

**TDMS No.** 20201 - 01  
**Test Type:** 26-WEEK  
**Route:** SKIN APPLICATION  
**Species/Strain:** MICE/TG.AC HEMI

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
TEF TRANSGENICS (TCDD)  
**CAS Number:** 1746-01-6

**Date Report Requested:** 06/15/2006  
**Time Report Requested:** 14:58:13  
**First Dose M/F:** NA / 04/21/03  
**Lab:** BAT

**C Number:** C20201A  
**Lock Date:** 07/24/2004

**Cage Range:** ALL  
**Date Range:** ALL

**Reasons For Removal:** ALL  
**Removal Date Range:** ALL

**Treatment Groups:** Include 001 0 NG/KG                      Include 002 121 NG/KG                      Include 003 760 NG/KG

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## SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF TEF TRANSGENICS (TCDD)

### FEMALE MICE

#### Organ

Liver

Liver: Hepatocyte

Lung: Bronchiole

Skin

Skin, Control Dermis

Skin, SOA No Mass

Skin, Site of Application

Spleen

Stomach, Forestomach

#### Morphology

Fatty Change

Hematopoietic Cell Proliferation

Myelodysplasia

Necrosis

Pigmentation

Degeneration

Inflammation

Hyperplasia

Inflammation Chronic

Hyperplasia

Inflammation Chronic

Hyperplasia

Inflammation Chronic

Hematopoietic Cell Proliferation

Myelodysplasia

Hyperplasia

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(TG.AC HEMI)  
 TERMINAL SACRIFICE AT 27 WEEKS**

DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

Liver  
 Fatty Change

**LESION RATES**

OVERALL (a)	1/20 (5%)	4/20 (20%)	8/20 (40%)
POLY-3 RATE (b)	1/17.89	4/16.59	8/15.16
POLY-3 PERCENT (g)	5.6%	24.1%	52.8%
TERMINAL (d)	1/17 (6%)	2/12 (17%)	7/11 (64%)
FIRST INCIDENCE	183 (T)	110	155

**STATISTICAL TESTS**

LIFE TABLE	P=0.003**	P=0.117	P<0.001**
POLY 3	P=0.002**	P=0.143	P=0.002**
POLY 1.5	P=0.004**	P=0.153	P=0.003**
POLY 6	P<0.001**	P=0.131	P<0.001**
LOGISTIC REGRESSION	P=0.008**	P=0.191	P<0.001**
COCH-ARM / FISHERS	P=0.011*	P=0.171	P=0.010**
ORDER RESTRICTED	P<0.001**	(e)	(e)
MAX-ISO-POLY-3	P=0.002**	(e)	(e)

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DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

---

Liver  
 Hematopoietic Cell Proliferation

**LESION RATES**

OVERALL (a)	1/20 (5%)	4/20 (20%)	7/20 (35%)
POLY-3 RATE (b)	1/17.89	4/15.57	7/16.24
POLY-3 PERCENT (g)	5.6%	25.7%	43.1%
TERMINAL (d)	1/17 (6%)	2/12 (17%)	4/11 (36%)
FIRST INCIDENCE	183 (T)	163	122

**STATISTICAL TESTS**

LIFE TABLE	P=0.010**	P=0.099	P=0.008**
POLY 3	P=0.015*	P=0.125	P=0.010**
POLY 1.5	P=0.019*	P=0.140	P=0.013*
POLY 6	P=0.011*	P=0.113	P=0.007**
LOGISTIC REGRESSION	P=0.021*	P=0.124	P=0.019*
COCH-ARM / FISHERS	P=0.029*	P=0.171	P=0.022*
ORDER RESTRICTED	P=0.004**	(e)	(e)
MAX-ISO-POLY-3	P=0.008**	(e)	(e)

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 TERMINAL SACRIFICE AT 27 WEEKS**

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DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

---

**Liver  
 Inflammation**

**LESION RATES**

OVERALL (a)	19/20 (95%)	19/20 (95%)	18/20 (90%)
POLY-3 RATE (b)	19/20.00	19/19.55	18/19.15
POLY-3 PERCENT (g)	95%	97.2%	94%
TERMINAL (d)	16/17 (94%)	12/12 (100%)	10/11 (91%)
FIRST INCIDENCE	74	57	84

**STATISTICAL TESTS**

LIFE TABLE	P=0.185	P=0.095	P=0.110
POLY 3	P=0.621N	P=0.689	P=0.714N
POLY 1.5	P=0.559N	P=0.726	P=0.654N
POLY 6	P=0.642N	P=0.622	P=0.744N
LOGISTIC REGRESSION	P=0.427N	P=0.767N	P=0.535N
COCH-ARM / FISHERS	P=0.410N	P=0.756N	P=0.500N
ORDER RESTRICTED	P=0.512N	(e)	(e)
MAX-ISO-POLY-3	P=0.515N	(e)	(e)

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 TERMINAL SACRIFICE AT 27 WEEKS**

DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

Liver  
 Myelodysplasia

**LESION RATES**

OVERALL (a)	0/20 (0%)	0/20 (0%)	2/20 (10%)
POLY-3 RATE (b)	0/17.89	0/15.11	2/15.55
POLY-3 PERCENT (g)	0%	0%	12.9%
TERMINAL (d)	0/17 (0%)	0/12 (0%)	0/11 (0%)
FIRST INCIDENCE	---	---	155

**STATISTICAL TESTS**

LIFE TABLE	P=0.074	(e)	P=0.183
POLY 3	P=0.079	(e)	P=0.202
POLY 1.5	P=0.084	(e)	P=0.216
POLY 6	P=0.072	(e)	P=0.187
LOGISTIC REGRESSION	P=0.097	(e)	P=0.253
COCH-ARM / FISHERS	P=0.093	(e)	P=0.244
ORDER RESTRICTED	P=0.035*	(e)	(e)
MAX-ISO-POLY-3	P=0.054	(e)	(e)

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 TERMINAL SACRIFICE AT 27 WEEKS**

---

DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

---

Liver  
 Necrosis

**LESION RATES**

OVERALL (a)	7/20 (35%)	9/20 (45%)	13/20 (65%)
POLY-3 RATE (b)	7/18.15	9/17.05	13/18.39
POLY-3 PERCENT (g)	38.6%	52.8%	70.7%
TERMINAL (d)	6/17 (35%)	5/12 (42%)	6/11 (55%)
FIRST INCIDENCE	165	110	97

**STATISTICAL TESTS**

LIFE TABLE	P=0.017*	P=0.163	P=0.014*
POLY 3	P=0.048*	P=0.307	P=0.047*
POLY 1.5	P=0.048*	P=0.333	P=0.050*
POLY 6	P=0.047*	P=0.278	P=0.044*
LOGISTIC REGRESSION	P=0.042*	P=0.309	P=0.048*
COCH-ARM / FISHERS	P=0.049*	P=0.374	P=0.056
ORDER RESTRICTED	P=0.028*	(e)	(e)
MAX-ISO-POLY-3	P=0.034*	(e)	(e)

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 TERMINAL SACRIFICE AT 27 WEEKS**

DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

Liver  
 Pigmentation

**LESION RATES**

OVERALL (a)	10/20 (50%)	9/20 (45%)	15/20 (75%)
POLY-3 RATE (b)	10/18.15	9/15.57	15/17.15
POLY-3 PERCENT (g)	55.1%	57.8%	87.5%
TERMINAL (d)	9/17 (53%)	7/12 (58%)	10/11 (91%)
FIRST INCIDENCE	165	163	129

**STATISTICAL TESTS**

LIFE TABLE	P=0.003**	P=0.356	P=0.005**
POLY 3	P=0.018*	P=0.575	P=0.031*
POLY 1.5	P=0.025*	P=0.618N	P=0.049*
POLY 6	P=0.013*	P=0.498	P=0.019*
LOGISTIC REGRESSION	P=0.008**	P=0.497	P=0.023*
COCH-ARM / FISHERS	P=0.044*	P=0.500N	P=0.095
ORDER RESTRICTED	P=0.017*	(e)	(e)
MAX-ISO-POLY-3	P=0.024*	(e)	(e)



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 TERMINAL SACRIFICE AT 27 WEEKS**

---

DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

---

Liver: Hepatocyte  
 Degeneration

**LESION RATES**

OVERALL (a)	0/20 (0%)	0/20 (0%)	4/20 (20%)
POLY-3 RATE (b)	0/17.89	0/15.11	4/16.12
POLY-3 PERCENT (g)	0%	0%	24.8%
TERMINAL (d)	0/17 (0%)	0/12 (0%)	2/11 (18%)
FIRST INCIDENCE	---	---	122

**STATISTICAL TESTS**

LIFE TABLE	P=0.006**	(e)	P=0.039*
POLY 3	P=0.005**	(e)	P=0.037*
POLY 1.5	P=0.005**	(e)	P=0.043*
POLY 6	P=0.004**	(e)	P=0.030*
LOGISTIC REGRESSION	P=0.009**	(e)	P=0.067
COCH-ARM / FISHERS	P=0.008**	(e)	P=0.053
ORDER RESTRICTED	P=0.003**	(e)	(e)
MAX-ISO-POLY-3	P=0.005**	(e)	(e)

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 TERMINAL SACRIFICE AT 27 WEEKS**

---

DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

---

Lung: Alveolus  
 Infiltration Cellular Histiocyte

**LESION RATES**

OVERALL (a)	0/20 (0%)	2/20 (10%)	1/20 (5%)
POLY-3 RATE (b)	0/17.89	2/15.40	1/14.77
POLY-3 PERCENT (g)	0%	13%	6.8%
TERMINAL (d)	0/17 (0%)	1/12 (8%)	1/11 (9%)
FIRST INCIDENCE	---	163	183 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.530	P=0.177	P=0.413
POLY 3	P=0.556	P=0.200	P=0.462
POLY 1.5	P=0.594	P=0.212	P=0.480
POLY 6	P=0.508	P=0.188	P=0.440
LOGISTIC REGRESSION	P=0.598	P=0.211	P=0.413
COCH-ARM / FISHERS	P=0.638	P=0.244	P=0.500
ORDER RESTRICTED	P=0.165	(e)	(e)
MAX-ISO-POLY-3	P=0.206	(e)	(e)

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 TERMINAL SACRIFICE AT 27 WEEKS**

DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

**Lung: Bronchiole  
 Inflammation**

**LESION RATES**

OVERALL (a)	0/20 (0%)	0/20 (0%)	2/20 (10%)
POLY-3 RATE (b)	0/17.89	0/15.11	2/14.77
POLY-3 PERCENT (g)	0%	0%	13.5%
TERMINAL (d)	0/17 (0%)	0/12 (0%)	2/11 (18%)
FIRST INCIDENCE	---	---	183 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.057	(e)	P=0.146
POLY 3	P=0.073	(e)	P=0.191
POLY 1.5	P=0.081	(e)	P=0.210
POLY 6	P=0.064	(e)	P=0.170
LOGISTIC REGRESSION	(e)	(e)	P=0.146
COCH-ARM / FISHERS	P=0.093	(e)	P=0.244
ORDER RESTRICTED	P=0.032*	(e)	(e)
MAX-ISO-POLY-3	P=0.053	(e)	(e)

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 TERMINAL SACRIFICE AT 27 WEEKS**

DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

**Lung: Interstitium  
 Inflammation**

**LESION RATES**

OVERALL (a)	1/20 (5%)	1/20 (5%)	3/20 (15%)
POLY-3 RATE (b)	1/18.15	1/15.11	3/15.68
POLY-3 PERCENT (g)	5.5%	6.6%	19.1%
TERMINAL (d)	0/17 (0%)	1/12 (8%)	1/11 (9%)
FIRST INCIDENCE	165	183 (T)	143

**STATISTICAL TESTS**

LIFE TABLE	P=0.133	P=0.684	P=0.203
POLY 3	P=0.166	P=0.719	P=0.247
POLY 1.5	P=0.181	P=0.737	P=0.271
POLY 6	P=0.148	P=0.697	P=0.220
LOGISTIC REGRESSION	P=0.190	P=0.747	P=0.313
COCH-ARM / FISHERS	P=0.195	P=0.756N	P=0.302
ORDER RESTRICTED	P=0.127	(e)	(e)
MAX-ISO-POLY-3	P=0.160	(e)	(e)

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 TERMINAL SACRIFICE AT 27 WEEKS**

---

DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

---

**Lung: Perivascular  
 Inflammation**

**LESION RATES**

OVERALL (a)	2/20 (10%)	2/20 (10%)	2/20 (10%)
POLY-3 RATE (b)	2/17.89	2/15.11	2/15.16
POLY-3 PERCENT (g)	11.2%	13.2%	13.2%
TERMINAL (d)	2/17 (12%)	2/12 (17%)	1/11 (9%)
FIRST INCIDENCE	183 (T)	183 (T)	155

**STATISTICAL TESTS**

LIFE TABLE	P=0.527	P=0.566	P=0.548
POLY 3	P=0.602	P=0.635	P=0.636
POLY 1.5	P=0.630	P=0.661	P=0.665
POLY 6	P=0.564	P=0.605	P=0.599
LOGISTIC REGRESSION	P=0.584	P=0.566	P=0.643
COCH-ARM / FISHERS	P=0.660	P=0.698N	P=0.698N
ORDER RESTRICTED	P=0.584	(e)	(e)
MAX-ISO-POLY-3	P=0.589	(e)	(e)

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---

DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

---

**Lung: Serosa  
 Inflammation Chronic**

**LESION RATES**

OVERALL (a)	7/20 (35%)	4/20 (20%)	4/20 (20%)
POLY-3 RATE (b)	7/17.89	4/15.98	4/15.94
POLY-3 PERCENT (g)	39.1%	25%	25.1%
TERMINAL (d)	7/17 (41%)	2/12 (17%)	2/11 (18%)
FIRST INCIDENCE	183 (T)	122	129

**STATISTICAL TESTS**

LIFE TABLE	P=0.509N	P=0.460N	P=0.502N
POLY 3	P=0.347N	P=0.307N	P=0.309N
POLY 1.5	P=0.322N	P=0.279N	P=0.273N
POLY 6	P=0.386N	P=0.340N	P=0.360N
LOGISTIC REGRESSION	P=0.355N	P=0.320N	P=0.314N
COCH-ARM / FISHERS	P=0.308N	P=0.240N	P=0.240N
ORDER RESTRICTED	P=0.256N	(e)	(e)
MAX-ISO-POLY-3	P=0.284N	(e)	(e)

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TERMINAL SACRIFICE AT 27 WEEKS

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DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

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Lymph Node, Mandibular  
Hyperplasia Lymphoid

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LESION RATES

OVERALL (a)	0/0 (0%)	1/1 (100%)	2/2 (100%)
POLY-3 RATE (b)	0/0.00	1/1.00	2/2.00
POLY-3 PERCENT (g)	0%	100%	100%
TERMINAL (d)	0/0 (0%)	1/1 (100%)	0/0 (0%)
FIRST INCIDENCE	---	183 (T)	155

STATISTICAL TESTS

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LIFE TABLE	(e)	(e)	(e)
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
ORDER RESTRICTED	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(TG.AC HEMI)  
 TERMINAL SACRIFICE AT 27 WEEKS**

DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

**Skin  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	4/4 (100%)	0/2 (0%)	0/6 (0%)
POLY-3 RATE (b)	4/4.00	0/1.71	0/4.69
POLY-3 PERCENT (g)	100%	0%	0%
TERMINAL (d)	4/4 (100%)	0/1 (0%)	0/3 (0%)
FIRST INCIDENCE	183 (T)	---	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.052N	P=0.227N	P=0.041N*
POLY 3	P<0.001N**	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P<0.001N**	P<0.001N**
LOGISTIC REGRESSION	P=0.052N	(e)	(e)
COCH-ARM / FISHERS	P=0.015N*	P=0.067N	P=0.005N**
ORDER RESTRICTED	P<0.001N**	(e)	(e)
MAX-ISO-POLY-3	P<0.001N**	(e)	(e)



TDMS No. 20201 - 01  
 Test Type: 26-WEEK  
 Route: SKIN APPLICATION  
 Species/Strain: MICE/TG.AC HEMI

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 TEF TRANSGENICS (TCDD)  
 CAS Number: 1746-01-6

Date Report Reqsted: 06/15/2006  
 Time Report Reqsted: 14:58:13  
 First Dose M/F: NA / 04/21/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(TG.AC HEMI)  
 TERMINAL SACRIFICE AT 27 WEEKS**

DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

**Skin  
 Inflammation Chronic**

**LESION RATES**

OVERALL (a)	3/4 (75%)	1/2 (50%)	4/6 (67%)
POLY-3 RATE (b)	3/4.00	1/1.71	4/5.48
POLY-3 PERCENT (g)	75%	58.6%	73%
TERMINAL (d)	3/4 (75%)	1/1 (100%)	2/3 (67%)
FIRST INCIDENCE	183 (T)	183 (T)	155

**STATISTICAL TESTS**

LIFE TABLE	P=0.210	P=0.773	P=0.290
POLY 3	P=0.679	P=0.694N	P=0.738N
POLY 1.5	P=0.689N	P=0.651N	P=0.700N
POLY 6	P=0.662	P=0.764N	P=0.750
LOGISTIC REGRESSION	P=0.584	P=0.773	P=0.803N
COCH-ARM / FISHERS	P=0.681N	P=0.600N	P=0.667N
ORDER RESTRICTED	P=0.575N	(e)	(e)
MAX-ISO-POLY-3	P=0.589N	(e)	(e)

TDMS No. 20201 - 01  
 Test Type: 26-WEEK  
 Route: SKIN APPLICATION  
 Species/Strain: MICE/TG.AC HEMI

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 TEF TRANSGENICS (TCDD)  
 CAS Number: 1746-01-6

Date Report Reqsted: 06/15/2006  
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 First Dose M/F: NA / 04/21/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(TG.AC HEMI)  
 TERMINAL SACRIFICE AT 27 WEEKS**

---

DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

---

**Skin, Control Dermis  
 Inflammation Chronic**

**LESION RATES**

OVERALL (a)	0/20 (0%)	0/20 (0%)	4/20 (20%)
POLY-3 RATE (b)	0/17.89	0/15.11	4/15.86
POLY-3 PERCENT (g)	0%	0%	25.2%
TERMINAL (d)	0/17 (0%)	0/12 (0%)	2/11 (18%)
FIRST INCIDENCE	---	---	122

**STATISTICAL TESTS**

LIFE TABLE	P=0.005**	(e)	P=0.035*
POLY 3	P=0.004**	(e)	P=0.036*
POLY 1.5	P=0.005**	(e)	P=0.042*
POLY 6	P=0.004**	(e)	P=0.029*
LOGISTIC REGRESSION	P=0.008**	(e)	P=0.061
COCH-ARM / FISHERS	P=0.008**	(e)	P=0.053
ORDER RESTRICTED	P=0.002**	(e)	(e)
MAX-ISO-POLY-3	P=0.005**	(e)	(e)

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TDMS No. 20201 - 01  
 Test Type: 26-WEEK  
 Route: SKIN APPLICATION  
 Species/Strain: MICE/TG.AC HEMI

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 TEF TRANSGENICS (TCDD)  
 CAS Number: 1746-01-6

Date Report Reqsted: 06/15/2006  
 Time Report Reqsted: 14:58:13  
 First Dose M/F: NA / 04/21/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(TG.AC HEMI)  
 TERMINAL SACRIFICE AT 27 WEEKS**

---

DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

---

**Skin, SOA No Mass  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	1/20 (5%)	7/20 (35%)	10/17 (59%)
POLY-3 RATE (b)	1/17.89	7/17.25	10/14.63
POLY-3 PERCENT (g)	5.6%	40.6%	68.4%
TERMINAL (d)	1/17 (6%)	3/12 (25%)	7/10 (70%)
FIRST INCIDENCE	183 (T)	122	84

**STATISTICAL TESTS**

LIFE TABLE	P=0.002**	P=0.014*	P<0.001**
POLY 3	P<0.001**	P=0.014*	P<0.001**
POLY 1.5	P<0.001**	P=0.015*	P<0.001**
POLY 6	P<0.001**	P=0.013*	P<0.001**
LOGISTIC REGRESSION	P=0.002**	P=0.026*	P<0.001**
COCH-ARM / FISHERS	P=0.002**	P=0.022*	P<0.001**
ORDER RESTRICTED	P<0.001**	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)

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TDMS No. 20201 - 01  
 Test Type: 26-WEEK  
 Route: SKIN APPLICATION  
 Species/Strain: MICE/TG.AC HEMI

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 TEF TRANSGENICS (TCDD)  
 CAS Number: 1746-01-6

Date Report Reqsted: 06/15/2006  
 Time Report Reqsted: 14:58:13  
 First Dose M/F: NA / 04/21/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(TG.AC HEMI)  
 TERMINAL SACRIFICE AT 27 WEEKS**

---

DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

---

**Skin, SOA No Mass  
 Inflammation Chronic**

**LESION RATES**

OVERALL (a)	3/20 (15%)	8/20 (40%)	13/17 (76%)
POLY-3 RATE (b)	3/17.89	8/15.56	13/15.45
POLY-3 PERCENT (g)	16.8%	51.4%	84.2%
TERMINAL (d)	3/17 (18%)	7/12 (58%)	8/10 (80%)
FIRST INCIDENCE	183 (T)	150	84

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P=0.017*	P<0.001**
POLY 3	P<0.001**	P=0.033*	P<0.001**
POLY 1.5	P<0.001**	P=0.046*	P<0.001**
POLY 6	P<0.001**	P=0.024*	P<0.001**
LOGISTIC REGRESSION	P<0.001**	P=0.027*	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.078	P<0.001**
ORDER RESTRICTED	P<0.001**	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)

---

TDMS No. 20201 - 01  
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 Species/Strain: MICE/TG.AC HEMI

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 TEF TRANSGENICS (TCDD)  
 CAS Number: 1746-01-6

Date Report Reqsted: 06/15/2006  
 Time Report Reqsted: 14:58:13  
 First Dose M/F: NA / 04/21/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(TG.AC HEMI)  
 TERMINAL SACRIFICE AT 27 WEEKS**

DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

**Skin, Site of Application**  
**Hyperplasia**

**LESION RATES**

OVERALL (a)	1/20 (5%)	13/20 (65%)	14/20 (70%)
POLY-3 RATE (b)	1/17.89	13/17.50	14/18.44
POLY-3 PERCENT (g)	5.6%	74.3%	75.9%
TERMINAL (d)	1/17 (6%)	8/12 (67%)	8/11 (73%)
FIRST INCIDENCE	183 (T)	110	84

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P<0.001**	P<0.001**
POLY 3	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**
LOGISTIC REGRESSION	P=0.002**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P=0.002**	P<0.001**	P<0.001**
ORDER RESTRICTED	P<0.001**	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)

TDMS No. 20201 - 01  
 Test Type: 26-WEEK  
 Route: SKIN APPLICATION  
 Species/Strain: MICE/TG.AC HEMI

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 TEF TRANSGENICS (TCDD)  
 CAS Number: 1746-01-6

Date Report Reqsted: 06/15/2006  
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 First Dose M/F: NA / 04/21/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(TG.AC HEMI)  
 TERMINAL SACRIFICE AT 27 WEEKS**

---

DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

---

**Skin, Site of Application**  
**Inflammation Chronic**

**LESION RATES**

OVERALL (a)	2/20 (10%)	17/20 (85%)	20/20 (100%)
POLY-3 RATE (b)	2/17.89	17/17.50	20/20.00
POLY-3 PERCENT (g)	11.2%	97.1%	100%
TERMINAL (d)	2/17 (12%)	12/12 (100%)	11/11 (100%)
FIRST INCIDENCE	183 (T)	110	84

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P<0.001**	P<0.001**
POLY 3	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**
LOGISTIC REGRESSION	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**
ORDER RESTRICTED	P<0.001**	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)

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TDMS No. 20201 - 01  
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 Species/Strain: MICE/TG.AC HEMI

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 TEF TRANSGENICS (TCDD)  
 CAS Number: 1746-01-6

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 First Dose M/F: NA / 04/21/03  
 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(TG.AC HEMI)  
 TERMINAL SACRIFICE AT 27 WEEKS**

---

DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

---

**Spleen  
 Hematopoietic Cell Proliferation**

**LESION RATES**

OVERALL (a)	3/20 (15%)	9/20 (45%)	11/20 (55%)
POLY-3 RATE (b)	3/17.89	9/15.57	11/16.94
POLY-3 PERCENT (g)	16.8%	57.8%	64.9%
TERMINAL (d)	3/17 (18%)	7/12 (58%)	7/11 (64%)
FIRST INCIDENCE	183 (T)	163	122

**STATISTICAL TESTS**

LIFE TABLE	P=0.005**	P=0.008**	P=0.002**
POLY 3	P=0.011*	P=0.012*	P=0.002**
POLY 1.5	P=0.015*	P=0.019*	P=0.003**
POLY 6	P=0.007**	P=0.008**	P<0.001**
LOGISTIC REGRESSION	P=0.012*	P=0.010**	P=0.006**
COCH-ARM / FISHERS	P=0.029*	P=0.041*	P=0.009**
ORDER RESTRICTED	P<0.001**	(e)	(e)
MAX-ISO-POLY-3	P=0.002**	(e)	(e)

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TDMS No. 20201 - 01  
 Test Type: 26-WEEK  
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 Species/Strain: MICE/TG.AC HEMI

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS  
 TEF TRANSGENICS (TCDD)  
 CAS Number: 1746-01-6

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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(TG.AC HEMI)  
 TERMINAL SACRIFICE AT 27 WEEKS**

---

DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

---

Spleen  
 Myelodysplasia

**LESION RATES**

OVERALL (a)	0/20 (0%)	0/20 (0%)	2/20 (10%)
POLY-3 RATE (b)	0/17.89	0/15.11	2/15.55
POLY-3 PERCENT (g)	0%	0%	12.9%
TERMINAL (d)	0/17 (0%)	0/12 (0%)	0/11 (0%)
FIRST INCIDENCE	---	---	155

**STATISTICAL TESTS**

LIFE TABLE	P=0.074	(e)	P=0.183
POLY 3	P=0.079	(e)	P=0.202
POLY 1.5	P=0.084	(e)	P=0.216
POLY 6	P=0.072	(e)	P=0.187
LOGISTIC REGRESSION	P=0.097	(e)	P=0.253
COCH-ARM / FISHERS	P=0.093	(e)	P=0.244
ORDER RESTRICTED	P=0.035*	(e)	(e)
MAX-ISO-POLY-3	P=0.054	(e)	(e)

---



TDMS No. 20201 - 01  
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 Lab: BAT

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(TG.AC HEMI)  
 TERMINAL SACRIFICE AT 27 WEEKS**

DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

**Stomach, Forestomach  
 Hyperplasia**

**LESION RATES**

OVERALL (a)	0/6 (0%)	0/4 (0%)	2/5 (40%)
POLY-3 RATE (b)	0/6.00	0/4.00	2/3.96
POLY-3 PERCENT (g)	0%	0%	50.5%
TERMINAL (d)	0/6 (0%)	0/4 (0%)	1/2 (50%)
FIRST INCIDENCE	---	---	155

**STATISTICAL TESTS**

LIFE TABLE	P=0.037*	(e)	P=0.107
POLY 3	P=0.038*	(e)	P=0.107
POLY 1.5	P=0.048*	(e)	P=0.129
POLY 6	P=0.029*	(e)	P=0.083
LOGISTIC REGRESSION	P=0.081	(e)	P=0.173
COCH-ARM / FISHERS	P=0.079	(e)	P=0.182
ORDER RESTRICTED	P=0.010**	(e)	(e)
MAX-ISO-POLY-3	P=0.027*	(e)	(e)

TDMS No. 20201 - 01  
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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(TG.AC HEMI)  
 TERMINAL SACRIFICE AT 27 WEEKS**

---

DOSE	Females		
	0 NG/KG	121 NG/KG	760 NG/KG

---

**Thymus  
 Atrophy**

**LESION RATES**

OVERALL (a)	3/20 (15%)	3/19 (16%)	5/19 (26%)
POLY-3 RATE (b)	3/18.15	3/15.55	5/16.17
POLY-3 PERCENT (g)	16.5%	19.3%	30.9%
TERMINAL (d)	2/17 (12%)	1/12 (8%)	1/10 (10%)
FIRST INCIDENCE	165	122	97

**STATISTICAL TESTS**

LIFE TABLE	P=0.178	P=0.534	P=0.202
POLY 3	P=0.230	P=0.593	P=0.279
POLY 1.5	P=0.246	P=0.613	P=0.301
POLY 6	P=0.205	P=0.574	P=0.248
LOGISTIC REGRESSION	P=0.280	P=0.655	P=0.377
COCH-ARM / FISHERS	P=0.250	P=0.644	P=0.317
ORDER RESTRICTED	P=0.212	(e)	(e)
MAX-ISO-POLY-3	P=0.238	(e)	(e)

---

## 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.
  - (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. The life table analysis regards tumors in animals dying prior to terminal kill as being (directly or indirectly) the cause of death.
  - (e) Value of Statistic cannot be computed.
  - (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
- Logistic regression is an alternative method for analyzing the incidence of non-fatal tumors.  
The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

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