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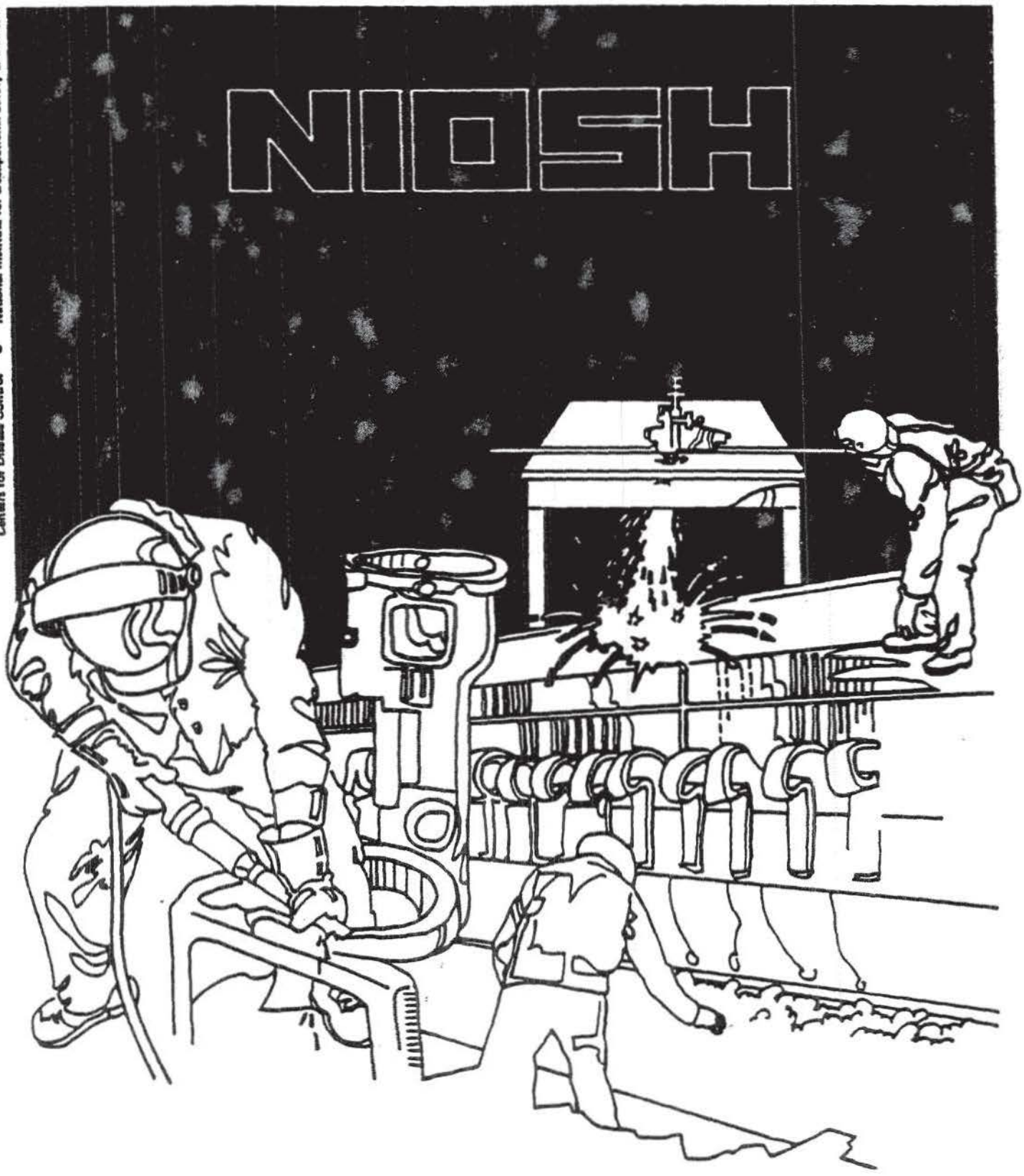

Health Hazard Evaluation Report

HETA 83-159-1473
SEAMLESS HOSPITAL PRODUCTS COMPANY
FAYETTE, ALABAMA

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 83-159-1473
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SEAMLESS HOSPITAL PRODUCTS COMPANY
FAYETTE, ALABAMA

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I. SUMMARY

On February 18, 1983, the National Institute for Occupational Safety and Health (NIOSH) received a request for a Health Hazard Evaluation from the United Rubber Workers International Union at the Seamless Hospital Products Company plastics facility in Fayette, Alabama, to evaluate possible high incidences of cancer and miscarriages among the female employees. Potential exposure exists to solvents, plastic fumes and dust, and ethylene oxide.

An on-site survey at the facility conducted November 9 and 10, 1983, consisted of medical evaluation of pregnancy outcomes (through interviews and questionnaires), and assay of airborne dust, organic solvents, ethylene oxide, and nitrosamines.

Air concentrations of benzene ranged from 0.10 to 0.37 ppm; ethylene oxide concentrations ranged from 1.4 to 5.8 ppm. NIOSH regards benzene and ethylene oxide as potential occupational carcinogens, and recommends that worker exposure be reduced to the lowest feasible limit. Air concentrations of all other chemicals measured were well below their lowest recommended exposure limits.

Eighty percent of the 390 production workers are women, with an average age of 26-27. The spontaneous abortion rate for 248 production employees was found to be 7.8 percent. The normal rate of spontaneous abortion is unknown but is estimated to be about 10-15 percent.

On the basis of preliminary epidemiological analysis, there does not appear to be evidence of an elevated rate of miscarriage in the female workers in this plant, or any unusual cluster of certain types of cancer.

It is recommended that ventilation be increased in the injection molding and extrusion areas, that suitable table top dispensers and bulk containers be used for solvents in the assembly area, and that exposure to ethylene oxide be reduced in the sterilizer/storage areas.

KEYWORDS: SIC 5086, ethylene oxide, organic solvents, plastics, miscarriages, cancer.

II. INTRODUCTION

On February 18, 1983, the United Rubber Workers International Union requested that the National Institute for Occupational Safety and Health (NIOSH) conduct a health hazard evaluation at the Seamless Hospital Products Company plastics facility in Fayette, Alabama, to evaluate suspected high incidences of cancer and miscarriages among the female employees from exposure to solvents, plastic fumes and dust, and ethylene oxide.

The University of North Carolina under a cooperative agreement with NIOSH was assigned the health hazard evaluation, May 24, 1983. An on-site survey at the facility was conducted November 9 and 10, 1983 by two industrial hygienists, a physician and a graduate student in epidemiology. The survey was delayed due to an extended strike at the facility during parts of the spring and summer.

The goals of the survey were to evaluate the working environment for possible excess exposure of employees to air contaminants, evaluate work related health problems among workers, interview certain workers with possible medical problems, and develop appropriate recommendations to management to reduce or alleviate any problems found.

III. BACKGROUND

The following information was obtained in initial discussions with management personnel and observation of plant operations.

The plant is a one-story structure built in 1961. There are 390 production workers. Approximately 180 workers each work the day and evening shifts and 30 work the midnight to 7:00 a.m. shift. The same work is performed on all shifts.

Eighty percent of the production workers are women, with an average age of 26-27. The turnover rate is less than 5 percent per year.

The plant manufactures up to 400 items of hospital supplies. The main processes are:

- Injection molding of small plastic products
- Extrusion manufacture of plastic tubing
- Thermoforming of large plastic items
- Filling and radiofrequency sealing of iodine solution bags
- Assembly of products into prepared hospital "kits" (such as catheter kits)
- Ethylene oxide sterilization of packaged products

In injection molding, various plastics (polyvinyl chloride, polystyrene, polypropylene and polyethylene) in granular form are heated to the plastic state and formed under pressure into the desired shape. In tubing extrusion, polyvinylchloride is heated to 300°F and extruded into the size tubing desired. In thermoforming, polystyrene is heated and formed to the shape desired. In solution filling, plastic bags are filled with iodine solution and sealed by radiofrequency sealers. Thirty five workers are involved in these four operations.

About 85 percent of the workers assemble individual items into the final products and package them. In assembly, a variety of organic solvents are used; primarily methyl ethyl ketone, tetrahydrofuran, and vinyl resins. The solvent mixtures are used to soften plastic products for assembly and as a carrier for resins used to bond various plastic parts to one another. Solvents and glues are used on the work tables in front of workers in a variety of makeshift shallow containers, and no effort is made to control the escape of vapors by evaporation or spillage or to capture evaporated vapors from the containers. Several of the table top solvent dispensers contained sponges, providing added surface area for evaporation. The solvents in the work-table containers are replenished from 1-gallon glass bottles of bulk solvents kept in the assembly area.

Sterilization of assembled packaged products is carried out in a separate warehouse in two large walk-in sterilizers with a 12%/88% mixture of ethylene oxide/freon. The sterilizers have provision for discharging the sterilant to the outside and replacing it with clean air before the sterilizers are opened after a sterilization period (5-8 hrs.). Sterilized packages are stored, and any ethylene oxide residual is allowed to "gas out" of the packages. Respirators are available for use by persons sterilizing packaged products. Sterilization is to be discontinued at this plant by January 1984.

Ventilation in the production areas is mainly by exhaust fans in the outer walls. Temperature control is by air-recirculating cooling/heating units. Temperature control in the sterilizer/warehouse is by overhead hot water heated space heaters.

Ten large injection molders are handled by approximately 16 employees per shift. When changing product line or servicing the machines, the maintenance personnel "purge" the machines of the remaining plastic, giving rise to large volumes of visible odorous fumes. The purging occurs several times per shift and there was a visible haze in the area during the survey. Exhaust fans in the exterior walls appeared to be used to remove fumes on a sporadic basis, in response to workers' complaints.

IV. METHODS AND MATERIALS

A. Environmental

Environmental evaluations consisted of interviews with management and operating personnel about environmental conditions, a walk-through industrial hygiene survey, examination of work techniques, review of materials being handled, and collection of air samples for particulates and vapors. Both personal and area air samples were collected and analyzed for total and respirable dust concentrations in air. Total particulate samples were collected in closed face mode on 37 mm diameter, 5µ pore size vinyl metricel filters at a rate of 1.7 liters/minute. Respirable samples were collected on 37 mm diameter, 5µ pore size vinyl metricel filters with MSA 10 milliter nylon pre-sampler at a flow rate of 1.7 liters/minute.

Three air samples were collected with Thermosorb/N^{R} tubes and analyzed for nitrosamines. These samples were desorbed by back-flushing the cartridges with a mixture of 25%/75% methanol/methylene chloride solution. A total volume of 1.9 mL was collected from each cartridge. This solution was then analyzed by gas chromatography using a Thermal Energy Analyzer (TEA) in the nitrosamine mode. The level of detection for dimethylnitrosamine was 70 ng. Air samples were also collected using charcoal tubes and analyzed for a variety of organic vapors by means of gas chromatography following elution by carbon disulfide.

Ventilation equipment and practices were observed and discussed with plant personnel. No air flow measurements were made.

Air was sampled for the presence of ethylene oxide near the sterilizers and in the area where sterilized products are stored before shipment.

B. Medical

The medical evaluation consisted of: 1) interviews with certain workers about possible health problems, 2) a review of available death certificates for cause of death, and 3) the distribution of a pregnancy questionnaire to all female employees. The union provided a list of names of people with health problems and the particular problem they thought might be important. On the union's recommendation, 7 workers were interviewed about their current and past health status and work-related problems. The union also supplied names of 8 deceased workers whose deaths were thought to be cancer-related. Seven of these, plus one more supplied by the personnel manager, had death certificates on file with the company. These were reviewed for primary and underlying cause of death.

Three hundred seventy-one questionnaires were distributed to all female employees in the plant. The questionnaire contained basic demographic information, dates of starting work and of marriage, a

detailed pregnancy history, and certain questions on lifestyle, such as smoking, that might affect the rate of spontaneous abortions. The pregnancy history consisted of a record of each pregnancy outcome (live birth, stillbirth, spontaneous abortion (miscarriage), or induced abortion), and the dates that each occurred. Job history information, including departments, dates of job changes, and dates of maternity and other leave of absences were obtained for all active employees.

V. EVALUATION CRITERIA

A. Environmental Criteria

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

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

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

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

The criteria for evaluating nuisance particulate concentrations in air are the ACGIH recommended limits of 10 milligram/ cubic meter (mg/m^3) for total dust and 5 mg/m^3 for respirable dust (2). The OSHA limits are 15 mg/m^3 for total dust and 5 mg/m^3 for respirable dust (6).

The criteria for evaluating the 24 organic vapors assayed are the current American Conference of Governmental Industrial Hygienists Threshold Limit Values (ACGIH-TLV), the U.S. Department of Labor Occupational Health Standards (OSHA), NIOSH Criteria Documents and other publications, and the NIOSH Registry of Toxic Effects of Chemical Substances. Values listed below reflect the lowest prescribed or recommended exposure limits found among the sources listed above.

Substance	Ceiling Limit or STEL[a] (ppm)	8-hour Time Weighted Average Limit (ppm)	Source	OSHA Standard (ppm)(6)
Isopentane	610	120	NIOSH (1)	1,000
n-Pentane	610	120	NIOSH (1)	1,000
2,2-Dimethylbutane	510	100	NIOSH (1)	none
3-Methylpentane	510	100	NIOSH (1)	none
2-Methylpentane	510	100	NIOSH (1)	none
n-Hexane	125	50	ACGIH (2)	500
Cyclopentane	900	600	ACGIH (2)	none
Methylcyclopentane	1,000	500	ACGIH (2)	none
n-Heptane	440	85	NIOSH (1)	500
Cyclohexane	375	300	ACGIH (2)	300
Methycyclohexane	500	400	ACGIH (2)	500
n-Octane	385	75	NIOSH (1)	500
1,1,1-Trichloroethane	350	350	NIOSH (4)	350
Methyl ethyl ketone	300	200	ACGIH (2)	200
Isopropanol	500	400	ACGIH (2)	400
Benzene	LFL[b]	LFL[b]	NIOSH (5)	10
Trichloroethylene	150	25	NIOSH (3)	100
Toluene	150	100	ACGIH (2)	200
Ethylene dichloride	15	5	NIOSH (4)	50
Xylenes; o,p,m	150	100	ACGIH (2)	100
Cyclohexanone	100	25	ACGIH (2)	50
Tetrahydrofuran	250	200	ACGIH (2)	200
Dimethylnitrosamine	-	0[c]	ACGIH (2)	0[c]
Ethylene oxide	LFL[b]	LFL[b]	NIOSH (7)	50[d]

[a] Short-term Exposure Limit

[b] NIOSH recommends that benzene and ethylene oxide be regarded in the workplace as potential occupational carcinogens and that exposures be reduced to the lowest feasible limit (LFL).

[c] no exposure limit: exposure to be completely avoided

[d] Limit of 1 ppm proposed 4/18/83

B. Medical

The goal of the interviews with employees was to investigate health problems and to discern any pattern in these complaints that might be suggestive of workplace hazards. In a similar fashion, the causes and characteristics of the deaths reviewed might suggest an occupational exposure. A limitation in the latter case was the fact that the choice of which death certificates to review was not based on comprehensive reporting of all deaths, but simply on recall by the union and personnel manager. It is unclear whether or not these reported deaths form an exhaustive or representative list of deaths among working or retired employees. Because of this limitation, and because of the small number (only 9) of deaths involved, only a striking anomaly among the causes of death would suggest an occupational cause. Examples include a cluster of a rare or unusual cancer, or a concentration of deaths from one cause among people working at similar jobs.

Because the initial request for a health hazard evaluation indicated the suspicion of "significant" spontaneous abortions, it is important to determine whether the occurrence of spontaneous abortion is especially high in this population. Since the questionnaire asks for information about all pregnancies, not just those since starting work, it was possible to compare the percentage of all pregnancies ending in spontaneous abortion that occurred before women started working at the plant to the percentage occurring after women started work. Job history information can pinpoint whether those who have had spontaneous abortions are concentrated in certain departments. In this evaluation, however, any analyses involving work histories is necessarily very limited. The employment records that were provided only classify jobs by general "departments" and do not clearly distinguish between very different tasks and possible exposures. The major department, termed "assembly," encompasses the majority of workers but this designation includes such jobs as working with glues and solvents, assembling plastic products into kits, or operating the radiofrequency machines.

VI. RESULTS AND DISCUSSION

A. Environmental

Area and personal air samples were taken for both total and respirable particulates at the locations indicated in Table 1. The amount of particulate released from each machine appeared to depend on the type material being injected, temperature of the machine, speed of machine, and surface area of the product. As indicated in Table 1, the respirable dust concentration in the injection molding area averaged 0.16 mg/m^3 and the total dust concentration in the same general area averaged 0.39 mg/m^3. Approximately one half of the airborne particulates are of respirable size. Two air samples for total particulates in the extruder room, one personal and one area, showed concentrations of 0.21 and 0.35 mg/m^3, respectively.

Table 1 Area and Personal Air Samples
for Total and Respirable Particulates
(November 10, 1983)

Sample Number, Type, Location and Description	Sampling Time (min.)	Results (mg/m^3)
19 Personal, operator injection machine #3, machine purged twice	8:12-10:45 a.m. (153)	0.21
15 Area, beside injection machine #3 6 ft. off floor	8:23-10:51 a.m. (148)	0.17[a]
20 Personal, operator injection machine #10, machine purged once	8:09-10:44 a.m. (155)	0.56
14 Area, beside injection machine #9, 5 ft. off floor	8:15-10:48 a.m. (153)	0.23[a]
16 Personal, operator injection machine #11	8:25-10:54 a.m. (149)	0.08[a]
17 Personal, extruder operator	8:20-10:52 a.m. (152)	0.21
18 Area, extruder room 7 ft. off floor between extruders	8:21-10:52 a.m. (151)	0.35

[a] Respirable dust. Remainder are total particulate concentrations.

Organic vapor air samples, both area and personal, were taken with charcoal tubes in several areas where solvents were being used. Results are shown in Table 2. Personal sampling for one to two hours on several workers assembling products, and one area sample revealed moderate exposures to the solvent vapors assayed (sample numbers 1000, 1001, 1002, 1009, 1008). Personal exposures to benzene ranged from 0.10 to 0.27 ppm. Because of its carcinogenic effects, NIOSH recommends that worker exposure to benzene be reduced to the lowest feasible limit.

Solvent vapor exposures found in sample no. 1001 were also computed for Threshold Limit Values for mixtures. The combined exposure index for this worker is 0.94, which does not exceed the TLV index of 1 for permissible exposures to solvent vapor exposures. Calculations are shown in Appendix II. It should be noted that the effects of the different solvents has been considered as additive rather than independent for purposes of this calculation.

Solvent vapor exposures from personal samples in the Extrusion area and the Iodine Room were also computed for Threshold Limit Values for mixtures. The combined exposure indices for these workers were 0.60 and 0.63, respectively. The highest solvent concentrations observed were in the extrusion room (isopropanol, 124 and 129 ppm). Fresh air turnover in this area was minimal.

Three air samples were taken near the ethylene oxide sterilizers and analyzed for ethylene oxide. Results are shown in Table 3. Ethylene oxide was detected in concentrations of from 1.4 to 5.8 ppm. Since NIOSH regards ethylene oxide as a potential carcinogen, exposures should be reduced to the lowest feasible limit.

No nitrosamines were detected in the three air samples collected with thermosorb tubes.

B. Medical

The seven interviews yielded no apparent pattern of work-related health problems. One man, a sterilizer operator, reported nausea and gastrointestinal illness associated with combination of hot weather and inadequate venting of the sterilizers. Three women reported ear, nose, or throat problems that they felt were caused or aggravated by the fumes of the solvents and glues they worked with. Three of the seven workers indicated that they had no current health problems and did not have work-related health complaints.

Of the eight death certificates reviewed, four listed cancer as a cause of death: two from breast cancer and one each from cervical cancer and lymphomatosis. The other four deaths were all attributed to other, different causes. The living cancer cases reported by the union included no predominant or unusual sites: Three were listed as "female," one as "throat." Three other women were reported as having pre-cancerous "female tissue." Finally, the union listed three women who had had a miscarriage and three who had had problems with their pregnancies.

Table 2 Concentration of Solvent Vapors in Air (ppm by Volume), Nov. 9-10, 1983

Sample Number	Type, Location and Description	Sampling Time (min)	Methyl Ethyl Ketone	Isopropanol	Benzene	Toluene	Cyclo-hexanone	Tetra-hydrofuran
1000	Personal, gluing strip to bag (25 min. away from work area)	1:15-3:03 p.m. (108)	65.2	29.5	0.14	0.01	-	-
1001	Personal, connecting, worker using solvent, (no break)	2:09-3:26 p.m. (77)	10.8	35.2	0.10	0.22	17.4	-
1002	Area, burning end of tubes, lapel	2:00-3:28 p.m. (88)	6.9	37.2	0.12	0.25	-	-
1009	Personal, assembling, worker using alcohol and glue (2-12 min. breaks)	1:16-3:04 p.m. (108)	32.7	72.6	0.13	0.0	-	-
1008	Personal, worker using solvents in ashtray, (15 min. break)	1:22-3:05 p.m. (103)	39.4	38.0	0.17	0.0	1.5	-
1007	Personal, mini-jector #2, worker using glue and silicon (15 min. break)	1:35-3:11 p.m. (96)	16.1	45.5	0.17	0.0	-	-
1003	Area, injection mold, area #4, 5' off floor	1:56-3:24 p.m. (88)	4.3	51.0	0.16	0.13	-	-
1004	Area, injection mold, area #8, 5½' off floor	1:52-3:20 p.m. (88)	4.7	51.4	0.15	0.29	-	-
1006	Personal, extrusion area, coiling (no break)	1:42-3:13 p.m. (91)	3.9	124.5	0.27	0.54	-	-
1005	Area, extrusion area, top of control panel, 5½' of floor	1:48-3:14 p.m. (86)	4.0	129.3	0.18	0.30	-	-
1011	Personal, Iodine Room, worker gluing sponge sticks	9:03-10:19 a.m. (76)	43.4	82.7	0.12	4.8	-	7.9
1010	Area, Iodine Room, 4' off floor near iodine filling area	9:05-10:18 a.m. (73)	8.2	59.1	0.37	1.5	-	0.0

(-) not analyzed

Table 3 Area Air Samples for Ethylene Oxide
November 10, 1983

Location	Sample Description		Air Volume (Liters)	Ethylene Oxide (mg)	(ppm)
In gassing-out area for sterilized materials, 5' above floor	#615	Front		0.13	--
		Back		0.046	--
		Total	73	0.18	1.4
On sterilizer operator's desk; sterilizers #1 and #2 operating.	#618	Front		0.49	--
		Back		0.17	--
		Total	63	0.66	5.8
Near ethylene oxide tanks 6' above floor; sterilizer #2 open.	#619	Front		0.14	--
		Back		0.26	--
		Total	67	0.2	1.7
BLANK	#616	BLANK	--	<0.003	--

Limit of Detection: 0.003 mg
Analytical Method (NIOSH): S 286

Of 371 questionnaires, 295 (80%) were returned at least partially completed and 34 (9%) were returned with the notation that the worker did not wish to participate. The other 42 (11%) were apparently never returned to supervisors as instructed. Of the 295 forms returned at least partially completed, 107 had incomplete pregnancy histories, such as missing birthdates or pregnancy outcome. The majority of these employees were followed up through another questionnaire (Appendix III) to obtain complete information on all their pregnancies. Sixty (61%) out of the 98 follow-up forms given out were returned completed properly.

The following results are based on the 248 women who provided complete pregnancy information. Table 4, below, compares the pregnancy outcomes of pre-employment pregnancies to the outcomes of pregnancies presumably during exposure to the working environment (employment). A pregnancy was considered "employment" if the date of outcome (date of birth, date of spontaneous abortion) was anytime after the date of first employment. No consideration was given to leave of absences or layoffs in this classification method. Although the two categories of pregnancies are mutually exclusive, the women involved overlap; some women had pregnancies both before and after they started working.

Table 4 Pregnancy Outcomes

	Pre Employment		Employment		Total
	N	%	N	%	
Live births	331	(92.2)	54	(88.5)	385
Spontaneous abortions	27	(7.5)	6	(9.8)	33
Stillbirths	1	(0.2)	1	(1.6)	2
Total Pregnancies	359	(100)	61	(100)	420

VII. CONCLUSIONS

A. Environmental

1. Benzene concentrations in air ranged from 0.1 to 0.37 ppm. Ethylene oxide (EtO) concentrations in air in the vicinity of the sterilizer/storage area ranged from 1.4 to 5.8 ppm.

2. Total and respirable particulate and other organic solvent vapors assayed were below applicable limits. No nitrosamines were detected in air.

3. Use of makeshift solvent dispensers and storage of bulk solvent in glass bottles in the assembly area presents an unnecessary exposure hazard to workers (albeit below mandatory limits), a spill hazard, and probably excessive use of solvents.

4. Periodic purging of injection molds, combined with minimal and sporadic fresh air supply and exhaust ventilation, results in unnecessary exposure of workers in this area to fumes. While concentrations are below applicable limits for inert particulates, these fumes may not be inert and may merit control to a lower concentration.

5. Minimal fresh air turnover in the extrusion room results in buildup of isopropanol concentration in air to an unnecessarily high exposure level (albeit below applicable limt), which a modest amount of ventilation could alleviate.

B. Medical

1. Except for some possible irritation caused by exposure to solvents and glues, the health interviews did not show any consistent work-related health problems. The cancer deaths for which death certificates were available did not show any unusual concentration of certain kinds of cancer. Since the latency period between exposure and development of cancer is long (15 years or greater), and this plant is relatively new (since 1961), it is very difficult to evaluate the risk of cancer in this population.

2. Although there is no absolute "normal" rate of spontaneous abortion, most sources estimate that somewhere around 10-15% is the normal range. The actual percentage obtained by self-report might vary depending on a number of factors. All women may not accurately recall or record their pregnancy history, perhaps excluding miscarriage. Furthermore, early spontaneous abortions can go unrecognized and some women might be more likely than others to seek health care and record early spontaneous abortions. Finally, the risk of spontaneous abortion depends upon the age at which a woman becomes pregnant

and a number of other medical factors. It appears from these data that the percentage of pregnancies ending in spontaneous abortion is higher among employed pregnancies than among pre-employment pregnancies. There are several factors, however, that make direct comparison between these two groups difficult. The pre-employment pregnancies, in general, happened much farther back in time, and women are less likely to recall and report spontaneous abortions that happened a number of years before. The average age at pregnancy was higher (26.3) among those carrying their pregnancies during employment than those before employment (21.9). Since the risk of spontaneous abortion increases with age, one might expect to see a higher rate among the employed group. Finally, the number of pregnancies (61) and the number of spontaneous abortions (6) is very low, making it difficult to evaluate whether or not the proportion of these pregnancies ending in spontaneous abortion is high, or whether certain jobs are associated with spontaneous abortion. However, in comparison to other populations, the percentage of pregnancies ending in spontaneous abortion among working women is below that usually found (10-15%). From these limited data, there does not appear to be evidence of an elevated rate of miscarriage in these workers.

VIII. RECOMMENDATIONS

1. If ethylene oxide sterilization is continued, engineering controls such as ventilation and enclosures should be implemented to reduce exposure to the lowest feasible limit.

2. Solvent dispensers designed to reduce evaporative loss (such as spring-loaded perforated-top dispensers) or other controls should be considered for use in the assembly area to reduce air concentrations of solvent. Bulk solvent should be kept in unbreakable containers or otherwise protected against spillage.

3. Increases in fresh air turnover in the extrusion and injection mold areas, and more regular use of exhaust ventilation in the mold area during purging should be considered.

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X. AUTHORSHIPS AND ACKNOWLEDGEMENTS

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(f) Alabama Department of Labor

Form Number ___ ___ ___

Survey of Pregnancy Outcomes

Questionnaire

1. Age ☐☐

2. Date of Birth ☐☐ Month ☐☐ Day ☐☐ Year

3. Race 1. White (non-Hispanic origin) 4. Asian
2. Black 5. American Indian
3. Hispanic 6. Not sure

4. When did you first start working for this company?

☐☐ Month ☐☐ Year

5. Have you ever been married? (Check one)

☐ No (0) ☐ Yes (1) If No, go to question 10

6. Are you presently married, widowed, divorced, separated, or have you never been married? (Circle one)

Married 1
Widowed 2
Divorced 3
Separated 4

7. When were you and your (present, last, or ex-) husband married?

☐☐ Month ☐☐ Year

APPENDIX I - Medical Questionnaire

8. If you are not married now, when did you become widowed/ permanently separated from your (present/last/ex-) husband?

☐☐ Month ☐☐ Year

9. If married more than once, when were you first married?

☐☐ Month ☐☐ Year

10. Have you ever been pregnant? This includes live births, stillbirths, miscarriages, tubal pregnancies, or induced abortions. (Check one)

☐ No (0) ☐ Yes (1) If No, go to question 14

11. Counting all pregnancies, including this one if you are presently pregnant, how many times have you been pregnant?

Number of Pregnancies ☐☐

12. Please fill out the chart below beginning with your first pregnancy on the left. Put a check in the box corresponding to the outcome of that pregnancy as indicated in the example.

Number of Pregnancy

Result		Example	Earliest 1	2	3	4	5	6	7	8	9	10	Latest 11
Live birth		✓											
Miscarriage													
Stillbirth													
Induced abortion													
Now pregnant													
Date of birth, miscarriage, or abortion	Year	1963											
	Month	02											

13. For each pregnancy that ended in miscarriage, did you go to a doctor, clinic, or hospital when it happened?

For each miscarriage, please give us the name and location of the doctor, clinic, or hospital.

	Did you go to a Doctor/Clinic? Yes	No	Doctor Name	Doctor City	Clinic/Hospital Name	Clinic/Hospital City
Miscarriage 1						
Miscarriage 2						
Miscarriage 3						
Miscarriage 4						
Miscarriage 5						

14. Do you smoke or use any other tobacco products now? (Circle one)

0 Non smoker
1 Cigarette smoker
2 Snuff or chewing tobacco
3 Pipes/Cigars

15. If you smoke cigarettes, how many packs per day do you usually smoke? (Circle one)

0 Less than one pack/day
1 About 1 pack/day
2 About 2 packs/day
3 More than 2 packs/day

16. Do you drink alcohol? (Circle one)

0 No If no skip question 17
1 Yes

17. If you drink alcohol, how many drinks per week do you drink?

Bottles of beer per week _____
Glasses of wine per week _____
Mixed drinks or shots of liquor per week _____

18. What is the highest grade of school you completed? (Circle one)

0 Elementary (0-8)
1 High School (9-12)
2 College
3 Technical school beyond high school

19. We may find it necessary to obtain information about your pregnancies from your doctor or hospital. We need your permission to review these medical records about you. Would you please sign below, giving us permission to review these (and only these) medical records, if this becomes necessary. This information will be kept confidential.

I hereby authorize the personnel involved in conducting this survey permission to review my medical records concerning the outcome of my pregnancies.

_____ Your signature

_____ Date

APPENDIX II

Threshold Limit Values for Mixtures, i.e.

$$\frac{C_1}{T_1} \; \frac{C_2}{C_2} - - - \frac{C_n}{T_n}$$

Where: C_n = atmospheric concentrations and

T_n = the TLV for the specific agent

(Using Intended TLV Change - 1975)

1. Personal, connecting, worker using solvent, (no break) — Charcoal tube 1001

Methyl Ethyl Ketone + Isopropanol + Benzene + Toluene + Cyclohexanone

$$\frac{10.8}{200} + \frac{35.2}{400} + \frac{0.10}{1} + \frac{0.22}{100} + \frac{17.4}{25} = 0.94^*$$

2. Personal, extrusion area, coiling (no break) — Charcoal tube 1006

Methyl Ethyl Ketone + Isopropanol + Benzene + Toluene

$$\frac{3.9}{200} + \frac{124.5}{400} + \frac{0.27}{1} + \frac{.54}{100} = 0.60^*$$

3. Personal, Iodine Room, worker gluing sponge sticks — Charcoal tube 1011

Methyl Ethyl Ketone + Isopropanol + Benzene + Toluene + Tetrahydrofuran

$$\frac{43.4}{200} + \frac{82.7}{400} + \frac{0.12}{1} + \frac{4.8}{100} + \frac{7.9}{200} = 0.63^*$$

* TLV for Mixtures (Permissible TLV = 1)

Form No. _ _ _

SEAMLESS QUESTIONNAIRE

1. Have you ever been pregnant? (Mark one)

☐ No (0) ☐ Yes (1)

If you have never been pregnant, you do not need to answer the rest of the questions. Thank you for your help.

2. How many times have you been pregnant? Please count all pregnancies, including those ending in a live birth, miscarriage, abortion or stillborn.

☐ Number of pregnancies

3. How many babies have you ever had (not counting miscarriages, stillborn children, stepchildren, or adopted children)?

☐ Number of babies

4. When were your children born? Please fill in the month and year that your children were born, even if they are no longer living, beginning with the oldest child. Please put the number of the month (Jan = 01, Feb = 02, etc.) and the year.

		Month	Year
Oldest	First baby	☐☐	☐☐
	Second baby	☐☐	☐☐
	Third baby	☐☐	☐☐
	Fourth baby	☐☐	☐☐
	Fifth baby	☐☐	☐☐
	Sixth baby	☐☐	☐☐
	Seventh baby	☐☐	☐☐
	Eight baby	☐☐	☐☐
	Ninth baby	☐☐	☐☐
Youngest	Tenth baby	☐☐	☐☐

5. Have you ever had a miscarriage or stillborn child?

☐ No (0) ☐ Yes (1)

If you answered no to this question, you do not need to answer any more questions, just return this form to your supervisor in the envelope provided. Thank you for your help.

6. When did you have your miscarriage(s) or stillborn child(ren)? Please fill in the month (Jan = 01, Feb = 02, etc.) and year that you had each miscarriage or stillborn child.

	Month	Year
First miscarriage or stillborn	☐☐	☐☐
Second miscarriage or stillborn	☐☐	☐☐
Third miscarriage or stillborn	☐☐	☐☐
Fourth miscarriage or stillborn	☐☐	☐☐
Fifth miscarriage or stillborn	☐☐	☐☐

7. If you had a miscarriage, did you go to a doctor or clinic when it happened? For each miscarriage you listed above, please give us the name of the doctor that you saw and the name of the clinic or hospital.

	Did you go to a doctor/ clinic?		Doctor		Hospital/ Clinic	
	Yes	No	Name	City	Name	City
First miscarriage	☐ (1)	☐ (0)				
Second miscarriage	☐ (1)	☐ (0)				
Third miscarriage	☐ (1)	☐ (0)				
Fourth miscarriage	☐ (1)	☐ (0)				
Fifth miscarriage	☐ (1)	☐ (0)				