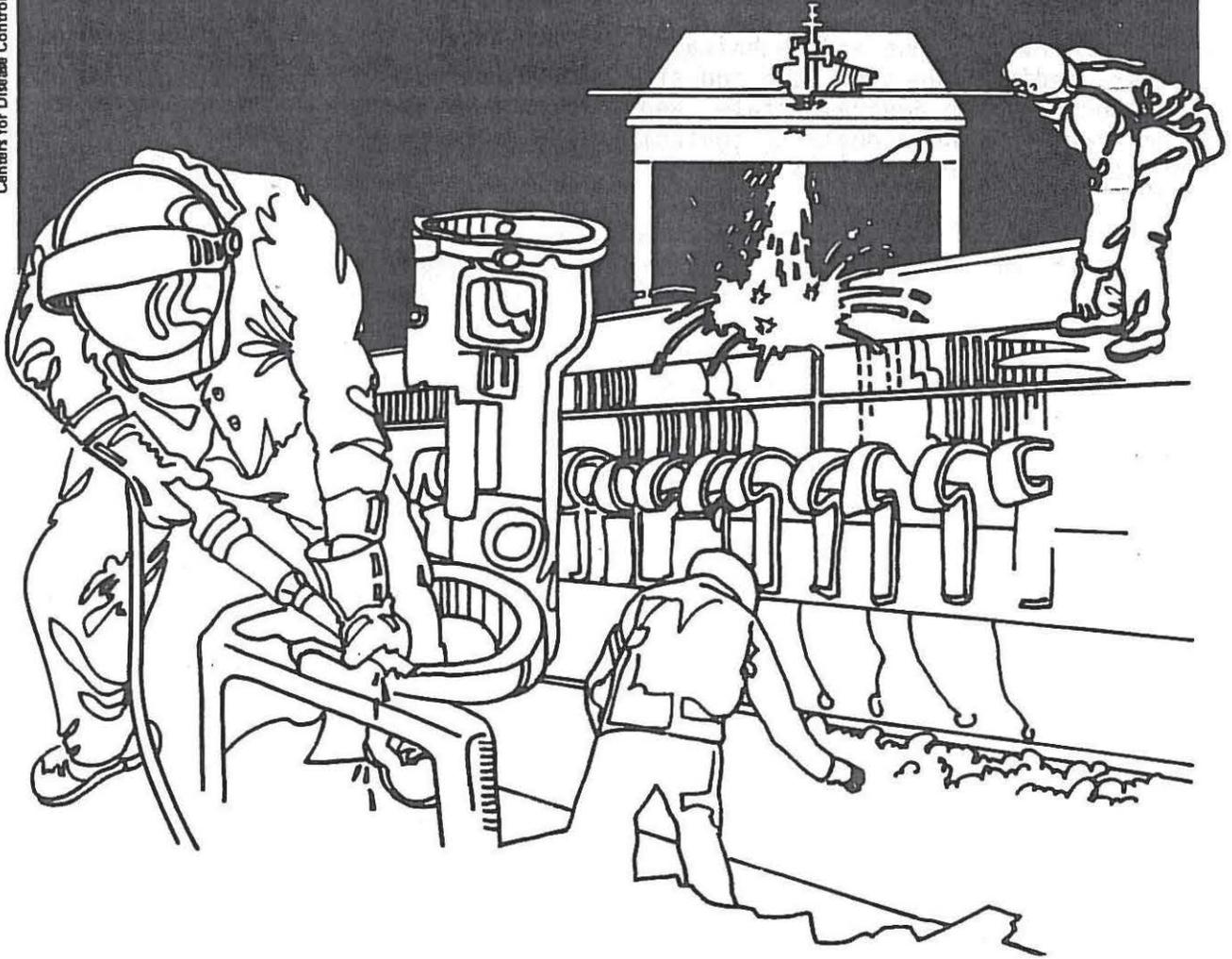


NIOSH



Health Hazard Evaluation Report

HETA 82-040-1119
SYNTHEX LTD. (USA)
MONUMENT, COLORADO

PREFACE

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

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

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

HETA 82-040-1119
MAY 1982
SYNTHES LTD. (USA)
MONUMENT, COLORADO

NIOSH INVESTIGATOR:
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I. SUMMARY

On November 9, 1981, the National Institute for Occupational Safety and Health (NIOSH) received a request to conduct a health hazard evaluation at the Synthes Ltd., Monument, Colorado. The request concerned employee exposures to 1,1,1-trichloroethane, trichloroethylene, perchloroethylene, phosphoric acid, and nitric acid in the electro-polishing of surgical implants.

On November 17, 1981, and February 10, 1982, NIOSH conducted industrial hygiene surveys to determine airborne concentrations of the solvents and acids used in the operation.

The maximum 8-hour time-weighted average (TWA) exposure concentration of 1,1,1-trichloroethane (8 mg/m^3) measured in the breathing zone of the electro polish operator was less than 1% of the 1900 mg/m^3 8-hour TWA OSHA Permissible Exposure Limit (PEL). The maximum 8-hour TWA general area concentrations of 1,1,1-trichloroethane (17 mg/m^3) were less than 1% of the referenced exposure criteria. The maximum 8-hour TWA concentrations of trichloroethylene and perchloroethylene measured in the breathing zone of the electro polish operator were 9 and 24 mg/m^3 , respectively. The maximum 8-hour TWA general area concentrations of trichloroethylene and perchloroethylene were 16 mg/m^3 and 50 mg/m^3 , respectively. Based on the potential carcinogen properties of these two compounds, NIOSH recommends that exposure be controlled to the lowest feasible level.

The air concentrations of phosphoric and nitric acids measured in the breathing zone of the electro polish operator were less than the minimum amount detectable ($<0.004 \text{ mg/per sample}$) by the analytical method. The general area samples were all less than the referenced limit of detection, except for the nitric acid samples obtained in the work bench and etching areas. These samples showed an 8-hour TWA concentration of 0.1 mg/m^3 , which is less than 2% of the 5 mg/m^3 NIOSH recommended exposure limit.

Based on the environmental sample results and available toxicological information, NIOSH concludes that a health hazard did not exist at the time of the surveys on November 17, 1981, and February 10, 1982. Recommendations to aid in providing a safe and healthful working environment are presented in Section VII of this report.

KEYWORDS: SIC 3841 (Surgical and Medical Instruments and Apparatus), 1,1,1-trichloroethane, trichloroethylene, perchloroethylene, phosphoric acid, and nitric acid.

II. INTRODUCTION

On November 9, 1981, NIOSH received a request from the manager of Technical Services of Synthes Ltd., Monument, Colorado, to determine if there was a health hazard from exposure to solvents and acids used in the electro-polishing of surgical implants. Environmental surveys were conducted on November 17, 1981, and February 10, 1982, to evaluate potential solvents and acids exposures to the one electro-polishing operator.

Preliminary findings of the evaluations were reported in a letter on April 19, 1982, to management.

III. BACKGROUND

The Synthes Ltd. (USA) manufactures stainless steel plates and screws for surgical implants. The company has been in this facility for 2-1/2 years and employs 100 persons (46 production workers) on three shifts, 5 days per week.

The electro-polishing is conducted by one operator in an isolated room for a period of 6 to 8 hours a day. Stainless steel screws and plates (surgical implants) are placed in a metal basket and put through a variety of pretreatments, including degreasing, etching, or pickling, etc. The electro-polishing room has 11 ventilated open surface tanks. Of the 11 tanks, two are degreasing tanks which contain perchloroethylene; one each contains phosphoric acid, nitric acid, and a coating solution. The remaining six tanks are water rinse tanks. The articles are placed in a perforated barrel or tray, which is hung on the cathode bar in such a way that the articles are completely immersed in the plating solution. The articles are then removed from the plating solution, rinsed, and sent to final inspection.

IV. METHODS

The November 17, 1981, survey consisted of collecting personal breathing zone and general air samples for 1,1,1-trichloroethane, trichloroethylene, and phosphoric and nitric acids. The 1,1,1-trichloroethane and trichloroethylene samples were collected via charcoal tube using a vacuum pump operating at 0.2 liters per minute (LPM) and analyzed according to NIOSH Method No. P&CAM 127.¹ The phosphoric and nitric acid samples were collected via a special silica gel tube using a vacuum pump operating at 0.2 LPM and analyzed according to NIOSH Method P&CAM No. 339.² The February 10, 1982, survey consisted of collecting personal breathing zone and area air samples for perchloroethylene. The samples were collected via charcoal tube using a vacuum pump operating at 0.05 LPM and analyzed according to NIOSH Method S-335.³

The face velocity of the two degreasing tanks were measured using a thermal anemometer. The measurements are reported as linear feet per minute (LFPM). The other nine tanks were not measured by NIOSH due to the company having an industrial ventilation consultant to revamp the ventilation system.

V. EVALUATION CRITERIA

Environmental

The environmental evaluation criteria used for this study are presented in Tables I and II.

Occupational health standards are established at levels designed to protect individuals occupationally exposed to toxic substances on an 8-hour-per-day, 40-hour-per-week basis over a normal working lifetime. NIOSH criteria are for up to a 10-hour workday, 40-hour workweek over a working lifetime.

Acute exposure to trichloroethylene and perchloroethylene is known to cause symptoms of central nervous system depression, including drowsiness, dizziness, weakness, tremor, loss of coordination, and mental confusion.⁴ Based on the potential carcinogen properties of these two compounds, NIOSH recommends that exposure be controlled to the lowest feasible level.

VI. RESULTS AND DISCUSSION

Table I presents the personal breathing zone and area air concentrations of 1,1,1-trichloroethane, trichloroethylene, and perchloroethylene. The maximum 8-hour TWA exposure concentration of 1,1,1-trichloroethane (8 mg/m^3) measured in the breathing zone of the electro polish operator was less than 1% of the 1900 mg/m^3 8-hour TWA OSHA Permissible Exposure Limit (PEL). The maximum 8-hour TWA general area concentrations of 1,1,1-trichloroethane (17 mg/m^3) was less than 1% of the referenced exposure criteria. The maximum 8-hour TWA concentrations of trichloroethylene and perchloroethylene measured in the breathing zone of the electro polish operator were 9 and 24 mg/m^3 , respectively. The maximum 8-hour TWA general area concentrations of trichloroethylene and perchloroethylene were 16 mg/m^3 and 50 mg/m^3 . Based on the potential carcinogen properties of these two compounds, NIOSH recommends that exposure be controlled to the lowest feasible level.

Table II presents the personal breathing zone and area air concentrations of phosphoric and nitric acids. The air concentrations of phosphoric and nitric acids measured in the breathing zone of the electro polish operator were less than the minimum amount detectable ($<0.004 \text{ mg/per sample}$) by the analytical method. The general area samples were all less than the referenced limit of detection, except

for the nitric acid samples obtained in the work bench and etching areas. These samples showed an 8-hour TWA concentration of 0.1 mg/m^3 , which is less than 2% of the 5 mg/m^3 NIOSH recommended exposure limit.

Degreasing Tank 240 with a collar-type exhaust hood had face velocity ranging from 100 LFPM to 400 LFPM with an average face velocity of 250 LFPM. Degreasing Tank 250 with the same type exhaust hood had a face velocity ranging from 150 LFPM to 500 LFPM with an average face velocity of 350 LFPM. The ACGIH Industrial Ventilation Manual recommends 1000 LFPM maximum slot velocity for these type solvent degreasing tanks.⁵

After the November 17, 1981, NIOSH environmental survey, Synthes Ltd. discontinued the use of 1,1,1-trichloroethane and trichloroethylene, and substituted perchloroethylene for the two degreasing tanks. The change reflected a 50% saving to the company and a better solvent for degreasing surgical implants.

Based on the environmental sample results and available toxicological information, NIOSH concludes that a health hazard did not exist at the time of the surveys on November 17, 1981, and February 10, 1982.

VII. RECOMMENDATIONS

1. Vapor degreasing tanks should be equipped with a condenser or vapor level thermostat to keep the vapor level below the top edge of the tank by a distance equal to one-half the tank width or 36 inches, whichever is shorter.⁵
2. Degreasers should be equipped with a boiling liquid thermostat to regulate the rate of vapor generation, and with a safety control at an appropriate height above the vapor line to prevent the escape of solvent in case of malfunction.
3. Work should be placed in and removed slowly from the degreaser at a rate no greater than 11 feet/minute (0.55 m/s), to prevent sudden disturbances to the vapor level.
4. An emergency quick-drenching facility should be located in near proximity to the degreaser for use in the event of accidental eye contact with the degreasing liquid.
5. All containers containing solvents and acids should be properly marked.
6. Good personal hygiene should be observed by the electro polish operator. Washing of hands before smoking, eating, and drinking will help reduce contamination.

VIII. REFERENCES

1. National Institute for Occupational Safety and Health. NIOSH manual of analytical methods. Vol 1, 2nd ed. Cincinnati, OH: National Institute for Occupational Safety and Health, 1977. (DHEW (NIOSH) publication no. 77-157-A).
2. National Institute for Occupational Safety and Health. NIOSH manual of analytical methods. Vol 7, 2nd ed. Cincinnati, OH: National Institute for Occupational Safety and Health, 1981. (DHHS (NIOSH) publication no. 82-100).
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4. National Institute for Occupational Safety and Health. Occupational diseases: a guide to their recognition. Revised ed. Cincinnati, OH: National Institute for Occupational Safety and Health, 1977. (DHEW (NIOSH) publication no. 77-181).
5. American Conference of Governmental Industrial Hygienists. ACGIH industrial ventilation: a manual of recommended practice. ACGIH Committee on Industrial Ventilation: Lansing, Michigan, 1982.

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. Synthes Ltd. (USA)
2. NIOSH, Region VIII
3. OSHA, Region VIII

For the purpose of informing the one affected employee, a copy of this report shall be given to the affected employee or posted by the employer in a prominent place accessible to the employee for a period of 30 calendar days.

TABLE I

Results of Personal Breathing Zone and General Area Concentrations of 1,1,1-Trichloroethane, Trichloroethylene, and Perchloroethylene

Synthes Ltd. (USA)
Monument, Colorado
HETA 82-040

Date	Job and/or Location	Sampling Period	Sample Volume (Liters)	Type of Sample	8-Hour TWA Air Concentration mg/m ³ *		
					1,1,1-Trichloroethane	Trichloroethylene	Perchloroethylene
11-17-81	Electro Polish Operator	0658-1235	63	P**	8	9	-
11-17-81	Electro Polish Helper	0703-1034	43	P	6	4	-
11-17-81	Vapor Degreaser Area	1030-1230	21	GA***	11	2	-
11-17-81	Vapor Degreaser Area	1030-1220	23	GA	2	1	-
11-17-81	Degreaser Area	0722-1030	37	GA	7	16	-
11-17-81	Cleaning Station Area	0715-1020	40	GA	17	5	-
11-17-81	Etching Area	0730-1230	48	GA	2	1	-
02-10-82	Electro Polish Operator	0818-1401	19	P	-	-	24
02-10-82	Degreasing Tank 240	0820-1404	18	GA	-	-	20
02-10-82	Degreasing Tank 250	0823-1406	20	GA	-	-	50
02-10-82	Electro Polish Platform	0825-1408	14	GA	-	-	8
02-10-82	Outside Room to Electro Polish	0829-1410	19	GA	-	-	1
Environmental Criteria (mg/m ³)					1910 (a)	****	****
Limit of Detection (mg/sample)					0.01	0.01	0.01

* mg/m³ = milligrams of substance per cubic meter of air sampled.

** P = personal sample

*** GA = general area

**** NIOSH recommends lowest feasible level (a suspect carcinogen).

(a) = Ceiling concentration - NIOSH

TABLE II

Results of Personal Breathing Zone and General Area Concentrations of
Phosphoric and Nitric AcidsSynthes Ltd. (USA)
Monument, Colorado
HETA 82-040

November 17, 1981

Job and/or Location	Sampling Period	Sample Volume (Liters)	Type of Sample	8-Hour TWA Air Concentration mg/m ³ *	
				Phosphoric Acid	Nitric Acid
Electro Polish Operator	1040-1240	26	P**	LD***	LD
Electro Polish Room	0705-1220	69	GA****	LD	LD
Electro Polish Room	0710-0930	14	GA	LD	LD
Electro Polish Room	0729-1235	23	GA	LD	LD
Caustic Storage Area	0714-1230	71	GA	LD	0.1
Work Bench Area	0725-1235	63	GA	LD	0.1
Etching Area	0727-1230	59	GA	LD	LD
Outside Room to Electro Polish	0738-1100	47	GA	LD	LD
Environmental Criteria (mg/m ³)				1 (a)	5 (b)
Limit of Detection (mg/sample)				0.004	0.004

* mg/m³ = milligrams of substance per cubic meter of air sampled.

** P = personal sample

*** LD = less than detectable limits

**** GA = general area

(a) = 8-hour TWA - OSHA

(b) = 8-hour TWA - NIOSH