

**TDMS No.** 20303-03

**Test Type:** 90-DAY

**Route:** RESPIRATORY EXPOSURE WHOLE BODY

**Species/Strain:** RATS/F 344

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

VINYLDENE CHLORIDE

**CAS Number:** 75-35-4

**Pathologist:** KOOISTRA, L. - GRUMBEIN, S.

F1\_R2

**Date Report Requested:** 08/18/2006

**Time Report Requested:** 14:35:45

**First Dose M/F:** 10/11/04 / 10/12/04

**Lab:** BNW

**C Number:** C20303

**Lock Date:** 06/01/2005

**Cage Range:** 1 - 9999

**Date Range:** 1-JAN-1940 to 17-SEP-2040

**Reasons For Removal:** ALL

**Removal Date Range:** JAN /1 /1940 - SEP /17 /2040

<b>Treatment Groups:</b>	Include 1 Control	Include 2 Control	Include 3 6.25 ppm
	Include 4 6.25 ppm	Include 5 12.5 ppm	Include 6 12.5 ppm
	Include 7 25 ppm	Include 8 25 ppm	Include 9 50 ppm
	Include 10 50 ppm	Include 11 100 ppm	Include 12 100 ppm

TDMS No. 20303-03

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

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**SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF VINYLDENE CHLORIDE**

**MALE RATS**

**Organ**

Kidney

Liver: Centrilobular

Nose: Olfactory Epithelium

Nose: Turbinate

**FEMALE RATS**

**Organ**

Liver

Lung

Nose: Olfactory Epithelium

Nose: Turbinate

**Morphology**

Nephropathy

Cytoplasmic Alteration

Atrophy

Mineralization

Necrosis

Atrophy

**Morphology**

Vacuolization Cytoplasmic

Inflammation Acute

Atrophy

Mineralization

Necrosis

Atrophy

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	Control	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm

**Heart  
Cardiomyopathy**

**LESION RATES**

OVERALL (a)	5/10 (50%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
POLY-3 RATE (b)	5/10.00	0/0.00	0/0.00	0/0.00	0/0.00	3/10.00
POLY-3 PERCENT (g)	50%	0%	0%	0%	0%	30%
TERMINAL (d)	5/10 (50%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	3/10 (30%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.252N	P=1.000	P=1.000	P=1.000	P=1.000	P=0.328N
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.329N
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.329N
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.329N
LOGISTIC REGRESSION	P=0.252N	(e)	(e)	(e)	(e)	P=0.328N
COCH-ARM / FISHERS	P=0.247N	P=1.000	P=1.000	P=1.000	P=1.000	P=0.325N
ORDER RESTRICTED	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	Control	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm

**Kidney  
 Nephropathy**

**LESION RATES**

OVERALL (a)	6/10 (60%)	3/10 (30%)	4/10 (40%)	4/10 (40%)	3/10 (30%)	1/10 (10%)
POLY-3 RATE (b)	6/10.00	3/10.00	4/10.00	4/10.00	3/10.00	1/10.00
POLY-3 PERCENT (g)	60%	30%	40%	40%	30%	10%
TERMINAL (d)	6/10 (60%)	3/10 (30%)	4/10 (40%)	4/10 (40%)	3/10 (30%)	1/10 (10%)
FIRST INCIDENCE	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.033N*	P=0.190N	P=0.331N	P=0.331N	P=0.190N	P=0.034N*
POLY 3	P=0.032N*	P=0.186N	P=0.333N	P=0.333N	P=0.186N	P=0.018N*
POLY 1.5	P=0.032N*	P=0.186N	P=0.333N	P=0.333N	P=0.186N	P=0.018N*
POLY 6	P=0.032N*	P=0.186N	P=0.333N	P=0.333N	P=0.186N	P=0.018N*
LOGISTIC REGRESSION	P=0.033N*	P=0.190N	P=0.331N	P=0.331N	P=0.190N	P=0.034N*
COCH-ARM / FISHERS	P=0.032N*	P=0.185N	P=0.328N	P=0.328N	P=0.185N	P=0.029N*
ORDER RESTRICTED	P=0.012N*	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.016N*	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	Control	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm

Liver  
Hepatodiaphragmatic Nodule

**LESION RATES**

OVERALL (a)	0/10 (0%)	1/10 (10%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	1/10.00	1/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	10%	10%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	1/10 (10%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	93 (T)	93 (T)	---	---	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.332N	P=0.500	P=0.500	(e)	(e)	(e)
POLY 3	P=0.334N	P=0.500	P=0.500	(e)	(e)	(e)
POLY 1.5	P=0.334N	P=0.500	P=0.500	(e)	(e)	(e)
POLY 6	P=0.334N	P=0.500	P=0.500	(e)	(e)	(e)
LOGISTIC REGRESSION	(e)	P=0.500	P=0.500	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.331N	P=0.500	P=0.500	(e)	(e)	(e)
ORDER RESTRICTED	P=0.375N	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.380N	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	Control	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm

Liver  
Vacuolization Cytoplasmic

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	10%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	---	---	---	---	---	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.107	(e)	(e)	(e)	(e)	P=0.500
POLY 3	P=0.107	(e)	(e)	(e)	(e)	P=0.500
POLY 1.5	P=0.107	(e)	(e)	(e)	(e)	P=0.500
POLY 6	P=0.107	(e)	(e)	(e)	(e)	P=0.500
LOGISTIC REGRESSION	(e)	(e)	(e)	(e)	(e)	P=0.500
COCH-ARM / FISHERS	P=0.105	(e)	(e)	(e)	(e)	P=0.500
ORDER RESTRICTED	P=0.064	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.076	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	Control	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm
<b>Liver: Centrilobular Cytoplasmic Alteration</b>						
<b>LESION RATES</b>						
OVERALL (a)	1/10 (10%)	1/10 (10%)	6/10 (60%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	1/10.00	1/10.00	6/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	10%	10%	60%	100%	100%	100%
TERMINAL (d)	1/10 (10%)	1/10 (10%)	6/10 (60%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)
<b>STATISTICAL TESTS</b>						
LIFE TABLE	P<0.001**	P=0.766	P=0.034*	P<0.001**	P<0.001**	P<0.001**
POLY 3	P<0.001**	P=0.760	P=0.018*	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.760	P=0.018*	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.760	P=0.018*	P<0.001**	P<0.001**	P<0.001**
LOGISTIC REGRESSION	P<0.001**	P=0.766	P=0.034*	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.763N	P=0.029*	P<0.001**	P<0.001**	P<0.001**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	Control	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm

**Lung  
Inflammation Acute**

**LESION RATES**

OVERALL (a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	0/10.00	0/10.00	0/10.00	0/10.00	1/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	10%
TERMINAL (d)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.414	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.766
POLY 3	P=0.415	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.760
POLY 1.5	P=0.415	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.760
POLY 6	P=0.415	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.760
LOGISTIC REGRESSION	P=0.414	(e)	(e)	(e)	(e)	P=0.766
COCH-ARM / FISHERS	P=0.414	P=0.500N	P=0.500N	P=0.500N	P=0.500N	P=0.763N
ORDER RESTRICTED	P=0.292	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.301	(e)	(e)	(e)	(e)	(e)



**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	Control	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm

**Nose: Olfactory Epithelium  
Atrophy**

**LESION RATES**

OVERALL (a)	0/10 (0%)	4/10 (40%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	4/10.00	10/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	40%	100%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	4/10 (40%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P=0.051	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 3	P<0.001**	P=0.033*	P<0.001**	P<0.001**	P<0.001**	P<0.001N**
POLY 1.5	P<0.001**	P=0.033*	P<0.001**	P<0.001**	P<0.001**	P<0.001N**
POLY 6	P<0.001**	P=0.033*	P<0.001**	P<0.001**	P<0.001**	P<0.001N**
LOGISTIC REGRESSION	(e)	P=0.051	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.043*	P<0.001**	P<0.001**	P<0.001**	P<0.001**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	Control	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm

**Nose: Olfactory Epithelium  
 Mineralization**

**LESION RATES**

OVERALL (a)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	10/10.00	10/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	100%	100%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 3	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001N**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001N**
POLY 6	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001N**
LOGISTIC REGRESSION	(e)	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**	P<0.001**
ORDER RESTRICTED	P=0.831	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	Control	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm

**Nose: Olfactory Epithelium  
Necrosis**

**LESION RATES**

OVERALL (a)	0/10 (0%)	2/10 (20%)	6/10 (60%)	9/10 (90%)	7/10 (70%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	2/10.00	6/10.00	9/10.00	7/10.00	10/10.00
POLY-3 PERCENT (g)	0%	20%	60%	90%	70%	100%
TERMINAL (d)	0/10 (0%)	2/10 (20%)	6/10 (60%)	9/10 (90%)	7/10 (70%)	10/10 (100%)
FIRST INCIDENCE	---	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P=0.234	P=0.009**	P<0.001**	P=0.003**	P<0.001**
POLY 3	P<0.001**	P=0.227	P<0.001**	P<0.001**	P<0.001**	P<0.001N**
POLY 1.5	P<0.001**	P=0.227	P<0.001**	P<0.001**	P<0.001**	P<0.001N**
POLY 6	P<0.001**	P=0.227	P<0.001**	P<0.001**	P<0.001**	P<0.001N**
LOGISTIC REGRESSION	(e)	P=0.234	P=0.009**	P<0.001**	P=0.003**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.237	P=0.005**	P<0.001**	P=0.002**	P<0.001**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Males					
	Control	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm

**Nose: Turbinate  
 Atrophy**

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	10/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	100%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	---	93 (T)	93 (T)	93 (T)	93 (T)

**STATISTICAL TESTS**

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	Control	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm

**Heart  
 Cardiomyopathy**

**LESION RATES**

OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	1/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	10%
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	1/10 (10%)
FIRST INCIDENCE	93 (T)	---	---	---	---	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.642	P=1.000	P=1.000	P=1.000	P=1.000	P=0.766
POLY 3	(e)	(e)	(e)	(e)	(e)	P=0.760
POLY 1.5	(e)	(e)	(e)	(e)	(e)	P=0.760
POLY 6	(e)	(e)	(e)	(e)	(e)	P=0.760
LOGISTIC REGRESSION	P=0.642	(e)	(e)	(e)	(e)	P=0.766
COCH-ARM / FISHERS	P=0.645	P=1.000	P=1.000	P=1.000	P=1.000	P=0.763N
ORDER RESTRICTED	(e)	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	Control	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm

**Kidney  
Nephropathy**

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	2/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	20%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	93 (T)	---	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.586N	(e)	(e)	P=0.234	(e)	(e)
POLY 3	P=0.590N	(e)	(e)	P=0.227	(e)	(e)
POLY 1.5	P=0.590N	(e)	(e)	P=0.227	(e)	(e)
POLY 6	P=0.590N	(e)	(e)	P=0.227	(e)	(e)
LOGISTIC REGRESSION	(e)	(e)	(e)	P=0.234	(e)	(e)
COCH-ARM / FISHERS	P=0.586N	(e)	(e)	P=0.237	(e)	(e)
ORDER RESTRICTED	P=0.348	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.355	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	Control	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm

Liver  
Hepatodiaphragmatic Nodule

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	2/10 (20%)	1/10 (10%)
POLY-3 RATE (b)	0/10.00	0/10.00	1/10.00	0/10.00	2/10.00	1/10.00
POLY-3 PERCENT (g)	0%	0%	10%	0%	20%	10%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)	2/10 (20%)	1/10 (10%)
FIRST INCIDENCE	---	---	93 (T)	---	93 (T)	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P=0.191	(e)	P=0.500	(e)	P=0.234	P=0.500
POLY 3	P=0.191	(e)	P=0.500	(e)	P=0.227	P=0.500
POLY 1.5	P=0.191	(e)	P=0.500	(e)	P=0.227	P=0.500
POLY 6	P=0.191	(e)	P=0.500	(e)	P=0.227	P=0.500
LOGISTIC REGRESSION	(e)	(e)	P=0.500	(e)	P=0.234	P=0.500
COCH-ARM / FISHERS	P=0.189	(e)	P=0.500	(e)	P=0.237	P=0.500
ORDER RESTRICTED	P=0.153	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.167	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	Control	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm

Liver  
Vacuolization Cytoplasmic

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	100%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	---	---	---	93 (T)	93 (T)

**STATISTICAL TESTS**

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



**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	Control	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm

**Liver: Centrilobular  
Cytoplasmic Alteration**

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	0%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	---	---	---	---	---	---

**STATISTICAL TESTS**

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

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	Control	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm

**Lung  
Inflammation Acute**

**LESION RATES**

OVERALL (a)	2/10 (20%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	2/10.00	0/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	20%	0%	0%	0%	0%	0%
TERMINAL (d)	2/10 (20%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
FIRST INCIDENCE	93 (T)	---	---	---	---	---

**STATISTICAL TESTS**

LIFE TABLE	P=0.205N	P=0.234N	P=0.234N	P=0.234N	P=0.234N	P=0.234N
POLY 3	P=0.193N	P=0.227N	P=0.227N	P=0.227N	P=0.227N	P=0.227N
POLY 1.5	P=0.193N	P=0.227N	P=0.227N	P=0.227N	P=0.227N	P=0.227N
POLY 6	P=0.193N	P=0.227N	P=0.227N	P=0.227N	P=0.227N	P=0.227N
LOGISTIC REGRESSION	P=0.205N	(e)	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	P=0.203N	P=0.237N	P=0.237N	P=0.237N	P=0.237N	P=0.237N
ORDER RESTRICTED	P=0.007N**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P=0.008N**	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
 TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	Control	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm

**Nose: Olfactory Epithelium  
 Atrophy**

**LESION RATES**

OVERALL (a)	0/10 (0%)	2/10 (20%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	2/10.00	10/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	20%	100%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	2/10 (20%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P=0.234	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 3	P<0.001**	P=0.227	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.227	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.227	P<0.001**	P<0.001**	P<0.001**	P<0.001**
LOGISTIC REGRESSION	(e)	P=0.234	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.237	P<0.001**	P<0.001**	P<0.001**	P<0.001**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	Control	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm

**Nose: Olfactory Epithelium  
Mineralization**

**LESION RATES**

OVERALL (a)	0/10 (0%)	5/10 (50%)	9/10 (90%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	5/10.00	9/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	50%	90%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	5/10 (50%)	9/10 (90%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P=0.022*	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 3	P<0.001**	P=0.008**	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.008**	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.008**	P<0.001**	P<0.001**	P<0.001**	P<0.001**
LOGISTIC REGRESSION	(e)	P=0.022*	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.016*	P<0.001**	P<0.001**	P<0.001**	P<0.001**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	Control	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm

**Nose: Olfactory Epithelium  
Necrosis**

**LESION RATES**

OVERALL (a)	0/10 (0%)	1/10 (10%)	3/10 (30%)	6/10 (60%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	1/10.00	3/10.00	6/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	10%	30%	60%	100%	100%
TERMINAL (d)	0/10 (0%)	1/10 (10%)	3/10 (30%)	6/10 (60%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	93 (T)	93 (T)	93 (T)	93 (T)	93 (T)

**STATISTICAL TESTS**

LIFE TABLE	P<0.001**	P=0.500	P=0.111	P=0.009**	P<0.001**	P<0.001**
POLY 3	P<0.001**	P=0.500	P=0.095	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.500	P=0.095	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.500	P=0.095	P<0.001**	P<0.001**	P<0.001**
LOGISTIC REGRESSION	P<0.001**	P=0.500	P=0.111	P=0.009**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500	P=0.105	P=0.005**	P<0.001**	P<0.001**
ORDER RESTRICTED	P<0.001**	(e)	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	P<0.001**	(e)	(e)	(e)	(e)	(e)

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)  
TERMINAL SACRIFICE AT 14 WEEKS**

DOSE	Females					
	Control	6.25 ppm	12.5 ppm	25 ppm	50 ppm	100 ppm

**Nose: Turbinate Atrophy**

**LESION RATES**

OVERALL (a)	0/10 (0%)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
POLY-3 RATE (b)	0/10.00	0/10.00	10/10.00	10/10.00	10/10.00	10/10.00
POLY-3 PERCENT (g)	0%	0%	100%	100%	100%	100%
TERMINAL (d)	0/10 (0%)	0/10 (0%)	10/10 (100%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
FIRST INCIDENCE	---	---	93 (T)	93 (T)	93 (T)	93 (T)

**STATISTICAL TESTS**

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

TDMS No. 20303-03

Test Type: 90-DAY

Route: RESPIRATORY EXPOSURE WHOLE BODY

Species/Strain: RATS/F 344

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

VINYLDENE CHLORIDE

CAS Number: 75-35-4

Pathologist: KOOISTRA, L. - GRUMBEIN, S.

Date Report Requested: 08/18/2006

Time Report Requested: 14:35:45

First Dose M/F: 10/11/04 / 10/12/04

Lab: BNW

**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 \*\*\*