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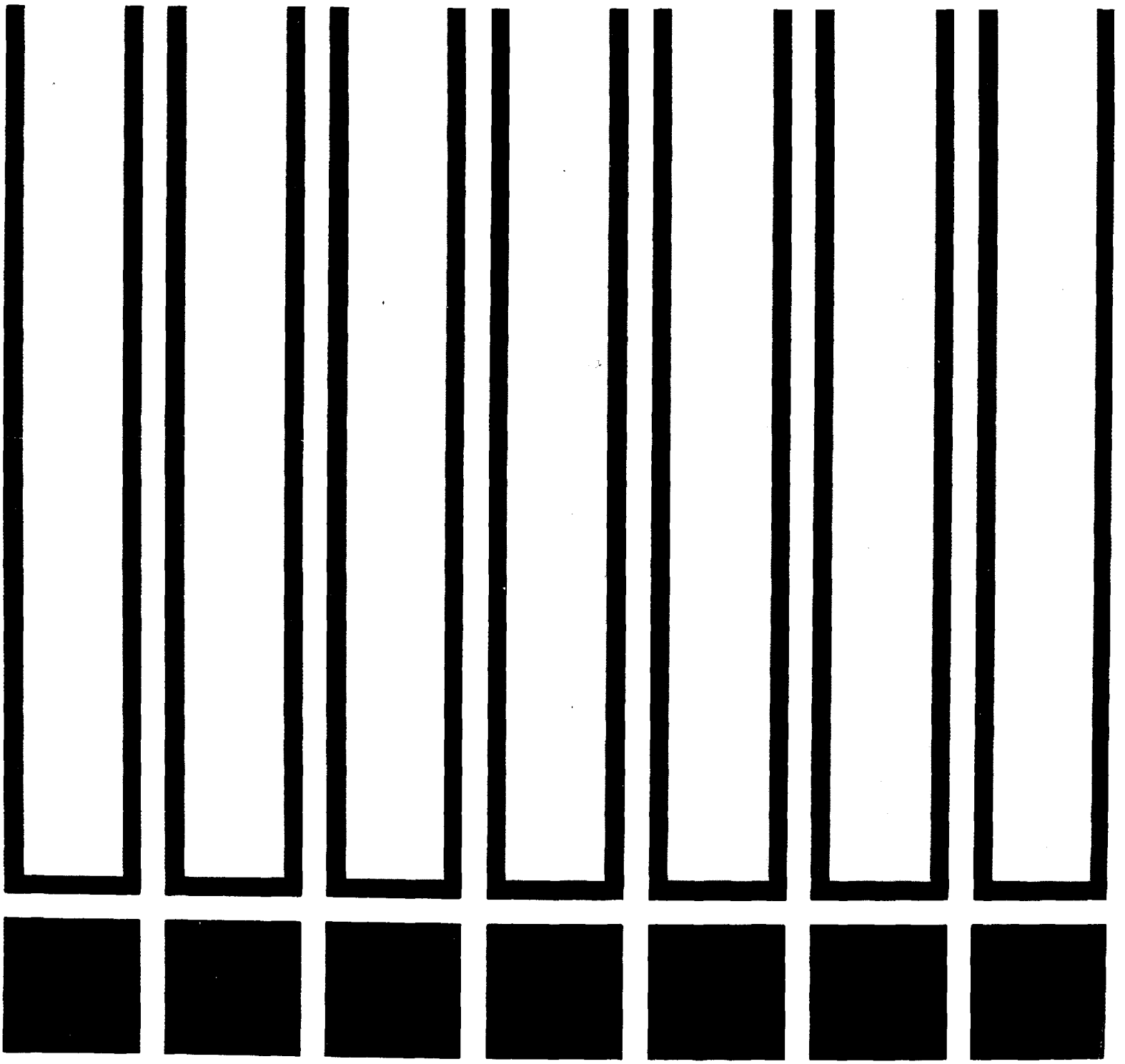
occupational exposure to

ORGANOTIN COMPOUNDS



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 ORGANOTIN COMPOUNDS

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
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NOVEMBER 1976

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

DHEW (NIOSH) Publication No. 77-115

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 the organotin compounds by members of the NIOSH staff and the valuable, constructive comments by the Review Consultants on organotins, by the ad hoc committees of the Society for Occupational and Environmental Health 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 organotins. A list of Review Consultants appears on page vi.

John F. Finklea, M.D.
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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 the recommended standard for organotin compounds. The Division Review staff for this document consisted of J. Henry Wills, Ph.D., Frank L. Mitchell, D.O., and Douglas L. Smith, Ph.D., with Peter G. Rentos, Ph.D. (Division of Technical Services), and Herbert E. Stokinger, Ph.D. (Division of Biomedical and Behavioral Science). Hervey B. Elkins, Ph.D., and Clara H. Williams, Ph.D., served as special reviewers.

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

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CRITERIA DOCUMENT:
RECOMMENDATIONS FOR AN OCCUPATIONAL
EXPOSURE STANDARD FOR ORGANOTIN COMPOUNDS

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I. RECOMMENDATIONS FOR AN ORGANOTIN STANDARD

The National Institute for Occupational Safety and Health (NIOSH) recommends that employee exposure to organotin compounds 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 work shift in a 40-hour workweek over a normal working life. Compliance with all sections of the standard should prevent adverse effects of organotin compounds on the health of employees and provide for their safety. Although NIOSH considers the workplace environmental limit to be a safe level based on current information, the employer should regard it as the upper boundary 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.

Organotin is the common name assigned to the group of compounds having at least one covalent bond between carbon and tin. The term "organotin" will be used throughout the document to refer to such compounds. Major subgroups will be referred to as mono-, di-, tri-, and tetraorganotins. The "action level" is set at half the recommended time-weighted average (TWA) workplace concentration limit. An employee is exposed or potentially exposed to organotins if that employee is involved in the occupational handling of the compounds or works in a plant containing organotins. "Occupational exposure" occurs when exposure exceeds the action level or if skin or eye contact with organotins occurs.

"Overexposure" to organotins occurs if an employee is known to be exposed to the organotins at a concentration in excess of the TWA concentration limit, or is exposed at any concentration sufficient to produce irritation of eyes, skin, or upper or lower respiratory tract. If exposure to other chemicals occurs, the employer shall comply also with the provisions of applicable standards for these other chemicals. "Emergency" is defined as any disruption in work process or practice, such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment, which is likely to result in unexpected exposure to organotin compounds in quantities which may cause physical harm.

Section 1 - Environmental (Workplace Air)

(a) Concentration

The employer shall control exposure to organotin compounds so that no employee is exposed at a concentration greater than 0.1 milligram, measured as tin, per cubic meter (mg/cu m) of air, determined as a TWA concentration for up to a 10-hour work shift in a 40-hour workweek.

(b) Sampling and Analysis

Environmental samples shall be collected and analyzed as described 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 shall be provided to employees or prospective employees who may be occupationally exposed to organotin compounds.

(a) Preplacement examinations shall include at least:

(1) Comprehensive medical and work histories.

(2) Comprehensive physical examination including the following tests and procedures:

(A) A 14- x 17-inch postero-anterior chest roentgenogram and determinations of the forced vital capacity (FVC) and the forced expiratory volume at 1 second (FEV 1).

(B) Determinations of activities in blood serum of glutamate-oxaloacetate transaminase (SGOT) and glutamate-pyruvate transaminase (SGPT) and other tests of hepatic function as desired by the attending physician.

(C) Eye examination including tests for visual acuity, color vision, pupillary reactions, and glaucoma. Particular attention should be given to the possible existence of choked disc.

(D) Electrocardiogram for workers over 40 years of age or where otherwise indicated.

(E) Neurologic examination to detect any prior history or evidence of increased intracranial pressure. If spinal fluid pressure is measured, the Queckenstedt maneuver should be performed.

(F) Urinalysis.

(3) An evaluation of the employee's ability to use positive or negative pressure respirators.

(4) Prospective employees or employees with evidence of a medical condition which could be directly or indirectly aggravated by exposure to organotin compounds should be counseled concerning the

advisability of their working with or continuing to work with these compounds.

(b) Periodic examination shall be made available on at least an annual basis or at some other interval determined by the responsible physician. These examinations shall include at least:

(1) Interim medical and work histories.

(2) Physical examination as outlined in paragraph (a)(2) of this section, except that the neurologic examination may be omitted at the discretion of the responsible physician.

(c) Initial medical examinations shall be made available to all employees within 6 months of the promulgation of a standard based on these recommendations. These examinations shall follow the requirements of the preplacement examination.

(d) If an emergency involving organotins arises, a qualified medical attendant designated by the employer shall examine all employees in the affected area, paying particular attention to the lungs and eyes, and determine the need for treatment. If contact with organotins occurs, any contaminated clothing and shoes shall be removed immediately and the eyes or skin shall be flushed immediately with water for at least 15 minutes.

(e) The employer shall provide appropriate medical services to any employee with adverse health effects reasonably assumed or shown to be due to exposure to organotin compounds in the workplace.

(f) The employer or successor thereto shall ensure that pertinent medical records are kept for all employees exposed to organotin compounds in the workplace for at least 5 years after termination of employment. These records shall be made available upon request 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

(a) Containers of organotins shall carry a label which bears the trade name of the product, the chemical name of the organotin contained therein, and information on the effects of the particular compound on human health. The trade name and pertinent information shall be arranged as in the example below.

TRADE NAME
(CHEMICAL NAME)

HARMFUL IF INHALED, SWALLOWED,
OR ABSORBED THROUGH SKIN

IRRITATING TO SKIN AND EYES

Avoid contact with eyes, skin, and clothing.
Keep container closed.
Use only with adequate ventilation.

First aid: In case of skin or eye contact, flush thoroughly with water for at least 15 minutes; consult a physician. If ingested, consult a physician.

(b) In areas where organotins are used, a sign containing information on the effects of the specific compounds on human health shall be posted in readily visible locations. This information shall be arranged as in the example below.

TRADE NAME
(CHEMICAL NAME)

HARMFUL IF INHALED, SWALLOWED,
OR ABSORBED THROUGH SKIN

IRRITATING TO SKIN AND EYES

Avoid inhaling vapor, dust, or mist.
Avoid contact with skin, eyes, mouth, and clothing.
Provide adequate ventilation.

First Aid: In case of skin or eye contact, flush thoroughly with running water for at least 15 minutes; consult physician. If ingested, consult a physician.

(c) If respirators are required, the following statement shall be added in large letters to the sign required in Section 3(b):

RESPIRATORY PROTECTION REQUIRED IN THIS AREA

(d) In any workplace or area where there is a likelihood of emergency situations arising, signs required by Section 3(b) shall be supplemented by additional signs giving emergency and first-aid instructions and procedures, the locations of first-aid supplies and emergency equipment, and the locations of emergency showers and eyewash fountains.

(e) All warning signs and labels shall be printed in English and in the predominant language of non-English-reading employees, unless the employer uses equally effective means to ensure that non-English-reading employees know the hazards associated with organotin compounds and the areas in which there may be occupational exposure to organotins. Employers

shall ensure that employees unable to understand these signs and labels also know these hazards and the locations of these areas.

Section 4 - Personal Protective Equipment and Clothing

The employer shall use engineering controls and safe work practices to keep the concentration of airborne organotins at or below the limit specified in Section 1(a) and shall provide protective clothing impervious to organotins to prevent skin and eye contact. Emergency equipment shall be located at clearly identified stations within the work area and shall be adequate to permit all employees to escape safely from the area. Protective equipment suitable for emergency use shall be located at clearly identified stations outside the work area.

(a) Protective Clothing

(1) The employer shall provide chemical safety goggles or face shields and goggles and shall ensure that employees wear the protective equipment during any operation in which organotins may enter the eyes.

(2) The employer shall provide appropriate impervious clothing, including gloves, aprons, suits, boots, or face shields (8-inch minimum) and goggles and shall ensure that employees wear protective clothing where needed to prevent skin contact.

(b) Respiratory Protection

(1) Engineering controls shall be used whenever feasible to maintain organotin concentrations at or below the TWA concentration limit.

Respiratory protective equipment shall be used in the following circumstances:

(A) During the time necessary to install or test the required engineering controls.

(B) For operations such as maintenance and repair activities causing brief exposure at concentrations in excess of the TWA concentration limit.

(C) During emergencies when concentrations of airborne organotins might exceed the TWA concentration limit.

(D) When engineering controls are not feasible to maintain atmospheric concentrations below the TWA concentration limit.

(2) When a respirator is permitted by paragraph (b)(1) of this section, it shall be selected and used in accordance with the following requirements:

(A) The employer shall establish and enforce a respiratory protective program meeting the requirements of 29 CFR 1910.134.

(B) The employer shall provide respirators in accordance with Table I-1 and shall ensure that employees use the respirators provided. The respiratory protective devices provided in conformance with Table I-1 shall comply with the standards jointly approved by NIOSH and the Mining Enforcement and Safety Administration (formerly Bureau of Mines) as specified under the provisions of 30 CFR 11.

TABLE I-1

REQUIREMENTS FOR RESPIRATOR USAGE
AT TWA CONCENTRATIONS IN EXCESS OF
THE ENVIRONMENTAL LIMIT

Concentration Range (mg/cu m, as tin)	Respirator Type
Less than or equal to 2.5	(1) Full facepiece respirator with combination high efficiency filter and organic vapor canister (pesticide respirator) (2) Supplied-air respirator with full facepiece operated in demand (negative pressure) mode (3) Self-contained breathing apparatus with full facepiece operated in demand mode
Less than or equal to 50.0	(1) Supplied-air respirator with full facepiece operated in continuous-flow (positive pressure) mode, worn with impervious clothing (2) Supplied-air respirator with full facepiece operated in pressure-demand (positive pressure) mode, worn with impervious clothing (3) Powered air-purifying respirator with hood, helmet, or full facepiece and with combination high efficiency filter and organic vapor canister
Greater than 50.0	(1) Self-contained breathing apparatus with full facepiece operated in pressure-demand mode (2) Combination supplied-air respirator with full facepiece and auxillary self-contained air supply operated in the pressure-demand mode
Emergency (entry into area of unknown concentration for emergency purposes, such as firefighting)	(1) Self-contained breathing apparatus with full facepiece operated in pressure-demand mode, worn with impervious clothing (2) Combination supplied-air respirator with full facepiece and an auxiliary self-contained air supply operated in the pressure-demand mode, worn with impervious clothing
Escape (from area of unknown concentration)	(1) Self-contained breathing apparatus with full facepiece operated in pressure-demand mode (2) Gas mask with full facepiece and with combination high efficiency filter and either front- or back-mounted organic vapor canister

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

(D) When a self-contained breathing apparatus is permitted in accordance with Table I-1, it shall be used pursuant to the following requirements:

(i) The employer shall provide initial training and refresher courses on the use, maintenance, and function of self-contained breathing apparatus.

(ii) If the self-contained breathing apparatus is operated in the negative-demand mode, a supervisor shall check employees and ensure that the respirators have been properly adjusted prior to use.

(iii) Whenever a self-contained breathing apparatus is supplied for escape purposes, the respirator shall be operated in the pressure-demand mode.

Section 5 - Informing Employees of Hazards from Organotins

(a) The employer shall provide information at the beginning of employment and on a semiannual basis thereafter on the hazards, relevant symptoms, appropriate emergency procedures, and proper conditions and precautions for the safe handling or use of organotin compounds to employees working in areas where exposure to organotin compounds is likely to occur. Employees engaged in maintenance and repair shall be included in these training programs.

(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 usage. The instructional program shall include a description of the general nature of the medical surveillance procedures and of the advantages to the employee of undergoing these examinations. As a minimum, instruction shall include the information in Appendix III, which shall be kept on file, readily accessible to employees at all places of employment where exposure may occur.

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

Section 6 - Work Practices

(a) Emergency Procedures

Employers shall take all necessary steps to ensure that employees are instructed in and follow the procedures specified below and any others appropriate for the specific operation or process for all work areas where there is a potential for emergencies involving organotins.

(1) Instructions shall include prearranged plans for obtaining emergency medical care and for transportation of injured employees.

(2) Approved eye, skin, and respiratory protection as specified in Section 4 shall be used by personnel essential to emergency operations. Employees not essential to emergency operations shall be evacuated from hazardous areas where inhalation, ingestion, or direct skin or eye contact may occur. The perimeter of these areas shall be

delineated, posted, and secured.

(3) Only personnel properly trained in the procedures and adequately protected against the attendant hazards shall shut off sources of organotins, clean up spills, and repair leaks. Spills and leaks shall be attended to immediately to minimize the possibility of exposure.

(4) Any spills of organotins shall be cleaned up immediately.

(5) Eyewash fountains and emergency showers shall be provided in accordance with 29 CFR 1910.151.

(b) Control of Airborne Organotins

Engineering controls, such as process enclosure or local exhaust ventilation, shall be used whenever feasible, to keep organotin concentrations within the recommended environmental limit. Ventilation systems shall be designed to prevent the accumulation or recirculation of organotins in the workplace environment and to effectively remove organotins from the breathing zones of employees. 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. 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.

(c) Storage

Containers of organotins shall be kept tightly closed at all times when not in use. Containers shall be stored in a safe manner to minimize accidental breakage or spillage and to prevent contact with strong oxidizers.

(d) Handling and General Work Practices

(1) Before maintenance work is undertaken, sources of organotins shall be shut off. If concentrations at or below the TWA environmental concentration limit cannot be assured, respiratory protective equipment, as described in Section 4 of this chapter, shall be used during such maintenance work.

(2) Employees who have skin contact with organotins shall immediately wash and shower, if necessary, for at least 15 minutes to remove all traces of organotins from the skin. Contaminated clothing shall be removed immediately and disposed of or cleaned before reuse. If contaminated clothing is to be reused, it shall be stored in a container, such as a plastic bag, which is impervious to the compound, prior to cleaning. Personnel involved in cleaning contaminated clothing shall be informed of the hazards involved and be provided with safety guidelines on the handling of these compounds.

Section 7 - Sanitation

(a) Eating and food preparation or dispensing (including vending machines) shall be prohibited in organotin work areas.

(b) Smoking shall not be permitted in areas where organotins are used, transfered, stored, or manufactured.

(c) Employees who handle organotins or equipment contaminated with organotins shall be instructed to wash their hands thoroughly with soap or mild detergent and water before eating or using toilet facilities.

(d) Waste material contaminated with organotins shall be disposed of in a manner not hazardous to employees. The disposal method must

conform with applicable local, state, and federal regulations and must not constitute a hazard to the surrounding population or environment.

Section 8 - Environmental Monitoring and Recordkeeping

Within 6 months of the promulgation of this standard, employers shall conduct an industrial hygiene survey at locations where organotins are released into workplace air to determine whether exposure to airborne concentrations of organotin is in excess of the action level. The employer shall keep records of these surveys. If the employer concludes that concentrations of airborne organotins are at or below the action level, the records must state the basis for this conclusion. Surveys shall be repeated at least annually and within 30 days of any process change likely to result in an increase of airborne organotin concentrations. If it has been determined that the environmental concentration of organotins might exceed the action level, then the employer shall fulfill the following requirements:

(a) Personal Monitoring

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

(2) Samples representative of the exposure in the breathing zone of the employee shall be collected in all personal monitoring. Procedures for the calibration of equipment, sampling, and analysis of organotin samples shall be as provided in Section 1(b).

(3) For each TWA concentration determination, a sufficient

number of samples shall be taken to characterize the employee's exposure. Variations in the employee's work schedule, location, and duties and changes in production schedules shall be considered when samples are collected.

(4) If an employee is found to be exposed above the action level, the exposure of that employee shall be monitored at least once every 3 months. If an employee is found to be overexposed, the exposure of that employee shall be measured at least once every week, control measures shall be initiated, and the employee shall be notified of the exposure and of the control measures being implemented. Such monitoring shall continue until two consecutive determinations, at least 1 week apart, indicate that the employee's exposure no longer exceeds the recommended environmental concentration limit; quarterly monitoring may then be resumed.

(b) Recordkeeping

Employers or their successors shall keep records of environmental monitoring for each employee for at least 5 years after the individual's employment has ended. These records shall include the name and social security number of the employee being monitored, duties and job locations within the work site, dates of measurements, sampling and analytical methods used and evidence for their accuracy, duration of sampling, number of samples taken, results of analyses, TWA concentrations based on these samples, and any personal protective equipment in use by the employee. Records for each employee, indicating date of employment with the company and changes in job assignment, shall be kept for the same 5-year duration. The employer shall make these records available upon request to authorized representatives of the Assistant Secretary of Labor for Occupational Safety

and Health or of the Director of the National Institute for Occupational Safety and Health. Employees or authorized representatives shall have access to information on their own exposures, and the employee or the employee's representative shall be given the opportunity to observe any measurement conducted in accordance with this section.

II. INTRODUCTION

This report presents the criteria and the recommended standard based thereon that were prepared to meet the need for preventing occupational disease or injury arising from exposure to organotins. 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 from which standards can be established to protect the health and to provide for the safety of employees from exposure to hazardous chemical and physical agents. Criteria for any 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 recommended standard for organotins are developed as part of a continuing series of documents published by NIOSH. The proposed standard applies only to workplace exposure to organotins arising from the processing, manufacture, or use of the substances 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 occupational environments is not warranted. It is intended to (1) protect against the development of systemic toxic effects and local effects on the eyes and skin, (2) be measurable by techniques that are valid, reproducible, and available to industry and government agencies, and (3) be attainable with existing technology.

The major concern in occupational exposure to organotins is the potential for liver, kidney, pulmonary, and central nervous system (CNS) damage at low concentrations. Dermatitis, irritation of the eyes, and irritation of the upper and lower respiratory tract have been associated with inhalation of, or skin or eye contact with, organotins and must be considered in any work practices program.

Very little information is now available on the toxic effects of the organotins on animals and on humans which is relevant to setting a standard for the working environment. Retrospective and prospective epidemiologic studies are needed to assess the potential occupational hazards from organotins. Both short-term and long-term inhalation studies on animals are necessary to assess the general toxic effects, particularly on the liver, kidneys, lungs, and CNS, of organotins which are used commercially or which may be used in the future. Chronic studies are also needed to investigate the carcinogenic, mutagenic, and teratogenic potentials of the organotin compounds.