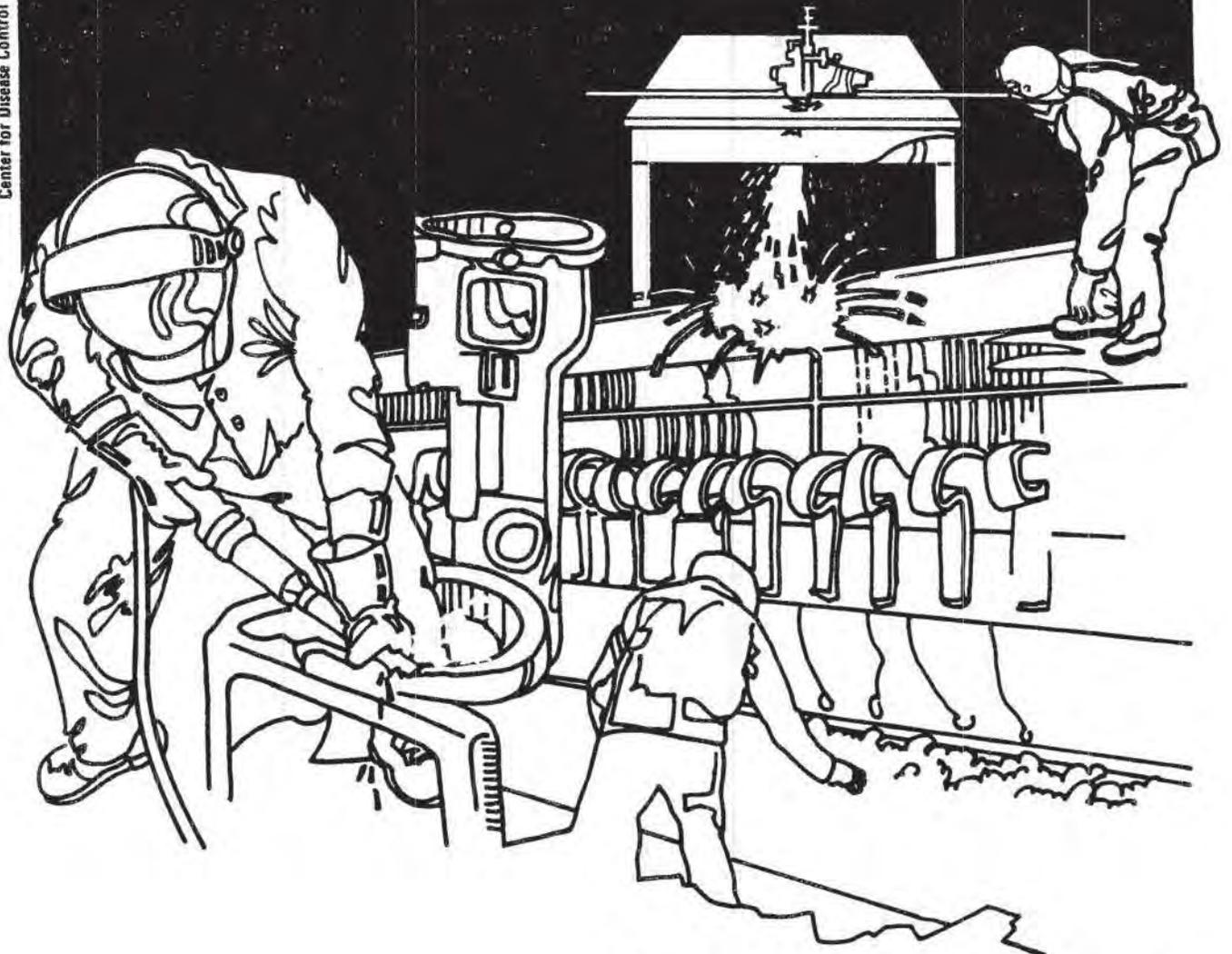


*ethylene dichloride*

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

# NIOSH



## Health Hazard Evaluation Report

79-80, 81-746

## 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.

HE 79-80, 81-746  
September 1980  
Cobe Laboratories, Inc.  
Lakewood and Arvada, Colorado

NIOSH INVESTIGATORS:  
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#### SUMMARY

A health hazard evaluation was conducted by the National Institute for Occupational Safety and Health (NIOSH) at Cobe Laboratories, Inc. in Lakewood and Arvada, Colorado on August 13-15, 1979 to evaluate complaints of skin and eye irritation, breathing difficulties and headaches.

Personal breathing zone and area samples were collected for the numerous chemical materials used in the production and assembly operations. Analysis of the environmental samples indicated the presence of isopropyl alcohol, cyclohexanone, tetrahydrofuran (THF), toluene, methyl ethyl ketone (MEK), ethylene oxide and Freon 12. Measured concentrations of these substances were all below NIOSH and OSHA recommended permissible exposure limits (PEL). Samples collected for toluene diisocyanate (TDI) and methylene bisphenyl isocyanate (MDI) showed no detectable levels. Environmental samples collected for methylene chloride revealed concentrations ranging from 15 ppm to 187 ppm (PEL - 75 ppm). Measured ethylene dichloride levels ranged from 1.5 ppm to 32 ppm (PEL - 1 ppm). Samples collected for perchloroethylene indicated concentrations ranging from 7 ppm to 29 ppm. (Because of carcinogenic potential, exposure to perchloroethylene should be kept as low as possible).

The medical evaluation was accomplished by completing a standard medical questionnaire with 140 Cobe employees. This questionnaire was designed to evaluate the cardiovascular, respiratory, and central nervous systems as well as skin. Review of these questionnaires delineated breathing difficulties primarily affecting workers laboring as assemblers on various lines. Of the responders (21 of 103) 20% complained of wheezing in the absence of any cold symptoms. Wheezing occurred most days, as much as three months each year. Twenty percent (24 of 118 responders) complained of chronic shortness of breath. Persistent cough was a complaint of 22% (31 of 140 responders). Within the past six months 50% (71 of 140 responders) reported headaches, of sufficient intensity to require minor pain relievers. No appreciable prevalence of eye/skin irritation, tumors, anemic blood disorders, or neurologic problems were noted.

Based on the environmental sample results, employee interviews and available toxicological information, NIOSH determined that a potential health hazard exists as a result of employees' exposures to methylene chloride, ethylene dichloride and possibly perchloroethylene. The medical findings of respiratory complaints may, in some part, be attributable to current and past chemical exposures of workers at Cobe Laboratories. Due to the job shuffling of assembly line workers no particular chemical substance, nor work area, responsible for these ill health effects could be determined. Recommendations for reducing exposures are made on page 6.

KEYWORDS: SIC 3840 (Surgical, Medical, and Dental Instruments and Supplies) methylene chloride, ethylene dichloride, perchloroethylene, isopropyl alcohol, cyclohexanone tetrahydrofuran, toluene, methyl ethyl ketone, ethylene oxide.

## INTRODUCTION

Under the Occupational Safety and Health Act of 1970 NIOSH investigates the toxic effects of substances found in the workplace. On April 10, 1979, NIOSH received a confidential request submitted by individual employees at Cobe Laboratories regarding exposure of employees to solvents, resins, and various other materials. The request stated that employees were experiencing nausea, headaches, skin and eye irritation, breathing problems, light-headedness and asthma-like conditions due to work exposures.

## BACKGROUND

Cobe Laboratories manufactures and markets medical therapeutic systems. The company has two manufacturing locations. Their largest facility is located in Lakewood, Colorado. The second and newest facility is in Arvada, Colorado. At the time of the NIOSH study Cobe employed approximately 800 production workers.

The majority of the work at Cobe involves cleaning and assembly operations. Isopropyl alcohol is the agent used for cleaning. Most of the assembly involves the "gluing" of various plastic components. The "glues" used consist of various combinations of solvents. The combinations vary depending on the type of materials involved and the desired final characteristics. Solvents used include methylene chloride, cyclohexanone, ethylene dichloride, tetrahydrofuran (THF), toluene and methyl ethyl ketone (MEK). Other procedures performed included a dry cleaning operation and a degreasing process using perchloroethylene, a sterilization process which uses ethylene oxide and certain proprietary operations using MDI or TDI urethanes. Due to the confidential nature of several of the procedures, no detailed process description by department will be presented. (Any additional process details will be provided where necessary to clarify sample results in the discussion section of this report).

## EVALUATION DESIGN AND METHODS

Walk-through surveys were conducted at the Lakewood and Arvada facilities on May 9 and 10, 1979. Follow-up environmental-medical surveys were performed at the two Cobe facilities on August 13-15, 1979.

During the follow-up surveys personal breathing zone and area environmental samples were collected in almost all departments in both facilities. Environmental samples were collected for methylene chloride, ethylene dichloride, isopropyl alcohol, cyclohexanone, tetrahydrofuran toluene, MEK, perchloroethylene, ethylene oxide, Freon 12, MDI, TDI and hexafluoroisopropanol (HFIP). Collection media, flowrates and analytical methods are presented in the Appendix.

A medical questionnaire designed to evaluate the cardiovascular, respiratory and central nervous systems, as well as the skin, was administered to 140 employees. The 140 employees interviewed consisted of a random selection of workers from both facilities and included all employees who wore environmental sampling equipment.

EVALUATION CRITERIA

## A. Environmental Standards

To assess the concentrations of air contaminants found in the place of employment, three primary sources of criteria were used: (1) NIOSH criteria for recommended standards for occupational exposure to substances (Criteria Documents); (2) recommended and proposed Threshold Limit Values (TLV's) and their supporting documentation as set forth by the American Conference of Governmental Industrial Hygienist (ACGIH) (1979) and (3) occupational health standards as promulgated by the U.S. Department of Labor (29 CFR 1910.1000).

In the following tabulation of criteria, appropriate values are presented:

<u>Substance</u>	<u>NIOSH Recommended Criteria</u>	<u>ACGIH TLV</u>	<u>OSHA Standard</u>
Methylene Chloride	75 ppm	200 ppm	500 ppm
Ethylene Dichloride	1 ppm	50 ppm	50 ppm
Isopropyl Alcohol	400 ppm	400 ppm	400 ppm
Cyclohexanone	-	50 ppm	50 ppm
Tetrahydrofuran	-	200 ppm	200 ppm
Toluene	100 ppm	100 ppm	200 ppm
Perchloroethylene	(1)	100 ppm	100 ppm
Methyl Ethyl Ketone	200 ppm	200 ppm	200 ppm
Ethylene Oxide	50 ppm	50 ppm	50 ppm
MDI	0.005 ppm	0.02 ppm	0.02 ppm
TDI	0.005 ppm	0.02 ppm	0.02 ppm
Freon 12	-	1000 ppm	1000 ppm

(1) NIOSH recommends levels be minimized and kept as low as possible.

## B. Physiological Effects

Methylene Chloride - Methylene chloride is irritating to the skin on repeated or prolonged contact. Splashing of the liquid into the eye is painfully irritating but is not likely to cause serious injury. Signs and symptoms of toxicity include fatigue, weakness, sleepiness, light-headedness, nausea and numbness and tingling of the limbs. Exposure to this agent may cause elevated carboxyhemoglobin levels which may be significant in smokers, workers with anemia or heart disease, or those exposed to carbon monoxide.

Ethylene Dichloride - The acute effects of ethylene dichloride are similar for all routes of entry: ingestion, inhalation and skin absorption. Acute exposures result in nausea, vomiting, dizziness, internal bleeding, bluish - purple discoloration of the mucous membranes and skin (cyanosis), rapid but weak pulse, and unconsciousness. Acute exposures can lead to death from circulatory and respiratory collapse. Chronic exposure may lead to respiratory and circulatory distress. Nursing mothers exposed to ethylene dichloride may unwittingly expose their infants via their-breast milk. Ethylene dichloride has also been found to be mutagenic, and teratogenic in animal studies, causing abnormalities in either the sperm or egg, crossing the placental barrier and adversely affecting the development of the fetus. NIOSH also currently suspects it to be a human carcinogen.

TDI and MDI - Isocyanates are strong irritants of the eyes, skin and mucous membrane and are potential sensitizers of the respiratory system. The onset of sensitization symptoms is insidious. Breathing difficulties become progressively worse with continued exposure. Initial symptoms include nightly shortness of breath and cough with progression to asthmatic bronchitis. When the respiratory illness becomes incapacitating, resulting in lost work time, a return to work causes an acute asthmatic attack almost immediately. Those persons sensitized must not be exposed to any concentrations and removed from any work involving MDI or TDI.

Perchloroethylene - Perchloroethylene causes central nervous system depression and liver damage. Signs and symptoms of toxicity include eye, nose and throat irritation, nausea, headache, dizziness, incoordination, flushing of the face and neck and signs of liver injury. Chronic exposure has caused peripheral neuropathy (loss of sensation in hands and feet). Perchloroethylene is strongly suspected of being a human carcinogen.

## RESULTS AND DISCUSSION

### A. Environmental

A review of the environmental results shows that the majority of the environmental concentrations of the substances which were evaluated were low and well within recommended levels (Tables 1-13). Isopropyl alcohol concentrations ranged from 3 ppm to 157 ppm (Maximum Permissible Exposure Level (PEL - 400 ppm). Cyclohexanone levels ranged from non-detected to 6.9 ppm (PEL - 50 ppm). Sample results for THF were from non-detected to 13.6 ppm (PEL - 200 ppm). Toluene concentrations ranged from 0.2 ppm to 1.4 ppm (PEL - 100 ppm). Two samples for MEK showed concentrations of 15 ppm and 18 ppm (PEL - 100 ppm). Concentrations of ethylene oxide measured during the sterilization procedures were from 2.1 ppm to 4.4 ppm (PEL - 50 ppm).

Tables 1, 4, 5, 12 and 13 contain environmental levels of methylene chloride which were measured during several different operations. The methylene chloride levels were all below the NIOSH recommended level of 75 ppm with the exception of the foamer assembly "gluing" operations in Optiflo II and the "bird feeder" process in Case Assembly. Time-weighted-average (TWA) concentrations for these procedures ranged from 93 ppm to 187 ppm. (All methylene chloride concentrations measured were below the ACGIH TLV and OSHA standard.) Local exhaust ventilation is present at the "bird feeders" with air flow being measured at 5 fpm to 50 fpm at the slots at the four stations. The gluing operations in Optiflo II are performed under large hoods. Air flow at the work site was negligible.

The current OSHA standard for ethylene dichloride is 50 ppm. In 1976, NIOSH recommended that no worker be exposed to ethylene dichloride in excess of 5 ppm. The NIOSH recommendation was based on reports of adverse effects on the nervous system and liver of workers exposed to 10-15 ppm ethylene dichloride. More recent studies show ethylene dichloride to be a carcinogen in two animal species. Based on this carcinogenic potential, NIOSH recommends that no worker be exposed in excess of 1 ppm. Ethylene dichloride is found in at least two of the "glues" used at Cobe. During the time of the survey at Cobe, environmental samples for ethylene dichloride were collected on workers in monitoring line production, reservoir assembly and on the solvent room worker. (Tables 1 and 13) Ethylene dichloride levels ranged from 1.5 ppm to 32 ppm. All concentrations measured were in excess of the NIOSH recommended level of 1 ppm. Exposure to ethylene dichloride is also of special concern because of the predominantly female work force. Ethylene dichloride has been found in the breast milk of women. Therefore nursing mothers exposed to ethylene dichloride may be unknowingly exposing their children to the chemical.

A similar situation exists with perchloroethylene. The TLV and current OSHA standard for perchloroethylene is 100 ppm. In 1976 NIOSH recommended an exposure limit of 50 ppm. Animal studies have since indicated that perchloroethylene causes liver cancer in laboratory mice. While the carcinogenic potential of perchloroethylene in the workplace is being further evaluated, NIOSH recommends that occupational exposure to perchloroethylene be minimized. Levels of perchloroethylene measured on the dry cleaning operator and on the degreaser operators ranged from 7 ppm to 29 ppm. (Table 6)

Environmental samples were collected for TDI and MDI in all locations where urethane material was being used. No detectable levels of either isocyanate were measured.

A sample for Freon 12 collected in Optiflo II showed a level of 10 ppm. The recommended standard is 1000 ppm.

Environmental samples for hexafluoroisopropanol (HFIP) were also collected in monitoring line production. Of the four samples collected, two had non-detectable levels and the remaining two samples showed concentrations of 0.65 ppm and 1 ppm of HFIP. The HFIP was only used under specially constructed hoods with face velocities measured at 100-200 fpm. There is no recommended exposure level for this material. However, it is felt that controls were adequate and exposures were not excessive.

#### B. Medical

The review of medical questionnaires found respiratory complaints of cough, shortness of breath, and wheezing. The predominance of headache in those interviewed may not be construed to be solely caused by the occupational environment. Headache represents one of man's most frequent physical discomforts. Medically speaking, its significance is often obtuse, for it may indicate disease, or some minor tension or fatigue, attributable to the affairs of a "bad" day. Fortunately, in most instances, it reflects the latter, and only exceptionally is it a harbinger of serious disease.

No appreciable prevalence of eye/skin irritation, tumors, anemic blood disorders, or neurologic problems were noted.

The majority of workers with respiratory complaints labored on various product assembly lines (Table 14-16). Their Cobe work histories detailed frequent "bumping" from one assembly job to another, throughout the course of their employment. Because of this interplant movement no particular work station or chemical substance can be deemed causative. Yet clearly, assembly line workers comprised the vast majority of those with health complaints.

#### RECOMMENDATIONS

1. Local exhaust ventilation should be improved at the "bird feeders" to reduce exposure to methylene chloride.
2. Local exhaust ventilation should be provided for the foamer assembly operation in Optiflo II to reduce employees' exposure to methylene chloride.
3. If possible, a substitute should be found for ethylene dichloride. If substitution is impossible local exhaust should be provided for all operations where ethylene dichloride is used and periodic environment monitoring should be conducted to ensure that the levels are maintained below the 1 ppm level. Pregnant women or nursing mothers especially should not work with material containing ethylene dichloride.
4. Engineering and work practice controls should continue to be used to minimize employee exposures to perchloroethylene. Environmental monitoring should be conducted periodically to document exposure levels.
5. The respirator program at Cobe should be reviewed. Section 1910.134 of OSHA, Respiratory Protection, outlines the minimal acceptable program.
6. Training programs on the effects of exposure or contact with chemicals, proper work practices, etc. provided by Cobe should be continued.
7. Preemployment histories and physical examinations should be given all new employees. Current employees exposed to perchloroethylene, ethylene dichloride, and methylene chloride should be given annual physical examinations. Particular emphasis should be given the respiratory, circulatory, and central nervous systems. The liver, kidneys, and skin should be thoroughly evaluated. Complete blood counts and urinalysis should be performed as well.
8. The Joint Labor-Management health and safety committee should become a viable part of normal plant activities. Meetings of this committee should be promoted and its recommendations should be honestly addressed.

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DISTRIBUTION AND AVAILABILITY OF DETERMINATION REPORT

Copies of this report are currently available, upon request, from NIOSH, Division of Technical Service, Publications Dissemination, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After 90 days, the report will be available through the National Technical Information Service (NTIS), Springfield, Virginia 21161.

- a. Cobe Laboratories, Inc., Lakewood, Colorado
- b. Requestors
- c. U.S. Department of Labor, Region VIII
- d. NIOSH, Region VIII

For the purpose of informing the "affected employees", the employer shall promptly "post" the determination report for a period of 30 days in a prominent place near where exposed employees work.

TABLE 1

Methylene Chloride and Ethylene Dichloride Concentrations  
Cobe Laboratories, Inc  
Lakewood, Colorado  
August 13, 1979

<u>Sample Location</u>	<u>Sample Description</u>	<u>Sample Number</u>	<u>Sampling Time</u>	<u>Sample Volume (liters)</u>	<u>Methylene Chloride (ppm)</u>	<u>Methylene Chloride TWA (ppm)</u>	<u>Ethylene Dichloride</u>	<u>Ethylene Dichloride TWA (ppm)</u>
Monitoring Lines Production	Stopcock Assembly (1)	CT-25	6:28-9:58	1.5	89	65	-	
		CT-27	10:00-14:11	1.8	45		-	
		CT-26	6:28-9:58	9.1	-		44	32
		CT-28	10:00-14:11	10.8	-		22	
Monitoring Lines Production	Stopcock Assembly (2)	CT-29	6:33-9:55	1.3	22	30	-	
		CT-31	9:58-14:09	1.6	36		-	
		CT-30	6:33-9:55	8.3	-		10	17
		CT-32	9:58-14:09	10.1	-		22	
Monitoring Lines Production	Stopcock Assembly (3)	CT-33	6:30-9:58	0.4	24	48	-	
		CT-35	9:55-14:10	1.4	68		-	
		CT-34	6:30-9:58	2.9	-		13	22
		CT-36	9:55-14:10	9.6	-		31	
August 14, 1979								
Blood Filters & Cardiotomy Reservoirs	Glue Up-per and Lower Reservoirs	CT-47	7:00-9:56	1.4	24	15	-	
		CT-49	9:56-14:45	2.3	10		-	
		CT-48	7:00-9:56	7.4	-		15	9
		CT-50	9:56-14:45	12.0	-		6	
Recommended Levels						75 ppm	1 ppm	

Table 2

## Isopropyl Alcohol Concentrations

Cobe Laboratories, Inc.  
Lakewood, ColoradoAugust 13, 1979

<u>Sample Location</u>	<u>Sample Description</u>	<u>Sample Number</u>	<u>Sampling Time</u>	<u>Sample Volume (liters)</u>	<u>Isopropyl Alcohol* (ppm)</u>	<u>TWA (ppm)</u>
Optiflow II	Alcohol wash(inner airstone assembly)	CT-1	7:13-10:55	3.8	26	33
		CT-2	10:57-14:13	3.5	38	
Optiflow II	Alcohol wash(inner filter)	CT-3	7:15-10:13	3.8	45	33
		CT-4	10:13-14:15	5.1	25	
<u>August 14, 1979</u>						
Hollow-fiber	Alcohol wash(housing manifold)	CT-58	6:20-10:15	4.4	157	144
		CT-69	10:15-14:21	4.6	133	
Finstock	Sandblasting and degreasing	CT-67	6:50-10:05	3.6	62	40
		CT-67	10:06-13:15	1.9	19	
Filter Reservoirs	Alcohol wash(cardiac manifold)	CT-61	6:15-9:55	4.3	113	109
		CT-66	9:55-14:15	4.2	106	
Finstock	Alcohol Dip	CT-57	6:41-10:00	1.7	41	22
		CT-70	10:03-13:45	20.0	3	

400 ppm

\*NIOSH Recommended Standard

Table 3

Cyclohexanone and Tetrahydrofuran (THF) Concentrations  
Cobe Laboratories, Inc  
Lakewood, Colorado  
August 13, 1979

<u>Sample Location</u>	<u>Sample Description</u>	<u>Sample Number</u>	<u>Sampling Time</u>	<u>Sample Volume (liters)</u>	<u>Cyclohexanone (ppm)</u>	<u>THF (ppm)</u>
Heart Lung	Gluer (1)	CT-17	6:48-14:15	3.5	-	N.D.
		CT-18	6:48-14:15	20.4	N.D.	-
Heart Lung	Gluer (2)	CT-19	6:51-14:15	4.8	-	N.D.
		CT-20	6:51-14:15	12.2	0.2	-
Needle Assembly	Gluer (1)	CT-21	6:20-14:07	5.3	-	N.D.
		CT-22	6:20-14:07	16.5	0.8	-
Needle Assembly	Gluer (2)	CT-23	6:22-14:07	6.6	-	N.D.
		CT-24	6:22-14:07	21.7	1.2	-
Recommended Levels					50 ppm	200 ppm

Table 4

Methylene Chloride and Toluene Concentrations  
Cobe Laboratories, Inc  
Lakewood, Colorado

August 14, 1979

<u>Sample Location</u>	<u>Sample Description</u>	<u>Sample Number</u>	<u>Sampling Time</u>	<u>Sample Volume (Liters)</u>	<u>Methylene Chloride (ppm)</u>	<u>Methylene Chloride (TWA) (ppm)</u>	<u>Toluene (ppm)</u>	<u>Toluene (TWA) (ppm)</u>
Finstock	Center Plate Primer (Alpha) (1)	CT-37	6:42-10:07	14.3	16	44	-	.8
		CT-37	10:08-13:45	3.2	70		-	
		CT-38	6:42-10:07	40.3	-		0.2	
		CT-40	10:08-13:45	11.2	-		1.4	
Finstock	Center Plate Primer (Alpha) (2)	CT-43	7:23-10:08	1.9	88	40	-	1
		CT-45	10:09-14:00	2.7	4.8		-	
		CT-44	7:23-10:08	5.9	-		1	
		CT-46	10:09-14:00	8.3	-		1	
Hollow Fiber	Primary Manifolds (EDC Solvent)	CT-54	6:35-14:20	10.2	-		5	

Recommended Levels

75 ppm

100 ppm

Table 5

Methylene Chloride Concentrations  
Cobe Laboratories, Inc  
Lakewood, Colorado

August 13, 1979

<u>Sample Location</u>	<u>Sample Description</u>	<u>Sample Number</u>	<u>Sampling Time</u>	<u>Sample Volume (liters)</u>	<u>Methylene Chloride (ppm)</u>	<u>Methylene Chloride TWA (ppm)</u>
Optiflo II	Connect stopcock and blood tubes	CT-5	7:08-10:19	8	57	49
		CT-6	10:21-14:13	9.8	43	
Optiflo Assembly	Putting cover on blood oxygenator	CT-8	6:56-10:11	1.6	42	26
		CT-9	10:11-14:16	2.0	14	
Optiflo Assembly	Glue fittings to blood oxygenator	CT-10	7:00-10:08	1.0	82	73
		CT-11	10:10-14:15	0.8	66	

August 14, 1979

Optiflo II	Glue together foamer assembly (1)	CT-56	7:08-10:14	3.9	159	124
		CT-71	10:14-14:12	5.0	96	
Hollow Fiber	Manifold press	CT-59	6:30-9:50	3.4	37	37
		CT-68	9:51-14:20	4.7	37	
Optiflo II	Glue together foamer assembly (2)	CT-62	7:07-10:38	4.3	167	187
		CT-65	10:38-14:17	4.4	207	

Recommended Level

75 ppm

Table 6

Perchloroethylene Concentrations  
Cobe Laboratories, Inc  
Lakewood, Colorado

<u>Sample Location</u>	<u>Sample Description</u>	<u>Sample Number</u>	<u>Sampling Time</u>	<u>Sample Volume (liters)</u>	<u>Perchloroethylene (ppm)</u>
August 13, 1979					
Optiflo II	Dry Cleaning Operation	CT-7	7:05-14:15	10	11
August 14, 1979					
Finstock	Degreaser Operator	CT-51	6:50-14:00	15.2	7
Finstock	Degreaser Operator & Sandblaster	CT-55	6:51-13:45	17.3	29

Table 7

Methyl Ethyl Ketone Concentrations  
Cobe Laboratories, Inc  
Lakewood, Colorado

August 14, 1979

<u>Sample Location</u>	<u>Sample Description</u>	<u>Sample Number</u>	<u>Sampling Time</u>	<u>Sample Volume (liters)</u>	<u>MEK (ppm)</u>
Finstock	Blood Side Primer	CT-52	6:41-14:30	17.2	15
Finstock	Water Side Primer	CT-53	6:40-14:00	17.7	18
					100 ppm
Recommended Level					

Table 8

Ethylene Oxide Concentrations  
Cobe Laboratories, Inc  
Lakewood, Colorado  
August 14, 1979

<u>Sample Location</u>	<u>Sample Description</u>	<u>Sample Number</u>	<u>Sampling Time</u>	<u>Sample Volume</u> (liters)	<u>Ethylene Oxide</u> (ppm)
Sterilization Area	Sterilizer Operator	CT-63	7:40-10:50	12.7	4.4
		CT-74	17:55-20:05	11.5	3.1
Sterilization Area	Area Sample	CT-64	7:41-10:55	16.2	2.9
					50 ppm
Recommended Level					

Table 9

Methylene Chloride, Cyclohexanone, Tetrahydrofuran (THF) and Ethylene Dichloride Concentrations  
Cobe Laboratories, Inc  
Lakewood, Colorado  
August 14, 1979

<u>Sample Location</u>	<u>Sample Description</u>	<u>Sample Number</u>	<u>Sampling Time</u>	<u>Sample Volume</u> (liters)	<u>Cyclohexanone</u> (ppm)	<u>THF</u> (ppm)	<u>Methylene Chloride</u> (ppm)	<u>Ethylene Dichloride</u> (ppm)
Solvent Storage	Area	CT-41	7:20-14:25	4.5	-	N.D.	70	-
		CT-42	7:20-14:25	11.5	N.D.	-	-	N.D.
Recommended Levels					50 ppm	200 ppm	75 ppm	1 ppm

Table 10  
Isopropyl Alcohol Concentrations

Cobe Laboratories, Inc.  
Arvada, Colorado

August 15, 1979

<u>Sample Location</u>	<u>Sample Description</u>	<u>Sample Number</u>	<u>Sampling Time</u>	<u>Sample Volume</u> (liters)	<u>Isopropyl Alcohol *</u> (ppm)	<u>TWA</u> (ppm)
PPD Folding Room	Folder 15	CT-78	6:33-10:55	3.4	26	31
		CT-79	10:55-14:17	3.2	37	
PPD Folding Room	Folder 7	CT-96	6:26-10:52	4.0	68	55
		CT-97	10:52-14:16	5.4	38	
PPD Folding Room	Folder 16	CT-100	7:25-10:50	5.2	117	98
		CT-101	10:50-14:15	3.9	73	
PPD Folding Room	Folder 5	CT-106	7:25-10:57	4.5	80	79
		CT-133	10:58-14:20	3.5	77	
PPD Folding Room	Folder 19	CT-127	6:30-10:54	1.8	48	51
		CT-128	10:55-14:17	4.0	55	
Tube Cutter	Cutter 10-1	CT-98	6:45-11:02	4.6	52	63
		CT-99	11:02-14:00	3.2	80	
Tube Cutter	Cutter 05-1	CT-125	6:40-10:30	4.5	62	62
		CT-126	10:30-14:21	4.9	61	

\*NIOSH recommended Standard

400 ppm

Table II  
 Cyclohexanone and Tetrahydrofuran (THF) Concentrations  
 Cobe Laboratories, Inc.  
 Arvada, Colorado  
 August 15, 1979

<u>Sample Location</u>	<u>Sample Description</u>	<u>Sample Number</u>	<u>Sampling Time</u>	<u>Sample Volume (liters)</u>	<u>Cyclohexanone (ppm)</u>	<u>THF (ppm)</u>
2nd Floor	Rework	CT-88	7:19-11:05	1.9	-	N.D.
		CT-90	11:05-14:00	1.4	-	N.D.
		CT-89	7:19-11:05	9.9	0.5	-
		CT-91	11:05-14:00	7.6	0.7	-
Final Assembly	Blood Tubing Assembler (1)	CT-92	7:00-10:41	2.9	-	4.7
		CT-94	10:41-14:24	1.9	-	5.4
		CT-93	7:00-10:41	9.3	2.4	-
		CT-95	10:41-14:24	6.1	3.3	-
Final Assembly	Blood Tubing Assembler (2)	CT-107	7:07-10:43	2.0	-	5.1
		CT-109	10:43-14:22	1.3	-	2.6
		CT-108	7:07-10:43	5.7	2.6	-
		CT-110	10:43-14:22	3.6	2.1	-
Sub Assembly	Assembling Drip Chambers (1)	CT-111	6:51-10:31	1.7	-	4.0
		CT-113	10:31-14:25	1.7	-	4.0
		CT-112	6:51-10:31	9.0	2.2	-
		CT-114	10:31-14:25	9.3	5.6	-
Sub Assembly	Assembling Drip Chambers (2)	CT-115	6:54-10:35	2.5	-	2.7
		CT-117	10:35-14:25	2.6	-	6.5
		CT-116	6:54-10:35	7.8	1.6	-
		CT-118	10:35-14:25	8.0	6.9	-
Sub Assembly	Assembling Drip Chambers (3)	CT-119	6:47-10:36	2.0	-	N.D.
		CT-121	10:37-14:26	2.0	-	13.6
		CT-120	6:47-10:36	6.9	1.8	-
		CT-122	10:37-14:26	7.0	5.7	-
Final Assembly	Blood Tubing Assembler (3)	CT-123	7:05-10:40	1.8	-	5.7
		CT-131	10:40-14:25	1.9	-	9.0
		CT-124	7:05-10:40	6.6	-	6.7
		CT-132	10:40-14:25	6.9	5.8	-

Recommended Levels

50 ppm

200 ppm

Table 12  
Methylene Chloride Concentrations  
Cobe Laboratories, Inc  
Arvada, Colorado  
August 15, 1979

<u>Sample Location</u>	<u>Sample Description</u>	<u>Sample Number</u>	<u>Sampling Time</u>	<u>Sample Volume (liters)</u>	<u>Methylene Chloride (ppm)</u>	<u>Methylene Chloride TWA (ppm)</u>
Case Assembly	Bird Feeder	CT-102	7:47-10:27	3.3	94	93
	Operator (1)	CT-103	10:28-14:20	4.8	92	
Case Assembly	Bird Feeder	CT-104	8:10-10:47	2.9	120	129
	Operator (2)	CT-105	10:47-14:20	3.9	135	
Recommended Level						75 ppm

Table 13  
Methylene Chloride, Tetrahydrofuran (THF), Cyclohexanone and Ethylene Dichloride Concentrations  
Cobe Laboratories, Inc  
Arvada, Colorado  
August 15, 1979

<u>Sample Location</u>	<u>Sample Description</u>	<u>Sample Number</u>	<u>Sampling Time</u>	<u>Sample Volume (liters)</u>	<u>Cyclohexanone (ppm)</u>	<u>THF (ppm)</u>	<u>Methylene Chloride (ppm)</u>	<u>Ethylene Dichloride (ppm)</u>
Solvent Room	Solvent Room Worker	CT-84	7:37-11:11	2.3	--	-	23	1.5
		CT-86	11:11-14:28	2.0	--	-	34	3.4
		CT-85	7:37-11:11	5.7	1.3	2.2	-	-
		CT-87	11:11-14:28	5.2	0.3	6.2	-	-
Solvent Room	Area Sample	CT-80	7:30-11:13	3.5	-	N.D.	3	-
		CT-82	11:13-13:55	2.5	-	N.D.	4	-
		CT-81	7:30-11:13	11.3	2	-	-	0.7
		CT-83	11:13-13:55	8.1	0.3	-	-	0.6
Recommended Levels					50 ppm	200 ppm	75 ppm	1 ppm

Table 14

Medical Findings  
Complaints of Chronic Cough in Past Year

<u>Job Titles</u>	<u>No. of People Responding</u>	<u>No. of Postive Responses (%)</u>	
Monitor Line/Needle Assembler	30	8	(26.6%)
Optiflow II Assembler	20	7	(35.0%)
General Assembler	47	12	(25.5%)
Electrical Mechanic	3	1	(33.3%)
Chemical Mixer	2	1	(50.0%)
Managerial Employees	27	2	(3.7%)
Manufacturing Engineer	4	0	(0%)
Potter	1	0	(0%)
Process Engineer	4	0	(0%)
Demolder	2	0	(0%)

TOTALS - No. of Respondents - 140 (100%)

No. of Positives Responses - 31 (22%)

No. of Positive Smokers - 20 (64.5%)

No. of Positive Non-smokers - 11 (35.5%)

Table 15

Medical Findings  
Complaints of Shortness of Breath for Three Months During Past Year

<u>Job Titles</u>	<u>No. of People Responding</u>	<u>No. of Positive Responses (%)</u>	
Monitor Line/Needle Assembler	28	7	(25.0%)
Optiflow II Assembler	18	5	(27.7%)
General Assembler	37	8	(21.6%)
Electrical Mechanic	2	1	(50.0%)
Chemical Mixer	2	0	(0%)
Managerial Employees	24	1	(4.1%)
Manufacturing Engineer	3	1	(33.3%)
Potter	1	1	(100%)
Process Engineer	2	0	(0%)
Demolder	2	0	(0%)

TOTALS - No. of Respondents - 118\*  
 No. of Positive Responses - 24 (20.33%)  
 No. of Positive Smokers - 15 (62.5%)  
 No. of Positive Non-smokers - 9 (37.5%)

\*The total number of employees responding to any question varies depending on their previous responses.

Table 16

Medical Findings  
Complaints of Wheezing in the Absence of Cold Symptoms

<u>Job Titles</u>	<u>No. of People Responding</u>	<u>No. of Positive Responses (%)</u>	
Monitor Line/Needle Assembler	27	8	(29.6%)
Optiflow II Assembler	18	3	(16.6%)
General Assembler	32	6	(18.7%)
Electrical Mechanic	2	1	(50.0%)
Chemical Mixer	1	0	(0%)
Managerial Employee	17	2	(11.7%)
Manufacturing Engineer	1	0	(0%)
Potter	1	0	(0%)
Process Engineer	2	1	(50%)
Demolder	2	1	(50%)

TOTALS - Number of Respondents - 103\*  
 Number of Positive Responses - 21 (20.3%)  
 Number of Positive Smokers - 14 (66.6%)  
 Number of Positive Non-smokers - 7 (33.3%)

\* The total number of employees responding to any question varies depending on their previous responses.

Table 17

## Medical Findings

Has a doctor ever told you that you had any of the following conditions?

	<u>No. of Respondents</u>	<u>No. Positive Responses (%)</u>	
Malignant tumor/growth	140	1	(.07%)
Benign tumor/growth/cyst	140	5	(3.5%)
Chronic bronchitis/asthma	140	6	(4.2%)
Had any therapy for skin conditions	140	4	(2.8%)
Had any therapy for sleep problems	140	5	(3.5%)
Had any therapy for nerve problems	140	9	(6.4%)
Had any therapy for lack of pep	140	8	(5.7%)

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**PUBLIC HEALTH SERVICE**  
**CENTER FOR DISEASE CONTROL**  
**NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH**  
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