CONTAINS NO CBI

Dow

The Dow Chemical Company

2030 Dow Center
Midland, Michigan 48667

October 25, 1991 29pp

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Document Processing Center
Office of Toxic Substances
Environmental Protection Agency
401 M Street SW
Washington, D.C. 20460

88920000051

Attn: 8(e) Coordinator

Re: PYRO-CHEK 77B
CAS No. 61262-53-1
CAP Agreement No. CAP-0111

Dear Sir/Madam:

The Dow Chemical Co. submits the enclosed document titled:

REPORT TO FERRO CORPORATION, DOMINANT LETHAL STUDY WITH PYRO-CHEK 77B IN ALBINO MICE, P.O. NO. 68281, IBT NO. 85533-08560

pursuant to TSCA Section 8(e) Compliance Audit Program.

The document contains information which may reasonably support the conclusion that the referenced chemical may present a substantial risk of injury to human health or the environment, as indicated in the Reporting Guide provided by EPA in connection with the CAP. The information is summarized below:

A DOMINANT LETHAL MUTAGENIC STUDY WAS CONDUCTED ON ALBINO MICE TREATED WITH PYRO-CHEK 77B (IV-213, HX-487). MALES WERE TREATED WITH SINGLE INTRAPERITONEAL INJECTIONS OF EITHER 0, 5,000, OR 10,000 MG PYRO-CHEK 77B PER KG OF BODY WEIGHT. FOLLOWING DOSE ADMINISTRATION, THE MALES WERE MATED WEEKLY WITH 3 UNTREATED VIRGIN FEMALES FOR 6 CONSECUTIVE WEEKS.

REDUCTIONS IN MALE FERTILITY WERE NOTED DURING WEEK 6 FOR THE 5,000 MG/KG GROUP AND DURING WEEKS 2 THROUGH 6 FOR THE 10,000 MG/KG GROUP. FERTILITY WAS REDUCED FOR FEMALES MATED WITH MALES GIVEN 10,000 MG/KG PYRO-CHEK 77B DURING WEEKS 2 THROUGH 5. ALL OTHER VALUES OBTAINED COMPARED FAVORABLY WITH THE CONCURRENT CONTROL.

ALTHOUGH EXPOSURE TO PYRO-CHEK 77B RESULTED IN REDUCED FERTILITY, A DOMINANT LETHAL MUTAGENIC EFFECT DID NOT OCCUR IN THIS TEST SYSTEM.

Dow requests guidance from EPA whether the Agency believes the information contained in this document satisfies the criteria in the CAP Reporting Guide. Any correspondence relating to this submission should reference document number CAP00021.

Sincerely,

Paul A. Wright

Paul A. Wright
Attorney
517/636-1853

CONTAINS NO CBI

Industrial BIO-TEST Laboratories, Inc.
1810 FRONTAGE ROAD
NORTHBROOK, ILLINOIS 60062

REPORT TO

FERRO CORPORATION

DOMINANT LETHAL STUDY WITH PYRO-CHEK 77B IN ALBINO MICE

P.O. NO. 68281

SEPTEMBER 24, 1976

IBT NO. 8533-08560

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Industrial BIO-TEST Laboratories, Inc.
1810 FRONTAGE ROAD
NORTHBROOK, ILLINOIS 60062

September 24, 1976

Mr. James L. Dever
Manager, Organic Research
Ferro Corporation
7040 Krick Road
P. O. Box 46349
Bedford, Ohio 44146

Dear Mr. Dever:

Re: IBT No. 8533-08560 - Dominant Lethal Mutagenic Study with Pyro-Chek 77B in Albino Mice - P. O. No. 68281

We are submitting herewith our laboratory report prepared in connection with the above study.

Very truly yours,

J. C. Calandra

J. C. Calandra
President

JCC:trm

REPORT TO

FERRO CORPORATION

DOMINANT LETHAL STUDY WITH PYRO-CHEK 77B IN ALBINO MICE

P.O. NO. 68281

SEPTEMBER 24, 1976

IBT NO. 8533-08560

I. Introduction

A mutation is a change in the character of a gene such that morphologic, physiologic and/or biochemical alterations are produced. If this change in gene character occurs in the germinal cell, the alteration can be transmitted to succeeding generations. Changes of this nature can be artificially induced (irradiation, chemical exposure) or they may be spontaneous. A dominant lethal mutation occurring in a male germinal cell may lead upon fertilization by the affected cell, to the failure of development of the resulting zygote beyond the blastocyst stage (implantation). Male mice, treated with the test compound, are mated with untreated females. The numbers of pre-implantation losses and early resorptions in female mice, dissected at mid-gestation, are used to calculate the mutation rate based on the induction of dominant lethal mutations.

II. Summary

A dominant lethal mutagenic study was conducted on albino mice treated with Pyro-Chek 77B (IV-213, HX-487). Males were treated with single intraperitoneal injections of either 0, 5,000, or 10,000 mg Pyro-Chek 77B per kg of body weight. Following dose administration, the males were mated weekly with 3 untreated virgin females for 6 consecutive weeks. The following results were obtained during the investigation.

One 10,000 mg/kg male died during the mating period. No other deaths occurred among control or treated males. For approximately 3 hours following dose administration, males exposed to 10,000 mg/kg Pyro-Chek 77B exhibited hypoactivity in comparison to the concurrent control males. Varying degrees of abdominal distension was observed among the test males of both treatment groups during the third week of the mating period. This condition continued throughout the remainder of the investigation. Gross necropsy examinations performed on all surviving males at the end of the mating period revealed the test males to have a white material in the abdominal cavity which had adhered to various organs. No untoward findings were noted among control males.

Reductions in male fertility were noted during week 6 for the 5,000 mg/kg group and during weeks 2 through 6 for the 10,000 mg/kg group. Fertility was reduced for females mated with males given 10,000 mg Pyro-Chek 77B during weeks 2 through 6. All other values obtained compared favorably with the concurrent control.

The numbers of implantation sites, deciduomata, and viable embryos were not altered by Pyro-Chek 77B exposure. Mutation rates regarding the percent of early deaths along with the comparisons of embryos per female in each treatment group to those of the control compared favorably between Pyro-Chek 77B treated groups and the control group.

It is concluded that, although exposure to Pyro-Chek 77B resulted in reduced fertility, a dominant lethal mutagenic effect did not occur in this test system.

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES, INC.

Report prepared by:

Clare Salamon, B.S.
Assistant Toxicologist
Rat Progeny

Sandra Smith
Group Leader
Rat Progeny

Report approved by:

Gerald L. Kennedy, Jr., B.S.
Section Head, Toxicology

Florence K. Kinoshita, Ph.D.
Technical Manager, Toxicology

M. L. Keplinger, Ph.D.
Manager, Toxicology

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III. Procedure

A. Experimental Animals

Charles River* strain albino mice were received at this laboratory at 60 to 70 days of age for use in the investigation.

B. Test Material

The material tested was Pyro-Chek 77B (IV-213, HX-487), an off-white powder.

C. Determination of Treatment Levels

Single, graded doses were administered by intraperitoneal administration to male mice to ascertain the maximum tolerated dose. Doses administered, along with pertinent observations, are presented in Table I.

TABLE I

TEST MATERIAL: Pyro-Chek 77B

Dominant Lethal Study - Albino Mice

Determination of Treatment Levels

Dose Level (mg/kg)	Number of Males Dead / Number of Males Treated	Observations
10,000	0/4	None
3,000	0/4	None
1,000	0/4	None
300	0/4	None
100	0/4	None
0	0/4	None

The dose levels employed in the main study were based on these findings.

* Charles River Breeding Laboratories, Wilmington, Mass.

D. Dose Administration and Group Organization

The test material was administered intraperitoneally as a 29 percent corn oil suspension (w/v) to male mice. Control males received the vehicle. The total volume given to each 5,000 mg/kg mouse was 25 ml/kg. The total volume given to each control and 10,000 mg/kg mouse was 50 ml/kg.

The organization of groups is presented in Table II.

TABLE II

TEST MATERIAL: Pyro-Chek 77B

Dominant Lethal Study - Albino Mice

Organization of Groups

Group	Dose Level (mg/kg)	Number of Males Treated
C	None	12
T-I	5,000	12
T-II	10,000	12

E. Mortality and General Observations

All animals were observed daily to detect possible deaths or untoward behavioral reactions. In addition, all surviving males were sacrificed following completion of the mating period and subjected to gross pathologic examinations. The testes of these males were preserved for possible future histopathologic examinations.

F. Reproductive Performance

After dose administration, each male was placed in a cage with 3 untreated virgin females. One week later, the females were removed from the breeding cages and marked to designate the male to which each was bred. At this time, all males were caged with 3 more females. This procedure continued for 6 consecutive weeks, the period of time required for maturation of the male mouse germ cells.

The females were sacrificed 15 days following initiation of cohabitation. An incision was made in the abdominal wall and the full extent of both uterine horns exposed immediately. Fetal swellings, implantation sites, and resorption sites (early and late differentiated) were recorded.

Resorption sites were divided into 2 groups, early deaths (deciduomata) and late deaths. Late deaths refer to embryos which have developed to a relatively advanced stage prior to death, as evidenced by the presence of visible placenta and fetal membranes or remnants thereof. The frequency of late deaths is apparently unaffected by mutagens and, therefore, would appear to be non-genetic in this test system. Deciduomata occur at the sites of implanted blastocysts which fail to develop following implantation. The mutagenicity of the chemical can be measured by the proportions of all implantations which are deciduomata.

Mutagenicity can also be measured by comparing the mean number of viable embryos in the test group to the number obtained in the control group. Calculation of the mutation rate using this criterion assumes that pre-implantation losses among non-affected test animals will be essentially the same as losses observed among control animals.

IV. Results

A. Mortality and General Observations

In comparison to the concurrent control males, males given 10,000 mg Pyro-Chek 77B/kg exhibited hypoactivity for approximately 3 hours after dose administration. No other behavioral reactions were noted among either test or control males. One 10,000 mg/kg male died during week 2. No other deaths occurred among test or control males.

Three weeks after dose administration, abdominal distension was noted among 3 of 12 of the 5,000 mg/kg males and 8 of 11 of the 10,000 mg/kg males. The percentage of affected males increased until all the males in both test groups exhibited some degree of abdominal distension. No external changes were noted among control males.

Following completion of the mating period, all surviving males were sacrificed and subjected to gross pathologic examinations. Also, at this time, all gonads were saved for possible future histopathologic examinations.

Necropsy examinations upon the test males revealed varying amounts of white material in the abdominal cavity which had adhered to various organs. No untoward findings were noted among control males.

B. Mating Performance

Male and female fertility indices are presented in Table III. Male fertility was reduced for the 5,000 mg/kg Pyro-Chek 77B group during week 6 and for the 10,000 mg/kg group during weeks 2 through 6. The percentage of pregnant females was reduced for weeks 2 through 6 for the 10,000 mg/kg treatment group. All other values obtained compared favorably with the concurrent control group.

The indices employed are as follows:

$$\text{Male Fertility Index} = \frac{\text{Number of Sires}}{\text{Number of Males Mated}} \times 100$$

$$\text{Female Fertility Index} = \frac{\text{Number of Pregnant Females}}{\text{Number of Females Mated}} \times 100$$

TABLE II

TEST MATERIAL: Pyro-Chek 77E

Dominant Lethal Study - Albino Mice

Mating Performance

Group	Dose Level (mg/kg)	Week No.	Male Fertility Index Fraction	Male Fertility Index Percent	Female Fertility Index Fraction	Female Fertility Index Percent
C	None	1	10/12	83.3	20/35*	57.1
		2	10/12	83.3	21/36	58.3
		3	11/12	91.7	22/36	61.1
		4	12/12	100.0	24/36	66.7
		5	11/12	91.7	27/36	75.0
		6	11/12	91.7	24/36	66.7
T-I	5,000	1	12/12	100.0	29/36	80.6
		2	12/12	100.0	30/35*	85.7
		3	12/12	100.0	25/36	69.4
		4	11/12	91.7	21/36	58.3
		5	11/12	91.7	27/36	75.0
		6	8/12	66.7	21/36	58.3
T-II	10,000	1	9/12	75.0	17/34	50.0
		2	8/12	66.7	16/36	44.4
		3	4/11**	36.4	8/33	24.2
		4	6/11	54.5	13/33	39.4
		5	7/11	63.6	13/33	39.4
		6	6/11	54.5	10/33	30.3

* Dam died.

** One male not utilized during the week 3 matings.

C. Sacrifice Data

Data pertaining to the numbers of corpora lutea, implantation sites, resorption sites (early and late differentiated) and embryos are presented in Table IV. Laboratory data have shown that the untreated female mouse has a mean of 13.5 corpora lutea. Therefore, the number of pregnant animals is multiplied by 13.5 to obtain the calculated number of corpora lutea.

Data obtained from females mated with the Pyro-Chek 77B treated males compared favorably with the control.

A reduction in the number of implantation sites and viable embryos occurred during week 6 for the 10,000 mg/kg group. This was due, however, to 2 dams accounting for 7 of the implantation sites and embryos.

TABLE IV

TEST MATERIAL: Pyro-Chek 77B

Dominant Lethal Study - Albino Mice

Reproductive Data

Group	Dose Level (mg/kg)	Week No.	Pregnant Females Examined	Calculated Corpora Lutea	Implantation Sites		Resorption Sites				Embryos	
							Early		Late			
				Total	Total	Mean	Total	Mean	Total	Mean	Total	Mean
C	None	1	20	270	225	11.3	8	0.4	1	0.1	216	10.8
		2	21	284	236	11.2	11	0.5	4	0.2	221	10.5
		3	22	297	248	11.3	9	0.4	2	0.1	237	10.8
		4	24	324	263	11.0	16	0.7	7	0.3	240	10.0
		5	27	365	317	11.7	0	0.0	22	0.8	295	10.9
		6	24	324	293	12.2	15	0.6	5	0.2	273	11.4
T-I	5,000	1	29	392	343	11.8	16	0.6	8	0.3	319	11.0
		2	30	405	362	12.1	17	0.6	4	0.1	341	11.4
		3	25	338	298	11.9	16	0.6	3	0.1	279	11.2
		4	21	284	240	11.4	7	0.3	1	0.1	232	11.0
		5	27	365	330	12.2	4	0.1	17	0.6	309	11.4
		6	21	284	249	11.9	12	0.6	1	0.1	236	11.2

TABLE IV continued

TEST MATERIAL: Pyro-Chek 77B

Dominant Lethal Study - Albino Mice

Reproductive Data

Group	Dose Level (mg/kg)	Week No.	Pregnant Females Examined	Calculated Corpora Lutea Total	Implantation Sites Total	Implantation Sites Mean	Resorption Sites Early Total	Resorption Sites Early Mean	Resorption Sites Late Total	Resorption Sites Late Mean	Embryos Total	Embryos Mean
T-II	10,000	1	17	230	206	12.1	11	0.6	2	0.1	193	11.4
		2	16	216	192	12.0	8	0.5	1	0.1	183	11.4
		3	8	108	98	12.3	4	0.5	1	0.1	93	11.6
		4	13	176	161	12.4	3	0.2	0	0.0	158	12.2
		5	13	176	165	12.7	1	0.1	7	0.5	157	12.1
		6	10	135	94	9.4 (10.9)	6	0.6	0	0.0	88	8.8 (12.1)

Note: Mean values in parentheses were obtained by omitting 2 dams that accounted for only 7 implantation sites and embryos.

D. Mutagenic Data

A summary of results of the mutagenic study is presented in Table V.

1. Pre-Implantation loss is calculated as follows:

$$\frac{\text{Number of Corpora Lutea - Number of Implantation Sites}}{\text{Number of Corpora Lutea}} \times 100$$

2. The mutation rate is calculated by comparing the number of early resorptions (deciduomata) to the total number of implantations for each group.

$$\frac{\text{Number of Early Resorption Sites}}{\text{Number of Implantation Sites}} \times 100 \text{ (See A in table)}$$

Another way of expressing the mutation rate, which takes into account pre-implantation losses, is to compare the mean number of normal embryos in each test group to the mean number of embryos in the control group.

$$\frac{\text{Embryos/Female Control - Embryos/Female Test}}{\text{Embryos/Female Control}} \times 100 \text{ (See B in table)}$$

Values presented for each group were obtained by comparing the mean values of that group to the values of the contemporary control group (a in table) and to cumulative control data (b in table). Values with a minus (-) sign indicate that the mean number of embryos for that group and week was greater than that of controls.

Mutation rates for the Pyro-Chek 77B treated animals compared favorably with those obtained for the concurrent control group.

TABLE V

TEST MATERIAL: Pyro-Chek 77B

Dominant Lethal Study - Albino Mice

Mutagenic Data

Group	Dose Level (mg/kg)	Week No.	Pre-Implantation Loss	Mutation Rate A	Mutation Rate B a	Mutation Rate B b
C	None	1	16.7	3.6	-	6.1
		2	16.9	4.7	-	7.9
		3	16.5	3.6	-	6.1
		4	18.8	8.1	-	13.0
		5	13.2	0.0	-	6.0
		6	9.6	5.1	-	1.7
T-I	5,000	1	12.5	4.7	-1.9	4.3
		2	10.6	4.7	-8.6	0.0
		3	11.8	5.4	-3.7	2.6
		4	15.5	2.9	-10.0	4.3
		5	9.6	1.2	-4.6	1.7
		6	12.3	4.8	1.8	3.4
T-II	10,000	1	10.4	5.4	-5.6	0.9
		2	11.1	4.2	-8.6	0.0
		3	9.3	4.1	-7.4	-0.9
		4	8.5	1.9	-22.0	-6.1
		5	6.3	0.6	-11.0	-4.3
		6	30.4(13.0)	6.4	22.8(12.9)	24.1(11.4)

Note: Data in parentheses obtained by omitting 2 dams accounting for only 7 implantation sites and embryos.

E. Individual Data

Mutation rates determined for each male are presented in Tables VI through VIII. X denotes no females were pregnant during that week.

TABLE VI

TEST MATERIAL: Pyro-Chek 77B

Dominant Lethal Study - Albino Mice

Mutagenic Data

Individual Sire Data

Group	Dose Level (mg/kg)	Sire No.	Week No.	Pre-Implantation Loss	Mutation Rate A		B
						a	b
C	None	1	1	X			
			2	X			
			3	7.4	4.0	-	-4.3
			4	11.1	16.7	-	21.7
			5	30.9	0.0	-	31.0
			6	-11.1	0.0	-	-29.3
		2	1	33.3	0.0	-	21.7
			2	25.9	5.0	-	21.1
			3	11.1	0.0	-	-4.3
			4	38.3	0.0	-	27.8
			5	44.4	0.0	-	44.0
			6	7.4	0.0	-	7.8
		3	1	3.7	0.0	-	-13.0
			2	11.1	8.3	-	3.5
			3	3.7	7.7	-	-4.3
			4	14.8	4.3	-	4.3
			5	16.0	0.0	-	11.2
			6	-11.1	10.0	-	-16.4
		4	1	-3.7	21.4	-	4.3
			2	3.7	7.7	-	-0.9
			3	11.1	4.2	-	0.0
			4	18.5	4.5	-	21.7
			5	6.2	0.0	-	-3.4
			6	8.6	8.1	-	5.2

TABLE VI continued

TEST MATERIAL: Pyro-Chek 77B

Dominant Lethal Study - Albino Mice

Mutagenic Data

Individual Sire Data

Group	Dose Level (mg/kg)	Sire No.	Week No.	Pre-Implantation Loss	Mutation Rate A	Mutation Rate B a	Mutation Rate B b
C	None	5	1	51.9	7.7	-	47.8
			2	18.5	0.0	-	3.5
			3	11.1	0.0	-	-4.3
			4	14.8	4.3	-	4.3
			5	11.1	0.0	-	5.2
			6	-3.7	0.0	-	-16.4
		6	1	13.6	2.9	-	1.7
			2	11.1	4.2	-	-0.9
			3	11.1	5.6	-	1.7
			4	18.5	9.1	-	21.7
			5	3.7	0.0	-	-6.0
			6	30.9	0.0	-	22.4
		7	1	-11.1	0.0	-	-30.4
			2	33.3	5.6	-	29.8
			3	14.8	4.3	-	4.3
			4	14.8	4.3	-	4.3
			5	7.4	0.0	-	-3.4
			6	3.7	15.4	-	5.2
		8	1	18.5	0.0	-	4.3
			2	13.6	2.9	-	3.5
			3	8.6	8.1	-	1.7
			4	33.3	7.4	-	27.8
			5	-1.2	0.0	-	-12.1
			6	11.1	8.3	-	5.2

TABLE VI continued

TEST MATERIAL: Pyro-Chek 77B

Dominant Lethal Study - Albino Mice

Mutagenic Data

Individual Sire Data

Group	Dose Level (mg/kg)	Sire No.	Week No.	Pre-Implantation Loss	Mutation Rate A		B
						a	b
C	None	9	1	13.6	8.6	-	10.4
			2	18.5	9.1	-	12.3
			3	40.7	0.0	-	39.1
			4	3.7	7.7	-	-4.3
			5	6.2	0.0	-	-0.9
			6	21.0	6.3	-	13.8
		10	1	0.0	0.0	-	-17.4
			2	6.2	2.6	-	-7.9
			3	-3.7	0.0	-	21.7
			4	0.0	0.0	-	-4.3
			5	11.1	0.0	-	5.2
			6	-3.7	4.8	-	-9.5
		11	1	33.3	0.0	-	21.4
			2	40.7	0.0	-	29.8
			3	55.6	0.0	-	47.8
			4	40.7	25.0	-	47.8
			5	14.8	0.0	-	0.9
			6	29.6	5.3	-	22.4
		12	1	X			
			2	X			
			3	X			
			4	11.1	0.0	-	-4.3
			5	X			
			6	X			

TABLE VII

TEST MATERIAL: Pyro-Chek 77B

Dominant Lethal Study - Albino Mice

Mutagenic Data

Individual Sire Data

Group	Dose Level (mg/kg)	Sire No.	Week No.	Pre-Implantation Loss	Mutation Rate A	Mutation Rate B a	Mutation Rate B b
T-I	5,000	13	1	-1.2	4.9	-17.6	-10.4
			2	3.7	2.6	-21.0	-11.4
			3	14.8	4.3	-1.9	4.3
			4	7.4	4.0	-20.0	-4.3
			5	7.4	0.0	-14.7	-7.8
			6	-1.2	12.2	-5.3	-3.4
		14	1	13.6	5.7	-1.9	4.3
			2	14.8	17.4	9.5	16.7
			3	0.0	14.8	-6.5	0.0
			4	7.4	0.0	-20.0	-4.3
			5	6.2	0.0	-16.7	-9.5
			6	13.6	2.9	0.9	2.6
		15	1	3.7	0.0	-20.4	-13.0
			2	3.7	5.1	-17.1	-7.9
			3	8.6	0.0	-13.9	-7.0
			4	25.9	0.0	0.0	13.0
			5	1.2	0.0	-16.7	-9.5
			6	7.4	4.0	-5.3	-3.4
		16	1	0.0	0.0	-25.0	-17.4
			2	3.7	3.8	-14.3	-5.3
			3	0.0	3.7	-20.4	-13.0
			4	13.6	5.7	-10.0	4.3
			5	8.6	0.0	8.3	13.8
			6	16.1	0.0	0.9	2.6

TABLE VII continued

TEST MATERIAL: Pyro-Chek 77B

Dominant Lethal Study - Albino Mice

Mutagenic Data

Individual Sire Data

Group	Dose Level (mg/kg)	Sire No.	Week No.	Pre-Implantation Loss	Mutation Rate A	Mutation Rate B a	Mutation Rate B b
T-I	5,000	17	1	-3.7	7.1	-11.1	-4.3
			2	11.1	8.3	-4.8	3.5
			3	25.9	0.0	7.4	13.0
			4	7.4	4.0	-20.0	-4.3
			5	40.7	0.9	35.8	39.7
			6	11.1	4.2	-0.9	0.9
		18	1	6.2	5.3	-11.1	-4.3
			2	21.0	0.0	1.9	9.6
			3	11.1	8.3	-1.9	4.3
			4	55.6	0.0	40.0	47.8
			5	3.7	11.5	-0.9	5.2
			6	30.9	10.7	27.2	28.4
		19	1	25.9	3.3	10.1	15.7
			2	11.1	8.3	-4.8	3.5
			3	14.8	0.0	-6.5	0.0
			4	11.1	0.0	-20.0	-4.3
			5	0.0	0.0	-19.3	-12.1
			6	X			
		20	1	8.6	8.1	4.3	10.4
			2	14.8	4.3	0.0	7.9
			3	11.1	8.3	7.4	13.0
			4	X			
			5	X			
			6	X			

TABLE VII continued

TEST MATERIAL: Pyro-Chek 77B

Dominant Lethal Study - Albino Mice

Mutagenic Data

Individual Sire Data

Group	Dose Level (mg/kg)	Sire No.	Week No.	Pre-Implantation Loss	Mutation Rate A	Mutation Rate B a	Mutation Rate B b
T-I	5,000	21	1	8.6	8.1	0.9	7.0
			2	23.5	3.2	7.6	14.9
			3	8.6	5.4	-1.9	4.3
			4	8.6	8.1	-13.0	1.7
			5	22.2	0.0	8.3	13.8
			6	11.1	2.8	-2.6	-0.9
		22	1	7.4	4.0	-6.5	0.0
			2	1.2	5.0	-21.0	-11.4
			3	3.7	3.8	-15.7	-8.7
			4	18.5	0.0	-10.0	4.3
			5	6.2	0.0	-7.3	-0.9
			6	X			
		23	1	23.5	3.2	7.4	13.0
			2	13.6	2.9	-7.6	0.9
			3	35.8	11.5	28.7	33.0
			4	3.7	0.0	-30.0	-13.0
			5	16.0	2.9	-0.9	5.2
			6	3.7	0.0	-9.6	-7.8
		24	1	44.4	0.0	30.6	34.8
			2	3.7	0.0	-23.8	-14.0
			3	3.7	3.8	-15.7	-8.7
			4	33.3	0.0	10.0	21.7
			5	11.1	0.0	-7.3	-0.9
			6	X			

TABLE VIII

TEST MATERIAL: Pyro-Chek 77B

Dominant Lethal Study - Albino Mice

Mutagenic Data

Individual Sire Data

Group	Dose Level (mg/kg)	Sire No.	Week No.	Pre-Implantation Loss	Mutation Rate A	Mutation Rate B a	Mutation Rate B b
T-II	10,000	25	1	25.9	0.0	7.4	13.0
			2	11.1	16.7	4.8	12.3
			3	X			
			4	X			
			5	X			
			6	X			
		26	1	X			
			2	X			
			3	X			
			4	X			
			5	3.7	0.0	-19.3	-12.1
			6	X			
		27	1	X			
			2	X			
			3	X			
			4	X			
			5	X			
			6	X			
		28	1	14.8	21.7	16.7	21.7
			2	8.6	0.0	-14.3	-5.3
			3	-3.7	0.0	-29.6	-21.7
			4	6.2	0.0	-27.0	-10.4
			5	3.7	0.0	-5.5	0.9
			6	11.1	0.0	-5.3	-3.4

TABLE VIII continued

TEST MATERIAL: Pyro-Chek 77B

Dominant Lethal Study - Albino Mice

Mutagenic Data

Individual Sire Data

Group	Dose Level (mg/kg)	Sire No.	Week No.	Pre-Implantation Loss	Mutation Rate A	Mutation Rate B a	Mutation Rate B b
T-II	10,000	29	1	X			
			2	X			
			3	X			
			4	X			
			5	X			
			6	X			
		30	1	3.7	5.1	-13.9	-7.0
			2	16.1	2.9	-4.8	3.5
			3	13.6	5.7	-1.9	4.3
			4	11.1	2.8	-17.0	-1.7
			5	1.2	2.5	-12.8	-6.0
			6	14.8	4.3	3.5	5.2
		31	1	18.5	0.0	2.8	8.7
			2	18.5	4.5	0.0	7.9
			3	X			
			4	X			
			5	3.7	0.0	-19.3	-12.1
			6	44.4	6.7	38.6	39.7
		32	1	0.0	0.0	-25.0	-17.4
			2	3.7	0.0	-23.8	-14.0
			3	14.8	4.3	-1.9	4.3
			4	-7.4	0.0	-45.0	-26.1
			5	3.7	0.0	-12.8	-6.0
			6	30.9	7.1	23.7	25.0

TABLE VIII continued

TEST MATERIAL: Pyro-Chek 77B

Dominant Lethal Study - Albino Mice

Mutagenic Data

Individual Sire Data

Group	Dose Level (mg/kg)	Sire No.	Week No.	Pre-Implantation Loss	Mutation Rate A	Mutation Rate B a	Mutation Rate B b
T-II	10,000	33	1	11.1	8.3	-1.9	4.3
			2	X			
			3		N.A.		
			4	7.4	4.0	-20.0	-4.3
			5	X			
			6	3.7	15.4	3.5	5.2
		34	1	-11.1	0.0	-38.9	-30.4
			2	0.0	3.7	-23.8	-14.0
			3	X			
			4	Male Died			
		35	1	13.6	2.9	-1.9	4.3
			2	14.8	4.3	-4.8	3.5
			3	X			
			4	-11.1	3.3	-45.0	-26.1
			5	18.5	0.0	-0.9	5.2
			6	X			
		36	1	14.8	8.7	2.8	8.7
			2	11.1	8.3	-4.8	3.5
			3	11.1	8.3	7.4	13.0
			4	77.8	0.0	70.0	73.9
			5	14.8	0.0	-5.5	0.9
			6	77.8	0.0	73.7	74.1

N.A. denotes data not available

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