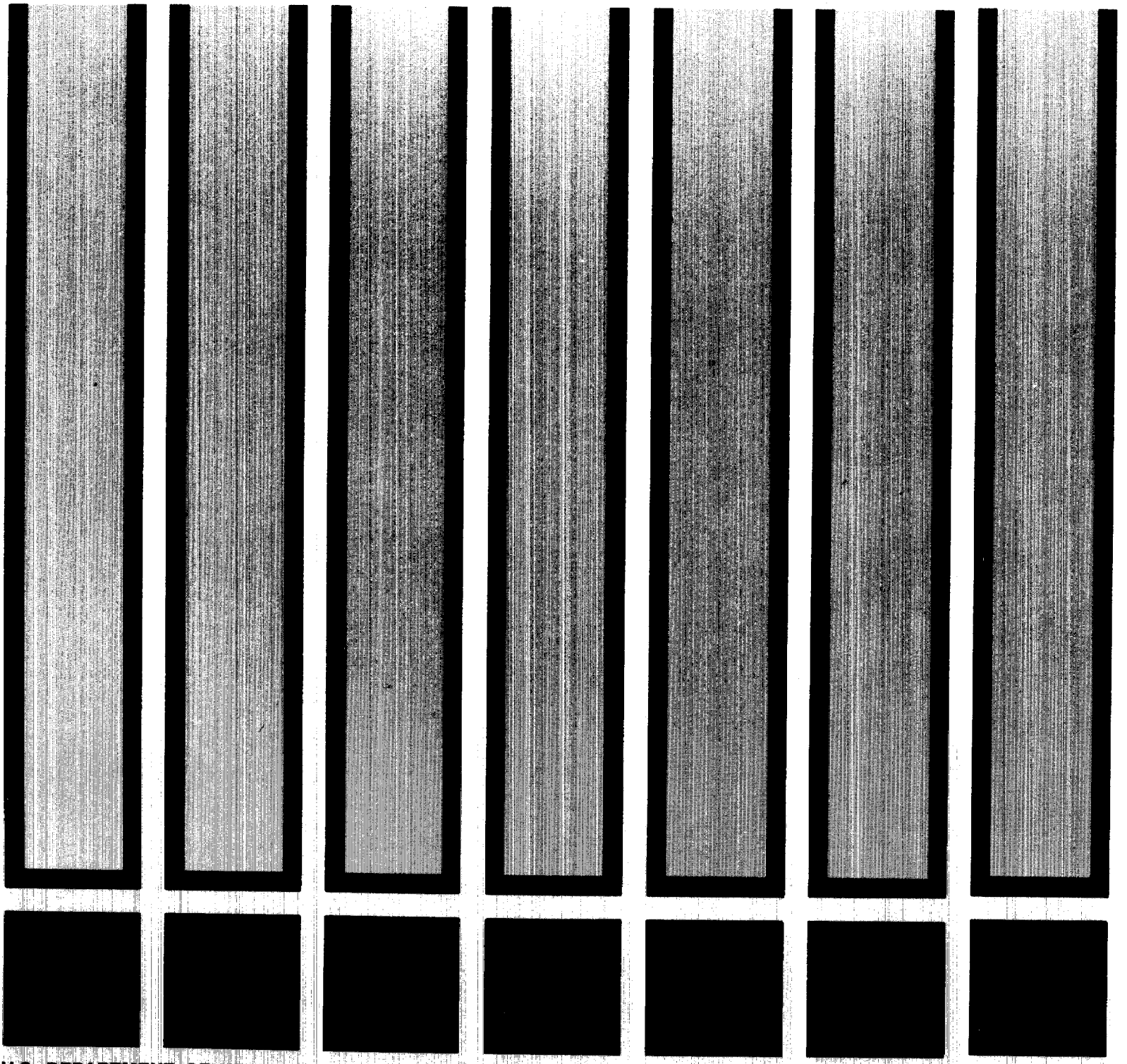
NIOSH

criteria for a recommended standard . . . . occupational exposure to

MALATHION



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

criteria for a recommended standard....

OCCUPATIONAL EXPOSURE TO

MALATHION

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

JUNE 1976

HEW Publication No. (NIOSH) 76-205

CONTENTS

CONTENTS

PREFACE

The Occupational Safety and Health Act of 1970 emphasizes the need for standards to protect the health and safety of workers exposed to an ever-increasing number of potential hazards at their workplace. The National Institute for Occupational Safety and Health has projected a formal system of research, with priorities determined on the basis of specified indices, to provide relevant data from which valid criteria for effective standards can be derived. Recommended standards for occupational exposure, which are the result of this work, are based on the health effects of exposure. The Secretary of Labor will weigh these recommendations along with other considerations, such as feasibility and means of implementation, in developing regulatory standards.

It is intended to present successive reports as research and epidemiologic studies are completed and as sampling and analytical methods are developed. Criteria and standards will be reviewed periodically to ensure continuing protection of the worker.

I am pleased to acknowledge the contributions to this report on malathion by members of my staff and the valuable constructive comments by the Review Consultants on Malathion, by the ad hoc committees of the American Industrial Hygiene Association and the Society of Toxicology, and by Robert B. O'Connor, M.D., NIOSH consultant in occupational medicine.

The NIOSH recommendations for standards are not necessarily a consensus of all the consultants and professional societies that reviewed this criteria document on malathion. Lists of the NIOSH Review Committee members and of the Review Consultants appear on the following pages.

John F. Finklea, M.D.
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 development of the criteria and recommended standard for malathion. The Division review staff for this document consisted of J. Henry Wills, Ph.D., Chairman, Herbert E. Christensen, D.Sc., and Richard A. Rhoden, Ph.D.

Stanford Research Institute developed the basic information for consideration by NIOSH staff and consultants under contract CDC-99-74-31. Jerry LR Chandler, Ph.D., had NIOSH program responsibility and served as criteria manager.

REVIEW COMMITTEE
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

Paul A. Baron, Ph.D.
Division of Physical Sciences and Engineering

Paul E. Caplan, M.S.
Division of Criteria Documentation and
Standards Development

Robert A. Rostand, M.D.
Division of Surveillance, Hazard Evaluations, and
Field Studies

Lester D. Scheel, Ph.D.
Division of Laboratories and Criteria Development

Samuel P. Tucker, Ph.D.
Division of Physical Sciences and Engineering

Kenneth C. Weber, Ph.D.
Appalachian Laboratory for Occupational Safety and
Health

Ronald J. Young
Division of Surveillance, Hazard Evaluations, and
Field Studies

Department of Labor Liaison:

Bradford A. Russell
Office of Standards Development
Occupational Safety and Health Administration

NIOSH REVIEW CONSULTANTS ON MALATHION

J. Blair Bailey, Ph.D.
Extension Entomologist
Department of Entomology
University of California
Riverside, California 92502

Clyde M. Berry, Ph.D.
Associate Director
Institute for Agricultural Medicine
University of Iowa at Oakdale
Oakdale, Iowa 52319

Dennis I. Chamot, Ph.D.
Assistant to the Executive Secretary
Council for Professional Employees, AFL-CIO
Washington, D.C. 20005

Keith T. Maddy, D.V.M., M.P.H.
Staff Toxicologist
Agricultural Chemicals and Feeds
California Department of Food and Agriculture
Sacramento, California 95814

Sheldon D. Murphy, Ph.D.
Associate Professor of Toxicology
Department of Physiology
Kresge Center for Environmental Health
School of Public Health
Harvard University
Boston, Massachusetts 02115

Richard D. O'Brien, Ph.D.
Director, Division of Biological Sciences
Cornell University
Ithaca, New York 14850

NIOSH REVIEW CONSULTANTS ON MALATHION (CONTINUED)

George Roush, Jr., M.D.
Corporate Medical Director
Monsanto Company
St. Louis, Missouri 63166

C. Boyd Shaffer, Ph.D.
Director of Toxicology
American Cyanamid Company
Wayne, New Jersey 07470

Geoffrey Woodard, Ph.D.
Pharmacologist
Woodard Research Corporation
Herndon, Virginia 22070

I. RECOMMENDATIONS FOR A MALATHION STANDARD

The National Institute for Occupational Safety and Health (NIOSH) recommends that employee exposure to malathion in the workplace be controlled by adherence to the following sections. The standard is designed to protect the health of employees for up to a 10-hour work shift and a 40-hour workweek during a working lifetime. Compliance with all sections of the standard should prevent adverse effects by malathion on the health of employees. 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 the workplace environmental limit is considered to be a safe exposure level based on current information, it should be regarded as the upper boundary of exposure and every effort should be made to maintain the exposure as low as is technically feasible. The criteria and standard will be subject to review and revision as necessary.

"Malathion" is defined as 0,0-dimethyl S-(1,2-dicarboethoxyethyl) dithiophosphate, regardless of production process, alone or in combination with other compounds. "Action level" is defined as one-half the recommended time-weighted average (TWA) environmental exposure limit for malathion. "Occupational exposure to malathion" is defined as exposure to airborne malathion at concentrations greater than the action level.

The criteria and recommended standard apply to any area in which malathion or materials containing malathion, alone or in combination with other substances, is produced, packaged, processed, mixed, blended,

handled, stored in large quantities, or applied.

"Overexposure" is defined as either known or suspected exposure above the TWA concentration or any exposure which leads to the development of signs or symptoms of absorption of organophosphorus compounds and cholinesterase (ChE) inhibition. Exposure to malathion at concentrations less than or equal to the action level will not require adherence to the recommended standard except for sections 2, 3(a), 4(a), 5, 6, 7(a-c), and 8(b). If employees are potentially exposed to chemicals such as pesticide vehicles, diluents, emulsifiers, or other pesticides, provisions of any applicable standards for such chemicals shall also be followed.

Section 1 - Environmental (Workplace Air)

(a) Concentration

When skin exposure is prevented, exposure to malathion in the workplace shall be controlled so that employees are not exposed to malathion at a TWA concentration greater than 15 mg/cu m of air for up to a 10-hour work shift, 40-hour workweek.

(b) Sampling and Analysis

Procedures for the collection and analysis of environmental air samples shall be as provided in Appendices I and II, or by any methods shown to be at least equivalent in accuracy, precision, and sensitivity to the methods specified.

Section 2 - Medical

Medical surveillance (medical management and biologic monitoring) shall be made available to workers as outlined below.

Physicians responsible for workers who may be occupationally exposed to organophosphate compounds should be familiar with the information contained in Appendix III which describes the diagnosis and treatment of intoxication by these compounds.

(a) Medical Examinations

(1) Preplacement and periodic medical examinations shall include:

(A) Comprehensive initial or interim medical and work histories.

(B) A physical examination which shall be directed toward, but not limited to, evidence of frequent headache, dizziness, nausea, tightness of the chest, dimness of vision, and difficulty in focusing the eyes.

(C) Determination, at the time of the preplacement examination, of a baseline or working baseline erythrocyte ChE activity (See (b), Biologic Monitoring).

(D) A judgment of the worker's physical ability to use negative or positive pressure regulators as defined in 29 CFR 1910.134.

(2) Periodic examinations shall be made available on an annual basis or at some other interval determined by the responsible physician.

(3) Medical records shall be maintained for all workers engaged in the manufacture or formulation of malathion and such records

shall be kept for at least 1 year after termination of employment.

(4) Pertinent medical information shall be available to authorized 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.

(b) Biologic Monitoring

(1) Definitions

(A) "Preexposure baseline" for erythrocyte ChE is defined as the mean of two ChE activity determinations, each of which is derived from a separate sample of blood taken at least 1 day apart after a period of at least 60 days without known exposure to any ChE-inhibiting compounds. If the determinations produce values differing by more than 15%, additional determinations on new samples must be performed until successive tests do not differ by more than 15%.

(B) "Working baseline" for erythrocyte ChE is defined as the mean of two ChE activity determinations, each of which is derived from a separate sample of blood taken at least 1 day apart and differing by no more than 15%, or the arithmetic mean of normal values for an appropriate control population of adults for that laboratory, whichever is higher. A "working baseline" need be determined only for an individual whose work history does not permit a preexposure baseline to be determined as specified in paragraph (b)(1)(A) of this section.

(C) "Mean of normal values" is defined as the arithmetic mean of erythrocyte ChE activities for healthy adults as determined by the laboratory's experience with repeated analyses, but which

is not inconsistent with the mean baseline activities presented in Appendix IV.

(2) Routine Monitoring

(A) All employees who are to be engaged in the manufacture or formulation of malathion shall have preexposure erythrocyte ChE baselines determined whenever their work histories allow an accurate preexposure determination, as specified in paragraph (b)(1)(A) of this section. Those new employees with work histories precluding preexposure baseline ChE determinations shall have working baseline determinations performed.

(B) Within 60 days after the effective date of a standard, all present employees potentially exposed to malathion shall have working baseline erythrocyte ChE activities determined.

(C) An employee who has been removed from malathion exposure shall not be allowed to return to work involving occupational malathion exposure until said employee's erythrocyte ChE activity has returned to at least 75% of the working or preexposure baseline value, or unless the responsible physician has approved said employee's return.

(D) All employees shall be provided a copy of their initial, periodic, and any special ChE test results as soon as possible after the test, plus an interpretation.

Section 3 - Labeling and Posting

(a) Labeling

Containers of malathion shall be labeled as follows:

MALATHION

CAUTION! HARMFUL IF INHALED OR SWALLOWED
HARMFUL IF LEFT ON SKIN

Do not breathe spray, vapor, or mist.
Do not take internally.

Avoid contact with eyes, skin, and clothing.
Wash hands before eating.
Take shower or bath after work.
Wear long-sleeved work clothing.
Change to clean clothing daily.

NOTE TO PHYSICIAN: Malathion is a cholinesterase inhibitor. Atropine sulfate is antidotal.

(b) Posting

The following sign shall be posted in a readily visible location at or near entrances to manufacturing and formulating areas containing malathion, and at other areas in which there is a risk of exposure:

TOXIC CHEMICAL

MALATHION IN USE

DO NOT BREATHE DUST OR MIST

Warning signs shall be printed in English and in the predominant language of non-English-speaking employees, if any, unless employers use equally effective means to ensure that non-English-speaking employees know the hazards associated with malathion and the areas in which there is exposure to malathion. Employers shall ensure that all illiterate employees also know these hazards and the location of these areas.

Section 4 - Personal Protective Equipment and Clothing

(a) Protective Clothing

Any employee whose work involves likely exposure of the skin to malathion or malathion formulations, eg, mixing or formulating, shall wear full-body coveralls or the equivalent, impervious gloves, and impervious footwear and, when there is danger of malathion coming in contact with the eyes, safety goggles shall be provided and worn. Any employee who applies malathion shall be provided with and required to wear the following protective clothing and equipment: goggles, whole-body coveralls, and impervious footwear.

(b) Respiratory Protection

Engineering controls shall be used wherever feasible to maintain airborne malathion concentrations below the recommended workplace environmental limit. Compliance with the workplace environmental limit by the use of respirators is allowed only when airborne malathion concentrations are in excess of the workplace environmental limit because required engineering controls are being installed or tested, when nonroutine maintenance or repair is being accomplished, or during emergencies. When a respirator is thus permitted, it shall be selected and used in accordance with the following requirements:

(1) For the purpose of determining the type of respirator to be used, the employer shall measure, when possible, the atmospheric concentration of malathion in the workplace initially and thereafter whenever process, worksite, climate, or control changes occur which are likely to increase the airborne malathion concentrations; this requirement does not apply when only atmosphere-supplying positive pressure respirators

are used. The employer shall ensure that no employee is exposed to malathion at or above the workplace environmental limit because of improper respirator selection, fit, use, or maintenance.

(2) A respiratory protective program meeting the requirements of 29 CFR 1910.134 and 30 CFR 11 shall be established and carried out by the employer.

(3) The employer shall provide respirators in accordance with Table I-1 and shall ensure that the appropriate respirator is worn.

(4) Respiratory protective devices described in Table I-1 shall be of the type approved under the provisions of 29 CFR 1910.134 and 30 CFR 11.

(5) Respirators specified for use in higher concentrations of malathion may be used in atmospheres of lower concentrations.

(6) The employer shall ensure that respirators are adequately cleaned, and that employees are instructed on the use of respirators assigned to them and on how to test for leakage.

(7) Canisters shall be discarded and replaced with fresh canisters in accord with the manufacturer's recommendation or if the odor of malathion breaks through. Unused canisters shall be discarded and replaced when seals are broken or on expiration of the manufacturer's recommended storage life if the seals are unbroken.

TABLE I-1

RESPIRATOR SELECTION GUIDE

Concentration of Malathion	Respirator Type
150 mg/cu m or less (dust)	Dust respirator
150 mg/cu m or less (aerosol or vapor)	(1) Chemical cartridge respirator with replaceable pesticide cartridge and half-mask facepiece (2) Type C supplied-air respirator, demand type (negative pressure), with half-mask facepiece
300 mg/cu m or less	Full-face gas mask, chin-style with pesticide canister
750 mg/cu m or less	(1) Full-face gas mask, chest- or back-mounted type (2) Type C supplied-air respirator, demand type (negative pressure), with full facepiece, hood, or shroud
Emergency (no concentration limit)	(1) Self-contained breathing apparatus (positive pressure) with full facepiece (2) Combination supplied-air respirator, pressure-demand type, with auxiliary self-contained air supply

Section 5 - Informing Employees of Hazards from Malathion

(a) Before work involving potential exposure to malathion begins, all new or reassigned employees shall be informed of the hazards of malathion, relevant symptoms of overexposure to malathion, appropriate emergency procedures, and of the conditions and precautions required for

safe handling of malathion.

(b) The information shall be posted in the work area, shall be kept on file, and shall be readily accessible to the worker at all places of employment where occupational exposure to malathion may occur.

(c) A program of employee education shall be instituted within 30 days after the promulgation of the standard. The program shall be designed to ensure that all employees occupationally exposed to malathion understand and remain aware of job hazards as well as emergency, maintenance, and cleanup procedures, and that they know how to correctly use and maintain respiratory protective equipment and protective clothing. The training shall be repeated at least annually after the employee's initial training required under this paragraph.

(d) In addition to the requirements of paragraph (c) above, employees occupationally exposed to malathion shall be kept currently informed through posting as specified in Section 3(b), and shall be instructed as to the availability of biologic monitoring information. The information specified in Section 2(b)(2) shall be kept on file and shall be readily accessible to each employee at or near each workplace where exposure to malathion may occur. In addition, all employees shall be informed of their biologic monitoring results as specified in Section 2(b)(2)(D).

Information as required shall be recorded on the "Material Safety Data Sheet" shown in Appendix V or on a similar form approved by the Occupational Safety and Health Administration, US Department of Labor.

Section 6 - Work Practices

(a) Each employer shall contact and advise a physician or other nearby medical service that an emergency arising from exposure to malathion may occur.

(b) All malathion spills shall be cleaned up as soon as possible. Continuous surveillance of spills shall be provided until decontamination is completed. Contaminated areas shall be roped off or access to them otherwise prevented. They shall also be posted.

(c) Spills of malathion on floors shall be absorbed with absorbing clay. Sweeping compound shall be utilized to facilitate the removal of all visible traces of malathion-contaminated clay.

(d) Equipment and fixtures contaminated with malathion shall be decontaminated with an alkaline solution (5% NaOH) or with an equivalent or superior decontaminating solution.

(e) If empty metal containers contaminated with malathion are to be disposed of in a sanitary landfill, they shall be decontaminated with strong alkaline solution (10% NaOH), or with an equivalent or superior decontaminating solution, and punctured before disposal.

(f) If empty malathion-contaminated metal drums or containers are to be reclaimed, they shall be decontaminated or sealed tightly, and the reclaimer informed of the prior malathion contamination.

(g) The employer shall provide for cleaning and laundering of work clothing and personal protective equipment, and for their decontamination as needed.

(h) Whenever malathion significantly contaminates clothing or the insides of personal protective equipment, the contaminated articles shall

be removed immediately, and the employee shall be required to wash with soap and water.

(i) Extra clothes shall be available for use when employees' personal clothing becomes contaminated with malathion.

(j) Employees potentially exposed to malathion while spraying shall remain upwind from the spray whenever possible.

(k) Employers shall ensure that persons who launder clothes contaminated with malathion understand the hazards associated with malathion's use.

Section 7 - Sanitation Practices

(a) Malathion-manufacturing and malathion-formulating facilities shall have eyewash fountains and showers as specified in 29 CFR 1910.151(c).

(b) The employer shall provide access to a free-flowing water source at fixed facilities, with soap and towels for all employees to use in emergencies.

(c) Employees shall be required to shower at the end of each work shift.

(d) Employees shall be prohibited from eating, drinking, or smoking in malathion-contaminated areas.

(e) Employees occupationally exposed to malathion shall be required to wash hands and face before eating, drinking, smoking, or applying cosmetics or dermal preparations.

Section 8 - Monitoring and Recordkeeping Requirements

Workers are not considered to have occupational exposure to malathion if environmental concentrations, as determined by an industrial hygiene survey conducted within 6 months of the promulgation of this recommended standard, do not exceed half the recommended TWA environmental limit, ie, action level. Surveys shall be repeated at least once every year and within 30 days after any process change likely to result in increased airborne concentrations of malathion. Records of these surveys, including the basis for concluding that airborne concentrations of malathion are at or below the action level, shall be maintained. If the survey indicates that airborne concentrations of malathion exceed the action level, then the following requirements apply:

(a) Personal Monitoring

(1) A program of personal monitoring shall be instituted to identify and measure, or permit calculation of, the exposure of all employees who are occupationally exposed to malathion. Interim monitoring of employee exposure to airborne concentrations of malathion shall be conducted at least every 6 months. If monitoring of an employee's exposure to malathion reveals that the employee is exposed at concentrations in excess of the recommended TWA environmental limit, the exposure of that employee shall be measured at least once every 30 days, control measures shall be initiated, and the employee shall be notified of the exposure and of the control measures being implemented to correct the situation. Such monitoring shall continue until two consecutive samplings, at least a week apart, indicate that employee exposure no longer exceeds the TWA environmental limit specified in Section 1(a). Semiannual monitoring may

then be resumed.

(2) In all personal monitoring, samples of airborne malathion shall be collected which, when analyzed, will provide an accurate representation of the concentration of malathion in the air which the worker breathes.

(3) For each TWA determination, a sufficient number of samples shall be taken to characterize each employee's exposure during each work shift. Variations in work and production schedules shall be considered in deciding when samples are to be collected. The number of representative TWA determinations for an operation or process shall be based on the variations in location and job functions of employees in relation to that operation or process.

(b) Recordkeeping Procedures

Records shall be maintained for at least 5 years and shall include sampling and analytical methods, types of respiratory protective devices used, and TWA concentrations found. Each employee shall have access to data on the employee's own environmental exposures and records. These records shall be made available to the designated representatives of the Secretary of Health, Education, and Welfare. Pertinent records of required medical examinations shall be maintained for 1 year after the worker's employment has ended and shall be 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 occupational diseases arising from exposure to malathion. 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."

The National Institute for Occupational Safety and Health (NIOSH), after a review of data and consultation with others, formalized a system for the development of criteria upon which standards can be established to protect the health of employees from exposure 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 practices and should not be used as a final goal.

These criteria for a standard for malathion are part of a continuing series of criteria developed by NIOSH. The proposed standard applies only to the manufacture, formulation, application, or other vocational exposure to malathion as applicable under the Occupational Safety and Health Act of 1970. The standard was not designed for the population-at-large, and any extrapolation beyond vocational exposures is not warranted. It is intended to (1) protect against development of acute and chronic systemic and local effects on the skin and eyes, (2) be measurable by techniques that are

valid, reproducible, and available to industry and government agencies, and (3) be attainable with existing technology.

No attempt has been made in this document to cope with all the literature on malathion, such as that concerning insect data. Currently available scientific evidence indicates that, compared with other organophosphates, malathion is of low toxicity in humans.

NIOSH believes that future research on malathion should be directed toward the effects on enzymes, particularly aliesterase, of chronic exposure to malathion and the physiologic significance of these effects. Additional data should be obtained on its potential mutagenic or carcinogenic effects. There should be research directed toward the development of an accurate field test for ChE monitoring, and toward simpler and more efficacious methods of collecting malathion aerosols and vapors. Also, NIOSH recommends that the rates and mechanisms of skin absorption of various malathion formulations be determined and that certain biochemical constants and rates be determined. These recommendations are discussed further in Chapter VII.