

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

Treatment Groups:	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

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

**Liver: Centrilobular
 Cytoplasmic Alteration**

LESION RATES

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)

STATISTICAL TESTS

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 ***