U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ■ Public Health Service
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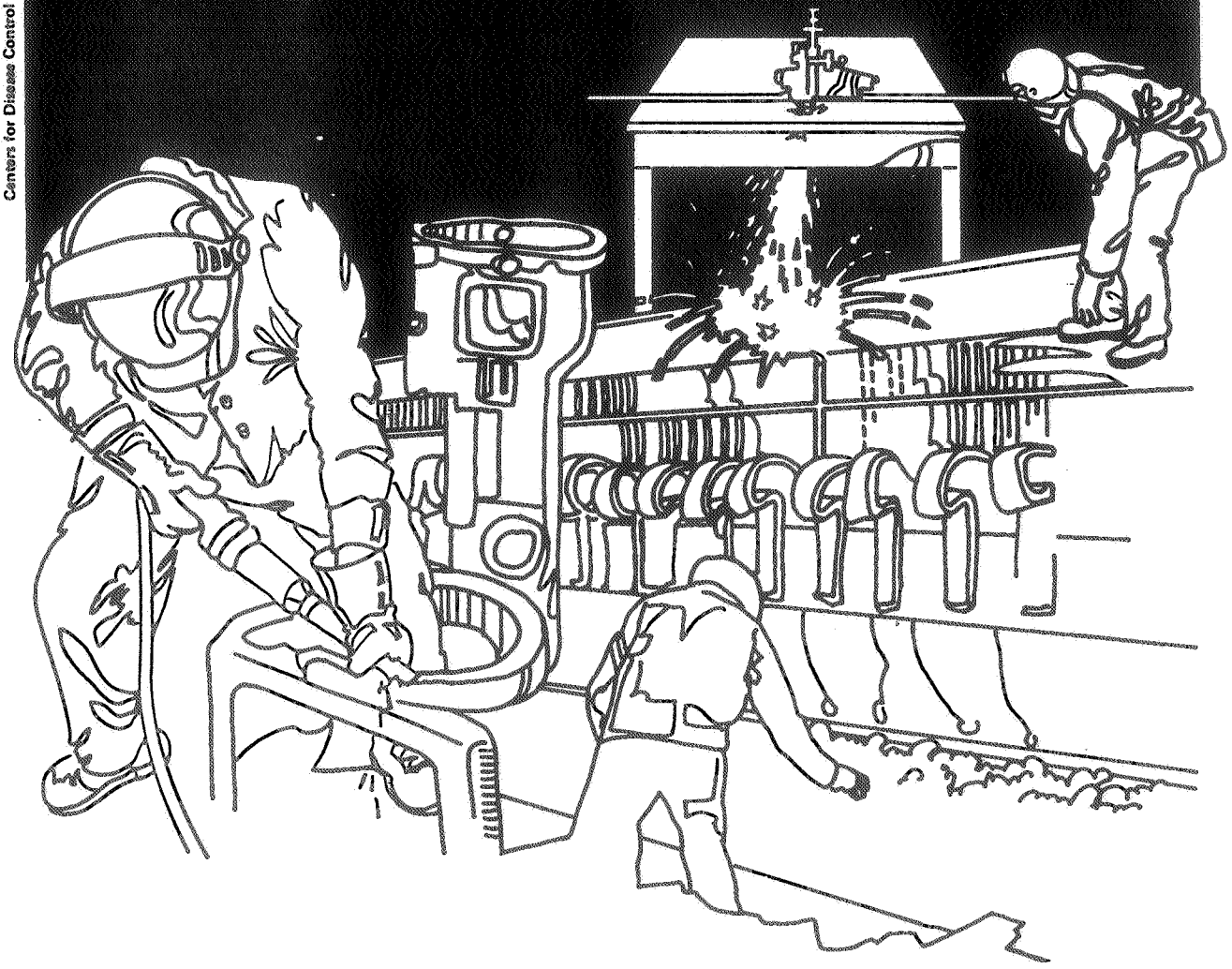
NIOSH



Health Hazard Evaluation Report

HETA 80-79-1189
REXALL DRUG COMPANY
ST. LOUIS, MISSOURI

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.

HETA 80-79-1189
SEPTEMBER 1982
REXALL DRUG COMPANY
ST. LOUIS, MISSOURI

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I. SUMMARY

On February 25, 1980, the National Institute for Occupational Safety and Health (NIOSH) received a request from the Oil, Chemical and Atomic Workers International Union to evaluate employee exposures to various chemicals at the Rexall Drug Company's drug manufacturing facility in St. Louis, Missouri. NIOSH conducted an initial walk-through inspection of the plant in April, 1980, and decided to focus its investigation on employee exposures involved in the production of ferrous sulfate, niacin, zinc gluconate, and multivitamin tablets.

Follow up environmental and medical surveys were conducted on February 25 - 27, April 10 - 14, and July 15, 1981. Respirable particulate breathing zone concentrations (For 24 samples) ranged from 0.1 to 2.1 milligrams per cubic meter of air (mg/m^3), 8-hour time-weighted average (TWA). Total particulate concentrations (For 42 samples) ranged from 0.4 to 32.5 mg/m^3; the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) for respirable particulates is 5.0 mg/m^3 and that for total particulates is 10 mg/m^3. Niacin concentrations (13 samples) ranged from 0.02 to 0.39 mg/m^3. Zinc gluconate concentrations (For 4 samples) ranged from 0.04 to 0.05 mg/m^3. There are currently no available criteria for evaluating airborne concentrations of niacin and zinc gluconate. Ferrous sulfate concentrations (32 samples) ranged from less than the detectable limit (2 ug/sample) to 7.83 mg/m^3; the ACGIH TLV for soluble iron salts, as iron (which includes ferrous sulfate) is 1 mg/m^3. Methylene chloride concentrations (10 samples) ranged from less than detectable (0.01 mg/sample) to 361 mg/m^3; the NIOSH criteria is 261 mg/m^3. Methyl alcohol concentrations (For 8 samples) ranged from less than detectable (0.01 mg/sample) to 80 mg/m^3; the NIOSH criteria is 262 mg/m^3. Isopropyl alcohol concentrations (32 samples) ranged from 14 to 1180 mg/m^3; the NIOSH Criteria is 984 mg/m^3.

In February, 1981, NIOSH evaluated effects of exposures to ferrous sulfate and niacin with a symptom questionnaire and measurement of serum iron and iron binding capacity. Five of seven ferrous sulfate workers reported cough, nose, throat, or skin irritation, or headache. All four employees who worked with ferrous sulfate on two consecutive days had increases (within the normal range) in both their serum iron level and percent saturation of iron binding capacity. In April, 11 of 13 niacin workers reported skin symptoms - redness, itching, tingling, flushing, warmth, or facial swelling - typically occurring early in the shift. In July, all eight niacin workers reported itching, but not redness or rash.

Based on the environmental sample results, employee interviews, and available toxicological information, NIOSH concludes that a health hazard did exist at the time of this investigation. Total dust, ferrous sulfate concentrations, isopropyl alcohol, and methylene chloride concentrations were above recommended environmental exposure criteria. Furthermore, ferrous sulfate workers had biochemical evidence of iron absorption (though probably not toxic amounts), and niacin workers had symptoms suggestive of the effects of overexposure to niacin. Recommendations to aid in providing a safe and healthful working environment are presented in Section VII of this report.

KEYWORDS: SIC 2834 (Pharmaceutical Preparations), total and respirable dusts, ferrous sulfate, niacin (Nicotinic Acid), zinc gluconate, methylene chloride, methyl alcohol, isopropyl alcohol.

II. INTRODUCTION

On February 25, 1980, the National Institute for Occupational Safety and Health (NIOSH) received a request from the Oil, Chemical and Atomic Workers International Union and its Local 5-136 to evaluate employee exposures to various chemicals at the Rexall Drug Company, St. Louis, Missouri. Employees reportedly had nosebleeds, blue discoloration of urine, chest tightness, and difficulty with breathing. Preliminary findings of the evaluations were reported in a letter on April 20, 1980 to the requestor and management.

III. BACKGROUND

This facility employs approximately 600 persons, 350 of which are production and maintenance workers. Batch production operations are conducted in three seven-story buildings. The total area used for production and storage of materials is 500,000 square feet. Production activities involve several thousand different chemicals in the formulation of 500 products. Over 90% of the products (e.g., vitamins, shampoos, lotions, creams, aspirin, etc.) are for human use, either internally or externally. Vitamin products for human consumption constitute 80% of the production. Chemicals are purchased from outside vendors, mixed according to formula, packaged, stored, and shipped to customers throughout the country. Production lines (e.g., tanks, equipment, machinery, etc.) are used for many different products.

The production of tablets involves the dispensing of chemicals (weighing of chemicals to be used in a batch), granulation of chemicals to appropriate particle size (this step is not necessary for all tablet products), oven drying in a walk-in oven, dry mixing of chemicals, compression of product into tablets, coating of tablets if specified, and the final packaging of the product. Several tons of tablets are produced per day. The cosmetic and ointment operations and the fluid operations involve the dispensing (weighing and/or measuring amounts) of chemicals, mixing, and final packaging of the product. Several thousand pints of various liquid products and several thousand pounds of lotions, creams, and similar products are processed each day.

NIOSH conducted an initial walk-through inspection of the plant on April 10-11, 1980. Self-administered, non-directed questionnaires completed by 23 workers in the tablet-manufacturing areas on the third and seventh floors suggested the following work-related health effects: rash associated with niacin production; nasal stuffiness, irritation, and bleeding associated with ferrous sulfate production; headache, nausea, and dizziness associated with use of isopropyl alcohol; and difficulty breathing and chest tightness associated with dust. One worker reported urine discoloration associated with production of Diurex, but production of this product had been discontinued prior to the NIOSH investigation.

Follow-up environmental and medical surveys were conducted on February 25-27, April 10-14, and July 15, 1981. Participants in the medical studies were notified by letter of their individual test results on May 15, 1981 (the July study involved no medical tests).

IV. EVALUATION DESIGN AND METHODS

A. Environmental

Personal and area air samples for particulates of ferrous sulfate, zinc gluconate, niacin, and total and respirable particulates were collected on preweighed M-5 PVC filters using MSA Model G personal sampling pumps operating at 1.7 liters per minute (LPM). Filters were set in 10 mm nylon cyclone separators to obtain respirable particulate samples. The amount of particulate was determined by weight gain on the filter. The ferrous sulfate was analyzed according to NIOSH Analytical Method P&CAM 173.[1] The zinc was analyzed according to NIOSH analytical method P&CAM 173.[1] Niacin was analyzed according to a method recently developed by NIOSH.

Personal breathing zone and general area air samples for isopropyl alcohol were collected via charcoal tube using vacuum pumps operating at 0.05, 0.10, and 0.2 LPM and analyzed according to NIOSH Method No. S-65[2] (modified). Personal breathing zone and general area air samples for methylene chloride were collected via charcoal tube using a vacuum pump operating at 0.05 LPM and analyzed according to NIOSH Method S-329[3] (modified). Personal breathing zone and general area air samples for methyl alcohol were collected via silica gel sorbent tube using a vacuum pump operating at 0.02 LPM and analyzed according to NIOSH Method No. S-59[2] (modified).

B. Medical

To evaluate the health effects of exposures to ferrous sulfate and isopropyl alcohol during the grinding, granulating, and compressing of ferrous sulfate tablets, NIOSH administered a symptom questionnaire in February 1981 to seven workers involved in these operations and to three unexposed "controls". NIOSH also tested pre- and post-shift nasal secretions from the exposed workers for the presence of blood (possibly due to nasal irritation from airborne dust) by both microscopic examination and the ortholidine reagent strip method. Finally, NIOSH tested pre- and post-shift blood specimens from all 10 workers for "volatiles" (which includes isopropyl alcohol), serum iron level, and iron binding capacity. Four exposed workers had the pre- and post-shift nasal secretion and blood tests on two consecutive days; the other three exposed workers worked with ferrous sulfate only on the second day of the survey.

To evaluate the health effects of exposure to niacin, isopropyl alcohol, zinc gluconate, and methyl alcohol, NIOSH administered a symptom questionnaire in April 1981 to 21 workers involved in mixing, granulating, and compressing niacin tablets (13 persons), granulating vitamin tablets (Super Plenamins) (5), granulating zinc gluconate tablets (2), and manufacturing Aspercream (1). (Among these workers were four who participated in the February medical study.) Six of these employees (two niacin, three vitamin, and the Aspercream worker) and one "unexposed" worker had from one to three blood specimens (pre-, mid-, and post-shift) tested for volatiles (which includes methyl, as well as isopropyl, alcohol) and the following parameters of liver function: asparatate aminotransferase (AST or SGOT), alanine aminotransferase (ALT or SGPT), lactate dehydrogenase (LDH), gamma glutamyl transpeptidase (GGTP), total and direct (unconjugated) bilirubin, alkaline phosphatase, and total serum proteins. In addition, the two other vitamin workers and the two zinc gluconate workers each had at least two (pre-, plus mid- and/or post-shift) blood tests for volatiles.

NIOSH administered another symptom questionnaire in July 1981 to eight workers involved in niacin tablet packaging and to two workers not working with niacin but exposed to methylene chloride and methyl alcohol in the film-coating area. In addition, NIOSH gave these 10 employees pre-printed cards on which to keep an hourly record of symptoms occurring during the shift.

V. EVALUATION CRITERIA

A. Niacin[4,5]

Niacin, also known as nicotinic acid, is a relatively weak vasodilator, commonly affecting the blood vessels of the skin, particularly of the face, neck, and upper chest, at oral doses of 50 to 100 mg and causing a feeling of warmth, itching, and redness. Some individuals may show this flushing of the skin at doses as low as 25 mg. The recommended daily dietary intake for adults ranges from 12 to 20 mg, depending on age and sex.[6] Rashes can occur following niacin administration and have been seen following ingestion of niacin-contaminated foods.[7] Gastrointestinal distress and abnormalities of liver function have been reported in persons exposed to high doses of niacin. There are no NIOSH, ACGIH, or OSHA criteria or standards for occupational exposure to niacin.

B. Ferrous Sulfate and Zinc Gluconate

Iron and zinc are essential nutrients.[6] Adult men and post-menopausal women require an average daily intake of 5 to 10 mg of iron and 8 to 10 mg of zinc. Menstruating, pregnant, and lactating women require greater amounts. Recommeded daily dietary allowances are about double these amounts, providing a margin of safety to prevent deficiency. The body handles modest excesses of iron by reducing the proportion of iron absorbed by the gastrointestinal tract. For purposes of controlling occupational exposure, zinc gluconate could be considered a nuisance dust. The ACGIH TLV for soluble iron salts (which included ferrous sulfate) is 1 mg/m^3.[8]

C. Isopropyl Alcohol, Methyl Alcohol, Methylene Chloride[9]

These compounds have similar effects. They are eye, nose, throat, and skin irritants, and they cause such symptoms as lightheadedness, sleepiness, fatigue, slowed reaction time, decreased ability to concentrate, and nausea. Methyl alcohol can impair vision, and methylene chloride can cause numbness and tingling of the hands and feet. The alcohols can be absorbed through the skin. NIOSH recommends that exposure to these compounds not exceed the following limits (all expressed as milligrams per cubic meter of air sampled):

	10-Hour Time-Weighted Average	15-Minute Ceiling
Isopropyl Alcohol[10]	984 mg/m^3	1968 mg/m^3
Methyl Alcohol[11]	262 mg/m^3	1048 mg/m^3
Methylene Chloride[12]	261 mg/m^3	1740 mg/m^3

VI. RESULTS AND DISCUSSION

A. Environmental

Results of the environmental samples collected on February 25-26, 1981, for respirable and total particulate, and for ferrous sulfate, are presented in Table I. Respirable particulate ranged from 0.1 to 2.1 mg/m^3 8-hour TWA; total particulate concentrations ranged from 0.4 to 32.5 mg/m^3 8-hour TWA. The ACGIH TLV for respirable particulates is 5.0 mg/m^3 and that for total particulates is 10 mg/m^3. Two of four personal total particulate air samples on the mixer operator exceeded (14.6 and 32.5 mg/m^3) the 10mg/m^3 TLV. Ferrous sulfate concentrations ranged from less than the detectable limit (2 ug/sample) to 7.83 mg/m^3. Two of three and three of five personal air samples collected on the grinders and mixer operators, respectively, exceeded the ferrous sulfate TLV of 1 mg/m^3. One area sample at the grinding operation also exceeded the 1 mg/m^3 ferrous sulfate TLV.

Results of the environmental samples collected on February 25-26, 1981, for isopropyl alcohol at the compressing operations involving ferrous sulfate tablets are presented in Table II. Isopropyl alcohol concentrations ranged from 14 to 827 mg/m^3. The maximum concentration (827 mg/m^3) was measured in the breathing zone of the granulation operator. The NIOSH recommended exposure limit is 984 mg/m^3 8-hour TWA. A significant amount (greater than 1/3 of the concentration for the front section) of isopropyl alcohol was found on the reference portion of the charcoal tubes for one sample obtained on the granulation foreman, and three on the granulation operator. It should be assumed that the value as reported is suspect and that the saturation limit of the charcoal may have been exceeded for isopropyl alcohol. Hence, the values for isopropyl alcohol are considered as minimum values.

Results of the environmental samples collected on April 14, 1981, for respirable and total particulate, and zinc gluconate during the mixing operations on the seventh floor involving zinc gluconate are presented in Table III. The respirable particulate concentration was 0.5 mg/m^3 and the total particulate concentration ranged from 0.01 to 2.7 mg/m^3 8-hour TAW. The air concentrations did not exceed the respective TLV of 10 mg/m^3. Zinc gluconate concentrations ranged from 0.01 to 0.05 mg/m^3. There is currently no specific criterion for evaluating airborne concentrations of zinc gluconate other than the nuisance dust TLV.

Results of the environmental samples collected on April 10, 13, and 14, 1981, for isopropyl alcohol at the Super Plenamins operations are presented in Table IV. Isopropyl alcohol concentrations ranged from 105 to 1180 mg/m^3 8-hour TWA. The NIOSH recommended exposure limit is 984 mg/m^3, 10-hour TWA and 1968 mg/m^3 expressed as a 15-minute ceiling concentration. The personal exposure of the manufacturing operator No. 2 on the seventh floor - Department 7A - exceeded the NIOSH recommended standard.

Results of the environmental samples collected on April 10-14, 1981, for respirable, total particulate, and niacin are presented in Table V. The respirable particulate concentrations ranged from 0.2 to 1.1 mg/m^3, 8-hour TWA and the total particulate concentrations ranged from 0.8 to 5.8 mg/m^3, 8-hour TWA. Both were below the ACGIH TLV's of 5 mg/m^3 and 10 mg/m^3, respectively. Niacin concentrations ranged from 0.02 to 0.49 mg/m^3. There are currently no available criteria for evaluating airborne concentrations of niacin.

Results of the environmental samples collected on April 10-13, 1981, for respirable, total particulate, and ferrous sulfate at the Super Plenamins operation are presented in Table VI. The one respirable particulate sample was 0.2 mg/m^3, 8-hour TWA. Total particulate concentrations ranged from 0.6 to 3.7 mg/m^3, 8-hour TWA. Ferrous sulfate ranged from 0.003 to 0.057 which was below the 1 mg/m^3 TLV for soluble iron salts. All samples were within their environmental criteria.

Results of the environmental samples collected on April 10, 1981, for operations involving methylene chloride or triethanolamin are presented in Table VII. Methylene chloride concentrations ranged from 1.3 mg/m^3 to 507 mg/m^3 with the methylene chloride operator exposed to the highest concentration (507) mg/m^3). The corresponding 8-hour TWA exposure for methylene chloride was 68 mg/m^3 and did not exceed the NIOSH recommended criteria of 261 mg/m^3 10-hour TWA. Results of the respirable and total particulate samples collected on July 15, 1981, (at the packaging operations on "G" line - third floor) - involving niacin are presented in Table VIII. Respirable particulate ranged from 0.1 to 0.4 mg/m^3, 8-hour TWA; total particulate concentrations ranged from 0.5 to 3.9 mg/m^3. All samples were well below the environmental criteria.

Results of environmental samples collected on July 15, 1981, for methylene chloride and methyl alcohol are presented in Table IX. Methylene chloride concentrations ranged from less than detectable (0.01 mg/sample) to 467 mg/m^3. Methyl alcohol concentrations ranged from less than detectable (0.01 mg/sample) to 80 mg/m^3, all within the NIOSH recommended standard of 262 mg/m^3 10-hour TWA and 1048 mg/m^3 expressed as a 15-minute ceiling concentration with the manufacturing operator exposed to the highest concentration (457 mg/m^3). The corresponding 8-hour TWA exposure concentration of 361 mg/m^3 exceeded the NIOSH recommended criteria of 261 mg/m^3 10-hour TWA.

B. Medical

1. February 1981 Survey

Five of the seven workers exposed to ferrous sulfate reported symptoms at work on the day they were interviewed; symptoms included cough (3 persons), nose or throat irritation (3, 1 with nosebleed), skin irritation (2), and headache (2). One of the three controls reported a symptom, fatigue, on the day of the interview.

The orthotolidine strip method proved to be a more sensitive indicator of occult blood in nasal secretions than the microscopic examination. All specimens from both exposed and unexposed workers, were positive for occult blood. Of the 11 pre- to post-shift comparisons, the test became more strongly positive in four cases and less strongly positive in two cases. Of the four workers who were tested on two consecutive days, the test became more strongly positive on both days in

one case, less strongly positive both days in one case, and remained stable in the other two cases. The worker who reported a nosebleed had a more strongly positive test post-shift, but not more strongly positive than two other workers.

Although none of the workers exposed to ferrous sulfate had an abnormally high serum iron level or percent saturation of iron binding capacity, there was tendency for both parameters to increase (within the "normal" range) during the course of the two-day interval of observation (Table X). Iron binding capacity also tended to increase slightly, but both the pre- to post-shift and day-to-day levels fluctuated less than those of serum iron or percent saturation. Thus, it does not appear that imprecise measurement of iron binding capacity would account for the increases in serum iron and percent saturation; if anything, the slight increases in iron binding capacity would tend to diminish the apparent size of the increases in serum iron and percent saturation.

The largest measured exposure to ferrous sulfate was a time-weighted average of 7.83 mg/m^3 in a mixer operator. Assuming a worker inhales as much as 10 m^3 of air during a shift (a resting air intake is 7 to 8 l/min,[13] or about 3.6 m^3 in 8 hours), this would represent daily a ferrous sulfate dose of 78.3 mg, or a daily iron dose of 45.7 mg, a physiologically appreciable, but probably not toxic, dose.

None of the blood specimens had any detectable volatiles (detection limit 70 ug/ml).

2. April Survey

Eleven (85%) of the 13 niacin workers reported either current or previous acute symptoms associated with exposure to niacin manufacture within the last 3 months. Two of the four workers manufacturing niacin at the time of NIOSH's investigation reported skin redness and itching within minutes of initiating niacin tablet manufacturing. Nine niacin workers reported flushing and skin redness, with warmth or tingling of the face, neck, arms, and chest. Ten reported itching associated with an erythematous, macular rash. Four reported swelling of the cheeks, lips, or eyes. The average onset of symptoms was about one hour after onset of exposure to niacin; six workers reported symptoms occurring within 15 minutes of onset of exposure. The 11 symptomatic workers reported that symptoms (1) persisted for the duration of the shift and were resolved

by the next morning, (2) developed on the first day of the production run, (3) occurred on every subsequent day of the run and recurred each time that niacin tablets were formulated, and (4) occurred only in association with niacin tablet production. The eight non-niacin workers did not report any similar skin symptoms.

The largest measured personal exposure to niacin was a time-weighted average of 0.39 mg/m^3 in a blending granulator operator; a TWA area concentration of 0.49 mg/m^3 was measured in the compressor area. If a worker inhales 10 m^3 of air during a shift, these would represent daily niacin doses of less than 5 mg, a toxicologically insubstantial amount.

Two of the five vitamin workers reported fatigue (and sleepiness in one case), and two others headache, occurring during the shift. Both zinc gluconate workers reported sleepiness. The largest measured personal exposure to zinc gluconate was a time-weighted average of 0.05 mg/m^3, resulting (assuming a daily inhalation of 10 m^3 of air) in a daily zinc gluconate dose of less than 0.5 mg, a physiologically insignificant amount.

None of the 24 blood specimens contained any detectable volatiles. Two (both vitamin workers) of the six workers who had liver function tests had normal results that were generally stable over the shift. The other vitamin worker had one test (SGPT) that increased to 13% above the reference value by the third specimen, but the test results as a whole showed no evidence of liver dysfunction. Each of the two niacin workers had a pre-shift test result above the reference value (SGPT in one case, total bilirubin in the other) that became normal mid- or post-shift. In both cases, all the other test results were stable within the normal range. The Aspercream worker had two post-shift test results that were above the reference value, but there were no preceding blood specimens for comparison.

3. July Survey

The eight niacin packaging workers had a variety of jobs. None had participated in the February or April surveys. All reported itching during the shift, in five cases beginning within 2 hours of starting work. None of the eight reported redness or rash, although specifically asked. Two persons reported headache, in both cases occurring 6 to 7 hours after starting work. Although not specifically asked, four workers reported eye discomfort, beginning as early as one hour to as late as four hours after starting work, and one also reported nasal irritation. Neither of the two non-niacin workers reported any symptoms the day of the survey.

VII. CONCLUSION

Based on the environmental sample results, employee interviews, and available toxicological information, NIOSH concludes that a health hazards did exist at the time of these surveys. Total dust and ferrous sulfate concentrations were above the ACGIH TLV 8-hour TWA, and the isopropyl alcohol and methylene chloride concentrations were above the NIOSH recommended standard. Furthermore, ferrous sulfate workers had biochemical evidence of absorption of ferrous sulfate (though probably not toxic amounts), and niacin workers had symptoms suggestive of the effect of niacin.

VIII. RECOMMENDATIONS

1. Until further environmental controls are implemented or existing ones improved, a conscientious respirator program should be initiated and enforced by management with support from the union. OSHA, through 29 CFR Part 1910.134, established the requirement for conducting a formal respiratory protection program for control of occupational diseases caused by breathing air which contains certain contaminants. A NIOSH document, "A Guide to Industrial Respiratory Protection", will serve as a reference source with information for establishing and maintaining a respirator program which meets the requirements of 29 CFR Part 1910.134. Any supplied air respirator may be used for methylene chloride by the manufacturing operator; however, chemical cartridge respirators should not be used with methylene chloride. A NIOSH approved dust type respirator should be used for total dust and ferrous sulfate by the mixer and grinding operators. A NIOSH approved organic vapor respirator should be used for isopropyl alcohol by the manufacturing operator No. 2 at the Super Plenamins operation

2. Respirators should be issued with caution. There may be individuals in this group for whom wearing a respirator carries certain specific dangers, e.g. highly increased resistance to airflow in a person with compromised pulmonary function may be associated with acute respiratory insufficiency. Therefore, any person who needs to wear a respirator should have a medical evaluation, including pulmonary function testing.

3. Engineering controls and methods should be evaluated and redesigned as the primary means of reducing worker exposures to total dust, ferrous sulfate, isopropyl alcohol, and methylene chloride. The use of respiratory protection should only be used as an interim control measure until the airborne levels are reduced below ACGIH TLV or the NIOSH recommended criteria.

4. All local exhaust ventilation systems should be serviced regularly to ensure that they are operating at maximum efficiency.

5. An educational program should be instituted so that employees are made aware of the potential hazards associated with the materials used at Rexall Drug Company.

6. All containers of isopropyl alcohol, methyl alcohol, and methylene chloride should be properly labeled.

7. Good personal hygiene and good work practices should be observed by all employees; washing of hands before smoking, eating, and drinking will help reduce contamination.

8. Better housekeeping is needed throughout all areas. All spills should be vacuumed up immediately.

IX. REFERENCES

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IX. AUTHORSHIP AND ACKNOWLEDGEMENTS

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X. DISTRIBUTION AND AVAILABILITY OF REPORT

Copies of this report are currently available upon request from NIOSH, Division of Standards Development and Technology Transfer, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After 90 days, the report will be available through the National Technical Information Service (NTIS), 5285 Port Royal, Springfield, Virginia 22161. 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:

1. Manager of Rexall Drug Company, St. Louis, Missouri
2. President of OCAW Local 5-136
3. OCAW International
4. NIOSH, Region VII
5. OSHA, Region VII

For the purpose of informing the 50 affected employees, copies of this report shall be posted by the employer in a prominent place accessible to the employees for a period of 30 calendar days.

TABLE I

Results of Personal Breathing Zone and General Area Concentrations of Respirable and Total Particulate and Ferrous Sulfate

Rexall Drug Company
St. Louis, Missouri
HETA 80-79

Date	Job and/or Location	Sampling Period	Sample Volume (Liters)	Type of Sample	8-Hour TWA Concentration mg/m3*		
					Respirable Particulate	Total Particulate	Ferrous Sulfate
2-25-81	Foreman Granulating	0714-1509	807	P**	-	0.5	0.09
2-25-81	Granulator Operator	0718-1511	804	P	-	1.8	0.46
2-25-81	Mixing Operator	0722-1515	804	P	-	0.4	0.08
2-25-81	Grinding Operator	0726-1503	777	P	-	7.5	2.83
2-25-81	Area Stokes Granulator	0749-1425	673	GA***	-	0.6	0.10
2-25-81	Area Grinding	0758-1435	658	GA	-	4.4	2.13
2-25-81	Area Stokes Granulator	0749-1425	653	GA	0.3	-	LD****
2-25-81	Area Grinding	0758-1435	753	GA	1.9	-	1.14
2-26-81	Manufacturing Operator	0711-1425	656	P	-	0.6	0.23
2-26-81	Foreman Granulating	0711-1425	738	P	-	0.4	0.12
2-26-81	Foreman Granulating	0711-1425	738	P	0.2	-	0.05
2-26-81	Granulator Operator	0727-1418	699	P	-	1.4	0.20
2-26-81	Granulator Operator	0727-1418	699	P	1.4	-	0.46
2-26-81	Granulator Operator	0730-1417	692	P	-	1.9	0.79
2-26-81	Grinder Operator	0715-1418	719	P	0.6	-	0.46
2-26-81	Grinder Operator	0715-1418	719	P	-	3.9	1.39
2-26-81	Mixer Operator	0719-1421	717	P	0.1	-	LD
2-26-81	Mixer Operator	0719-1421	717	P	-	14.6	1.67
2-26-81	Mixer Operator	0723-1437	738	P	-	6.7	1.36
2-26-81	Mixer Operator	0801-1424	753	P	-	32.5	7.83

(continued)

TABLE I (continued)

Date	Job and/or Location	Sampling Period	Sample Volume (Liters)	Type of Sample	8-Hour TWA Concentration mg/m3*		
					Respirable Particulate	Total Particulate	Ferrous Sulfate
2-27-81	Compresser Operator	0713-1430	726	P	-	5.0	0.59
2-27-81	Compresser Operator	0713-1430	726	P	2.1	-	0.76
2-27-81	Compresser Operator	0722-1420	711	P	0.7	-	0.25
2-27-81	Compresser Operator	0722-1420	711	P	-	4.2	0.21
Limit of Detection					0.01 mg	0.01 mg	2 ug
Environmental Criteria (8-hour TWA) (mg/m3)					5	10	1*****

* mg/m3 = milligrams of substance per cubic meter of air sampled
** P = personal sample
*** GA = general area sample
**** LD = less than detectable limits
***** Iron salts, soluble, as iron

TABLE II

Results of Personal Breathing Zone and General Area Concentrations of Isopropyl Alcohol at the Compressing Operations Involving Ferrous Sulfate Tablets

Rexall Drug Company
St. Louis, Missouri
HETA 80-79

Date	Job and/or Location	Sampling Period	Sample Volume (Liters)	Type of Sample	Isopropyl Alcohol mg/m^3*
2-25-81	Foreman Granulation	0714-1509	49	P**	245****
2-25-81	Granulation Operator	0718-1511	35	P	455****
2-25-81	Granulation Operator	0722-1515	46	P	303****
2-25-81	Grinder Operator	0726-1502	44	P	43
2-25-81	Area Stokes Granulation	0749-1425	39	GA***	146
2-25-81	Area Grinder	0758-1435	35	GA	62
2-26-81	Granulation Operator	0730-1417	35	P	827****
2-26-81	Mixer Operator	0723-1437	45	P	14
2-26-81	Area Granulation	0748-1400	36	GA	211
2-26-81	Area Granulation	0749-1400	48	GA	398
2-26-81	Area Grinder	0759-1423	34	GA	3
Limit of Detection (mg/sample)					0.01

Environmental criteria for isopropyl alcohol is 984 mg/m^3 for 8-hour TWA and 1968 mg/m^3 for a 15-minute ceiling.

* mg/m^3 = milligrams of substance per cubic meter of air sampled
** P = personal sample
*** GA = general area sample
**** A significant amount (greater than 1/3 of the concentration for the front section) of isopropyl alcohol only was found on the reference portion of the charcoal tube. It should be assumed that the value as reported is suspect and that the saturation limit of the charcoal may have been exceeded for isopropyl alcohol. Hence, the values for isopropyl alcohol are considered as minimum values.

TABLE III

Results of Personal Breathing Zone and General Area Concentrations of Respirable and Total Particulate and Zinc Gluconate

Rexall Drug Company
St. Louis, Missouri
HETA 80-79

Date	Job and/or Location	Sample Period	Sample Volume (Liters)	Type of Sample	8-Hour TWA Concentration mg/m^3*		
					Respirable Particulate	Total Particulate	Zinc Gluconate
4-14-81	Manufacturing Operator No. 1 Department 7A	0714-1433	622	P**	-	1.2	0.04
4-14-81	Manufacturing Operator No. 2 Department 7A	0716-1433	615	P	-	2.7	0.05
4-14-81	Area 7th Floor	0740-1428	598	GA***	0.5	-	0.01
4-14-81	Area 7th Floor	0740-1428	601	GA	-	1.8	0.05
Limit of Detection					0.01 mg	0.01 mg	1 ug
Environmental Criteria (8-hour TWA) (mg/m^3)					5	10	no standard****

* mg/m^3 = milligrams of substance per cubic meter of air sampled
** P = personal sample
*** GA = general area sample
**** There is no standard for soluble zinc

TABLE IV

Results of Personal Breathing Zone and General Area Concentrations of Isopropyl Alcohol at the Super Plenamin Operations

Rexall Drug Company
St. Louis, Missouri
HETA 80-79

Date	Job and/or Location	Sampling Period	Sample Volume (Liters)	Type of Sample	Isopropyl Alcohol mg/m^3*	
4-10-81	Super Plen Granulator No. 1	0720-1107	21	P**	380	(461)[a]
4-10-81	Super Plen Granulator No. 1	1108-1505	21	P	572	
4-10-81	Super Plen Granulator No. 2	0725-1104	22	P	330	(332)
4-10-81	Super Plen Granulator No. 2	1105-1507	24	P	361	
4-10-81	Super Plen Granulator No. 3	0728-1108	22	P	454	(419)
4-10-81	Super Plen Granulator No. 3	1110-1509	24	P	425	
4-10-81	Area by Alcohol Mix Tank	0815-1150	20	GA***	49	(105)
4-10-81	Area by Alcohol Mix Tank	1152-1428	14	GA	253	
4-10-81	Area by Super Plen Mix Tank	0820-1154	21	P	190	(247)
4-10-81	Area by Super Plen Mix Tank	1156-1428	15	P	507	
4-13-81	Manufacturing Operator No. 1	0725-1110	22	P	422	
4-13-81	Manufacturing Operator No. 2	0730-1105	18	P	195	
4-13-81	Area Sample by Mixing Tank	0738-1105	25	GA	213	
4-14-81	Manufacturing Operator No. 1 Zn on 7th Floor - Department 7A	0714-1103	26	P	124	(526)
4-14-81	Manufacturing Operator No. 1 Zn	1202-1433	22	P	1478	

(continued)

TABLE IV (continued)

Date	Job and/or Location	Sampling Period	Sample Volume (Liters)	Type of Sample	Isopropyl Alcohol mg/m^3*
4-14-81	Manufacturing Operator No. 2 Zn on 7th Floor - Department 7A	0716-1103	15	P	1491 (1180)
4-14-81	Manufacturing Operator No. 2 Zn	1200-1433	18	P	1484
4-14-81	Area by Floor Mixer Zn	0741-1105	25	GA	754 (898)
4-14-81	Area by Floor Mixer Zn	1107-1427	21	GA	1385
4-14-81	General Area Zn by Alcohol Mixer	0742-1108	15	GA	396 (416)
4-14-81	General Area Zn by Alcohol Mixer	1110-1427	19	GA	597
Limit of Detection					0.01 mg
Environmental Criteria (mg/m^3)					984

* mg/m^3 = milligrams of substance per cubic meter of air sampled
** P = personal sample
*** GA = general area sample
a = concentration in parentheses is the calculated 8-hour TWA

TABLE V

Results of Personal Breathing Zone and General Area Concentrations of Respirable and Total Particulate and Niacin

Rexall Drug Company
St. Louis, Missouri
HETA 80-79

Date	Job and/or Location	Sampling Period	Sample Volume (Liters)	Type of Sample	8-Hour TWA Concentrations mg/m³* Respirable Particulate	Total Particulate	Niacin
4-10-81	Granulator - Blending Operator No. 1	0718-1119	410	P**	1.1	-	<0.05
4-10-81	Granulator - Blending	0718-1119	410	P	-	5.8	0.39
4-10-81	Granulator - Blending Area	0807-1110	311	GA***	0.3	-	<0.06
4-10-81	Granulator - Blending Area	0807-1110	311	GA	-	0.8	<0.06
4-10-81	Compressor Operator No. 1	0740-1503	753	P	0.2	-	<0.03
4-10-81	Compressor Operator No. 1	0740-1503	753	P	-	2.6	0.15
4-10-81	Compressor Area	1208-1533	298	GA	VOID	-	VOID
4-10-81	Compressor Area	1208-1533	298	GA	-	3.62	0.49
4-10-81	Compressor Operator No. 2	1553-2230	675	P	0.3	-	0.03
4-10-81	Compressor Operator No. 2	1553-2230	675	P	-	3.0	0.09
4-14-81	Compressor Operator No. 1	0706-1123	242	P	0.5	-	<0.02
4-14-81	Compressor Operator No. 1	0706-1123	242	P	-	2.5	0.32
4-14-81	Compressor Area - 7th Floor	0733-1113	230	GA	0.7	-	0.08
4-14-81	Compressor Area - 7th Floor	0733-1113	230	GA	-	2.9	0.37
Limit of Detection					0.01 mg	0.01 mg	1 ug
Environmental Criteria (8-hour TWA) (mg/m³)					5	10	no standard****

* mg/m³ = milligrams of substance per cubic meter of air sampled
** P = personal sample
*** GA = general area sample
**** There is no standard for niacin

TABLE VI

Results of Personal Breathing Zone and General Area Concentrations of
Respirable and Total Particulate and Ferrous Sulfate at the Super Plenamins Operation

Rexall Drug Company
St. Louis, Missouri
HETA 80-79

Date	Job and/or Location	Sampling Period	Sample Volume (Liters)	Type of Sample	8-Hour TWA Concentrations mg/m3*		
					Respirable Particulate	Total Particulate	Ferrous Sulfate
4-10-81	Granulating Operator No. 1	0721-1504	789	P**	-	1.4	0.023
4-10-81	Granulating Operator No. 2	0725-1507	785	P	-	2.3	0.057
4-10-81	Granulating Operator No. 3	0728-1509	784	P	-	1.3	0.011
4-10-81	Area by Mix Tank Granulating	0818-1428	629	GA***	0.2	-	<0.003
4-10-81	Area by Mix Tank Granulating	0818-1428	629	GA	-	1.4	0.022
4-13-81	Granulating Operator No. 1	0725-1110	382	P	-	3.7	0.037
4-13-81	Granulating Operator No. 2	0730-1105	365	P	-	0.6	0.008
4-13-81	Area by Mixing Tank	0738-1105	352	GA	-	0.9	0.009
Limit of Detection					0.01 mg	0.01 mg	2 ug
Environmental Criteria (8-hour TWA)					5(a)	10(a)	1(a)

* mg/m^3 = milligrams of substance per cubic meter of air sampled
** P = personal sample
*** GA = general area sample
(a) = 8-hour TWA - TLV

TABLE VII

Results of Personal Breathing Zone and General Area Concentrations During Operations Involving Triethanolamine and/or Methylene Chloride

Rexall Drug Company
St. Louis, Missouri
HETA 80-79

Date	Job and/or Location	Sampling Period	Sample Volume (Liters)	Type of Sample	Methylene Chloride mg/m^3
4-10-81	Triethanolamine Operator	0703-1435	46	P**	1.3
4-10-81	Area by Triethanolamine Vat	0755-1353	35	GA***	1.4
4-10-81	Methylene Chloride Operator	1330-1435	7	P	507 (68)a
Limit of Detection					0.001 mg
Environmental Criteria (8-hour TWA) (mg/m^3)					261

* mg/m^3 = milligrams of substance per cubic meter of air sampled
** P = personal sample
*** GA = general area sample
a = concentration in parentheses is the calculated 8-hour TWA

TABLE VIII

Results of Personal Breathing Zone and General Area Concentrations of Respirable and Total Particulate at the Packaging Operations on "G" Line - 3rd Floor Involving Niacin

Rexall Drug Company
St. Louis, Missouri
HETA 80-79

					8-Hour TWA Concentration mg/m^3*	
Date	Job and/or Location	Sampling Period	Sample Volume (Liters)	Type of Sample	Respirable Particulate	Total Particulate
7-15-81	Packing Operator No. 1	0659-1338	612	P**	0.1	-
7-15-81	Packing Operator No. 1	0659-1338	612	P	-	0.5
7-15-81	Packing Operator No. 2	0705-1338	598	P	0.4	-
7-15-81	Packing Operator No. 2	0705-1338	598	P	-	1.2
7-15-81	Packing Operator No. 3	0707-1337	609	P	0.2	-
7-15-81	Packing Operator No. 3	0707-1337	609	P	-	0.5
7-15-81	Packing Operator No. 4	0708-1335	616	P	0.4	-
7-15-81	Packing Operator No. 4	0708-1335	616	P	-	1.1
7-15-81	Packing Operator No. 5	0710-1336	614	P	0.3	-
7-15-81	Packing Operator No. 5	0710-1336	614	P	-	1.7
7-15-81	Packing Operator No. 6	0712-1336	622	P	0.2	-
7-15-81	Packing Operator No. 6	0712-1336	622	P	-	1.3
7-15-81	Floor Inspector	0713-1332	618	P	0.1	-
7-15-81	Floor Inspector	0713-1332	618	P	-	0.5
7-15-81	Area Sample by Crandell Filler	0739-1340	580	GA***	0.4	-
7-15-81	Area Sample by Crandell Filler	0739-1340	580	GA	-	3.9
Limit of Detection					0.01 mg	0.01 mg
Environmental Criteria (8-hour TWA) (mg/m^3)					5	10

* mg/m^3 = milligrams of substance per cubic meter of air sampled
** P = personal sample

TABLE IX

Results of Personal Breathing Zone and General Area Concentrations of Methylene Chloride and Methyl Alcohol on July 15, 1981

Rexall Drug Company
St. Louis, Missouri
HETA 80-79

Job and/or Location	Sampling Period	Sample Volume (Liters)	Type of Sample	Methylene Chloride mg/m^3*	Methyl Alcohol mg/m^3
Film Coater	0714-0958	5	P**	LD***	LD
Film Coater	1003-1500	4	P	142	80
Manufacturing Operator	0718-0950	3	P	230 (361)[a]	LD
Manufacturing Operator	0956-1500	3	P	467	LD
Mixing Tank Area	0726-1500	10	GA****	240	LD
Coating Pans Area	0731-1501	10	GA	53	8
Coating Room 3rd Floor Area	0900-0908	5	GA	2	LD
Mixing Room 5th Floor Area	0917-0945	5	GA	16	4
Limit of Detection (mg/sample)				0.01	0.01
Environmental Criteria (8-hour TWA) (mg/m^3)				261	262

* mg/m^3 = milligrams of substance per cubic meter of air sampled
** P = personal sample
*** LD = less than detectable limits
**** GA = general area sample
a = concentration in parentheses is the calculated 8-hour TWA

TABLE X

Serum Iron and Iron Binding Capacity (IBC) Test Results, February 1981

Rexall Drug Company
St. Louis, Missouri
HETA 80-79

	First Day Tested									Next Day									Overall Change****		
	Iron*			IBC*			% Saturation			Iron			IBC			% Saturation					
Participant	Pre**	Post**	Diff***	Pre	Post	Diff	Pre	Post	Diff	Pre	Post	Diff	Pre	Post	Diff	Pre	Post	Diff	Iron	IBC	% Sat
Exposed****																					
A	66	108	+64	360	390	+8	18	28	+56	96	116	+21	372	390	+5	26	30	+15	+76	+ 8	+67
B	98	106	+ 8	336	318	-5	29	33	+14	130	142	+ 9	318	342	+8	41	42	+ 2	+45	+ 2	+45
C	96	86	-13	330	360	+9	29	24	-17	80	114	+43	360	372	+3	22	31	+41	+19	+13	+ 7
D	66	52	-21	354	366	+3	19	14	-26	96	96	0	360	378	+5	27	25	- 7	+45	+ 7	+32
E	84	90	+ 7	294	300	+2	29	30	+ 3												
F	154	124	-19	348	354	+2	44	35	-20												
G	66	116	+76	420	414	-1	16	28	+75												
Median	84	106	+ 7	348	360	+2	29	28	+ 3	96	115	+15	360	375	+5	27	31	+ 9	+45	+ 8	+39
Unexposed																					
X	78			348																	
Y	104			402																	
Z	128	84	-34	450	468	+4	28	18	-36												

* ug iron/dl serum
** Pre and post mean pre-shift and post-shift, respectively
*** Diff means percent change between pre and post
**** Percent change from first day pre-shift to second day post-shift