Medical surveillance shall be made available as outlined below to all workers occupationally exposed to ketones.

TABLE I-1

.

RECOMMENDED EXPOSURE LIMITS FOR THE KETONES

Ketone	TWA Concentration Limits			
	mg/cu m	Approximate ppm equivalents		
Acetone	590	250		
Methyl ethyl ketone	590	200		
Methyl n-propyl ketone	530	150		
Methyl n-butyl ketone	4	1		
Methyl n-amyl ketone	465	100		
Methyl isobutyl ketone	200	50		
Methyl isoamyl ketone	230	50		
Diisobutyl ketone	140	25		
Cyclohexanone	100	25		
Mesityl oxide	40	10		
Diacetone alcohol	240	50		
Isophorone	23	4		

.

(a) Preplacement examinations shall include at least:

(1) Comprehensive medical and work histories with special emphasis directed toward disorders of the nervous system, the respiratory system, and the eyes.

(2) Physical examination giving particular attention to the central and peripheral nervous systems, the respiratory system, and the eyes.

(3) Urinalysis, as an indicator of kidney function. In addition, appropriate tests for liver function should be considered by the responsible physician. For workers occupationally exposed to methyl nbutyl ketone, an electrodiagnostic examination including electromyography and nerve conduction velocity measurements shall be provided.

(4) A judgment of the worker's ability to use positive and negative pressure respirators.

(b) Periodic examinations shall be made available annually or more frequently when considered necessary by the responsible physician. These examinations shall include at least:

(1) Interim medical and work histories.

(2) Physical examination as outlined in paragraphs (a)(2)and (a)(3) of this section.

(c) During examinations, applicants or employees found to have medical conditions that might be directly or indirectly aggravated by exposure to ketones, for example, a case of preexisting neuropathy in the case of methyl n-butyl ketone, shall be counseled on the increased risk of impairment of their health by working with these substances.

In addition, employees who are occupationally exposed to methyl nbutyl ketone shall be made aware that repeated exposure can produce adverse effects on the nervous system and that accompanying signs and symptoms are insidious. If indicated by the electrodiagnostic examinations on those workers with occupational exposure to methyl n-butyl ketone, a neurologic consultation should be obtained, particularly in the presence of suspected neurologic abnormalities on preemployment or interim examination.

(d) Appropriate medical management shall be made available to those workers who suffer effects from exposure to ketones.

(e) Pertinent medical records shall be maintained for all employees occupationally exposed to ketones in the workplace. Records of environmental exposures applicable to an employee shall be included in that employee's medical records. Such records shall be kept for at least 30 years after termination of employment. These records shall be made available to the designated medical representatives of the Secretary of Health, Education, and Welfare, of the Secretary of Labor, of the employer, and of the employee or former employee.

Section 3 - Labeling and Posting

All labels and warning signs shall be printed both in English and in the predominant language of non-English-reading workers. Workers unable to read the labels and signs provided shall receive information regarding hazardous areas and shall be informed of the instructions printed on labels and signs. Because acetone, methyl ethyl ketone, methyl n-propyl ketone, methyl n-butyl ketone, methyl isobutyl ketone, and mesityl oxide are flammable while methyl n-amyl ketone, diisobutyl ketone, methyl isoamyl ketone, cyclohexanone, diacetone alcohol, and isophorone are combustible, all labels and warning signs shall bear the appropriate designation.

(a) Containers

Shipping and storage vessels containing ketones shall carry, in a readily visible location, the following pertinent label that bears the name of the specific ketones contained therein, the trade name of the product, if appropriate, and information on the effects of exposure to the compound on human health in addition to, or in combination with, labels required by other statutes, regulations, or ordinances. The information shall be arranged as in the following examples:

(1) Label for methyl n-butyl ketone:

METHYL N-BUTYL KETONE (TRADE NAME) FLAMMABLE MAY CAUSE NERVE DAMAGE IF INHALED, SWALLOWED, OR ABSORBED THROUGH SKIN

Keep away from heat, sparks, and open flames.In case of fire, use foam, dry chemical, or carbon dioxide fire extinguisher.Avoid breathing vapor.Do not get on skin, in eyes or mouth, or on clothing.Keep containers closed when not in use.Use only with adequate ventilation.

First Aid: If substance contacts skin, immediately wash affected area with soap and water. In case of eye contact, flush eye with copious amounts of running water. If overexposure should occur, consult a physician. (2) Label for the other 11 ketones:

NAME OF KETONE (TRADE NAME)

FLAMMABLE! (or: COMBUSTIBLE!)

HARMFUL IF INHALED, SWALLOWED, OR ABSORBED THROUGH SKIN

Keep away from heat, sparks, and open flames. In case of fire, use foam, dry chemical, or carbon dioxide fire extinguisher. Avoid breathing vapor. Do not get on skin, in eyes or mouth, or on clothing. Keep containers closed when not in use. Use only with adequate ventilation.

First Aid: If substance contacts skin, immediately wash affected area with soap and water. In case of eye contact, flush eye with copious amounts of running water. If overexposure should occur, consult a physician.

(b) Work Area

1

Warning placards shall be affixed in readily visible locations in or near areas of occupational exposure to ketones. The information shall be arranged as in the following examples:

(1) Warning placard for methyl n-butyl ketone:

HAZARDOUS AREA METHYL n-BUTYL KETONE (TRADE NAME) FLAMMABLE MAY CAUSE NERVE DAMAGE IF INHALED, SWALLOWED, OR ABSORBED THROUGH SKIN

Prevent sources of heat, sparks, or open flames. No smoking permitted. In case of fire use fire extinguishers at (location). Avoid breathing vapor. Avoid contact with skin, eyes, and clothing.

(2) Warning placard for the other 11 ketones:

HAZARDOUS AREA NAME OF KETONE (TRADE NAME) FLAMMABLE! (or: COMBUSTIBLE!) HARMFUL IF INHALED, SWALLOWED, OR ABSORBED THROUGH SKIN

Prevent sources of heat, sparks, or open flames. No smoking or eating. In case of fire, use fire extinguishers at (location). Avoid breathing vapor. Avoid contact with skin, eyes, and clothing.

(3) Respiratory Protection

If respiratory protection is required in accordance with Section 4, the following statement in large letters shall be added to the required sign:

RESPIRATORY PROTECTION REQUIRED IN THIS AREA

Section 4 - Personal Protective Equipment and Clothing

(a) Respiratory Protection

The employer shall use engineering controls when needed to keep concentrations of airborne ketones at or below the recommended environmental limits. Compliance with this standard by the use of respirators is permitted only during installation and testing of engineering controls, during performance of nonroutine maintenance or repair, or during emergencies. When use of a respirator is permitted, it shall be selected and used in accordance with the following requirements: (1) To determine the type of respirators to be used, the employer shall measure the concentration of airborne ketones in the workplace initially and thereafter whenever control, process, operational, worksite, or climatic changes occur that are likely to increase the concentration of airborne ketones.

(2) The employer shall ensure that no employee is exposed to ketones at concentrations above the recommended limits because of improper respirator selection, fit, use, or maintenance.

(3) A respiratory protection program shall be established. Requirements are found in 29 CFR 1910.134.

(4) The employer shall provide respirators in accordance with Table I-2 and shall ensure that the employees use the respirators properly when they are required. Respiratory protective devices shall be those approved by NIOSH and the Mine Safety and Health Administration.

(5) Respirators specified for use in higher concentrations of a specific airborne ketone may be used in an atmosphere of the same ketone at lower concentrations.

(6) The employer shall ensure that employees are properly instructed in the use of respirators assigned to them and in ways to test for leakage, proper fit, and proper operation.

(b) Protective Clothing

The employer shall provide appropriate protective clothing to employees who may have skin contact with liquid ketones. Protective clothing, including aprons, coats or coveralls, gloves, and boots, shall be made of material resistant to penetration by ketones. The employer shall ensure that personal protective clothing is regularly inspected for defects

TABLE I-2

RESPIRATOR SELECTION GUIDE FOR KETONES*

Ketone	Multiples of TWA Concentration Limit				Emergency Entry	Fire- fighting
	Less Than or Equal to		Greater Than			
	10X	50X	100X	100x		
Acetone	CDFHIJ	KL	KL	KL	KL	СК
Methyl n-butyl ketone	ABEG	CDFJ	HI	KL	KL	К
Methyl ethyl and methyl n-propyl ketone	В	CDFJ HI	KL	KL	KL	K
Other eight ketones**	В	CDFJ	HI	KL	KL	ĸ

*See Respirator Code on the following page

** Methyl n-amyl ketone, methyl isobutyl ketone, methyl isoamyl ketone, diisobutyl ketone, cyclohexanone, mesityl oxide, diacetone alcohol, or isophorone

RESPIRATOR CODE

Code	Respirator Type Approved under Provisions of 30 CFR 11
A	Chemical cartridge respirator with half-mask facepiece and organic vapor cartridge
В	Chemical cartridge respirator with full facepiece and organic vapor cartridge
С	Gas mask with full facepiece and chin-type organic vapor can- ister
D	Gas mask with full facepiece and back- or front-mounted organic vapor canister
E	Type C supplied-air respirator, with half-mask facepiece, operated in demand (negative pressure) mode
F	Type C supplied-air respirator, with full facepiece, opera- ted in demand (negative pressure) mode
G	Type C supplied-air respirator, with half-mask facepiece, operated in continuous-flow or pressure-demand mode
Н	Type C supplied-air respirator, with full facepiece, opera- ted in continuous-flow or pressure-demand mode
I	Type C supplied-air respirator with hood, helmet, or suit
J	Self-contained breathing apparatus, with full facepiece, operated in demand (negative pressure) mode
К	Self-contained breathing apparatus, with full facepiece, operated in pressure-demand or other positive pressure mode
L	Combination Type C supplied-air respirator, with full face- piece, operated in pressure-demand mode and equipped with auxiliary positive pressure self-contained air supply

and that it is worn by employees when necessary to prevent skin contact with liquid ketones.

(c) Eye Protection

The employer shall provide chemical safety goggles or face shields (20-cm minimum) with goggles and ensure that they are worn by employees where eye contact with liquid ketones is likely. Regulations concerning the selection, use, design, cleaning, limitations, precautions, and maintenance of eye protection equipment appear in 29 CFR 1910.133.

Section 5 - Informing Employees of Hazards from Ketones

(a) All new and current employees working with ketones shall be informed of the hazards, relevant signs and symptoms of overexposure, appropriate emergency procedures, including first aid, and proper conditions and precautions concerning safe use and handling of these compounds. Employees shall be informed, preferably by medical personnel, that ketones can irritate the eyes, nose, and throat and may cause impaired judgment at unknown concentrations and narcosis at high concentrations.

(b) The employer shall institute a continuing education program, conducted by persons qualified by experience or training, to ensure that all employees have current knowledge of job hazards, proper maintenance and cleanup methods, and proper respirator use. The instructional program shall include a description of the general nature of the environmental and medical surveillance procedures and of the advantage to the employees of participating in these surveillance procedures. As a minimum, instruction shall include the information in Appendix II, which shall be kept on file

and shall be readily accessible to employees at all places of employment where ketones are present.

(c) Required information shall be recorded on the "Material Safety Data Sheet" shown in Appendix II or on a similar form approved by the Occupational Safety and Health Administration, US Department of Labor.

Section 6 - Work Practices

(a) Control of Airborne Ketones

Engineering controls, such as process enclosure or local exhaust ventilation, shall be used when needed to keep exposures to ketones at or below the permissible exposure limits. Ventilation systems, if used, shall be designed to limit accumulation or recirculation of ketones in the workplace environment. Exhaust ventilation systems discharging to outside air must conform to applicable local, state, and Federal air pollution regulations and must not constitute a hazard to employees or to the general population. Ventilation systems shall be subject to regular preventive maintenance and cleaning to ensure effectiveness, which shall be verified by airflow measurements taken at least every 3 months. Motors in the exhaust systems shall be explosion proof, and all moving parts shall be made of nonsparking materials.

(b) Confined Spaces

Entry into and work in confined spaces, such as tanks, pits, vessels, or tank cars, that may contain ketones shall be controlled by adherence to the following requirements (or their equivalent).

(1) Before entering a confined space an employee shall obtain a permit. Permits shall be signed by an authorized representative

of the employer and shall certify that proper preventive and protective measures have been followed.

(2) Confined spaces that have contained ketones shall be cleaned with water and purged with air. Confined spaces should be isolated by locking out associated valves and switches to prevent accidental entry of ketones. They shall be tested to ensure that there is an adequate supply of oxygen and to ensure that ketones and other contaminants are not present in unsafe amounts and concentrations. Adequate ventilation shall be maintained while employees are in the confined space.

(3) An employee entering a confined space shall be furnished with appropriate personal protective equipment and shall be connected by a lifeline harness to another worker outside, who shall also be equipped for entry with approved personal protective equipment and have contact with a third party. The standby person shall keep in communication with the person in the confined space. The third person, equipped to aid the other two if necessary, shall observe their activities.

(c) Storage and Handling

(1) Containers of ketones shall be kept tightly closed at all times when not in use. They shall be of a type designed to contain flammable or combustible liquids and shall be stored safely to minimize the possibility of breaks, spills, or leaks. Ketones shall be kept away from excessive heat, sparks, and flames.

(2) Employers shall ensure that improperly informed, trained, and equipped personnel are not involved in storing, loading, unloading, or processing ketones.

(3) Guidelines and regulations on the storage and handling of flammable and combustible liquids are found in 29 CFR 1910.106.

(d) Cleanup and Waste Disposal

(1) Spills of liquid ketones shall be cleaned up promptly and in a manner that will minimize the inhalation of, skin contact with, and hazard of fire from the ketones.

(2) Rags, mops, and other materials contaminated with ketones shall be stored in closed metal containers.

(3) Waste material containing ketones shall be disposed of in a manner that is not hazardous to employees or to the general population and that conforms to applicable local, state, and Federal regulations.

(e) Emergency Procedures

(1) The employer shall formulate emergency evacuation, medical, and firefighting procedures and shall ensure that employees are instructed in these procedures and that the instructions are posted in all work areas where emergencies such as large spills involving ketones might occur. Emergency procedures shall include prearranged plans for immediate evacuation, transportation, and medical assistance for affected employees, including alerting designated medical facilities to the impending arrival of affected workers.

(2) Necessary emergency equipment, including respirators, shall be available in readily accessible locations, and employees shall be instructed in its use.

(3) Employees not essential to emergency operations shall be evacuated from hazardous areas during emergencies. The perimeters of these areas shall be delineated, posted, and secured. Employers shall ensure that personnel who are not trained in emergency procedures and protected against the attendant hazards do not shut off sources of ketones, clean up spills, control and repair leaks, and fight fires where ketones are present.

(4) Employers shall provide emergency drench showers, eyewash fountains, and washroom facilities that are readily accessible to workers in all areas where skin or eye contact with liquid ketones is likely. If liquid ketones are splashed on the clothing or skin, contaminated clothing and shoes shall be promptly removed and the skin washed thoroughly with soap and water. If liquid ketones get into the eyes, the affected area shall be irrigated immediately with copious quantities of running water.

(5) The employer shall ensure, through regularly scheduled inspection and maintenance, that all emergency equipment, including washing facilities, is in proper working order.

Section 7 - Sanitation

(a) Regulations concerning plant sanitation are found in 29 CFR 1910.141.

(b) The employer shall provide appropriate changing and shower rooms. Requirements for such rooms are found in 29 CFR 1910.141(e).

(c) Clothing that has been contaminated by ketones shall be discarded or decontaminated by laundering or drying under an exhaust hood or by an equivalent method.

(d) The employer shall inform persons involved in laundering or otherwise handling clothing or equipment contaminated with ketones of the potential hazards of exposure to ketones.

(e) Employers shall prohibit the use of ketones for handwashing and other personal cleaning purposes.

(f) Employees who handle ketones shall be instructed by their employer to wash their hands thoroughly with soap and water before using toilet facilities, eating, or smoking.

Section 8 - Monitoring and Recordkeeping Requirements

(a) Each employer with a place of employment where ketones are manufactured, processed, stored, used, handled, or otherwise present shall determine by an industrial hygiene survey if there is occupational exposure to ketones. Records of these surveys, including the basis for concluding that there is no occupational exposure to ketones, shall be maintained. Surveys shall be repeated at least annually and within 30 days of any change likely to alter concentrations of any of these compounds in the workplace air.

(b) If it is determined that there is occupational exposure to ketones, the employer shall fulfill the following requirements:

(1) A program of personal monitoring shall be instituted to identify and measure, or to permit calculation of, the exposure of each employee occupationally exposed to airborne ketones. Source and area monitoring may be used to supplement personal monitoring.

(2) In all personal monitoring, samples representative of the breathing zones of the employees shall be collected.

(3) For each TWA concentration determination, a sufficient number of samples shall be taken to characterize the employees' exposures during each workshift. Variations in work and production schedules and in employees' locations and job functions shall be considered in choosing sampling times, locations, and frequencies.

(4) Each operation in each work area shall be evaluated at least every 3 months if it is determined that there is occupational exposure.

(5) If an employee is found to be exposed to ketones in excess of any of the TWA concentration limits specified in Section 1a, the exposure of that employee shall be measured at least once a week, control measures shall be initiated, and the employee shall be notified of the extent of the exposure and of the control measures being implemented. Such monitoring shall continue until two consecutive determinations, 1 week apart, indicate that the employee's exposure no longer exceeds the appropriate limits. Routine monitoring may then be resumed.

(c) Recordkeeping

Records of workplace environmental monitoring shall be kept for at least 30 years after the employee's last occupational exposure to ketones. These records shall include the dates and times of measurements, job function and location of the employee within the worksite, methods of sampling and analysis used, types of respiratory protection in use at the time of sampling, TWA concentrations found, and identification of the exposed employee. Employees shall be able to obtain information on their own workplace environmental exposures. Workplace environmental monitoring

records shall be made available to designated representatives of the Secretary of Labor and of the Secretary of Health, Education, and Welfare.

Pertinent medical records shall be retained by the employer for 30 years after termination of employment. Records of environmental exposures applicable to an employee should be included in medical records. These medical records shall be made available to the designated medical representatives of the Secretary of Labor, of the Secretary of Health, Education, and Welfare, of the employer, and of the employee or former employee.

II. INTRODUCTION

This report presents the criteria and the recommended standard based thereon which were prepared to meet the need for preventing impairment of health from workplace exposure to ketones. The criteria document fulfills the responsibility of the Secretary of Health, Education, and Welfare under Section 20(a)(3) of the Occupational Safety and Health Act of 1970 to "...develop criteria dealing with toxic materials and harmful physical agents and substances which will describe...exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience."

After reviewing data and consulting with others, NIOSH formalized a system for the development of criteria upon which standards can be established to protect the health and to provide for the safety of employees exposed to hazardous chemical and physical agents. Criteria for a recommended standard should enable management and labor to develop better engineering controls resulting in more healthful work environments, and simply complying with the recommended standard should not be regarded as the final goal.

These criteria for a standard for ketones are part of a continuing series of criteria developed by NIOSH. The proposed standard applies only to workplace exposure to ketones arising from the processing, manufacture, and use of these ketones. The standard is not designed for the populationat-large, and any extrapolation beyond the occupational environment is not warranted. It is intended to (1) protect against injury from ketones, (2)

be measurable by techniques that are valid, reproducible, and available to industry and official agencies, and (3) be attainable with existing technology.

There are a number of areas that need further research with respect to ketones. The possibilities of carcinogenic, mutagenic, teratogenic, and reproductive effects from ketones have not been thoroughly investigated. Epidemiologic studies on all of the ketones are also needed. Furthermore, toxicologic information from repeated exposures of experimental animals is deficient for most of the ketones. Animal experiments are needed to determine if ketones other than methyl n-butyl ketone produce peripheral neuropathy. The effects of various mixtures of the ketones and interactions that may occur have not been studied. Research in this complex area is needed. Pharmacokinetic studies (absorption, distribution, metabolism, and excretion) are also needed to help investigators understand the mechanism of action of ketones on the nervous system.

Exposure to ketones in the workplace is a major concern because one of these compounds has caused a neurologic disorder, and all of them may cause irritation of the eyes, nose, and throat, impaired judgment, and narcosis in humans. Exposure occurs primarily when ketones are inhaled or absorbed through the skin.