Health Hazard Evaluation Report
PREFACE

The Hazard Evaluations and Technical Assistance Branch of NIOSH conducts field investigations of possible health hazards in the workplace. These investigations are conducted under the authority of Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 669(a)(6) which authorizes the Secretary of Health and Human Services, following a written request from any employer or authorized representative of employees, to determine whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found.

The Hazard Evaluations and Technical Assistance Branch also provides, upon request, medical, nursing, and industrial hygiene technical and consultative assistance (TA) to Federal, state, and local agencies; labor; industry and other groups or individuals to control occupational health hazards and to prevent related trauma and disease.

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

On September 21, 1981, the National Institute for Occupational Safety and Health (NIOSH) received a request to evaluate occupational exposures to organophosphate pesticides at the Hopkins Agricultural Chemical Company in Atlanta, Illinois. The requestor was concerned with exposures to Counter® and Thimet® during formulation and packaging operations.

In December 1981, NIOSH investigators conducted an initial survey, followed by environmental surveys in January 1982, and November-December, 1982 when Counter® was in production. During these surveys personal breathing zone and general area air samples, along with wipe samples, were collected for measurement of exposures to the Counter®. In addition, records of red blood cell cholinesterase (RBC ChE) levels were reviewed and confidential medical questionnaires were administered to the employees in the formulation and packaging areas.

Personal breathing zone air samples collected during the January 1982 survey showed 8-hour time weighted average (TWA) concentrations of Counter® ranging from 0.024 to 0.173 milligrams per cubic meter of air (mg/M³), with a mean of 0.085 mg/M³. Analysis of wipe samples revealed no Counter® contamination in samples collected in the lunchroom or the locker rooms. Results of the survey of December 1982, showed 8-hour TWA concentrations of Counter® ranging from 0.017 to 0.133 mg/M³, with a mean of 0.084 mg/M³. Concentrations of Counter® were highest for the sealing line employees (average: 0.116 mg/M³), followed by the formulator (average: 0.084 mg/M³), and lowest for the stackers (average - 0.024 mg/M³). The measured airborne concentrations for sealing line employees represent "potential exposures". Since respirators were utilized the "actual exposures" would be expected to be significantly lower. Currently, there is no federal standard for occupational exposure to Counter®. However, the manufacturer recommends an 8-hour TWA of 0.05 mg/M³. Since Thimet® possesses similar toxicological properties and is formulated and packaged using the same machinery as Counter®, similar occupational exposures would be expected for this substance.

Review of the company medical monitoring records indicated one instance where an employee's RBC ChE levels had fallen below 70% of the baseline level. Review of the medical questionnaires indicated two of nine employees reported work related health problems. One employee reported dermatitis, and one employee complained of occasional headaches.

On the basis of the data obtained in this investigation, NIOSH has determined that a potential health hazard from exposures to Counter® existed at the time of this survey. Recommendations related to this evaluation are included in the full body of the report.

Key Words: SIC 2879, Counter® (Terbufos), Thimet® (Phorate), organophosphate, pesticides, pesticide-formulation, pesticide-packaging.
II. INTRODUCTION

On September 21, 1981, a representative of the Hopkins Agricultural Chemical Company, Atlanta, Illinois, requested a NIOSH health hazard evaluation to assess employee exposures during formulation and packaging of organophosphate pesticides. A previous evaluation of the facility had been conducted by NIOSH (HE 78-113-589), during which no environmental exposures above the recommended evaluation criteria were found.

On December 1, 1981, NIOSH investigators conducted an initial survey of the facility. This included an opening conference, followed by a walk-through inspection of the areas of concern. On January 12, 1981, an environmental survey was conducted during which personal breathing zone air samples and wipe samples were collected. On March 31, 1982, the results of the samples, along with preliminary recommendations for reducing exposures, were transmitted by letter to the requestor.

Following a seasonal delay in production operations, a follow-up environmental survey was conducted on November 30, 1982, during which personal and general area air samples were collected. In addition, medical records were collected and confidential employee interviews were conducted. On March 7, 1983, the results of the environmental samples were transmitted by letter to the requestor.

III. BACKGROUND

A. General Information/Process Description

The facility formulates and packages the organophosphate pesticides Counter® (Terbufos) and Thimet® (Phorate). Both of these materials are alternately produced, utilizing the same workforce and machinery. Production is seasonal, usually beginning in the fall and lasting until early spring. Production occurs one work-shift per day and utilizes 7 employees; one formulator, three sealing line operators, and three bag stackers. An additional formulator works on a second shift to prepare material for the next day.

During formulation, a technical grade of the organophosphate (86 - 89% Counter®, or 84.5% Thimet®) is piped in from storage tanks and sprayed onto inert clay in a rotary mixing drum. Following mixing, the insecticide is screened for size and then transferred to a hopper. The entire mixing operation takes place in an enclosed room equipped with its own ventilation system. Access to this room is restricted. The formulator, located in an adjacent control room above the operation, is responsible for operating the controls for the machinery used in this process.

The sealing line is located in a large area behind the formulation room. At this location, the insecticide is dispensed from the hopper into 20 and 50 pound bags. The bags proceed by conveyor through an automatic sealer and are then transported to the shipping area. One employee, located next to the hopper, positions the empty bags onto the line for filling. A second employee, located approximately five feet
away from the operation, replenishes the supply of bags and occasionally removes unsealed bags from the line in order to obtain samples for quality control testing. A third employee, located approximately ten feet down the packaging line, insures that the bags are properly sealed before leaving the area. The three employees who work at this line periodically rotate among the various work stations. Engineering controls include enclosures and local exhaust ventilation at the dispensing area and at various points along the sealing line. In addition to the standard personal protective clothing and equipment required in the plant, workers at the sealing line are required to wear NIOSH/MSHA approved pesticide respirators.

Following sealing, the bags are transported by conveyor to the adjacent warehouse area. Here the bags are stacked on pallets and wrapped in a transparent plastic. A forklift is used to move the pallets to the appropriate storage area within the warehouse. Three employees are utilized for stacking and wrapping operations.

B. Company Program for Exposure Control and Medical Monitoring

The company has many detailed policies and procedures in effect that are designed to limit employee exposures to the substances used in the plant. Some key elements of this program are as follows:

Separate change rooms are provided and required to be utilized by the employees when entering and leaving the plant. Personal clothing is stored in a "clean" locker room. This is connected by a shower room to the "contaminated" locker room where work clothing is stored. Employees are required to use the showers at the end of each work shift.

Personal protective equipment is provided for the employees engaged in the formulation and packaging operations. Required work clothing consists of coveralls, protective gloves, rubber shoe covers, and hard hats. All work clothing is laundered daily. A respirator program, meeting OSHA requirements, is in place for those employees at the sealing line and other areas of the plant as appropriate. Qualitative respirator fit testing is conducted using irritant smoke and isoamyl acetate. Respirators are cleaned daily by an employee trained in respirator maintenance and care.

A medical monitoring program has been put in place for all plant personnel. Baseline red blood cell and plasma cholinesterase levels are initially established, and monitoring of these levels is conducted weekly for each employee involved in pesticide formulation and packaging operations. All results are immediately reviewed by a physician, transmitted to the plant management, and the worker is notified of the results and any significant changes in these levels.

Measurements of the local exhaust ventilation at the bagger and sealing line is conducted daily. Inspections of general housekeeping are conducted regularly and any deficiencies are noted and remedied. Areas where personal protective equipment is necessary are clearly posted. Eye wash and emergency shower facilities are present in close proximity to the formulation and packaging areas. Monthly safety meetings are conducted, with additional meetings held when any process change occurs.
IV. MATERIALS AND METHODS

A. Environmental

Records of two inspections conducted by the Occupational Safety and Health Administration (OSHA) and the previous NIOSH health hazard evaluation report were reviewed. Both OSHA inspections were in response to incidents of organophosphate poisoning during nonroutine maintenance activities. Although no air samples were collected, wipe samples obtained during one inspection did indicate some Counter® contamination in the lunchroom area. The previous NIOSH evaluation revealed no concentrations of Counter®, total particulate, respirable particulate, or respirable free silica in excess of the recommended environmental criteria.

In order to measure the current exposures of personnel involved in the production operations, an environmental survey was conducted by NIOSH personnel on January 12, 1982, during which Counter® was being formulated and packaged. Air samples were collected near the breathing zone of the employees using battery-powered sampling pumps operating at approximately 200 cubic centimeters of air per minute (cc/min). The pumps were attached via Tygon® tubing to a collection media consisting of a glass fiber filter followed in-line by a chromosorb tube. The location, duration, and other information pertinent to sample collection is provided in Table 1. In addition, in order to assess the presence of Counter® contamination wipe samples were collected in the lunchroom, in the "clean" and "contaminated" change rooms, and at the sealing line using Whatman® smear tabs. All samples were desorbed with acetonitrile and analyzed with a gas chromatograph equipped with a flame photometric detector operated with a phosphorus filter.

Following the initial environmental survey, the local exhaust ventilation system at the sealing line was cleaned and inspected in order to increase collection efficiency. Upon resumption of operations, a follow-up environmental survey was conducted by NIOSH investigators on November 30 and December 1, 1982, in order to determine if exposures had effectively been reduced by this action. During this survey, personal breathing zone and area air samples were collected and analyzed in the manner utilized for the previous survey. Information pertinent to sample collection is presented in Table 1.

Due to similarities in toxicity and evaluation criteria (see section V), no samples were collected for Thimet®. Since this material is produced using the same equipment and in the same manner as Counter®, it was assumed that the exposure data for Counter® would reflect exposures to Thimet®.

B. Medical

Company records of blood cholinesterase monitoring were obtained for each of the employees at the Counter® formulation and packaging operations. In addition, confidential medical questionnaires were administered to the employees in the area. Information was solicited regarding the employees work history and the presence of any general or work related health problems.
C. Review of Exposure Controls

A review was conducted to determine the effectiveness of procedures and practices in the following areas: medical surveillance, engineering controls, work practices, labeling and posting, personal protective clothing and equipment, sanitation and personal hygiene, and monitoring and record keeping.

V. EVALUATION CRITERIA

A. Toxicology

1. General Toxicity of Organophosphates

The organophosphate (OP) pesticides are characterized by the similarity of their mechanism of toxic action, but may differ in their inherent toxicity, and to some extent, their rate of absorption and excretion. The primary hazard of these substances results from their interference with the action of the cholinesterase (ChE) group of enzymes, specifically their inhibitory effect on acetylcholinesterase (AChE) which is responsible for the breakdown of acetylcholine (ACh). Acetylcholine acts as a chemical mediator which transmits impulses between the nerves of the nervous system (the cholinergic nerve synapses) resulting in the stimulation of various target organs throughout the body (e.g., muscles, glands). After performing its function, ACh is destroyed rapidly by AChE. If the AChE is prohibited from acting, as in the case of OP inhibition, the result is an accumulation of ACh. This results in excessive stimulation, and subsequently decreased transmission with widespread disruption of nerve function.

The signs and symptoms of OP poisoning become apparent when a critically low concentration of ACh is reached at the nerve synapses, usually the result of a single high exposure. Due to their rapid metabolism and excretion, accumulation of organophosphates does not occur. However, small repeated exposures can result in progressive inhibition of cholinesterase, resulting in symptoms similar to those produced by a single high dose.

The symptoms of OP poisoning can be divided into three major groups; mild, moderate, and severe. Mild poisoning causes symptoms of headache, fatigue, dizziness, blurred vision, excessive sweating, nausea and vomiting, stomach cramps, diarrhea, and salivation. Moderately severe poisoning causes all of the symptoms found in mild poisoning, but in addition, the patient is unable to walk, often complains of chest discomfort and tightness, exhibits marked miosis (constriction of the pupils), and exhibits muscle twitching. Severe OP poisoning may result in rapid onset of unconsciousness, local or generalized seizures, and other manifestations of a cholinergic crisis.

Presently, no method exists for the determination of ChE levels in the nervous system of a living subject. However, the activity of ChE present in red blood cells has been found to be similar to the activity
of ChE present in the nervous system following organophosphate exposure. Therefore, a measurement of red blood cell (RBC) cholinesterase activity provides a valuable means for assessing the degree of AChE inhibition.2

Information regarding other non-ChE related effects of organophosphate compounds is very limited. Degeneration of the axons and myelin sheath of the nervous system has been reported from prolonged exposure to some compounds. Some reports of chronic depression associated with behavioral changes has been reported, however, this has not been confirmed through controlled scientific studies.3

2. Specific Toxicity of Thimet® and Counter®

Thimet® (Phorate) is a highly toxic material which is readily absorbed through skin contact, inhalation, and ingestion. The acute oral lethal dose for 50% of a population (LD₅₀) in male rats is 2.3 milligrams of substance per kilograms of body weight (mg/kg). The dermal LD₅₀ for male rats is 6.2 mg/kg, and for females 2.5 mg/kg. Animal data from inhalation studies indicates the no-effect dose for man would be approximately between 0.1 or 0.03 mg/kg/day.5

Counter® (Terbufos) is also readily absorbed into the body by all routes. The acute LD₅₀ in male rats is 3.5 mg/kg, and 1.15 mg/kg for females. The dermal LD₅₀ for rabbits is 1.0 mg/kg.2

B. Environmental Criteria

As a guide to the evaluation of the hazards posed by workplace exposures, NIOSH field staff employ environmental evaluation criteria for assessment of a number of chemical and physical agents. These criteria are intended to suggest levels of exposure to which most workers may be exposed up to 10 hours per day, 40 hours per week for a working lifetime without experiencing adverse health effects. It is, however, important to note that not all workers will be protected from adverse health effects if their exposures are maintained below these levels. A small percentage may experience adverse health effects because of individual susceptibility, a pre-existing medical condition, and/or a hypersensitivity (allergy).

In addition, some hazardous substances may act in combination with other workplace exposures, the general environment, or with medications or personal habits of the worker to produce health effects even if the occupational exposures are controlled at the level set by the evaluation criterion. These combined effects are often not considered in the evaluation criteria. Also, substances such as organophosphate pesticides are absorbed by direct contact with the skin and mucous membranes, and thus potentially increase the overall exposure. Finally, evaluation criteria may change over the years as new information on the toxic effects of an agent becomes available.

The primary sources of environmental evaluation criteria for the workplace are: 1) NIOSH Criteria Documents and recommendations, 2) the
American Conference of Governmental Industrial Hygienists' (ACGIH) Threshold Limit Values (TLV's), and 3) the U.S. Department of Labor (OSHA) occupational health standards. Often, the NIOSH recommendations and ACGIH TLV's are lower than the corresponding OSHA standards. Both NIOSH recommendations and ACGIH TLV's usually are based on more recent information than are the OSHA standards. The OSHA standards also may be required to take into account the feasibility of controlling exposures in various industries where the agents are used; the NIOSH-recommended standards, by contrast, are based solely on concerns relating to the prevention of occupational disease. In evaluating the exposure levels and the recommendations for reducing these levels found in this report, it should be noted that industry is legally required to meet only those levels specified by an OSHA standard.

A time-weighted average (TWA) exposure refers to the average airborne concentration of a substance during a normal 8- to 10-hour workday. Some substances have recommended short-term exposure limits or ceiling values which are intended to supplement the TWA where there are recognized toxic effects from high short-term exposures.

The OSHA standard for Phorate (Thimet®) is 0.05 mg/M3 as an 8-hour TWA. Presently, no environmental criteria for Counter® has been established by the previously mentioned groups. However, the American Cyanamid Company has recommended exposure be limited to 0.05 mg/M3 as an 8-hour TWA.

It should be noted that environmental criteria exist for only a small number of the over 1,500 pesticides. In addition, adherence to environmental limits does not always adequately protect the employee from significant dermal exposure. Therefore, in addition to compliance with established environmental limits, NIOSH recommends that emphasis be placed on work practices, engineering controls, employer and employee education, and medical surveillance in order to fully protect workers from the adverse effects of pesticide exposure in manufacturing and formulating operations. A complete listing of these recommendations is contained in the NIOSH Criteria for a Recommended Standard... Occupational Exposure During the Manufacture and Formulation of Pesticides.

C. Medical Criteria

Unacceptable exposure to ChE inhibitors is demonstrated when the activity of the RBC ChE is decreased to below 70% of the baseline. (A baseline 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.) In such instances, the employee shall be advised of the findings, and an industrial hygiene survey shall be conducted in the workplace of the affected employee unless the cause of the exposure is known and corrective action has been initiated. This survey shall include an assessment of the dermal exposure potential. Based on the results of this survey, necessary corrective action shall be accomplished.
In addition, an employee whose RBC ChE activity is decreased to below 60% of the employee's baseline level shall be removed from potential exposure and placed under medical observation. An employee who has been removed from pesticide exposure shall not be allowed to return to work involving occupational pesticide exposure until his RBC ChE activity has returned to at least 75% of the working or preexposure baseline values or unless the responsible physician has approved his return. The NIOSH criteria document should be consulted for a complete listing of the medical surveillance recommendations.

VI. RESULTS

A. Environmental

Personal breathing zone air samples collected during the initial environmental survey showed 8-hour TWA concentrations of Counter® ranging from 0.024 to 0.173 mg/M³, with a mean of 0.085 mg/M³. During the follow-up environmental survey, 8-hour TWA concentrations of Counter® ranged from 0.017 to 0.133 mg/M³, with a mean of 0.084 mg/M³. Concentrations of Counter® were highest for the sealing line employees (average: 0.116 mg/M³), followed by the formulator (average: 0.047 mg/M³), and lowest for the stackers (average: 0.024 mg/M³). However, the measured concentrations for sealing line employees represent "potential exposures". Since respirators were utilized the "actual exposures" would be expected to be significantly lower. A complete listing of the environmental results is provided in Tables 1 and 2.

Analysis of the wipe samples indicated the presence of Counter® only in the sample collected on the packaging line. No Counter® was detected in the wipe samples collected in the lunchroom, or the "clean" or "contaminated" locker rooms. The limit of detection was 0.02 micrograms per sample.

B. Medical

Review of the 1982 company medical monitoring records of employees engaged in the formulation and packaging operations indicated RBC ChE levels in only one employee had fallen below 70% of the baseline level. A follow-up by the company revealed the employee was taking a medication at that time, which may have affected this value. All other values were above 70% of the baseline level.

Review of the medical questionnaires indicated two of nine employees with potentially work related health problems. One employee complained of an allergic type skin problem, and one employee complained of occasional headaches.

VII. DISCUSSION AND CONCLUSIONS

The results of the environmental surveys indicate that airborne concentrations of Counter® were found to be in excess of the...
manufacturer’s recommendation at the sealing line, and in the formulating control room. As previously noted, the actual exposures for the sealing line personnel would be expected to be substantially lower due to the use of respirators. NIOSH policy is that respirators should be used as a means of protecting the worker for the period of time required for the development, installation, testing, maintenance, or repair of required engineering controls, or during periods of emergencies, maintenance, repair, or cleanup of spills etc. The company indicated that it is also their policy to reduce exposures below the recommended criteria using engineering controls, and to use respirators as a backup to further ensure worker safety.

Attempts by the company to improve the efficiency of the local exhaust ventilation system between the spring and fall of 1982 did reduce exposures (average sealer exposure: 0.16 mg/M³ before improvements, 0.10 mg/M³ after improvements); however, the airborne concentrations still remained in excess of the recommended criteria. At the time of the follow-up survey, the company indicated that plans were underway to further improve the efficiency of the local exhaust ventilation system at the sealing line. This change would be expected to further reduce the potential exposures.

Review of the records of the OSHA inspections indicated that there were two instances during which employees suffered severe organophosphate poisoning. Both instances were during non-routine maintenance operations, and not during Counter® or Thimet® production. Further incidents of this nature can only be avoided through a strict adherence to proper procedures regarding work practices and personal protective equipment.

The discrepancy in sample results between this evaluation and the previous NIOSH evaluation appear to be due largely to the difference in sampling methodology used in the two studies. The previous NIOSH evaluation utilized only a membrane filter for the collection media, while this evaluation utilized a media consisting of a filter followed by a sorbent tube. Since a substantial portion of the organophosphate was collected as a vapor, the results of this evaluation indicated higher contaminant levels.

VIII. RECOMMENDATIONS

In order to further reduce exposures to Counter® and Thimet® in formulation and packaging operations, the following recommendations are made:

1. The company should proceed with plans to increase the efficiency of the local exhaust ventilation system at the packaging line. Following these changes, an industrial hygiene survey should be conducted to determine the effectiveness of these modifications.

2. The check-weighing procedure currently used by the company appears to further contribute to the exposure of employees during sealing operations. This procedure should be closely examined in order to
determine if the addition of local exhaust ventilation or a modification of work practices might reduce this potential exposure.

3. Steps should be taken to reduce contaminant concentration in the formulation control room. Although this room is physically separated from the room in which actual formulation occurs, there appears to be substantial levels of organophosphate entering the control room environment.

4. The company has been supplied with copies of the recommendations contained in the NIOSH criteria document on formulation and packaging of organophosphate pesticides. Periodic reviews of plant operations should be conducted to ensure that all areas of these recommendations are being adhered to.

5. During non-routine maintenance operations, a supervisor should initially, and thereafter periodically, review the operational procedure, personal protective equipment and work practices of the employees to ensure that exposures are minimized as much as possible.

IX. REFERENCES


X. AUTHORSHIP AND ACKNOWLEDGEMENTS

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XI. DISTRIBUTION AND AVAILABILITY OF DETERMINATION REPORT

Copies of this Determination Report are currently available upon request from NIOSH, Division of Standards Development and Technology Transfer, Information Resources and Dissemination Section, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After 90 days the report will be available through the National Technical Information Services (NTIS), Springfield, Virginia. Information regarding its availability through NTIS can be obtained from NIOSH publications office at the Cincinnati address.
Copies of this report have been sent to the following:

1. Hopkins Agricultural Chemical Company
2. International Chemical Workers Union
3. U.S. Department of Labor, OSHA - Region V
4. NIOSH Regional Offices/Divisions

For the purposes of informing the affected employees, copies of the report should be posted in a prominent place accessible to the employees, for a period of 30 calendar days.
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Evaluation Criteria - 0.05 mg/M³ as recommended by American Cyanamid.

Abbreviations: TWA - Time weighted average
mg/M³ - Milligrams of contaminant per cubic meter of air
< LOD - Less than the limit of detection: 0.2 micrograms per sample for samples collected 1/12, and 0.05 micrograms per samples for samples collected 11/30 and 12/01.

† Designates area sample; all other samples are personal breathing zone air samples

*Formula for calculating estimated 8-Hour time weighted average:

\[
8\text{-Hour TWA} = \frac{\text{Concentration} \times \text{Exposed Time (430 minutes)}}{\text{Total Time (480 minutes)}}
\]

where: 430 minutes is the estimated exposure time (excluding change time & breaks).
480 minutes is the length of the daily work shift (excluding lunch break).