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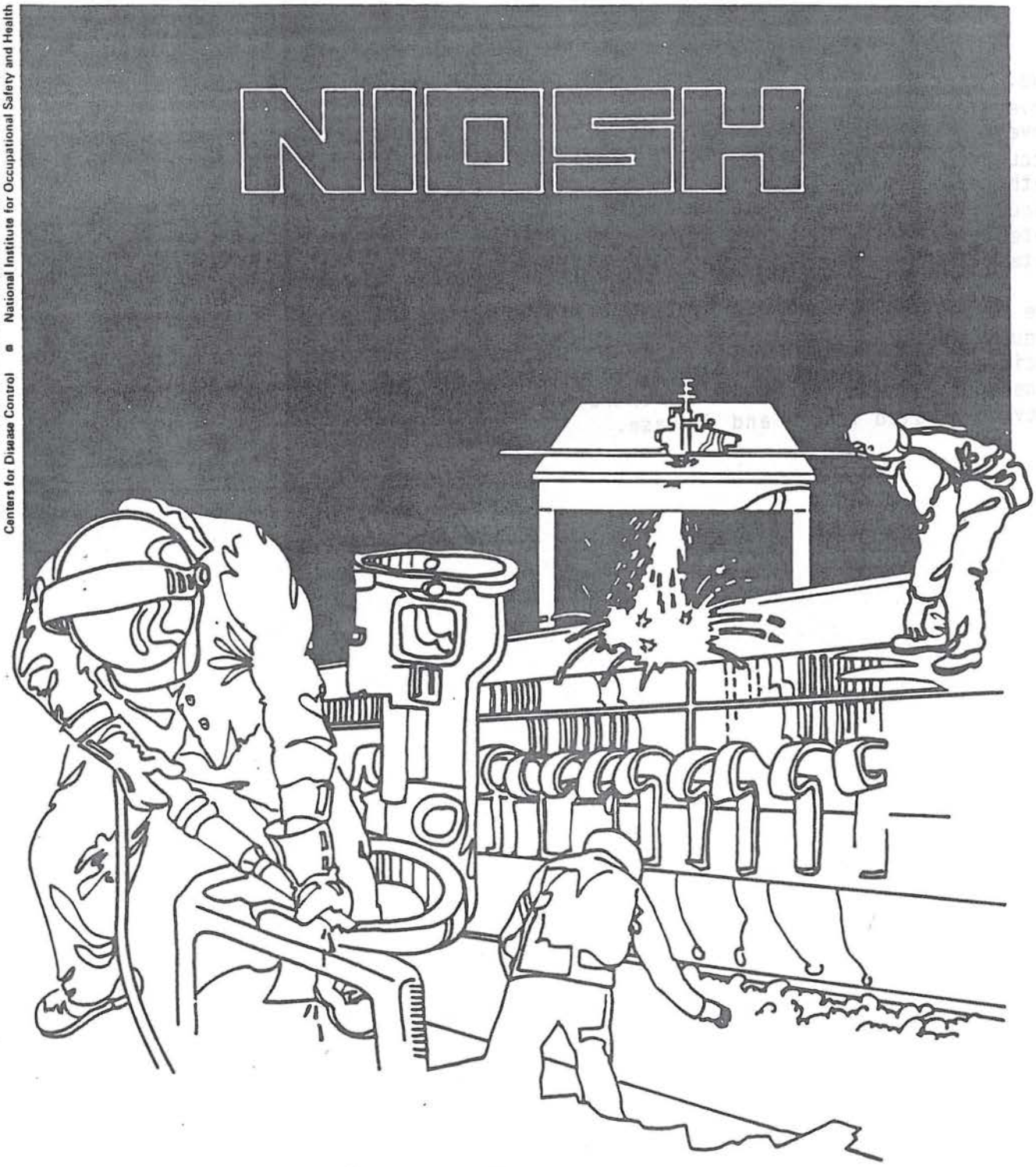

Health Hazard Evaluation Report

HETA 89-003-1546
BASF WYANDOTTE CORPORATION
RENSSELAER, NEW YORK

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 80-008-1546
JANUARY 1985
BASF WYANDOTTE CORPORATION
RENSSELAER, NEW YORK

NIOSH Investigators:
Jane E. Gordon, Ph.D.
Philip Taylor, M.D.
Susan Hearn
William Halperin, M.D.

I. SUMMARY:

In October, 1979, NIOSH received a request to conduct a health hazard evaluation from workers at the now BASF Wyandotte Plant in Rensselaer, New York, formerly owned and operated by GAF. The concern centered around the dinitroaniline herbicide, oryzalin, and its possible association with the occurrence of several adverse pregnancy outcomes which had occurred during its manufacture.

All 1,126 employees who had worked at the plant from 1972-1980 were identified. Cross-referencing their names with the N.Y. State registries of births, fetal and childhood deaths for the period yielded 286 matches. Of these, the 270 singleton pregnancies to wives of male workers were classified as to their possible exposure to oryzalin and the outcome of the pregnancy. Potential exposure was based upon personnel records indicating employment in one of the departments where oryzalin was manufactured during the period from May, 1974 through June, 1976. Of the 15 exposed pregnancies, 3 had some adverse outcome and 36 of the 255 unexposed pregnancies were also affected. The data do not provide definitive evidence of a significant excess for the following conditions: low birthweight, fetal death, congenital malformations, prematurity, and infant death. The original cluster of heart malformations was confirmed when misclassification biases were considered.

Based on the findings of this study, NIOSH investigators conclude that workers who were involved in the manufacture of oryzalin as well as other chemicals at the GAF plant, experienced an unusual cluster of birth defects, particularly those of the heart. However, the study could not confirm whether or not they were at greater risk of adverse pregnancy outcomes than other workers in the same plant. Recommendations are incorporated in Section XIII of this report.

KEY WORDS: SIC 281,284,286,287 (industrial inorganic chemicals, cleaning agents and cosmetics, industrial organic chemicals, agricultural chemicals); pesticides; pregnancy

II. INTRODUCTION

On October 17, 1979, an authorized representative of the International Chemical Workers Union formally requested that NIOSH investigate the occurrence of three birth defects, one miscarriage, and one infant death, which had occurred between June, 1975 and June, 1976, among the employees at the BASF Wyandotte plant in Rensselaer, New York.

Many chemicals were in use at this facility. Of those chemicals being manufactured, the employees were suspect of oryzalin (Surflan ®), a dinitroaniline herbicide, since its manufacture at that plant was limited to the period from May, 1974 through June, 1976.

To assess the extent of reproductive casualties among plant employees, a cohort of all employees who had ever worked in the plant during 1972 - 1980 was identified and classified by department, job title, and dates of employment to define their potential exposure to oryzalin. The employee roster was cross-referenced against the computerized New York State birth, fetal and infant death tapes for the 9 year period in order to ascertain the outcomes of deliveries to residents of a 6 county area in upstate New York.

III. BACKGROUND

The BASF Wyandotte facility was operated by the GAF Corporation from 1965 to April, 1978; preceded by the General Aniline and Film

Corporation, dating from the early 1940's. BASF produces a variety of pigments and dyestuffs, compounds for cosmetics, and a wide range of industrial chemicals. There are currently 398 employees, 222 of whom are involved in chemical production work. Oryzalin has not been manufactured at this plant since July, 1976, when the plant was owned and operated by the GAF Corporation.

NIOSH did not conduct industrial hygiene surveys at the time of the oryzalin production. Surveys were made of the plant (1973 and 1977) as a part of studies of benzidine and other azo dyes.

Oryzalin (3,5-dinitro-N^4, N^4-dipropylsulfanalamide) is manufactured from potassium 4-chloro 3,5-dinitro benzene sulfonate using three synthetic steps: amination, chlorination and amidation. Oryzalin, registered solely to Eli Lilly and Company, is a dinitroaniline herbicide which was approved for U.S. use in 1975 as a surface applied preemergence application to control annual grasses and broadleaf weeds in soybean crops and in cotton crops in Texas. It also has application for weed control in fruit and nut crops, vineyards, and woody ornamental plants.

The Special Pesticides Review Division of EPA, and their Environmental Fate Branch of the Hazard Evaluation Division, have released oryzalin reports (March, 1980) estimating worker exposure at the plant in question, and evaluating the available scientific evidence to determine whether the cluster of adverse pregnancy outcomes at BASF

warranted EPA regulatory action (1). Their conclusion was that no action was necessary. However, joint meetings between EPA, OSHA, NIOSH, BASF, GAF, Lilly, and the union (ICWA) resulted in an agreement that NIOSH would conduct an epidemiologic study of employees to determine the extent of adverse reproductive outcomes and the possible association with parental exposure to oryzalin.

IV. EVALUATION DESIGN AND METHODS

A. Identification of Study Cohort

All persons employed during the period from January 1, 1972 through December 31, 1980 were identified from company personnel records (N=1126). Each record was microfilmed and the complete work history and available demographic characteristics were coded by NIOSH staff using standard NIOSH procedures. The roster of employee names and other relevant identifiers was cross-referenced against the New York State computerized birth, fetal and death records for residents of the 6 counties in the vicinity of the plant site, over the 9 year interval, to identify all known deliveries to the cohort; 286 records were linked. Of the identified pregnancies, 96% occurred to the wives of male workers. The few pregnancies among female employees were not included in the analysis.

B. Classification of Exposure

Pregnancies, rather than employees, were the focus of the analysis. A pregnancy (identified through state records) was classified as "exposed" when the estimated date of conception occurred either within the interval of oryzalin production (May, 1974 through June, 1976) or subsequent to that period and before the end of 1980, and occurred to the spouse of a worker with a chemical related occupation assigned to the production departments (identified by the union and the company as buildings 81 or 87) during oryzalin manufacture (2).

Unexposed pregnancies were those which occurred within the 9 year study interval to women whose partners had never worked in or around the oryzalin production processes according to the company personnel records. This includes a subgroup of pregnancies which occurred to company employees whose jobs were non-chemical related.

C. Classification of Adverse Pregnancy Outcomes

Each of the state records identified through the linking process was classified as having been a normal live birth or a pregnancy ending in an adverse outcome. The following identifies the definitions or coding scheme for each of the adverse outcomes considered:

1) low birthweight - less than or equal to 2500 grams;

2) fetal death (official registration in N.Y.S. is required after 13 weeks gestation) - any cause, coded using ICDA;

3) congenital malformation - any type, coded by a N.Y. State standardized scheme;

4) short gestation - less than or equal to 32 weeks; and

5) infant death - any cause, ICDA code for primary underlying cause of death assigned by the NIOSH nosologist.

For each record with more than one adverse outcome, a decision was made as to the category in which it should be placed for analysis (there were not enough like combinations of adverse outcomes to establish multiple outcome groups). Examples of this process included classifying as congenitally malformed, infants whose birth record noted a congenital malformation which was also listed as the underlying cause of death on their death certificate (2 infants); the records where low birthweight and/or short gestation existed simultaneously for a fetal death, the record was classified for analysis as a fetal death.

The operating null hypothesis was of no association between paternal occupational exposure to oryzalin and any adverse pregnancy outcome. The relevent underlying biologic hypotheses were of:

1) acute or chronic damage to sperm, semen, or germinal tissue,

2) mutagenic effects to sperm, and/or

3) transmission of the agent from the father, such as on contaminated clothing, to the pregnant wife and subsequent feto-toxic or teratogenic effects.

D. Statistical Analysis

Maternal age at delivery and previous live births, both potential confounding variables, were evaluated for their association with exposure and disease outcomes. Neither of these factors was a confounder in this data set, and therefore, no statistical controls were needed.

The remaining analysis for this cohort study consisted of a series of two way tables for each combination of exposure and disease outcomes. A rate ratio (RR) was estimated and used as a measure of association for each exposure-disease relationship. Each risk estimate was bounded by 95% confidence limits, calculated using test-based interval estimation. The calculations were performed on an HP-67 programmable calculator, utilizing the programs developed by Rothman and Boice (3).

V. RESULTS

The analyses were restricted to the pregnancies which occurred to the wives of male employees and to those who had single births. These decisions were made because twins are considered to be at increased risk of perinatal problems. In these data there were two sets of twins; one set died of problems related to immaturity and whose father had a non-chemical related job, while the other set were normal live

borns whose father worked with chemicals other than oryzalin. Of the twelve births to female employees, 9 were to women who had non-chemmical related jobs, only one of these pregnancies ended in a fetal death (due to maternal complications). The other 3 pregnancies were to female chemical workers, none worked with oryzalin, and the pregnancies resulted in normal live births.

The exposed and unexposed groups did not differ significantly on the distribution of maternal age or number of previous live births, the two items of available data which could possibly have affected the analysis of the exposure - disease relationship (Table 1).

From the same table, an adverse pregnancy outcome was reported for 20.0% of the 15 exposed pregnancies and 14.1% of the 255 unexposed. The data were insufficient to rely on an overall X^2 statistic to evaluate observed vs. expected distributions. The specific causes recorded on the N.Y.S. vital records for the fetal and infant deaths and the congenitally malformed infants are listed in Table 2. Two of the three diagnosed malformations reported to us in the original request as malformations of the heart were identified by the vital records linking process. The third heart malformation was not reported on the birth certificate and the child died at age 8, in January, 1984. Therefore, the vital record available for this child resulted in his classification in these analyses as a normal live birth. (The problem of misclassification will be discussed later in this report).

For the primary analysis, to insure uniformity, the classification of exposure and outcomes of pregnancy were used as derived from company and state records systems. The analytic strategy adopted consisted of several comparisons, first for the occurrence of any adverse pregnancy outcome (APO) and then for each of the specific APOs with at least one exposed pregnancy. Within each of these APO classifications, Analysis I compared pregnancies ever ("EVER") exposed to oryzalin (via the father) to those never ("NEVER") exposed; Analysis II compared pregnancies occurring during ("DURING") the oryzalin production period to: a) non-chemical ("NO CHEM.") exposed pregnancies and to b) other chemical ("OTH. CHEM.") exposed pregnancies; and Analysis III compared pregnancies occurring after oryzalin production ceased, but whose parents had been involved in oryzalin production, to the 2 groups described above in Analysis II a and b. The results of each ofthese is listed in Table 3. (Note, that to accomodate the occurrence of zero cells, 0.5 was added to each cell so a computation could be made.) None of the resulting estimates of risk (RR) reaches statistical significance for the comparisons described.

As anticipated, multiple pregnancies occurred to many individuals. Selected analyses were repeated using the parent as the unit of analysis (for exposure classification and whether or not they had an affected child). This minimized the effect of multiple adverse pregnancy outcomes per family. The results from these analyses were identical to those reported above.

VI. DISCUSSION:

In the U.S., the following are often cited as the approximate background rates for adverse pregnancy outcomes:

1) spontaneous abortion - 15% of pregnancies;
2) major birth defects - 3% of live births;
3) low birthweight - 7% of live births;
4) infant mortality - 15 per 1000 live births (4).

In the study area, upstate N.Y., the 1980 rates for fetal and infant death are 10.0 and 10.5 per 1000 live births, respectively (Table 4) and the rate of low birthweight, live borns was 6.3% (5). For the 6 county catchment area, the 1980 fetal death rate was 8.5/1000 live births and the infant death rate was 12.5/1000 live births (Table 5). In the study population, the average annual rate, over the 9 year study interval, of the various adverse outcomes considered did not exceed the usual background rates, and often fell below them (fetal death, 4.9/1,000; malformations, 3/1,000; infant death, 1.3/1,000). These rates are crude due to small numbers over a rather extended period.

The statistical power of this study to detect small increases in risk of any of the conditions in association with oryzalin exposure was limited at the outset given the available number of pregnancies. The

study population was sufficient to detect risks of 2.7 or greater, with 95% confidence, for the most common adverse outcomes (e.g., spontaneous abortion), and only much greater risks for the less frequent outcomes (e.g., malformation).

The limited sample size was only one of several drawbacks of this study. Practical considerations precluded access to 1) family medical records, and therefore more comprehensive and accurate diagnoses of pregnancy outcomes; and 2) personal interviews of study participants and their wives in order to ascertain information on risk factors relevant to pregnancy outcomes.

Relying on vital records data alone often results in the inability to identify all pregnancies (e.g., early spontaneous abortions) and complete, accurate reporting of several pregnancy outcomes, particularly the more subtle adverse outcomes diagnosed after the discharge of a live born from the hospital, such as heart malformations or murmurs. Relevant to this study would be the unavailability of any information on early spontaneous abortions, and on birth defects not diagnosed or recorded at birth and not serious enough to have caused an early death. We may, therefore, have an underestimate of pregnancies and of several of the outcome events of interest. This is evident when the agreement between the vital records and information collected by the union on pregnancy outcomes among exposed workers is compared (Table 6).

The effects of misclassification of exposure and/or disease on the results of a study analysis have been extensively reviewed in the scientific literature (6). For this study, misclassification of rare heart anomalies, which are cited in the literature as ranging from 0.02-2.2 per 1,000 births (7), significantly alters the outcome of the analysis. Table 3C infers no group differences for anomalous births, while Table 7, using reclassified data (one affected child shifting from unexposed to exposed; the other, and exposed child shifting from unaffected to affected) shows a significant difference and confirms the presence of the originally reported cluster. The interpretation of this finding however, does not imply causality due to oryzalin exposure.

Although the entire cohort of 1,126 employees was available for study, there were not enough people in non-chemical occupations who became parents during the study interval to serve as an unexposed comparison group. The vast majority of the people who did not work with oryzalin worked with a multitude of other chemicals not specifically identified in this study (possibly as many as 1,000 different chemicals annually). Similarly, the oryzalin workers were undoubtedly exposed to other chemical agents pre- and post-employment in the time-limited manufacture of oryzalin, and possibly had concommitent exposures as well due to the practice of migrating to multiple departments for short periods without being officially transferred there. This is a source of potential misclassification of exposure status. The

resulting multiplicity of exposures in both study groups undoubtedly limited our ability to evaluate pregnancy outcomes associated with differences of exposure to a single agent. These multiple chemical exposures potentially included azo dyes which were also manufactured at this plant and have been previously linked with congenital heart malformations (7). Evidence such as this makes it impossible to implicate any specific agent(s) with the observed cluster particularly among such a small group of workers.

Finally, the biologic mechanisms underlying this study were limited to those operating through paternal exposure, yet no direct measure of semen parameters could be made for consideration of a direct effect. We cannot comment, therefore, on whether infertility might have everbeen a problem for any of the almost 950 chemical workers, one-tenth of whom were likely to have been exposed to oryzalin, for whom no evidence of pregnancy during the study interval was found in the N.Y.S. vital records system.

VII. CONCLUSION

Our epidemiologic findings do not suggest that workers who were involved in the manufacture of oryzalin were at greater risk of the adverse pregnancy outcomes: low birthweight, fetal death, prematurity, or infant death than those involved in other chemical or non-chemical occupations within the plant. We did document a cluster of congenital

heart malformations among exposed pregnancies when more than just the vital statistics and company data were used. In light of the problems of potential misclassification of exposure, ascertainment of accurate, complete information from state vital records, and the a priori recognition of a cluster of adverse pregnancy outcomes at this plant, it is not possible based upon epidemiologic study to conclude whether a true association did or did not exist between the adverse outcomes and paternal exposure to oryzalin or any other chemical exposure. This study did not address the question of effects on semen, or of infertility, therefore, no conclusions can be drawn on these two forms of reproductive effects.

VIII. RECOMMENDATIONS

1. As a prudent step, proper engineering and work practice controls should be in place and operational at facilities for worker exposure to any chemical, including oryzalin. Given the limitations of data on the hazards of oryzalin, these steps are prudent.

2. Given the limitations of this epidemiologic assessment, those concerned with the safety of oryzalin should consider the extensive toxicologic information considered by the Environmental Protection Agency on their decision to allow continued registration of this product. Further information is available from Robert Taylor, Product Manager (25) Fungicides-Herbicides Branch, Registration Division, EPA, 401 M St., S.W., Washington, D.C. 20460.

IX. REFERENCES

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X. AUTHORSHIP AND ACKNOWLEDGEMENTS

The authors are grateful for the contributions made to the project by:

Dr. Gerald Probst
Elanco Products Co.
Indianiapolis, Indiana

Dr. Stan Frankowski
GAF Corp.
Wayne, N.J.

Ron Cole and Jane Wittig
BASF
Rensselaer, N.Y.

Roger Scales and Paul Obermayer
ICWU - Local 227
Rensselaer, N.Y.

Jan Auerbach
US - EPA
Washington, D.C.

Dr. David Logan
OSHA
Washington, D.C.

Phil Quickenton
NYS-Dept. of Health Statistics
Albany, N.Y.

NIOSH:
Clorinda Battaglia
Edith Dodd
Bettie Walpole
Richard Hornung
Shiu Lee
Mary Carroll

Evaluation Conducted and Report Prepared by:

Jane E. Gordon, Ph.D.
Genotoxicity and Reproductive Activity
IWSB, DSHEFS, NIOSH

Philip R. Taylor, M.D.
formerly of IWSB, DSHEFS, NIOSH
assigned to N.Y.S. Health Dept.

William E. Halperin, M.D.
Chief, IWSB
DSHEFS, NIOSH

Susan Hearn
formerly of IWSB, DSHEFS, NIOSH

No environmental evaluations.

Originating Office:

Hazard Evaluations and Technical Assistance Branch
Division of Surveillance, Hazard Evaluations, and Field Studies
Cincinnati, Ohio 45226

Report Typed By:

Sylvia Morgan
Janet Graydon
IWSB

XI. DISTRIBUTION AND AVAILABILITY OF REPORT

Copies of this report are currently available, upon request, from NIOSH, Division of Technical Services, Information Resources and Dissemination Section, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After 90 days, the report will be available through the National Technical Information Service (NTIS), Springfield, Virginia 22161.

Copies of this report have been sent to:

1. BASF Wyandotte Co., Rensselaer, N.Y.
2. Authorized representative of employees - International Chemical Workers Union - Local 227, Rensselaer, N.Y.
3. Eli Lilly Corp., Indianapolis, Indiana.
4. NIOSH - Region II
5. OSHA - Region II
6. U.S. EPA, Office of Pesticides, Washington, D.C.
7. GAF, Wayne, NJ

For the purpose of informing 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 1

DESCRIPTIVE CHARACTERISTICS OF STUDY POPULATION

	Exposed		Unexposed	
Descriptor	N (=15)	%	N (=255)	%
Mother's Age: mean	26.2		25.0	
19	--	--	25	9.8
20-24	6	40.0	94	36.9
25-29	6	40.0	104	40.7
30-34	2	13.3	26	10.2
35+	1	6.7	6	2.4
Father's Age: mean	27.2		27.5	
19	--	--	5	2.0
20-24	5	33.3	66	25.9
25-29	7	46.7	104	40.8
30-34	--	--	58	22.7
35+	3	20.0	22	8.6
Previous Live Births: mean	1.3		1.3	
None	6	40.0	78	30.6
1	4	26.6	91	35.7
2	1	6.7	53	20.8
3	3	20.0	17	6.7
4+	1	6.7	16	6.2

Table 1 (cont'd.)

DESCRIPTIVE CHARACTERISTICS OF STUDY POPULATION (Cont'd)

	Exposed			Unexposed		
Descriptor	N	(N*)	%	N	(N*)	%
Timing of Conception (re: oryzalin production)						
before	--		--	92		36.1
during	11		73.3	70		27.5
after	4		26.7	93		36.4
Adverse Pregnancy Outcome:						
None	12	(12.8)	80.0	219	(218.2)	85.9
Low birthweight	--	(0.9)	---	17	(16.1)	6.7
Fetal death	1	(0.7)	6.7	11	(11.3)	4.3
Malformed	1	(0.4)	6.7	6	(6.6)	2.3
Premature	--	(0.1)	---	2	(1.9)	0.8
Infant death	1	(0.1)	6.7	--	(0.9)	--
Any adverse Outcome	3	(2.2)	20.0	36	(36.8)	14.1
TOTAL	15	--	100.0	255	--	100.0

N * = EXPECTED

Table 2

CAUSE OF DEATH AND / OR CONGENITAL MALFORMATION

CONDITION	EXPOSED (N)	UNEXPOSED (N)
FETAL DEATH:		
o maternal complications of pregnancy	-	1
o haemolytic disease (unspecified)	1	5
o stillbirth (unspecified)	-	5
MALFORMATION:		
o anencephaly	-	1
o anomaly of heart valve	-	1
o heart malformation (unspecified)	1	-
o adactylia	-	1
o absence of arms or legs	-	1
o malformation of skin	-	1
o malformation of respiratory system **	-	1
INFANT DEATH*:		
o acute bronchitis	1	-
o anencephaly	-	(1)
o anomaly of heart valve	-	(1)
o heart malformation (unspecified)	(1)	--

* Numbers in parentheses indicate the infant was counted as malformed.
** Affected child was female, unless noted, others were male.

Table 3

RESULTS

ORYZALIN EXPOSURE COMPARISON (N)	# DISEASED Exp.	# DISEASED Unexp.	RR	(95% CONFIDENCE INTERVAL)
A . ANY ADVERSE OUTCOME:		UNIT = PREGNANCY		
I : Ever / Never (15) (255)	3	36	1.4	(0.5 , 4.2)
I I : During / No Chem. (11) (23)	1	0	7.2	(0.5 , 106.4)
During / Oth. Chem. (11) (232)	3	36	1.8	(0.6 , 4.8)
I I I : After / No Chem. (4) (23)	0	0	4.8	(0.1 , 214.5)
After / Oth. Chem. (4) (232)	0	36	0.6	(0.05, 9.0)

Table 3 (cont'd.)

RESULTS (CONT'D)

ORYZALIN EXPOSURE COMPARISON (N)	# DISEASED Exp.	# DISEASED Unexp.	RR	(95% CONFIDENCE INTERVAL)
B . FETAL DEATH:		UNIT = PREGNANCY		
I : Ever / Never (13) (230)	1	11	1.6	(0.2 , 11.5)
I I : During / No Chem. (9) (23)	1	0	7.2	(0.3 , 162.2)
During / Oth. Chem. (9) (207)	1	11	2.1	(0.3 , 14.5)
I I I : After / No Chem. (4) (23)	0	0	4.8	(0.1 , 214.5)
After / Oth. Chem. (4) (207)	0	11	1.8	(0.1 , 25.6)

Table 3 (cont'd)

RESULTS (CONT'D)

ORYZALIN EXPOSURE COMPARISON (N)	# DISEASED Exp.	# DISEASED Unexp.	RR	(95% CONFIDENCE INTERVAL)
C . BIRTH DEFECTS:		UNIT = PREGNANCY		
I : Ever / Never (13) (225)	1	6	2.9	(0.4 , 22.2)
I I : During / No Chem. (9) (23)	1	0	7.2	(0.3 , 162.2)
During / Oth. Chem. (4) (202)	0	6	3.1	(0.2 , 48.2)
I I I : After / No Chem. (4) (23)	0	0	4.8	(0.1 , 214.5)
After / Oth. Chem. (4) (202)	0	6	3.1	(0.2 , 48.2)

Table 4

UPSTATE NEW YORK HEALTH STATISTICS: 1970, 1975, 1980

Year	General Fertility Rate [1]	Live Birth Rate [2]	Fetal Death Rate [3]	Infant Death Rate [4]
1970	81.1	16.6	14.9	17.7
1975	56.3	12.4	10.4	14.2
1980	56.6	13.0	10.0	10.5

1. Number of live births per 1,000 female population ages 15 - 44

2. Number of live births per 1,000 population

3. Spontaneous fetal deaths 20 or more weeks gestation per 1,000 live births plus spontaneous fetal deaths of 20 or more weeks.

4. Deaths under 1 year of age occurring during the year per 1,000 live births occurring during that year.

Source: Vital Statistics of New York State - 1981, State Department of Health, Bureau of Health Statictics.

Table 5

1980 FETAL AND INFANT DEATH RATES FOR THE SIX N.Y. STATE STUDY COUNTIES

County	Fetal Death Rate [1]	Infant Death Rate [2]
Albany	11.2	12.5
Columbia	10.7	13.5
Greene	8.7	17.5
Rensselaer	6.9	15.4
Saratoga	4.5	8.1
Schenectady	9.3	13.2
6 Counties Overall	8.5	12.5
Upstate N.Y.	10.0	10.5

1. Spontaneous fetal deaths 20 or more weeks gestation per 1,000 live births plus spontaneous fetal deaths of 20 or more weeks.

2. Deaths under 1 year of age occurring during the year per 1,000 live births occurring during that year.

Source: Vital Statistics of N.Y. State - 1981 State Department of Health, Bureau of Health Statistics

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Appendix

In order to address the question of whether vital records alone were an adequate resource for identifying pregnancies, and their outcome, among this cohort of workers, a telephone survey was conducted among the 119 male employees identified by union and/or company records as being potentially exposed to oryzalin. Table A-1 describes the group surveyed. The overall response rate among the 111 surviving male interviewees was 84.7%. Among that group, 26.1% (29 men) reported the birth of one or more children during the interval from January, 1974 - December, 1980.

Limited information was available about the 17 non-respondents. As shown in Table A-2, they appeared to be similar in age to the respondents who had reported births (average age was 37 years). Three of the 17 men were known to have had a total of 6 live births recorded on the New York State vital records system during the study interval. Each of these births was recorded as normal.

Table A-2 further describes the 26 men who were interviewed and reported a birth, 6 of those men also reported a miscarriage. The N.Y. State records provided information on 19 of the 26 men reporting live births (73.1%), and of the 6 men also reporting a miscarriage, 3 appeared in the vital records system (50%). Of those 19 men, union and company records agreed on the oryzalin exposure status of 10. The remainder were classified as oryzalin exposed by the union, but as exposed to other chemicals by the company records. This could be due to the practice of migrating between departments without official transfers.

The 26 men reported a total of 39 live births and 9 miscarriages. The vital records identified 26 live births (66.7% of those self-reported) and 4 miscarriages (44.4% of those self-reported) for an agreement of 30 of the 48 self-reported pregnancies.

A total of 7 birth defects, of any kind, were self-reported. Three were classified for purposes of this investigation only, as minor birth defects (tongue-tied, deformed toe, pyloric spasms). These might not have been classified as birth defects if subjected to the rigors of the standard N.Y State system of birth defect coding. No minor defects were identified for any pregnancies using only the state records. Of the 4 major malformations which were self-reported (3 heart, 1 anencephaly), the records identified 2 of the heart malformations and the anencephalic child. The third heart malformation was known to the study through personal communication and a 1984 death certificate. (See Discussion section and Table 7). This child had a heart malformation at birth, but it was not noted on the certificate of live birth for unknown reasons.

Of the 9 self-reported miscarriages, no known cause could be given by the father for 8 of them. One man did mention a "heart problem". That particular miscarriage was in the vital records system as due to an unspecified haemolytic disease.

The men reporting pregnancies were also asked if they had any medical conditions diagnosed and treated by a physician during the study interval. Six men reported one problem, 4 additional men reported 2 problems. One of these 10 men parented a child with a major birth defect, a second man fathered one of the miscarriages. The list of conditions reported consists of: dermatitis, boils, strep throat, hives/rash, heart condition, cough, chemical burn, nasal problem, and back injury.

Overall, it appears that for this investigation vital records were clearly adequate for identifying major malformations. Two thirds of the pregnancies were identified using vital records alone. Without documentation for each self-reported birth <u>not</u> found in the vital records system, it is not possible to confirm the true extent nor explanation for the potential discrepancy.

Table A-1 Potentially Exposed Male Employees in Telephone Survey

Men Surveyed	N	Percent
Total	119	100.0
Union	90	75.6
Non-union	29	24.4
Deceased	8	6.7
Refused	4	3.4*
Not Located	13	11.7*
Male employees with live born children 1/74 - 12/80	29	26.1

* Percent of 111 surviving male interviewees;
Overall response rate = 94/111 x 100 = 84.7%

Table A-2 Respondent/Non-Respondent Differences Among Potentially Exposed Male Workers Reporting Pregnancies

	Respondents (N=26)		Non-Respondents (N=17)	
	N	%	N	%
Age				
average	37.2		37.0	
range	28 - 59		29 - 52	
25-29	2	7.7	1	5.9
30-34	10	38.5	5	29.4
35-39	6	23.1	7	41.2
40-44	3	11.5	--	--
45-49	2	7.7	3	17.6
50-54	2	7.7	1	5.9
55-59	1	3.8	--	--
Men with live born children (1/74 - 12/80)				
Total	26	100.0	3	100.0
self report only	7	26.9	--	--
records only	--	--	3	100.0
records and self report	19	73.1	--	--
Men reporting miscarriages (1/74 - 12/80)			NA	
Total	6	100.0	--	
self report only	3	50.0	--	
records only	--	--	--	
records and self report	3	50.0	--	

Table A-2 Respondent/Non-Respondent Differences Among Potentially Exposed Male Workers Reporting Pregnancies (Cont'd)

	Respondents (N=26)		Non-Respondents (N=17)	
	N	%	N	%
Reported Pregnancies (1/74 - 12/80)				
Total	48	100.0	6	100.0
Live Births	39	81.3	6	100.0
Miscarriages	9	18.7	--	--
Self report				
Live Births	39	NA		
Miscarriages	9		--	--
Records				
Live Births	26	NA	6	100.0
Miscarriages	4		--	--
Agreement (records/self-report)	30 of 48			
Congenital Malformations				
Live Births:				
Total	7	100.0	--	--
(% of live births)		(17.9)		
Minor:				
self report *	3	42.9	--	--
records	--	--	--	--
Major:				
self-report	4	57.1	--	--
(% of live births)		(10.2)		
records	3	NA	--	--
Agreement (records/self-report)	3 of 4			
Major Malformations (self reported for live births)			--	--
Heart	3	NA		
Anencephaly	1	NA		
Agreement (records/self-report)	2 of 3; 1 of 1			

* tongue-tied; deformed toe; pyloric spasms

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