

**TDMS No.** 93027 - 47  
**Test Type:** 90-DAY  
**Route:** DOSED FEED  
**Species/Strain:** HAMSTERS/SYRIAN

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
Peroxisome project (2,4-Dichlorophenoxyacetic acid)  
**CAS Number:** 94-75-7

**Date Report Requested:** 06/24/2009  
**Time Report Requested:** 13:53:21  
**First Dose M/F:** 03/06/95 / NA  
**Lab:** BAT

F1\_Rev1\_H1

**C Number:** C93027C  
**Lock Date:** 06/12/1996  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Male  
**TDMSE Version:** 2.1.0

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**SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF PEROXISOME PROJECT (2,4-DICHLOROPHENOXYACETIC ACID)**

**MALE HAMSTERS**

**Organ**

Epididymis

Kidney

Prostate

Seminal Vesicle

**Morphology**

Atrophy

Mineralization

Nephropathy

Atrophy

Atrophy

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	12 PPM	100 PPM	500 PPM	1000 PPM	5000 PPM
<b>Epididymis Atrophy</b>						
<b>LESION RATES</b>						
OVERALL (a)	0/7 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/2 (100%)	0/10 (0%)
POLY-3 RATE (b)	0/7.00	0/0.00	0/0.00	0/0.00	2/2.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	100%	0%
TERMINAL (d)	0/7 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	2/2 (100%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	92 (T)	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	P=0.028*	(e)
POLY 1.5	(e)	(e)	(e)	(e)	P=0.028*	(e)
POLY 6	(e)	(e)	(e)	(e)	P=0.028*	(e)
COCH-ARM / FISHERS	P=0.323N	(e)	(e)	(e)	P=0.028*	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	P<0.001**	(e)

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TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	12 PPM	100 PPM	500 PPM	1000 PPM	5000 PPM
<b>Gallbladder</b>						
<b>Infiltration Cellular Mixed Cell</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	8/10 (80%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	8/10 (80%)
<b>POLY-3 RATE (b)</b>	8/10.00	0/0.00	0/0.00	0/0.00	0/0.00	8/10.00
<b>POLY-3 PERCENT (g)</b>	80%	0%	0%	0%	0%	80%
<b>TERMINAL (d)</b>	8/10 (80%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	8/10 (80%)
<b>FIRST INCIDENCE</b>	92 (T)	---	---	---	---	92 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	(e)	(e)	(e)	(e)	(e)	P=0.702
<b>POLY 1.5</b>	(e)	(e)	(e)	(e)	(e)	P=0.702
<b>POLY 6</b>	(e)	(e)	(e)	(e)	(e)	P=0.702
<b>COCH-ARM / FISHERS</b>	P=0.673	(e)	(e)	(e)	(e)	P=0.709N
<b>MAX-ISO-POLY-3</b>	(e)	(e)	(e)	(e)	(e)	P=1.000

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	12 PPM	100 PPM	500 PPM	1000 PPM	5000 PPM
<b>Kidney Mineralization</b>						
<b>LESION RATES</b>						
OVERALL (a)	4/10 (40%)	7/10 (70%)	6/9 (67%)	7/10 (70%)	8/10 (80%)	8/10 (80%)
POLY-3 RATE (b)	4/10.00	7/10.00	6/9.00	7/10.00	8/10.00	8/10.00
POLY-3 PERCENT (g)	40%	70%	66.7%	70%	80%	80%
TERMINAL (d)	4/10 (40%)	7/10 (70%)	6/9 (67%)	7/10 (70%)	8/10 (80%)	8/10 (80%)
FIRST INCIDENCE	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	P=0.201	P=0.186	P=0.245	P=0.186	P=0.077	P=0.077
POLY 1.5	P=0.201	P=0.186	P=0.245	P=0.186	P=0.077	P=0.077
POLY 6	P=0.201	P=0.186	P=0.245	P=0.186	P=0.077	P=0.077
COCH-ARM / FISHERS	P=0.199	P=0.185	P=0.242	P=0.185	P=0.085	P=0.085
MAX-ISO-POLY-3	P=0.029*	P=0.089	P=0.132	P=0.089	P=0.029*	P=0.029*

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Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	12 PPM	100 PPM	500 PPM	1000 PPM	5000 PPM
<b>Kidney</b>						
<b>Nephropathy</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	3/10 (30%)	6/10 (60%)	5/9 (56%)	7/10 (70%)	3/10 (30%)	8/10 (80%)
<b>POLY-3 RATE (b)</b>	3/10.00	6/10.00	5/9.00	7/10.00	3/10.00	8/10.00
<b>POLY-3 PERCENT (g)</b>	30%	60%	55.6%	70%	30%	80%
<b>TERMINAL (d)</b>	3/10 (30%)	6/10 (60%)	5/9 (56%)	7/10 (70%)	3/10 (30%)	8/10 (80%)
<b>FIRST INCIDENCE</b>	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P=0.083	P=0.186	P=0.259	P=0.082	P=0.678	P=0.024*
<b>POLY 1.5</b>	P=0.083	P=0.186	P=0.259	P=0.082	P=0.678	P=0.024*
<b>POLY 6</b>	P=0.083	P=0.186	P=0.259	P=0.082	P=0.678	P=0.024*
<b>COCH-ARM / FISHERS</b>	P=0.088	P=0.185	P=0.255	P=0.089	P=0.686N	P=0.035*
<b>MAX-ISO-POLY-3</b>	P=0.011*	P=0.089	P=0.140	P=0.032*	P=1.000	P=0.007**

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	12 PPM	100 PPM	500 PPM	1000 PPM	5000 PPM
<b>Liver</b>						
<b>Infiltration Cellular Mixed Cell</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	10/10 (100%)	10/10 (100%)	9/10 (90%)	8/10 (80%)	9/9 (100%)	10/10 (100%)
<b>POLY-3 RATE (b)</b>	10/10.00	10/10.00	9/10.00	8/10.00	9/9.00	10/10.00
<b>POLY-3 PERCENT (g)</b>	100%	100%	90%	80%	100%	100%
<b>TERMINAL (d)</b>	10/10 (100%)	10/10 (100%)	9/10 (90%)	8/10 (80%)	9/9 (100%)	10/10 (100%)
<b>FIRST INCIDENCE</b>	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P=0.472	(e)	P=0.500N	P=0.227N	(e)	(e)
<b>POLY 1.5</b>	P=0.472	(e)	P=0.500N	P=0.227N	(e)	(e)
<b>POLY 6</b>	P=0.472	(e)	P=0.500N	P=0.227N	(e)	(e)
<b>COCH-ARM / FISHERS</b>	P=0.472	(e)	P=0.500N	P=0.237N	(e)	(e)
<b>MAX-ISO-POLY-3</b>	P=0.213N	(e)	P=0.158N	P=0.066N	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	12 PPM	100 PPM	500 PPM	1000 PPM	5000 PPM
<b>Lung Hemorrhage</b>						
<b>LESION RATES</b>						
OVERALL (a)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	2/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	10%
TERMINAL (d)	2/10 (20%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	92 (T)	---	---	---	---	92 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.500N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.500N
COCH-ARM / FISHERS	P=0.450N	(e)	(e)	(e)	(e)	P=0.500N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.274N



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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	12 PPM	100 PPM	500 PPM	1000 PPM	5000 PPM
<b>Pancreas</b>						
<b>Inflammation Chronic</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	7/10 (70%)	9/10 (90%)	9/10 (90%)	7/10 (70%)	7/10 (70%)	9/10 (90%)
<b>POLY-3 RATE (b)</b>	7/10.00	9/10.00	9/10.00	7/10.00	7/10.00	9/10.00
<b>POLY-3 PERCENT (g)</b>	70%	90%	90%	70%	70%	90%
<b>TERMINAL (d)</b>	7/10 (70%)	9/10 (90%)	9/10 (90%)	7/10 (70%)	7/10 (70%)	9/10 (90%)
<b>FIRST INCIDENCE</b>	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P=0.387	P=0.292	P=0.292	P=0.678	P=0.678	P=0.292
<b>POLY 1.5</b>	P=0.387	P=0.292	P=0.292	P=0.678	P=0.678	P=0.292
<b>POLY 6</b>	P=0.387	P=0.292	P=0.292	P=0.678	P=0.678	P=0.292
<b>COCH-ARM / FISHERS</b>	P=0.385	P=0.291	P=0.291	P=0.686N	P=0.686N	P=0.291
<b>MAX-ISO-POLY-3</b>	P=0.136	P=0.136	P=0.136	P=1.000	P=1.000	P=0.136

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TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	12 PPM	100 PPM	500 PPM	1000 PPM	5000 PPM
<b>Prostate Atrophy</b>						
<b>LESION RATES</b>						
OVERALL (a)	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	3/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	30%	0%	0%	0%	0%	0%
TERMINAL (d)	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	92 (T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.095N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.095N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.095N
COCH-ARM / FISHERS	P=0.084N	(e)	(e)	(e)	(e)	P=0.105N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.025N*

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TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	12 PPM	100 PPM	500 PPM	1000 PPM	5000 PPM
<b>Seminal Vesicle Atrophy</b>						
<b>LESION RATES</b>						
OVERALL (a)	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
POLY-3 RATE (b)	3/10.00	0/0.00	0/0.00	0/0.00	0/0.00	0/10.00
POLY-3 PERCENT (g)	30%	0%	0%	0%	0%	0%
TERMINAL (d)	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/10 (0%)
FIRST INCIDENCE	92 (T)	---	---	---	---	---
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.095N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.095N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.095N
COCH-ARM / FISHERS	P=0.084N	(e)	(e)	(e)	(e)	P=0.105N
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.025N*

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TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	12 PPM	100 PPM	500 PPM	1000 PPM	5000 PPM
<b>Stomach, Glandular Mineralization</b>						
<b>LESION RATES</b>						
OVERALL (a)	5/10 (50%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	7/10 (70%)
POLY-3 RATE (b)	5/10.00	0/0.00	0/0.00	0/0.00	0/0.00	7/10.00
POLY-3 PERCENT (g)	50%	0%	0%	0%	0%	70%
TERMINAL (d)	5/10 (50%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	7/10 (70%)
FIRST INCIDENCE	92 (T)	---	---	---	---	92 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.329
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.329
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.329
COCH-ARM / FISHERS	P=0.292	(e)	(e)	(e)	(e)	P=0.325
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.188

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TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	0 PPM	12 PPM	100 PPM	500 PPM	1000 PPM	5000 PPM
<b>Testes</b>						
<b>Atrophy</b>						
<b>LESION RATES</b>						
<b>OVERALL (a)</b>	3/10 (30%)	2/10 (20%)	2/9 (22%)	5/10 (50%)	3/10 (30%)	1/10 (10%)
<b>POLY-3 RATE (b)</b>	3/10.00	2/10.00	2/9.00	5/10.00	3/10.00	1/10.00
<b>POLY-3 PERCENT (g)</b>	30%	20%	22.2%	50%	30%	10%
<b>TERMINAL (d)</b>	3/10 (30%)	2/10 (20%)	2/9 (22%)	5/10 (50%)	3/10 (30%)	1/10 (10%)
<b>FIRST INCIDENCE</b>	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)
<b>STATISTICAL TESTS</b>						
<b>POLY 3</b>	P=0.201N	P=0.500N	P=0.552N	P=0.329	P=0.678	P=0.292N
<b>POLY 1.5</b>	P=0.201N	P=0.500N	P=0.552N	P=0.329	P=0.678	P=0.292N
<b>POLY 6</b>	P=0.201N	P=0.500N	P=0.552N	P=0.329	P=0.678	P=0.292N
<b>COCH-ARM / FISHERS</b>	P=0.198N	P=0.500N	P=0.556N	P=0.325	P=0.686N	P=0.291N
<b>MAX-ISO-POLY-3</b>	P=0.150N	P=0.310N	P=0.358N	P=0.188	P=1.000	P=0.136N

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Route: DOSED FEED

Species/Strain: HAMSTERS/SYRIAN

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Peroxisome project (2,4-Dichlorophenoxyacetic acid)

CAS Number: 94-75-7

Date Report Requested: 06/24/2009

Time Report Requested: 13:53:21

First Dose M/F: 03/06/95 / NA

Lab: BAT

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN HAMSTERS(SYRIAN)  
TERMINAL SACRIFICE AT 14 WEEKS

DOSE	Males					
	0 PPM	12 PPM	100 PPM	500 PPM	1000 PPM	5000 PPM
<b>Urinary Bladder Mineralization</b>						
<b>LESION RATES</b>						
OVERALL (a)	5/10 (50%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	5/9 (56%)
POLY-3 RATE (b)	5/10.00	0/0.00	0/0.00	0/0.00	0/0.00	5/9.00
POLY-3 PERCENT (g)	50%	0%	0%	0%	0%	55.6%
TERMINAL (d)	5/10 (50%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	5/9 (56%)
FIRST INCIDENCE	92 (T)	---	---	---	---	92 (T)
<b>STATISTICAL TESTS</b>						
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.582
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.582
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.582
COCH-ARM / FISHERS	P=0.550	(e)	(e)	(e)	(e)	P=0.586
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	P=0.409

TDMS No. 93027 - 47

Test Type: 90-DAY

Route: DOSED FEED

Species/Strain: HAMSTERS/SYRIAN

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**

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**LEGEND**

- (a) Number of tumor-bearing animals/number of animals examined at site.
  - (b) Number of tumor-bearing animals/Poly-3 number
  - (d) Observed incidence at terminal kill.
  - (e) Value of Statistic cannot be computed.
  - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
  - (g) Poly-3 adjusted lifetime tumor incidence.
  - (I) Interim sacrifice
  - (T) Terminal sacrifice
  - # Tumor rates based on numbers of animals necropsied.
  - \* To the right of any statistical result, indicates significance at ( $P \leq 0.05$ ).
  - \*\* To the right of any statistical result, indicates significance at ( $P \leq 0.01$ ).
  - N Indicates a negative trend for all tests
- The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

\*\*\* END OF REPORT \*\*\*