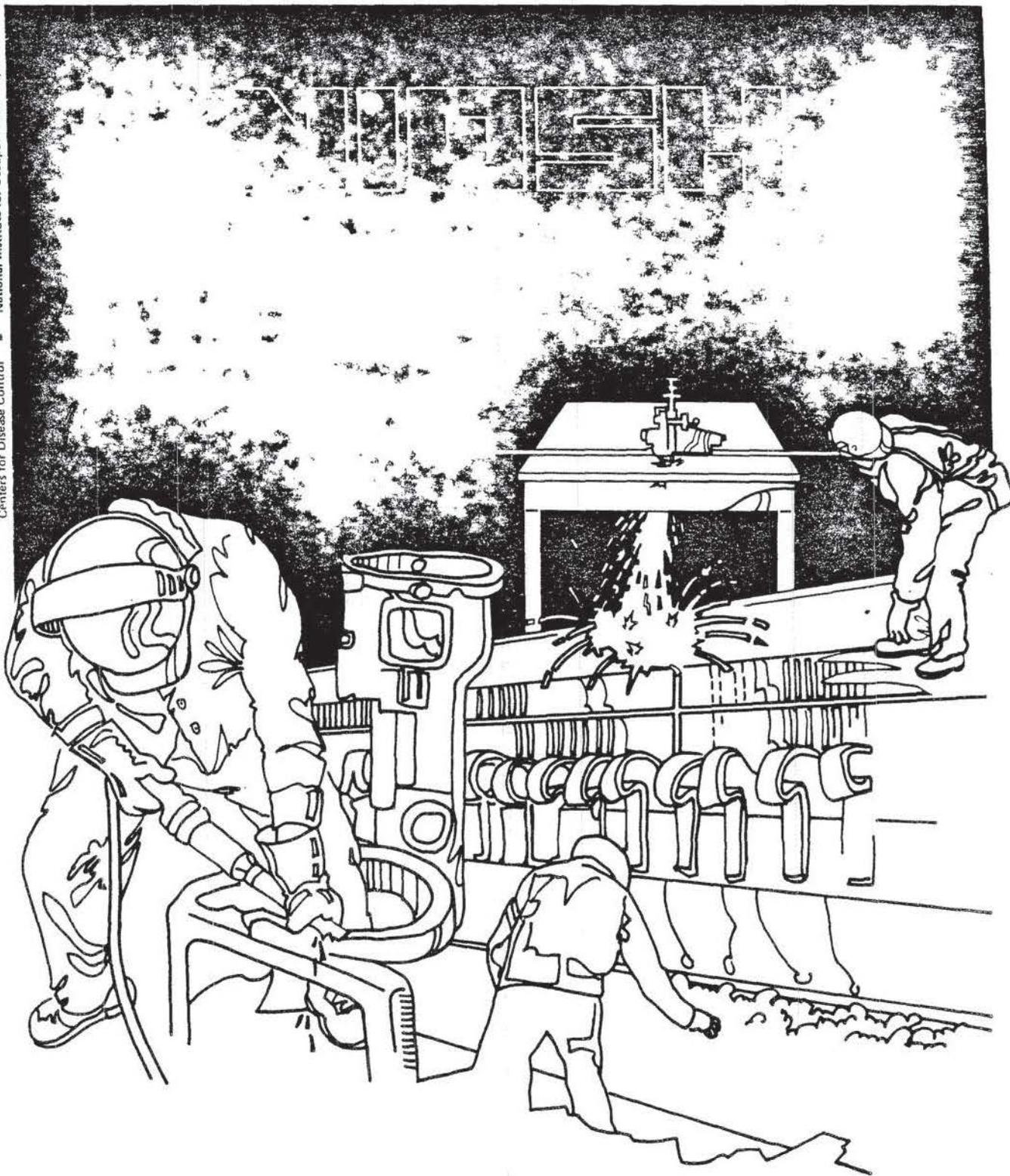


U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ■ Public Health Service
Centers for Disease Control ■ National Institute for Occupational Safety and Health



Health Hazard Evaluation Report

80-065-780

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. 699(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.

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

I. SUMMARY

A health hazard evaluation was conducted by the National Institute for Occupational Safety and Health (NIOSH) at Clorox Company in Jersey City, New Jersey, on April 29-30 and May 29-30, 1980. The investigation evaluated reported skin rashes, muscle cramps of upper and lower extremities, excessive fatigue, acute onset of shortness of breath on entry into the work area, nose bleeds and conjunctivitis believed related to exposure to proteolytic bacterial enzymes (Esperase 4.0M) during the manufacture of the laundry detergent Clorox 2.

Air samples for total dust and proteolytic enzymes were taken using a high-volume sampler and high efficiency glass fiber filter. Particle size-mass distributions were determined with a cascade impactor. None of the 15 high-volume area samples exceeded the 3.9 ug/M³ ACGIH TLV for enzyme-dust (range 0.002 - 1.57 ug/M³; mean 0.57; SD± 0.54), or the 1.0 mg/M³ total dust level (range 0.17 - 0.87 ug/M³; mean 0.40; SD± 0.20) utilized by Clorox Company as an engineering design criterion for dusts containing proteolytic enzymes. The particle size-mass distributions indicate that approximately 50% of the total dust is in the respirable range (mass median diameter of 4.4 µm); insufficient dust was collected on the impaction plates for enzyme analysis. Personal breathing zone exposures to total dust were determined using low volume samplers. Thirteen percent (6/45) of the samples exceeded the 1.0 mg/M³ total dust design specification (range 0.19 - 3.7 ug/M³; mean 0.74; SD± 0.74).

The medical evaluation involved 24 employees: 13 regularly exposed to the enzyme-detergent dusts, two previously exposed and nine not exposed. These workers were evaluated by questionnaire, physical examination, pulmonary function tests, and a radioallergosorbent test (RAST). The prevalence of upper and lower respiratory tract symptoms, skin rash or postshift wheezes on physical examination was not different between the exposed and nonexposed groups. Three of 12 exposed employees demonstrated evidence of sensitization to the enzyme as manifested by a positive RAST. None of the nonexposed workers had a positive RAST. All three of the employees with positive RAST were symptomatic or were noted to develop wheezes (on auscultation) after a work shift. Among the 13 exposed employees there was a significant fall in FEV₁ at the end of the work shift (p<0.05).

The data collected during this investigation show that immunologic sensitization to the bacterial enzymes in Clorox 2 is occurring among some workers exposed to the enzyme products. Exposure is associated with symptoms. This study suggests that the enzyme levels in the ambient air of the work environment are too high and should be reduced to prevent sensitization of further Clorox 2 employees. Recommendations for eliminating peak exposures, use of an enzyme-to-total dust relationship to estimate enzyme levels in personal samples, and establishing an effective environmental and medical surveillance program are presented in Part IX of this report.

KEYWORDS: SIC 2840 (Soap, Detergents, and Cleaning Preparations)
detergent enzymes, proteolytic enzymes, Esperase 4.0M, sensitization.

II. INTRODUCTION

Under the Occupational Safety and Health Act of 1970, the National Institute for Occupational Safety and Health (NIOSH) is authorized to investigate toxic effects of substances found in the workplace. On February 5, 1980, NIOSH received a request for a health hazard evaluation from an authorized representative of Local 8-406, Oil, Chemical and Atomic Workers International Union (OCAW). The request was made to evaluate the health status of workers exposed to the formulation of Clorox 2. The investigation specifically requested evaluation of skin, nasal and respiratory symptoms, conjunctivitis, fatigue, and muscle cramps in workers exposed to Clorox 2.

III. BACKGROUND

A. Operation

The Jersey City Facility of Clorox Company has been in operation since 1965. The company produces Clorox liquid bleach, Liquid Plumr, Formula 409, Twice-as-Fresh, and Clorox 2. There are currently 34 salaried and as many as 215 hourly employees. Clorox 2 has been produced at the facility since April 1972. The enzyme formulation was introduced in August 1978.

Some potential exposures identified in the Clorox 2 line include proteolytic bacterial enzyme, soda ash, sodium perborate, perfumes, whiteners, and bluing agents. The enzyme (Esperase 4.0M by Novo Industries, Inc.), is produced from a nonsubtilis species of Bacillus. There are approximately 15 exposed employees working two shifts. Each shift includes a blender operator, filler operator, line (filler-operator) mechanic, quality control technician, two general laborers, and a package inspector. During the process, the powder enzyme concentrate is received in a 1800 lb bag, which is suspended above an enzyme weigh hopper. The enzyme is dispensed to the enzyme weigh hopper by gravity and metered automatically to the force-feed assembly unit via a time-operated addition screw. The soda ash and sodium perborate are stored in silos on the roof and are added into the ready weigh hopper and force-feed assembly by gravity. The detergent-enzyme mixture is then pumped into the rotating blender where it is mixed with the trace additives (whiteners, brighteners, etc.). The detergent is then processed through a scalping screen to achieve the proper particle diameter. This is now the finished product in which the actual concentration of receipt enzyme is between 0.01% and 0.1%. The finished product is belt conveyed into the finished product hopper. The finished product hopper feeds lines which pack the detergent into cartons which are inspected, cased, and conveyed to a warehouse.

B. Exposure Controls

1. Dust Suppressed Enzyme

Chemical dust suppression is a technique which materially reduces the dustiness of the enzyme granule by adding sufficient mechanical strength to the granulate to eliminate or minimize fragmentation. The enzymes (as received from Novo Industries, Inc.) are "spheroidized" into pellets with an inner core consisting mainly of enzymes and inorganic salts. The enzymes are also encapsulated by a layer of "inert" ingredients which include lubricants, fillers, binders and enzyme stabilizers.

2. Ventilation

The blending area is ventilated both by dilution (design specification - 36 room air changes per hour) and local exhaust procedures. The particulate collected by local exhaust systems is filtered through a high efficiency bag collector equipped with automatic bag cleaning equipment. The filling-packaging area is ventilated by dilution ventilation (design specification - 19 room air changes per hour). The filling machine is also equipped with local exhaust ventilation. Both the blending and filling-packaging areas are equipped with outlets to a central vacuum system. The vacuum manifold extends the length of the Clorox 2 production line and has removable 2-inch diameter flexible access ducts. A supplementary portable dust collector is available for remote reclaim activity and to augment dust collection where needed.

IV. STUDY DESIGN AND METHODS

An initial walk-through orientation survey of the Clorox 2 line was conducted by NIOSH investigators on March 5-6, 1980. During the walk-through survey, information on the processes and the materials used in the plant was obtained. Preliminary health questionnaires were completed on 17 Clorox 2 line employees, and a preliminary assessment of symptoms determined. An initial environmental survey was conducted on April 29 and 30, 1980.

On May 29-30, 1980, a more complete medical and environmental evaluation was conducted.

A. Environmental

Air samples for total particulate and proteolytic enzyme-dust were taken with a conventional high volume sampler and high efficiency 8" x 10" glass fiber filter. The samplers were strategically positioned within the blending and filling areas at locations best situated to approximate employee exposure conditions. Samples were taken for 7.5 to 8 hours at a flow rate of 36 cubic feet per minute (cfm). The total dust concentrations were determined gravimetrically by obtaining a tare weight of the filter prior to sampling and reweighing to the nearest 0.0001 gm. The total dust levels are reported either as milligrams of total dust per cubic meter of air (mg/M^3) or micrograms of total dust per cubic meter of air (ug/M^3). The proteolytic enzyme content was determined using a modification of the N,N-dimethylcaesin method (1,2). Enzyme concentrations are reported as micrograms proteolytic activity per cubic meter of air (ug/M^3), based on Esperase 4.0M containing 2.6% pure crystalline proteolytic enzyme.

A cascade impactor (3) was used to prepare a particle size-mass distribution to determine the probable sites of particulate deposition in the respiratory tract. The sampler consists of a stack of 8 multi-hole jet plates stacked in order of diminishing hole diameters and interspersed with collecting plates. A 81-mm diameter, 0.8 μ m average pore size Metrice® filter is mounted on each plate. A vacuum pump draws the air sample through the holes in the jet plates at 1.0 cfm. The particle size distribution of the dust was obtained by weighing the powder collected on the plates after the sampling period. The impactor was positioned adjacent to the high volume sampler; sampling periods were the same.

Personal breathing zone exposures to total particulates were determined. The total particulates were collected on a 37-mm, 0.8 μ m average pore size polyvinyl chloride copolymer membrane filter contained in a three piece closed-face cassette. The sampler was attached to the workers shirt lapel at the breathing zone; air was pulled through the sampler by means of a personal vacuum pump operating at 2.0 liters per minute.

B. Medical

A total of 24 employees participated in the study. Thirteen employees currently working on the Clorox 2 line (referred to below as the "exposed" workers) were evaluated by: (1) questionnaire, (2) physical examination, including chest auscultation performed before and after work shifts), (3) pulmonary function tests (FVC, FEV₁, FEF₂₅₋₇₅, and FEV₁/FVC%) performed before and after a work shift using an Ohio-Medical dry rolling seal spirometer, and (4) serum tested for specific IgE antibodies to the Esperase bacterial enzyme using the radioallergosorbent test (RAST). The RAST was performed using methods previously reported (4-7).

Similarly evaluated were (1) two workers previously exposed to Clorox 2, neither of whom were removed from the line for medical reasons; and (2) nine volunteer "controls" from the shipping department who had no Clorox 2 exposure. The 11 employees, however, had no after-shift pulmonary function tests.

RASTs were performed by laboratory personnel who had no knowledge of exposures or symptoms.

The medical questionnaire sought to obtain information on (a) past medical problems prior to employment at Clorox Company, (b) atopic status of worker and family, and (c) present health status, including smoking history and symptoms related to eyes, nose, throat and lower respiratory tract and skin. Employees were asked whether they thought reported symptoms were work related.

The physical examination paid particular attention to the systems described above and concentrated on eyes, nose, throat, skin, and chest.

An employee was designated as having possible detergent enzyme-induced disease if he had a history of exposure to the detergent enzyme and one or more of the following conditions: (1) respiratory symptoms with onset in or after 1978, (2) evidence on physical examination of work-related abnormalities, e.g. wheezing arising postshift, or dermatitis, (3) abnormal pulmonary function tests, (4) positive RAST.

V. EVALUATION CRITERIA

A. Environmental

Table 1 below shows the Threshold Limit Value (TLV) proposed by the American Conference of Governmental Industrial Hygienists (ACGIH) based on 100% crystalline active pure enzyme (8) with the corresponding equivalent expression in terms of 2.6% crystalline active pure enzyme in Esperase 4.0M

Table 1
Equivalency of TLV

TLV Proposed by ACGIH	Esperase 4.0M Equivalent*
0.06 ug/M ³ as 100% Crystalline Active Pure Enzyme	3.9 ug/M ³ as 2.6% Crystalline Active Pure Enzyme

*See Appendix I for mathematics of the conversion.

B. Medical

A few years following the introduction of enzymes in detergents (in the 1960's), it was determined that detergent industry workers could be sensitized to the dust (6,7,9,10). The sensitization was manifested mainly by upper and lower respiratory symptoms, including an asthmatic syndrome characterized by wheezing developing several hours after leaving the plant (7).

For the purpose of this report, an employee is defined to be "sensitized" to the enzyme if his/her RAST (which measures specific IgE antibodies) is positive (considered as percent binding greater than twice the laboratory control values). An atopic individual is defined by questionnaire as one with a history of atopic disease or evidence of such disease in his immediate family. In this study, routine skin testing was not performed, and thus the prevalence of atopy may be under-or over-estimated.

Data analysis:

1. Pre- and postshift changes in pulmonary function tests among the exposed were compared using paired students t-test.
2. The prevalence of positive or negative RAST according to exposure groups was assessed by Fisher's exact test.
3. The prevalence of abnormal pulmonary function tests between the exposed and nonexposed were compared by Fisher's exact test.
4. Spirometry values were compared using pooled and paired t-tests for the following: (1) Exposed vs nonexposed, (2) symptomatic vs asymptomatic among the exposed, and (3) among the exposed, the pre- to-post-shift change in FEV₁ in the positive RAST individuals compared to workers with negative RASTs.

VI. RESULTS

A. Environmental

Table 2 shows the levels of proteolytic enzyme and total dust for the blending and filling operations. The enzyme results are reported in terms of Esperase containing approximately 2.6% proteolytic enzyme; the ACGIH TLV is stated in terms of 100% pure crystalline proteolytic enzyme. This means that the proposed TLV stated in terms of a 2.6% crystalline enzyme content is 3.9 ug/M^3 . Therefore, in terms of the data presented in Table 2, a concentration of 3.9 ug/M^3 or less would be within the proposed TLV. The average enzyme-dust levels determined over the 8-hour work shifts were 0.64 ug/M^3 ($n = 8$; $SD \pm 0.61$) for the blending area and 0.49 ug/M^3 ($n = 7$; $SD \pm 0.47$) for the filling area. The corresponding average total dust levels were 410 ug/M^3 ($n = 8$; $SD \pm 180$) and 380 ug/M^3 ($n = 7$; $SD \pm 240$), respectively. By comparison, the Clorox Company (as other enzyme detergent manufacturers) utilize a 1.0 mg/M^3 total dust level as a guideline for controlling workplace dust containing proteolytic enzymes.

Particle size distributions of airborne particulates in the blending and filling areas were determined aerodynamically using a cascade impactor (Tables 3 and 4, respectively). The mass median diameters and geometric standard deviations of the distributions as estimated from log-normal plots are shown in Figures 1 and 2, respectively. The particle size determinations indicate that the total dust particles were largely within the respirable range (i.e. $< 5 \text{ um}$) in both areas. Insufficient dust was collected on the samplers impaction plates for enzyme analysis. Although longer sampling times (> 8 -hours) might have provided reasonable quantities of dust for enzyme analysis, it may also have resulted in agglomeration of particles in lower plates (11). Thus, sampling periods greater than 8 hours were not conducted.

Table 5 summarizes the mean total dust concentrations by job classification. (The individual sample results by job classification are presented in Appendix II and III.) The relative dust concentrations by job classification are: Blender operator $>$ line mechanic $>$ package inspector $>$ filler operator $>$ laborer $>$ quality control technician. Although the exposures encountered by the latter four job classifications were relatively comparative (mean 0.57 mg/M^3 ; $SD \pm 0.06$), they differed significantly from those determined for the blender operators (mean 1.73 mg/M^3 ; $SD \pm 1.33$). This is not surprising based on the nature of the blender operator's job which requires continued handling of dry, powder materials.

B. Questionnaire and Physical Examinations

Demographic and health data of the 24 workers is shown in Table 6. Symptoms identified from the questionnaire and the results of physical examination are reported in Table 7. The symptoms are listed as the total positive for the specific symptoms, with the number arising 1978 or after in parenthesis. This date coincides with the introduction of enzymes into the plant. The prevalence of symptoms appears to be similar for both the exposed and nonexposed groups. The large proportion of smokers in each group (92% and 78%) may have contributed to the reported symptoms. On physical examination, no abnormalities of conjunctiva, nose or upper respiratory tract were found. Wheezing occurred postshift in two exposed workers (both smokers) and one nonexposed employee.

C. Radioallergosorbent Test (RAST)

Table 8 lists the results of the RAST by exposure category. The three positive results were all among the exposed:

filler operator/line mechanic	6.2 x control
blender operator	3.4 x control
filler operator	2.6 x control

The individuals with positive RAST were in job categories with three of four highest reported average total dust concentrations: filler operator, blender operator and line mechanic. Moreover, the latter two categories, the ones with highest dust levels, also had the highest percent binding. It is interesting, however, that the other line mechanic and blender operator had negative serological tests.

No positive RAST occurred among the nine nonexposed workers or the two exposed only in the past.

Table 9 lists those symptoms occurring since 1978 and RAST status in the exposed population. Of the three workers with positive RAST, two had onset of symptoms since 1978. The symptoms included eye and nose irritation; there was preexisting chest symptoms in one, and nose, throat and chest (cough, phlegm and wheeze) in the other. The third reported nasal symptoms prior to 1978. However, this individual developed wheezing on auscultation after work.

Two of the three individuals with positive RAST reported improvement of symptoms on weekends. One claimed the symptoms were not worse than during the first year they arose; the others described symptoms as the same or better.

Among the nine exposed workers with negative RAST, five reported onset of symptoms in 1978 or after; one of five developed wheezing postshift. One employee with a negative RAST had skin lesions (areas of thickening and hardening of skin on fingers and right hand) which began in February 1980; this could be compatible with a type of contact dermatitis.

No history could be ascertained in any workers of definite repeated lower respiratory symptoms (chest tightness, cough and breathlessness) on entry into the enzyme area.

D. RAST and Atopy (Table 10)

Of the three workers with positive RAST, two were designated as being atopic.

E. Chest Symptoms and Atopy (Table II)

Among 13 exposed workers, five of seven with chest symptoms were atopic; of six without chest symptoms, two were atopic.

F. Spirometry

1. Of the 13 exposed individuals, one employee was excluded because of entirely invalid tests (coughing during procedure). A second worker did not return for the postshift spirometry. Pre and postshift values for FVC, FEV₁, and FEF₂₅₋₇₅ with the percent predicted in parentheses is shown in Table 12 for 11 workers. As shown in Table 13, a fall in FVC and FEF₂₅₋₇₅, was noted but was not statistically significant. There was, however, with FEV₁, a mean decrease of 0.114 liters which was significant ($p < 0.05$).

2. Abnormal pulmonary function tests were defined as FEV₁/FVC less than 70% and FVC, FEV₁ or FEF₂₅₋₇₅ less than 80% of predicted.

(a) Symptomatic vs asymptomatic workers among the exposed workers.

Among five symptomatic individuals, four had normal pulmonary tests; of six asymptomatic workers, five were normal. These numbers are too small for analysis (nonsignificant by Fisher's exact test).

(b) Exposed vs nonexposed.

Among the twelve exposed, nine had normal pulmonary function tests, while among the 9 nonexposed, five were normal (nonsignificant by Fisher's exact test).

3. Comparison of Spirometry Values (Table 12)

(a) Symptomatic (chest symptoms) vs asymptomatic among exposed workers.

Mean percent predicted FVC in symptomatic workers (86.76) and in asymptomatic workers (98.40) were not significantly different ($t = 1.42$, $p > 0.05$).

Mean percent predicted FEV₁ in symptomatic workers (91.55) and in asymptomatic workers (101.58) were not significantly different ($t = 1.15$, $p > 0.05$).

(b) Exposed vs nonexposed.

For FVC, mean percent predicted for exposed (92.58) and for nonexposed (84.86) were not significantly different ($t = 0.25$, $p > 0.05$).

For FEV₁, mean percent predicted for exposed (96.55) and nonexposed (82.83) were not significantly different ($t = 1.62$, $p > 0.05$).

(c) Mean change in FEV₁ pre- to post shift.

Mean change in FEV₁ among positive RAST individuals (0.13 liters) was not significantly different than mean change FEV₁ among negative RAST individuals (0.094 liters) ($t = 0.0328$, $p > 0.05$).

G. RAST and Respiratory Impairment

Respiratory impairment is defined as for abnormal pulmonary function tests.

As shown in Table 14, only one of three workers with a positive RAST had normal pulmonary function tests; six of eight with negative RAST were normal. There may possibly be a trend toward an association between impairment of ventilatory function in presence of RAST (and atopy).

VII. DISCUSSION

Proteolytic enzymes have been added to laundry products, ostensibly because they can enhance protein-stain removal. Past studies (6,7,10,12,13) have shown that some factory workers exposed to the bacterial enzyme dust developed both upper and lower respiratory symptoms ranging from nasal stuffiness, rhinorrhea, lacrimation and throat irritation, to chest tightness, cough and breathlessness. Positive skin tests, presence of specific IgE antibodies and positive challenge tests point to an immunologic mechanism.

As determined by our health questionnaire, the frequency of respiratory symptoms was similar in the exposed and nonexposed workers. We could not, therefore, conclude that there is an excess prevalence of symptoms attributable to enzyme dust exposure. There were no reported episodes of shortness of breath with acute onset or overt wheezing, sometimes occurring after leaving work, as has been reported (7).

On the other hand, the number of abnormal pulmonary function tests appeared to be greater among exposed, although the samples are very small. When one looks for evidence of sensitization to the enzyme, we find three exposed workers showing elevated specific serum IgE antibody to the enzymes as shown by the RAST; of the three, two had symptoms with onset in 1978 or later and one developed wheezing postshift. Two of the three showed a drop in FVC and FEV₁ from pre to postshift (but less than 15%). It is not unusual for only a small percentage of workers exposed to allergen to become sensitized. Although it has been 10 years since the initial publications concerning sensitization to bacterial enzyme in detergent were first published and claims made that decreasing dust exposure levels would reduce health problems, there are still exposures of sufficient magnitude to cause sensitization. This situation exists despite the introduction of the new technology known as marumerization to reduce the dustiness of the enzyme-granulate. Although the concentrations of enzyme-dust measured on the Clorox 2 line are below the proposed ACGIH TLV, sensitization is occurring, indicating that the workplace levels are too high.

It is likely that peak exposure levels were not completely considered by our high-volume area sampling data, as indicated by the personal sampling data, which more accurately reflects a worker's actual breathing zone exposure. For example, the personal breathing zone exposures for the blender operators (mean 1.73 mg/M³ total dust; SD± 1.33) were significantly greater than the corresponding exposure concentrations determined by the high-volume area samples (mean 0.41 mg/M³ total dust; SD± 0.18). Thus, the enzyme-dust concentration determined by high-volume area samplers may be proportionately less than the actual exposure concentrations.

In this small population, the RAST was quite specific, with no false positive tests among nonexposed persons. The test was sufficiently sensitive to detect three of nine exposed individuals with symptoms. Conceivably, other symptomatic individuals are in the process of becoming sensitized, but their antibody levels remain below detection by the sensitivity of the tests. Skin (prick) tests to enzyme extracts could be performed (since they are more sensitive) for complete assessment.

As in other studies (5,13), the RAST was positive more frequently in atopic than nonatopic individuals. Unlike Pepys, et al. (13), we set positive results as twice controls, rather than choosing an arbitrary count level which separated the groups.

Pepys, et al., found an association between prevalence of positive RAST and amount of exposure. Our three positive cases all worked in jobs having the highest (or near highest) total dust.

Pepys, et al., also found an association between positive RAST and impaired respiratory function. This seemed true in this study to the limited extent described above. The latter, however, does not prove a causal relationship.

Three limitations of this study should be noted:

1. It was not possible to complete both preand post-shift pulmonary function tests on controls.
2. It is possible that some other component(s) of the Clorox 2 formulation can act as upper respiratory tract irritants in high concentrations. It should be emphasized, however, that in the low concentrations of total dust ($<1 \text{ mg/M}^3$) measured, sensitization (an immunologic mechanism, rather than irritation) is the likely mechanism.
3. End-of-shift chest auscultation was only performed on the exposed workers.

VIII. SUMMARY OF EVALUATION FINDINGS

A. Among the 12 exposed individuals with blood drawn, three had evidence of sensitization by positive RAST (specific IgE to enzyme) while none of the nonexposed were positive. All three positives had either symptoms that were likely occupational in origin or had wheezes postshift on auscultation.

B. There was a possible relationship between abnormal pulmonary function tests and positive RAST.

C. Among the exposed workers, there was a significant postshift drop in FEV_1 . No statistically significant differences in spirometry were noted between exposed vs unexposed individuals or symptomatic vs asymptomatic (among exposed) workers.

D. No excess prevalence of symptoms or of wheeze or rash on examination was found among workers exposed to the bacterial enzymes compared to those not exposed. No firm evidence for recurrent episodes of acute onset of breathlessness (i.e., asthma) was found.

E. None of the 15 high-volume area samples for enzyme-dust exceeded the 3.9 ug/M³ ACGIH TLV.

F. Thirteen percent (6/45) of the personal samples exceeded the 1.0 mg/M³ total dust engineering control specification utilized by Clorox Company. None of the 15 high-volume total dust samples exceeded this guideline.

IX. RECOMMENDATIONS

A. Environmental

1. Enzyme-dust concentrations should be reduced to levels as low as feasible to prevent sensitization of further Clorox 2 line employees. The incidence of sensitization depends upon the amounts of enzyme antigen in the work room, duration of exposure, and to some extent the susceptibility of the workers (11). When dust concentrations are high all persons, atopic and non-atopic, are at risk, though not all become sensitized. At low dust levels, atopic persons are more susceptible than non-atopics. Therefore, the possibility of sensitization is greater under increased or peak exposure conditions. Several sources of peak exposures were observed during our survey and corresponding exposure control recommendations follow:

- a. The blender operator must open the weigh hopper to determine the level of enzyme granulate in order to properly calibrate the timer that controls addition of the granulate. Exposure to enzyme granulate dust would be greatly minimized by establishing a definite negative pressure (in-flow of air) in the hopper.
- b. Re-current mechanical jams on the filling-packaging line causes the product to fall to the floor with resultant dust generation. The equipment should be adjusted to establish smooth product flow, and procedures instituted for immediate clean-up of the spilled product using the existing central vacuum system.
- c. Reclaiming of damaged product. Damaged cartons are thrown in buggies and taken to the central product reclaim area. The product is then either fed into an automatic reclaim device which cuts the carton and separates the product, or a worker manually cuts the carton and dumps the product into a ventilated reconditioning hopper for re-cycling to the finished-product hopper. If the worker dumps the material when a product is coming from the sweco filter to the finish hopper a concentrated back dusting occurs. This exposure could be eliminated by merely coordinating the product dumping and finished product transfer activities so that they don't occur simultaneously.

d. Entry of product blender. Although this procedure was not observed by NIOSH investigators maximum exposure control precautions should be established. Several recommendations are:

- i. Either a continuous flow air line respirator or an open-circuit self-contained breathing apparatus should be used.
- ii. Disposable coveralls should be taped at the wrists and neck to prevent the powder from getting beneath the coveralls. Disposable gloves also should be worn.
- iii. Upon completion of the activity the worker(s) should shower.

2. The personal vs high-volume area sampling data collected during our study suggest that the area samplers do not provide an accurate estimate of the workers actual exposures to total dust or enzyme-dust. The personal samples show the total dust concentrations to be significantly higher than those reported for the high-volume area samples. Personal samplers have long been advocated as the best means of determining the exposure levels of workers. In general, the inability of personal samples to ensure sufficient sample is collected for enzyme analysis has minimized their use in evaluating workplace exposures to proteolytic enzymes. Enzyme-dust concentrations determined in high-volume area samples, however, can be used to estimate the corresponding enzyme-dust level in personal total dust samples. Analysis of our data indicates that there is a relatively constant ratio between the enzyme-dust and total dust concentrations for the blending and filling areas. The respective ratios (based on the average concentrations - see Table 2) are 0.16 and 0.14. The concentration of enzyme in a personal total dust sample would be calculated by multiplying the personal breathing zone total dust concentration ($\mu\text{g}/\text{M}^3$) by the ratio factor (mean of 0.15 as determined by the data in Table 2). This hypothesis is based on limited data, and may or may not be verified by further environmental testing. If this relationship is supported by further testing it would better approximate the actual exposures to the proteolytic enzyme by Clorox 2 line employees.

3. The existing environmental surveillance programme should be continued or modified, if necessary, according to the aforementioned recommendation. This surveillance programme involves collection of a two-hour high-volume area sample in both the blending and filling-packaging areas twice per shift, daily. The total dust and enzyme-dust concentrations are determined for each sample. The following are offered with respect to a data reporting system.

- i. The individual results should be displayed graphically so that a deteriorating trend in performance of the engineering controls could be detected quickly.
- ii. Weekly and monthly summaries should be prepared and used to determine whether any trend exists in results - with respect to carton size, production rate or seasonal variations. These summaries could also be used as a source of data for comparison with medical history of Clorox 2 line employees.

4. Recommendations concerning modifications and repairs of the local exhaust ventilation system for the enzyme weigh hopper, sweco filter and blender were presented to Clorox and OCAW representatives at the March 6, 1980, closing conference.

5. According to several employees, the information made available to the workers at the time of the introduction of the enzymes was not clear. An "education" session apparently was held and the workers were told that they could possibly become allergic to the enzymes and an "asthmatic condition" could show up if sensitized to it. Some workers were unsure whether the enzymes were living organisms or not. It is recommended that the Clorox Company in cooperation with Novo Industries, Inc. and OCAW institute an education and training program for all Clorox 2 line employees. This program should include (as a minimum) background information on detergent enzymes and associated potential health effects, and emphasize the paramount importance of proper work practices and procedures to minimize exposure. The importance of very careful hygienic techniques should be highlighted.

B. Medical

1. Medical Management

a. Preemployment examination - this examination should include:

i. History and physical examination with attention to smoking history and evidence of atopic disease (eczema, dermatitis, hayfever, asthma). Skin tests to a battery of common allergens (or RAST to a battery of common allergens) could identify atopic individuals. Individuals with evidence of chronic respiratory disease or an atopic constitution should be kept under close medical supervision.

ii. Baseline PA chest X-rays and baseline pulmonary function tests using an approved spirometer to estimate FEV_{1.0}, FVC and FEF₂₅₋₇₅.

b. Periodic examination. Periodic medical examination, at least yearly (and more frequently on atopic individuals and those with chronic lung disease) should be performed on all Clorox 2 line employees to determine whether the occurrence of sensitization is effectively controlled and to ensure that other adverse effects are not occurring from the Clorox 2 formulation. This should include:

i. Examination by a physician for related skin, eye, nose, throat and respiratory symptoms and signs; preferably, there should be continuity of care with the same physician who is familiar with the situation and problem.

ii. Pulmonary function tests, including pre- and postshift assessment.

iii. RAST

2. Medical Management of Affected Employees

a. For symptomatic workers who have already become sensitized, the problem is more difficult. One does not want to disrupt their employment if at all possible. Currently, they are not unable to work. However, as previous investigators have suggested, sensitized individuals should be transferred to other jobs unless it is found possible to create "contamination-free working conditions," or kept under close medical supervision (10).

3. Other Medical Considerations

a. A system for rapid, thorough investigation of any "acute" episodes by medical personnel should be established.

b. To complete an immunologic assessment (i.e. to better define those individuals who are sensitized and those who are atopic) consideration should be given to skin (prick) testing for sensitization and passive cutaneous anaphylaxis in a monkey.

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XII. DISTRIBUTION AND AVAILABILITY OF DETERMINATION REPORT

Copies of this Determination Report are currently available, upon request, from NIOSH, Division of Technical Services, Information and Dissemination Section, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After ninety (90) days, the report will be available through the National Technical Information Service (NTIS), Springfield, Virginia 22161. Information regarding its availability through NTIS can be obtained from NIOSH, Publications Office at the Cincinnati, Ohio address.

Copies of this report have been sent to:

1. President, Local 8-406, Oil, Chemical and Atomic Worker International Union.
2. Occupational Physician, Oil, Chemical and Atomic Workers International Union.
3. Corporate Safety Director, The Clorox Company.
4. Director, Regulatory Affairs, Novo Industries, Inc.
5. U.S. Department - OSHA, Region II.
6. NIOSH, Region II.

For the purpose of informing the approximately 15 "affected employees" the employer shall promptly "post" for a period of 30 calendar days, the Determination Report in a prominent place(s) near where the exposed employees work.

APPENDIX I

Equivalency of the ACGIH TLV*

The bases for the different terms of expression for enzyme concentration are the percentage purity of an equivalent enzyme concentration and the specific proteolytic enzyme on which the percentage purity is based. Pure Esperase has an activity of 80 Anson Units per gram. One Anson Unit is equivalent to 3.25 Kilo Novo Proteolytic Units (KNPU). Application of the $0.06 \mu\text{g}/\text{M}^3$ ACGIH TLV* to Esperase results in a TLV for Esperase of:

$$0.06 \times 10^{-6} \text{ gm}/\text{M}^3 \times 80 \text{ Anson Units}/\text{gm} \times 3.25 \text{ KNPU}/\text{Anson Unit} \\ = 15.6 \times 10^{-6} \text{ KNPU}/\text{M}^3$$

However, based on the activity of the product (Esperase 4.0M equals 4.0 KNPU/gm) the $15.6 \times 10^{-6} \text{ gm}/\text{M}^3 = 3.9 \mu\text{g}/\text{M}^3$

*ACGIH TLV based on 100% crystalline active pure enzyme.

Appendix II

Personal Breathing Zone Exposures to Total Particulates

Clorox Company
Jersey City, New Jersey

April/May 1980

<u>Sample No. *</u>	<u>Job Classification</u>	<u>Sample Volume</u> <u>m³</u>	<u>Airborne Concentration</u> <u>mq/m³</u>
01	Blender Operator	0.70	1.77
02	" "	0.64	0.67
03	" "	0.71	0.68
04	" "	0.70	2.01
05	" "	0.83	3.69
06	" "	0.85	0.80
07	" "	0.75	3.71
08	" "	0.72	0.50
09	Line Mechanic	0.71	0.31
10	" "	0.68	1.28
11	" "	0.71	0.34
12	" "	0.81	0.42
13	" "	0.79	1.00
14	" "	0.76	0.49
15	Filler Operator	0.69	0.48
16	" "	0.68	0.34
17	" "	0.72	0.47
18	" "	0.70	0.34
19	" "	0.84	0.84
20	" "	0.86	0.55
21	" "	0.80	0.57
22	" "	0.88	0.75
<u>Environmental Criteria</u>			<u>1.0</u>

* Dates and shifts are not provided because they would identify the worker sampled.

Appendix III

Personal Breathing Zone Exposures to Total Particulates*

Clorox Company
Jersey City, New Jersey

April/May 1980

<u>Sample No.*</u>	<u>Job Classification</u>	<u>Sample Volume</u> <u>m³</u>	<u>Airborne Concentration</u> <u>mg/m³</u>
23	Packer Inspector	0.69	0.52
24	" "	0.49	0.20
25	" "	0.71	0.92
26	" "	0.71	0.63
27	" "	0.91	0.51
28	" "	0.83	0.59
29	" "	0.84	0.61
30	" "	0.86	0.67
31	Laborer	0.70	0.57
32	" "	0.66	0.45
33	" "	0.63	0.43
34	" "	0.70	0.44
35	" "	0.68	0.47
36	" "	0.83	0.22
37	" "	0.77	0.66
38	" "	0.78	0.78
39	" "	0.83	0.50
40	Quality Control	0.71	0.58
41	" "	0.67	0.19
42	" "	0.66	0.29
43	" "	0.68	0.49
44	" "	0.69	0.22
45	" "	0.71	0.42

Environmental Criteria

1.0

*Dates and shifts are not provided because they would identify the worker sampled.

Figure 1: Particle Size Distribution - Ending Area

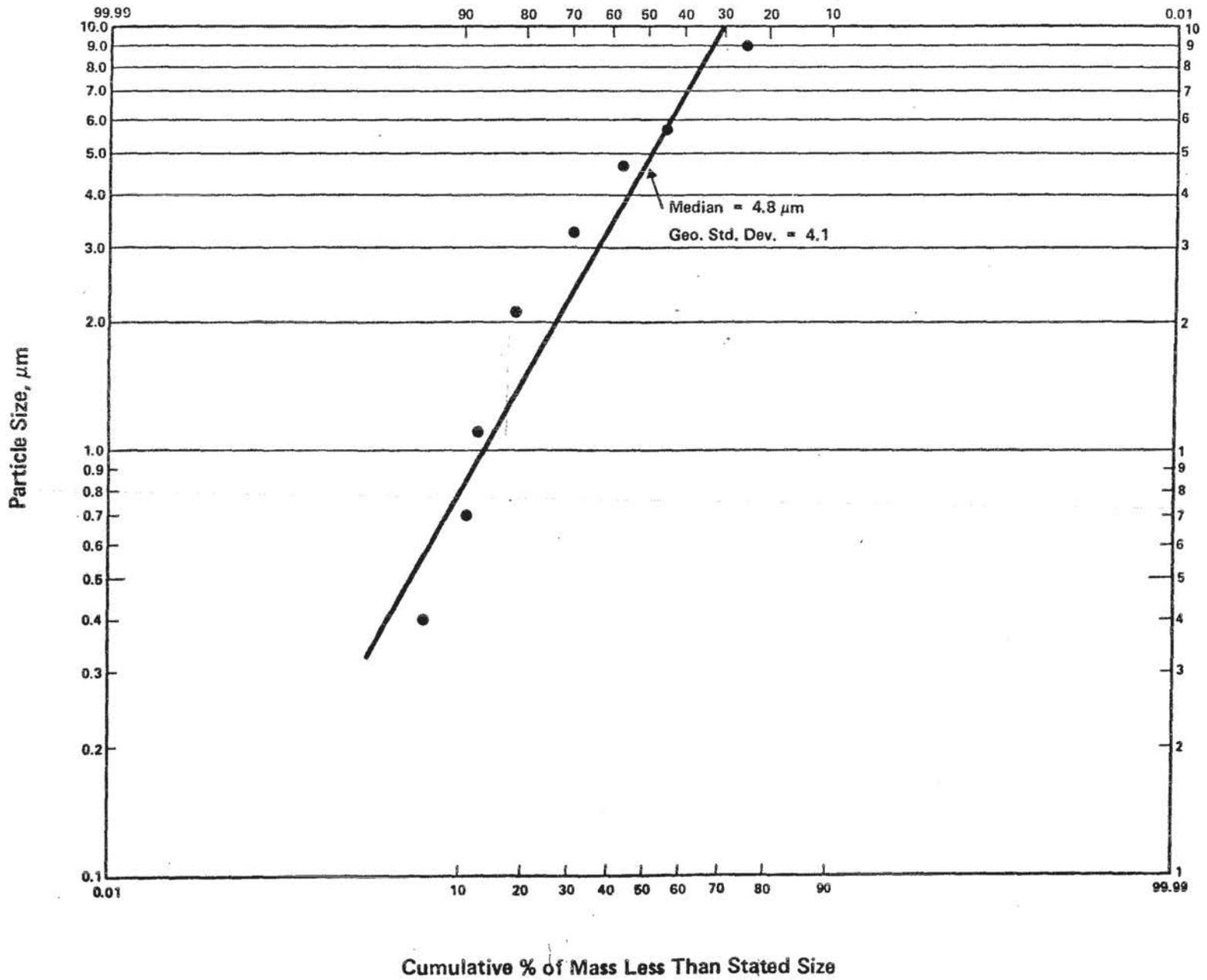


Figure 2: Particle Size Distribution - Filling Area

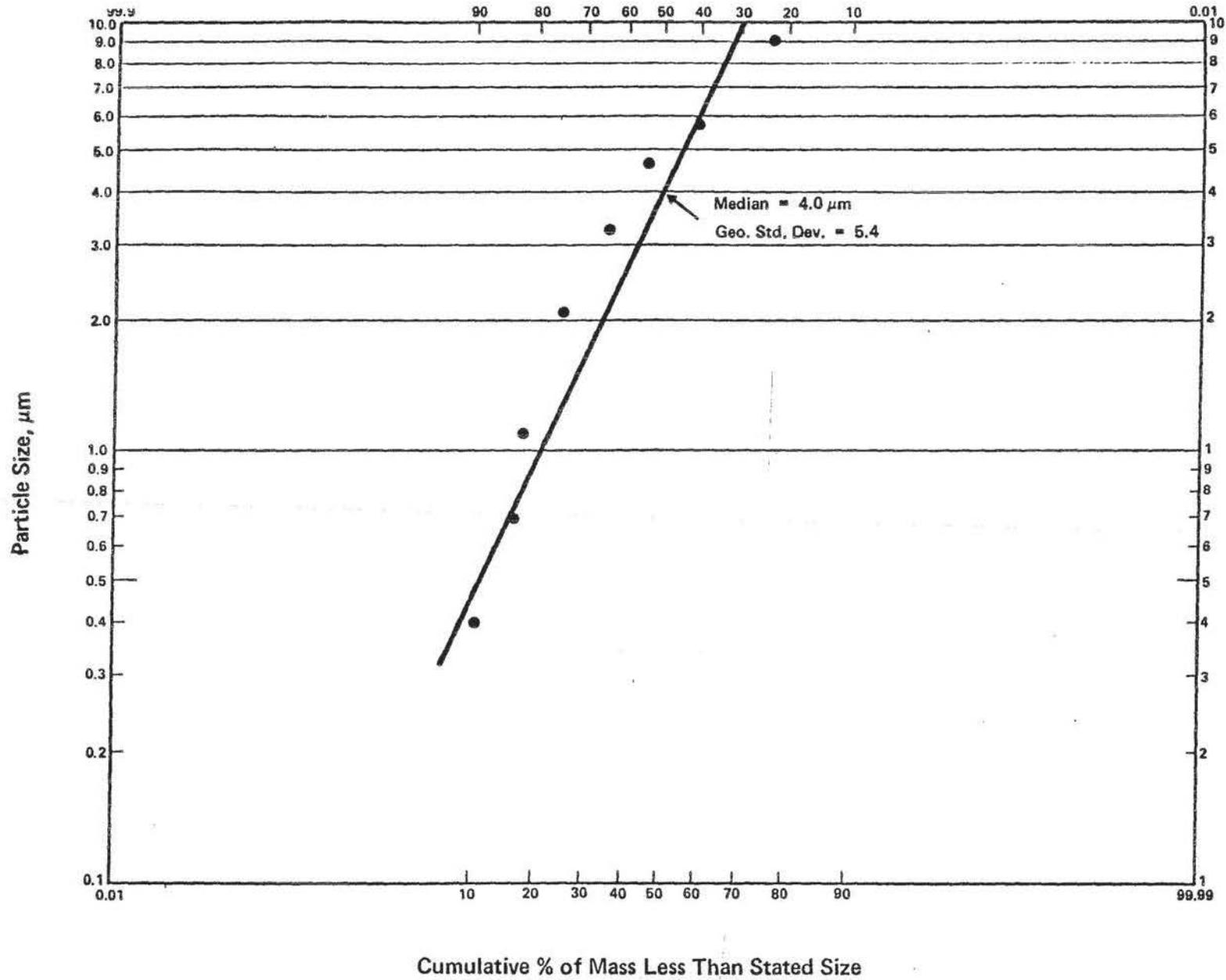


TABLE 2

Total Particulate and Enzyme - Dust Levels in the Blending and Filling Area

Clorox Company
Jersey City, New Jersey

April/May 1980

Date	Shift	Sampler Location	Sample Volume m ³	Airborne Concentration - $\mu\text{g}/\text{m}^3$			
				Total Particulate	Mean \pm SD	Enzyme-Dust*	Mean \pm SD
4-29	2nd	Blending Area	473	170		0.05	
4-30	1st	" "	495	570		1.03	
5-1	"	" "	511	500		0.83	
"	2nd	" "	483	200		ND**	
5-28	1st	" "	499	560		ND	
5-29	1st	" "	528	400		1.57	
"	2nd	" "	498	290		1.21	
5-30	1st	" "	473	620		0.41	
					410 \pm 180		0.64 \pm 0.61
4-30	1st	Filling Area	502	270		0.68	
5-1	"	" "	506	280		0.76	
"	2nd	" "	486	180		0.06	
5-28	"	" "	499	310		0.71	
5-29	1st	" "	529	870		1.21	
"	2nd	" "	488	240		ND	
5-30	1st	" "	470	490		ND	
					380 \pm 240		0.49 \pm 0.47
Environmental Criteria				1000		3.9	

*Micrograms of proteolytic activity per cubic meter of air, based on 80 Anson U/gm of Esperase Standard.

**None detected. Detection limit of 1 μg of enzyme per filter.

TABLE 3

Particle Size-Mass Distribution for Clorox 2 Particulate - Blender Area

Clorox Company
Jersey City, New Jersey
May 1980

<u>Stage</u>	<u>Particle Size Range (μm)</u>	<u>% Sample Mass in Size Range</u>	<u>Cumulative % of Sample Mass Less than Size Range</u>
0	9.0 - 10.0	23.6	76.7
1	5.8 - 9.0	16.9	59.8
2	4.7 - 5.8	11.8	48.0
3	3.3 - 4.7	12.1	35.9
4	2.1 - 3.3	11.1	24.8
5	1.1 - 2.1	7.4	17.4
6	0.7 - 1.1	1.5	15.9
7	0.4 - 0.7	5.7	10.2
Final	0.0 - 0.4	10.2	0.0

TABLE 4

Particle Size-Mass Distribution for Clorox 2 Particulate - Filling Area

Clorox Company
Jersey City, New Jersey
May 1980

<u>Stage</u>	<u>Particle Size Range (μm)</u>	<u>% Sample Mass in Size Range</u>	<u>Cumulative % Sample Mass Less Than Size Range</u>
0	9.0 - 10.0	25.5	75.5
1	5.8 - 9.0	19.4	56.1
2	4.7 - 5.8	12.4	43.7
3	3.3 - 4.7	13.4	30.3
4	2.1 - 3.3	11.5	18.8
5	1.1 - 2.1	6.7	12.1
6	0.7 - 1.1	1.4	10.7
7	0.4 - 0.7	4.3	6.4
Final	0.0 - 0.4	6.4	0.0

TABLE 5

Summary of Personal Breathing Zone Exposures to Total Particulates

Clorox Company
Jersey City, New Jersey

April/May 1980

<u>Job Classification</u>	<u>No. of Samples</u>	<u>Airborne Concentration - mg/M³</u>		
		<u>Mean</u>	<u>SD±</u>	<u>Range</u>
Blender Operator	8	1.73	1.33	0.50 - 3.71
Line Mechanic	6	0.64	0.40	0.31 - 1.28
Packer Inspector	8	0.58	0.20	0.20 - 0.92
Filler Operator	8	0.54	0.18	0.34 - 0.84
Laborer	9	0.50	0.16	0.22 - 0.78
Quality Control Technician	6	0.37	0.16	0.19 - 0.58
Environmental Criteria		1.0		

TABLE 6
 DEMOGRAPHIC AND HEALTH DATA
 CLOROX COMPANY
 JERSEY CITY, NEW JERSEY
 May 29-30, 1980

	Exposed	Exposed in Past	Nonexposed
N	13	2	9
M/F	9/4	1/1	6/3
Mean Age (yrs) range	37.5 21.56	38 27-49	38 25-54
Cigarette Smokers	12 (92%)	0	7 (77.8%)
Atopic Status	7 (54%)	1 (50%)	2 (22%)

TABLE 7

SYMPTOMS & SIGNS INCLUDING THOSE OCCURRING AS OF 1978

CLOROX COMPANY
JERSEY CITY, NEW JERSEY

May 29-30, 1980

Type of Exposure	N	SYMPTOMS REPORTED								PHYSICAL EXAMINATION					
		Eye/Nose	Throat	Chest (general)	Cough/Phlegm/Wheezing/		/Breath- /less- ness	Skin Rash in Past	Fatigue	Muscle Cramps	Loss of Weight	Wheeze	Skin Rash	Hyper-tension	
Exposed	13	7(5)	7(3)	7(5)	3	4	5	4	7	8	4	1	3*	3	1
Exposed in Past	2	0	0	0	0	0	0	0	1	1	1	1	0	0	0
Non-exposed	9	4(2)	5(3)	7(3)	5	6	7	5	3	2	2	1	1	1**	1

*2 postshift
**psoriasis

†Occurring after 1978 in parentheses

TABLE 8

ESPERASE PERCENT BINDING LEVELS

CLOROX COMPANY
JERSEY CITY, NEW JERSEY

May 29-30, 1980

GROUP	EMPLOYEE NUMBER	JOB TITLE	% BINDING	GROUP	EMPLOYEE NUMBER	JOB TITLE	% BINDING
Exposed Total 12 Positive RAST 3	1	Filler/ Operator/ Mechanic	8.0*	Exposed in past Total 2 Positive RAST 0 Non- exposed Total 9 Positive RAST 0	13		1.4
	2	Filler/ Operator/ Mechanic	1.2		14		1.3
	3	Laborer	1.0		15	Shipping	1.1
	4	Package Inspector	1.1		16	Shipping	1.1
	5	Filler/ Operator	3.4*		17	Shipping	1.3
	6	Filler/ Operator	0.8		18	Shipping	1.3
	7	Blender/ Operator	4.4*		19	Shipping	1.3
	8	Laborer	1.2		20	Shipping	1.0
	9	Laborer	1.1		21	Shipping	1.3
	10	Blender/ Operator	1.3		22	Shipping	0.6
	11	Quality Control	1.6		23	Shipping	1.1
	12	Quality Control	1.3				

*Significant Binding

Control #1 1.5

Control #2 1.1

TABLE 9

SYMPTOMS SINCE 1978 BY RAST AMONG EXPOSED

CLOROX COMPANY
JERSEY CITY, NEW JERSEY

May 29-30, 1980

RAST	NOSE	THROAT	CHEST (general)	COUGH/WHEEZE/S.O.B.			HISTORY OF RASH	PRESENT	WHEEZE OCCURRING POSTSHIFT
Positive N=3	2	1	1	1	1	0	2	0	1
Negative N=9	3	2	3	2	2	3	4	3	1

TABLE 10

RAST AND ATOPIC STATUS AMONG EXPOSED*

CLOROX COMPANY
JERSEY CITY, NEW JERSEY

May 29-30, 1980

	POSITIVE RAST	NEGATIVE RAST	N
Atopic	2	4	6
Nonatopic	1	5	6
Total	3	9	12

*Blood was not drawn on one exposed employee

TABLE 11

CHEST SYMPTOMS AND ATOPY AMONG EXPOSED WORKERS

	CHEST SYMPTOMS	NO. WITH CHEST SYMPTOMS	N
Atopic	5	2	7
Nonatopic	2	4	6
Total	7	6	13

TABLE 12

SPIROMETRY - CURRENTLY EXPOSED

CLOROX COMPANY
JERSEY CITY, NEW JERSEY

May 29-30, 1980

EMPLOYEE	SHIFT	JOB TITLE	FVC (% PRED)	FEV ₁ (% PRED)	FEF ₂₅₋₇₅ (% PRED)	FEV ₁ / FVC
1	Pre	Package Inspector	2.66 (91.16)	2.23 (98.08)	2.22 (83.29)	83.83
	Post		2.46 (84.30)	2.07 (91.04)	2.46 (92.43)	84.15
2	Pre	Laborer	4.81 (95.29)	3.96 (98.90)	4.81(111.50)	82.33
	Post		4.59 (90.93)	3.64 (90.91)	3.53 (81.84)	79.30
3	Pre	Laborer	4.73(125.76)	3.43(122.13)	2.63 (90.61)	72.52
	Post		4.58(121.77)	3.15(112.16)	2.54 (87.73)	68.78
4	Pre	Filler Operator Mechanic	4.52 (91.78)	3.76 (95.33)	4.52(104.82)	83.19
	Post		4.36 (88.53)	3.62 (91.78)	4.36(101.11)	83.03
5	Pre	Package Inspector	3.08 (79.50)	2.66 (87.44)	3.08 (89.77)	86.36
	Post		-	-	-	-
6	Pre	Blender Operator	4.65 (92.54)	4.63(113.70)	7.75(172.53)	99.57
	Post		4.78 (95.12)	4.62(113.46)	6.83(152.02)	96.65
7	Pre	Laborer	5.37 (91.17)	4.46 (95.06)	4.48 (90.37)	83.05
	Post		5.00 (84.89)	4.15 (88.45)	4.55 (91.79)	83.00
8	Pre	Quality Control	2.81 (92.19)	1.94 (83.24)	1.12 (43.06)	69.04
	Post		2.67 (87.60)	2.02 (86.67)	1.78 (68.19)	75.66
9	Pre	Filler Operator	3.86 (66.67)	3.07 (67.27)	3.22 (67.41)	79.53
	Post		3.52 (60.79)	2.76 (60.47)	2.71 (56.74)	78.41
10	Pre	Filler Operator (Mechanic)	5.95(110.86)	4.78(116.02)	4.25(100.47)	80.34
	Post		5.98(111.42)	4.71(114.32)	4.27(100.98)	78.76
11	Pre	Quality Control	2.44 (76.54)	2.04 (85.39)	3.49(127.17)	83.61
	Post		2.67 (83.75)	2.25 (94.18)	2.67 (97.41)	84.27
12	Pre	Blender Operator	3.11 (84.44)	2.24 (81.63)	1.83 (61.93)	72.03
	Post		3.21 (87.16)	2.30 (83.82)	1.53 (51.75)	71.65

TABLE 12A

SPIROMETRY - EXPOSED IN PAST

CLOROX COMPANY
JERSEY CITY, NEW JERSEY

May 29-30, 1980

JOB	FVC (% PRED)	FEV ₁ (% PRED)	FEF ₂₅₋₇₅ (% PRED)	FEV ₁ / FVC
Liquid Clorox (Clorox 2 Laborer 10/79-3/80)	3.75 (97.15)	3.20 (103.59)	3.75 (104.72)	85.33
Pelletizer Clorox 2 8/78-11/79)	4.57 (106.23)	3.80 (117.14)	4.57 (134.02)	83.15

TABLE 12B

SPIROMETRY - NONEXPOSED

Shipping	4.11 (89.86)	3.42 (93.75)	3.74 (94.09)	83.21
	2.66 (88.80)	2.18 (93.64)	2.66 (99.00)	81.95
	3.42 (109.99)	2.57 (107.33)	2.01 (74.87)	75.15
	5.14 (99.36)	4.50 (108.07)	5.71 (125.82)	87.55
	3.63 (89.61)	3.08 (98.28)	4.03 (118.59)	84.85
	4.38 (84.67)	3.20 (79.29)	1.99 (48.13)	73.06
	3.40 (77.82)	2.13 (67.15)	1.10 (35.82)	62.65
	2.66 (63.94)	2.02 (58.52)	1.66 (41.23)	75.94
	2.67 (59.69)	1.29 (39.47)	0.59 (18.09)	48.31

TABLE 13

SPIROMETRY ANALYSIS (EXPOSED)

CLOROX COMPANY
JERSEY CITY, NEW JERSEY

May 29-30, 1980

TEST	MEAN DECREASE LITERS PRE- POSTSHIFT	t VALUE
FVC	-0.099	1.685
FEV ₁	-0.1140	2.06*
FEF ₂₅₋₇₅	-0.281	1.655

*p < 0.05

TABLE 14

RAST AND RESPIRATORY IMPAIRMENT
(Among Exposed)

RAST		TOTAL	ATOPIC
Negative	Total	8	3
	Ventilatory Impairment	2	2
Positive	Total	3	2
	Ventilatory Impairment	2	1