P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Test Type: 90-DAY

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E

Super®; OTNE)

Route: SKIN APPLICATION
Species/Strain: RATS/F344/N Tac

CAS Number: 54464-57-2

Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Date Report Requested: 03/30/2016

Lab: MBA

F1_Rev1 RD 0% Vehicle (without High Dose)

NTP Study Number: C20307

Lock Date: 12/23/2009

Cage Range: ALL

Date Range: ALL

Reasons For Removal: ALL

Removal Date Range: ALL

Treatment Groups: Include 002 vehicle Include 003 6.25% Include 004 12.5%

Include 005 25% Include 006 50% Include 009 vehicle

Include 010 6.25% Include 011 12.5% Include 012 25%

Include 013 50%

Study Gender: Both

TDMSE Version: 3.0.2.3_002

PWG Approval Date: NONE

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E

Super®; OTNE)

Route: SKIN APPLICATION **CAS Number:** 54464-57-2 **First Dose M/F:** 12/12/06 / 12/13/06

Species/Strain: RATS/F344/N Tac

Lab: MBA

Date Report Requested: 03/30/2016 Time Report Requested: 14:54:57

SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF ETHANONE, 1-(1,2,3,4,5,6,7,8-OCTAHYDRO-2,3,8,8-TETRAMETHYL-2-NAPHTHALENYL)- (ISO-E SUPER®; OTNE)

MALE RATS

Experiment Number: 20307 - 03

Test Type: 90-DAY

Organ Morphology

Kidney Nephropathy
Skin, Site of Application Hyperkeratosis
Hyperplasia

FEMALE RATS

Organ Morphology

Kidney Inflammation Chronic Liver Inflammation Chronic Skin, Site of Application Hyperkeratosis

Hyperplasia

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION

Experiment Number: 20307 - 03

Test Type: 90-DAY

Species/Strain: RATS/F344/N Tac

CAS Number: 54464-57-2

Date Report Requested: 03/30/2016

Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

Males							
DOSE	vehicle	6.25%	12.5%	25%	50%		
Harderian Gland Inflammation Chronic							
LESION RATES							
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)		
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00		
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%		
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)		
FIRST INCIDENCE							
STATISTICAL TESTS							
POLY 3	(n)	(n)	(n)	(n)	(n)		
POLY 1.5	(n)	(n)	(n)	(n)	(n)		
POLY 6	(n)	(n)	(n)	(n)	(n)		
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)		
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)		

Experiment Number: 20307 - 03

Species/Strain: RATS/F344/N Tac

Route: SKIN APPLICATION

Test Type: 90-DAY

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

CAS Number: 54464-57-2

Date Report Requested: 03/30/2016

First Dose M/F: 12/12/06 / 12/13/06

Time Report Requested: 14:54:57

Lab: MBA

			Males			
DOSE	vehicle	6.25%	12.5%	25%	50%	
Heart Cardiomyopathy						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	
FIRST INCIDENCE	92 (T)					
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	
POLY 1.5	(e)	(e)	(e)	(e)	(e)	
POLY 6	(e)	(e)	(e)	(e)	(e)	
COCH-ARM / FISHERS	P=1.000N	(e)	(e)	(e)	(e)	
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

CAS Number: 54464-57-2 **Route: SKIN APPLICATION**

Species/Strain: RATS/F344/N Tac

Experiment Number: 20307 - 03

Test Type: 90-DAY

Date Report Requested: 03/30/2016 Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

			Males			
DOSE	vehicle	6.25%	12.5%	25%	50%	
Kidney Inflammation Chronic						
LESION RATES						
OVERALL (a)	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	
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	
FIRST INCIDENCE						
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	
POLY 1.5	(n)	(n)	(n)	(n)	(n)	
POLY 6	(n)	(n)	(n)	(n)	(n)	
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION

Experiment Number: 20307 - 03

Test Type: 90-DAY

Species/Strain: RATS/F344/N Tac

CAS Number: 54464-57-2

Date Report Requested: 03/30/2016

Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

			Males			
DOSE	vehicle	6.25%	12.5%	25%	50%	
Kidney Mineralization						
LESION RATES						
OVERALL (a)	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	
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	
FIRST INCIDENCE						
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	
POLY 1.5	(n)	(n)	(n)	(n)	(n)	
POLY 6	(n)	(n)	(n)	(n)	(n)	
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

CAS Number: 54464-57-2

Date Report Requested: 03/30/2016

Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

	Males							
DOSE	vehicle	6.25%	12.5%	25%	50%			
Kidney Nephropathy								
LESION RATES								
OVERALL (a)	8/10 (80%)	9/10 (90%)	10/10 (100%)	10/10 (100%)	10/10 (100%)			
POLY-3 RATE (b)	8/10.00	9/10.00	10/10.00	10/10.00	10/10.00			
POLY-3 PERCENT (g)	80%	90%	100%	100%	100%			
TERMINAL (d)	8/10 (80%)	9/10 (90%)	10/10 (100%)	10/10 (100%)	10/10 (100%)			
FIRST INCIDENCE	92 (T)	92 (T)	92 (T)	92 (T)	92 (T)			
STATISTICAL TESTS								
POLY 3	P=0.102	P=0.500	P=0.227	P=0.227	P=0.227			
POLY 1.5	P=0.102	P=0.500	P=0.227	P=0.227	P=0.227			
POLY 6	P=0.102	P=0.500	P=0.227	P=0.227	P=0.227			
COCH-ARM / FISHERS	P=0.103	P=0.500	P=0.237	P=0.237	P=0.237			
MAX-ISO-POLY-3	P=0.029*	P=0.274	P=0.066	P=0.066	P=0.066			

Test Type: 90-DAY

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

CAS Number: 54464-57-2 **Route: SKIN APPLICATION**

Species/Strain: RATS/F344/N Tac

Date Report Requested: 03/30/2016

First Dose M/F: 12/12/06 / 12/13/06

Time Report Requested: 14:54:57

Lab: MBA

			Males			
DOSE	vehicle	6.25%	12.5%	25%	50%	
Kidney: Pelvis Inflammation Chronic						
LESION RATES						
OVERALL (a)	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	
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	
FIRST INCIDENCE						
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	
POLY 1.5	(n)	(n)	(n)	(n)	(n)	
POLY 6	(n)	(n)	(n)	(n)	(n)	
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	

Test Type: 90-DAY

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION Species/Strain: RATS/F344/N Tac **CAS Number:** 54464-57-2

Date Report Requested: 03/30/2016 Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

			Males			
DOSE	vehicle	6.25%	12.5%	25%	50%	
Kidney: Renal Tubule Casts						
LESION RATES						
OVERALL (a)	0/10 (0%)	1/10 (10%)	1/10 (10%)	0/10 (0%)	1/10 (10%)	
POLY-3 RATE (b)	0/10.00	1/10.00	1/10.00	0/10.00	1/10.00	
POLY-3 PERCENT (g)	0%	10%	10%	0%	10%	
TERMINAL (d)	0/10 (0%)	1/10 (10%)	1/10 (10%)	0/10 (0%)	1/10 (10%)	
FIRST INCIDENCE		92 (T)	92 (T)		92 (T)	
STATISTICAL TESTS						
POLY 3	P=0.500	P=0.500	P=0.500	(e)	P=0.500	
POLY 1.5	P=0.500	P=0.500	P=0.500	(e)	P=0.500	
POLY 6	P=0.500	P=0.500	P=0.500	(e)	P=0.500	
COCH-ARM / FISHERS	P=0.500	P=0.500	P=0.500	(e)	P=0.500	
MAX-ISO-POLY-3	P=0.180	P=0.158	P=0.158	(e)	P=0.158	

Test Type: 90-DAY

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION CAS Number: 54464-57-2

Species/Strain: RATS/F344/N Tac

Date Report Requested: 03/30/2016

First Dose M/F: 12/12/06 / 12/13/06

Time Report Requested: 14:54:57

Lab: MBA

	·		Males			
DOSE	vehicle	6.25%	12.5%	25%	50%	
Liver						
Inflammation Chronic						
LESION RATES						
OVERALL (a)	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	
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	
FIRST INCIDENCE						
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	
POLY 1.5	(n)	(n)	(n)	(n)	(n)	
POLY 6	(n)	(n)	(n)	(n)	(n)	
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

CAS Number: 54464-57-2 **Route: SKIN APPLICATION**

Species/Strain: RATS/F344/N Tac

Experiment Number: 20307 - 03

Test Type: 90-DAY

Date Report Requested: 03/30/2016 Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

			Males			
DOSE	vehicle	6.25%	12.5%	25%	50%	
Lung Inflammation Chronic						
LESION RATES						
OVERALL (a)	5/10 (50%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	
POLY-3 RATE (b)	5/10.00	0/0.00	0/0.00	0/0.00	0/0.00	
POLY-3 PERCENT (g)	50%	0%	0%	0%	0%	
TERMINAL (d)	5/10 (50%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	
FIRST INCIDENCE	92 (T)					
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	
POLY 1.5	(e)	(e)	(e)	(e)	(e)	
POLY 6	(e)	(e)	(e)	(e)	(e)	
COCH-ARM / FISHERS	P=1.000N	(e)	(e)	(e)	(e)	
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION CAS Number: 54464-57-2

Species/Strain: RATS/F344/N Tac

Experiment Number: 20307 - 03

Test Type: 90-DAY

Date Report Requested: 03/30/2016

Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

			Males			
DOSE	vehicle	6.25%	12.5%	25%	50%	
Lung Mineralization						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	
FIRST INCIDENCE						
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	
POLY 1.5	(n)	(n)	(n)	(n)	(n)	
POLY 6	(n)	(n)	(n)	(n)	(n)	
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	

Species/Strain: RATS/F344/N Tac

Route: SKIN APPLICATION

Test Type: 90-DAY

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

CAS Number: 54464-57-2

First Dose M/F: 12/12/06 / 12/13/06

Date Report Requested: 03/30/2016

Time Report Requested: 14:54:57

Lab: MBA

			Males			
DOSE	vehicle	6.25%	12.5%	25%	50%	
Lung: Interstitium Inflammation Focal						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	
FIRST INCIDENCE	92 (T)					
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	
POLY 1.5	(e)	(e)	(e)	(e)	(e)	
POLY 6	(e)	(e)	(e)	(e)	(e)	
COCH-ARM / FISHERS	P=1.000N	(e)	(e)	(e)	(e)	
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	

Species/Strain: RATS/F344/N Tac

Test Type: 90-DAY

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION CAS Number: 54464-57-2 First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

Date Report Requested: 03/30/2016

Time Report Requested: 14:54:57

			Males			
DOSE	vehicle	6.25%	12.5%	25%	50%	
Lymph Node, Mesenteric Infiltration Cellular Histiocyt	e					
LESION RATES						
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00	
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%	
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	
FIRST INCIDENCE	92 (T)					
STATISTICAL TESTS						
POLY 3	(e)	(e)	(e)	(e)	(e)	
POLY 1.5	(e)	(e)	(e)	(e)	(e)	
POLY 6	(e)	(e)	(e)	(e)	(e)	
COCH-ARM / FISHERS	P=1.000N	(e)	(e)	(e)	(e)	
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)	

Test Type: 90-DAY

Route: SKIN APPLICATION

Species/Strain: RATS/F344/N Tac

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Date Report Requested: 03/30/2016 Time Report Requested: 14:54:57

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

CAS Number: 54464-57-2

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

	Males							
DOSE	vehicle	6.25%	12.5%	25%	50%			
Lymph Node: Iliac Hyperplasia Diffuse								
LESION RATES								
OVERALL (a)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)			
POLY-3 RATE (b)	0/0.00	0/0.00	0/0.00	0/0.00	0/0.00			
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%			
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)			
FIRST INCIDENCE								
STATISTICAL TESTS								
POLY 3	(n)	(n)	(n)	(n)	(n)			
POLY 1.5	(n)	(n)	(n)	(n)	(n)			
POLY 6	(n)	(n)	(n)	(n)	(n)			
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)			
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)			

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION

Test Type: 90-DAY

Species/Strain: RATS/F344/N Tac

CAS Number: 54464-57-2

Date Report Requested: 03/30/2016

Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06 Lab: MBA

	Males							
DOSE	vehicle	6.25%	12.5%	25%	50%			
Pancreas: Acinus								
Atrophy								
LESION RATES								
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)			
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00			
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%			
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)			
FIRST INCIDENCE	92 (T)							
STATISTICAL TESTS								
POLY 3	(e)	(e)	(e)	(e)	(e)			
POLY 1.5	(e)	(e)	(e)	(e)	(e)			
POLY 6	(e)	(e)	(e)	(e)	(e)			
COCH-ARM / FISHERS	P=1.000N	(e)	(e)	(e)	(e)			
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)			

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

CAS Number: 54464-57-2

Route: SKIN APPLICATION Species/Strain: RATS/F344/N Tac

Experiment Number: 20307 - 03

Test Type: 90-DAY

Date Report Requested: 03/30/2016

Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

			Males			
DOSE	vehicle	6.25%	12.5%	25%	50%	
Skin Hyperplasia						
LESION RATES						
OVERALL (a)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	
POLY-3 RATE (b)	0/10.00	1/10.00	0/10.00	0/10.00	0/10.00	
POLY-3 PERCENT (g)	0%	10%	0%	0%	0%	
TERMINAL (d)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	
FIRST INCIDENCE		92 (T)				
STATISTICAL TESTS						
POLY 3	P=0.500N	P=0.500	(e)	(e)	(e)	
POLY 1.5	P=0.500N	P=0.500	(e)	(e)	(e)	
POLY 6	P=0.500N	P=0.500	(e)	(e)	(e)	
COCH-ARM / FISHERS	P=0.500N	P=0.500	(e)	(e)	(e)	
MAX-ISO-POLY-3	P=0.214N	P=0.158	(e)	(e)	(e)	

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION Species/Strain: RATS/F344/N Tac

Test Type: 90-DAY

CAS Number: 54464-57-2

Time Report Requested: 14:54:57

Date Report Requested: 03/30/2016

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

			Males			
DOSE	vehicle	6.25%	12.5%	25%	50%	
Skin Inflammation						
LESION RATES						
OVERALL (a)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	
POLY-3 RATE (b)	0/10.00	1/10.00	0/10.00	0/10.00	0/10.00	
POLY-3 PERCENT (g)	0%	10%	0%	0%	0%	
TERMINAL (d)	0/10 (0%)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	
FIRST INCIDENCE		92 (T)				
STATISTICAL TESTS						
POLY 3	P=0.500N	P=0.500	(e)	(e)	(e)	
POLY 1.5	P=0.500N	P=0.500	(e)	(e)	(e)	
POLY 6	P=0.500N	P=0.500	(e)	(e)	(e)	
COCH-ARM / FISHERS	P=0.500N	P=0.500	(e)	(e)	(e)	
MAX-ISO-POLY-3	P=0.214N	P=0.158	(e)	(e)	(e)	

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION

Test Type: 90-DAY

Species/Strain: RATS/F344/N Tac

CAS Number: 54464-57-2

First Dose M/F: 12/12/06 / 12/13/06

Time Report Requested: 14:54:57

Date Report Requested: 03/30/2016

Lab: MBA

	Males							
DOSE	vehicle	6.25%	12.5%	25%	50%			
Skin, Site of Application Hyperkeratosis								
LESION RATES								
OVERALL (a)	0/10 (0%)	1/10 (10%)	3/10 (30%)	4/10 (40%)	5/10 (50%)			
POLY-3 RATE (b)	0/10.00	1/10.00	3/10.00	4/10.00	5/10.00			
POLY-3 PERCENT (g)	0%	10%	30%	40%	50%			
TERMINAL (d)	0/10 (0%)	1/10 (10%)	3/10 (30%)	4/10 (40%)	5/10 (50%)			
FIRST INCIDENCE		92 (T)	92 (T)	92 (T)	92 (T)			
STATISTICAL TESTS								
POLY 3	P=0.004**	P=0.500	P=0.095	P=0.033*	P=0.008**			
POLY 1.5	P=0.004**	P=0.500	P=0.095	P=0.033*	P=0.008**			
POLY 6	P=0.004**	P=0.500	P=0.095	P=0.033*	P=0.008**			
COCH-ARM / FISHERS	P=0.006**	P=0.500	P=0.105	P=0.043*	P=0.016*			
MAX-ISO-POLY-3	P=0.004**	P=0.158	P=0.025*	P=0.007**	P<0.001**			

Test Type: 90-DAY

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION Species/Strain: RATS/F344/N Tac **CAS Number:** 54464-57-2

Date Report Requested: 03/30/2016 Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

			Males			
DOSE	vehicle	6.25%	12.5%	25%	50%	
Skin, Site of Application Hyperplasia						
LESION RATES						
OVERALL (a)	0/10 (0%)	2/10 (20%)	4/10 (40%)	5/10 (50%)	8/10 (80%)	
POLY-3 RATE (b)	0/10.00	2/10.00	4/10.00	5/10.00	8/10.00	
POLY-3 PERCENT (g)	0%	20%	40%	50%	80%	
TERMINAL (d)	0/10 (0%)	2/10 (20%)	4/10 (40%)	5/10 (50%)	8/10 (80%)	
FIRST INCIDENCE		92 (T)	92 (T)	92 (T)	92 (T)	
STATISTICAL TESTS						
POLY 3	P<0.001**	P=0.227	P=0.033*	P=0.008**	P<0.001**	
POLY 1.5	P<0.001**	P=0.227	P=0.033*	P=0.008**	P<0.001**	
POLY 6	P<0.001**	P=0.227	P=0.033*	P=0.008**	P<0.001**	
COCH-ARM / FISHERS	P<0.001**	P=0.237	P=0.043*	P=0.016*	P<0.001**	
MAX-ISO-POLY-3	P<0.001**	P=0.066	P=0.007**	P<0.001**	P<0.001**	

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION

Test Type: 90-DAY

Species/Strain: RATS/F344/N Tac

CAS Number: 54464-57-2

Date Report Requested: 03/30/2016 Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

	Females							
DOSE	vehicle	6.25%	12.5%	25%	50%			
Clitoral Gland Inflammation Chronic								
LESION RATES								
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)			
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00			
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%			
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)			
FIRST INCIDENCE	92 (T)							
STATISTICAL TESTS								
POLY 3	(e)	(e)	(e)	(e)	(e)			
POLY 1.5	(e)	(e)	(e)	(e)	(e)			
POLY 6	(e)	(e)	(e)	(e)	(e)			
COCH-ARM / FISHERS	P=1.000N	(e)	(e)	(e)	(e)			
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)			

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION

Test Type: 90-DAY

Species/Strain: RATS/F344/N Tac

CAS Number: 54464-57-2

Date Report Requested: 03/30/2016 Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

	Females							
DOSE	vehicle	6.25%	12.5%	25%	50%			
Harderian Gland Inflammation Chronic								
LESION RATES								
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)			
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00			
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%			
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)			
FIRST INCIDENCE	92 (T)							
STATISTICAL TESTS								
POLY 3	(e)	(e)	(e)	(e)	(e)			
POLY 1.5	(e)	(e)	(e)	(e)	(e)			
POLY 6	(e)	(e)	(e)	(e)	(e)			
COCH-ARM / FISHERS	P=1.000N	(e)	(e)	(e)	(e)			
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)			

Test Type: 90-DAY

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION

Species/Strain: RATS/F344/N Tac

CAS Number: 54464-57-2

Date Report Requested: 03/30/2016 Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06 Lab: MBA

Females							
DOSE	vehicle	6.25%	12.5%	25%	50%		
Heart Cardiomyopathy							
LESION RATES							
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)		
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00		
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%		
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)		
FIRST INCIDENCE	92 (T)						
STATISTICAL TESTS							
POLY 3	(e)	(e)	(e)	(e)	(e)		
POLY 1.5	(e)	(e)	(e)	(e)	(e)		
POLY 6	(e)	(e)	(e)	(e)	(e)		
COCH-ARM / FISHERS	P=1.000N	(e)	(e)	(e)	(e)		
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)		

Test Type: 90-DAY

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION Species/Strain: RATS/F344/N Tac

CAS Number: 54464-57-2

Date Report Requested: 03/30/2016 Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

	Females							
DOSE	vehicle	6.25%	12.5%	25%	50%			
Kidney Inflammation Chronic								
LESION RATES								
OVERALL (a)	2/10 (20%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)			
POLY-3 RATE (b)	2/10.00	0/10.00	0/10.00	1/10.00	0/10.00			
POLY-3 PERCENT (g)	20%	0%	0%	10%	0%			
TERMINAL (d)	2/10 (20%)	0/10 (0%)	0/10 (0%)	1/10 (10%)	0/10 (0%)			
FIRST INCIDENCE	92 (T)			92 (T)				
STATISTICAL TESTS								
POLY 3	P=0.262N	P=0.227N	P=0.227N	P=0.500N	P=0.227N			
POLY 1.5	P=0.262N	P=0.227N	P=0.227N	P=0.500N	P=0.227N			
POLY 6	P=0.262N	P=0.227N	P=0.227N	P=0.500N	P=0.227N			
COCH-ARM / FISHERS	P=0.264N	P=0.237N	P=0.237N	P=0.500N	P=0.237N			
MAX-ISO-POLY-3	P=0.029N*	P=0.066N	P=0.066N	P=0.274N	P=0.066N			

Test Type: 90-DAY

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION Species/Strain: RATS/F344/N Tac **CAS Number:** 54464-57-2

Date Report Requested: 03/30/2016 Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

			Females			
DOSE	vehicle	6.25%	12.5%	25%	50%	
Kidney Mineralization						
LESION RATES						
OVERALL (a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	0/10 (0%)	
POLY-3 RATE (b)	1/10.00	0/10.00	0/10.00	2/10.00	0/10.00	
POLY-3 PERCENT (g)	10%	0%	0%	20%	0%	
TERMINAL (d)	1/10 (10%)	0/10 (0%)	0/10 (0%)	2/10 (20%)	0/10 (0%)	
FIRST INCIDENCE	92 (T)			92 (T)		
STATISTICAL TESTS						
POLY 3	P=0.584N	P=0.500N	P=0.500N	P=0.500	P=0.500N	
POLY 1.5	P=0.584N	P=0.500N	P=0.500N	P=0.500	P=0.500N	
POLY 6	P=0.584N	P=0.500N	P=0.500N	P=0.500	P=0.500N	
COCH-ARM / FISHERS	P=0.583N	P=0.500N	P=0.500N	P=0.500	P=0.500N	
MAX-ISO-POLY-3	P=0.172N	P=0.158N	P=0.158N	P=0.274	P=0.158N	

Test Type: 90-DAY

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION Species/Strain: RATS/F344/N Tac

CAS Number: 54464-57-2

Date Report Requested: 03/30/2016

Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

	Females							
DOSE	vehicle	6.25%	12.5%	25%	50%			
Kidney Nephropathy								
LESION RATES								
OVERALL (a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)			
POLY-3 RATE (b)	1/10.00	0/10.00	0/10.00	0/10.00	0/10.00			
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%			
TERMINAL (d)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)			
FIRST INCIDENCE	92 (T)							
STATISTICAL TESTS								
POLY 3	P=0.362N	P=0.500N	P=0.500N	P=0.500N	P=0.500N			
POLY 1.5	P=0.362N	P=0.500N	P=0.500N	P=0.500N	P=0.500N			
POLY 6	P=0.362N	P=0.500N	P=0.500N	P=0.500N	P=0.500N			
COCH-ARM / FISHERS	P=0.360N	P=0.500N	P=0.500N	P=0.500N	P=0.500N			
MAX-ISO-POLY-3	P=0.056N	P=0.158N	P=0.158N	P=0.158N	P=0.158N			

Test Type: 90-DAY

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION

Species/Strain: RATS/F344/N Tac

CAS Number: 54464-57-2

Date Report Requested: 03/30/2016 Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

	Females						
DOSE	vehicle	6.25%	12.5%	25%	50%		
Kidney: Pelvis Inflammation Chronic							
LESION RATES							
OVERALL (a)	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	1/10.00		
POLY-3 PERCENT (g)	0%	0%	0%	0%	10%		
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	1/10 (10%)		
FIRST INCIDENCE					92 (T)		
STATISTICAL TESTS							
POLY 3	P=0.144	(e)	(e)	(e)	P=0.500		
POLY 1.5	P=0.144	(e)	(e)	(e)	P=0.500		
POLY 6	P=0.144	(e)	(e)	(e)	P=0.500		
COCH-ARM / FISHERS	P=0.142	(e)	(e)	(e)	P=0.500		
MAX-ISO-POLY-3	P=0.056	(e)	(e)	(e)	P=0.158		

Test Type: 90-DAY

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION

Species/Strain: RATS/F344/N Tac

CAS Number: 54464-57-2

Date Report Requested: 03/30/2016 Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

	Females							
DOSE	vehicle	6.25%	12.5%	25%	50%			
Kidney: Renal Tubule Casts								
LESION RATES								
OVERALL (a)	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			
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%			
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)			
FIRST INCIDENCE								
STATISTICAL TESTS								
POLY 3	(n)	(n)	(n)	(n)	(n)			
POLY 1.5	(n)	(n)	(n)	(n)	(n)			
POLY 6	(n)	(n)	(n)	(n)	(n)			
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)			
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)			

Test Type: 90-DAY

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION

Species/Strain: RATS/F344/N Tac

CAS Number: 54464-57-2

Date Report Requested: 03/30/2016 Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

			Females			
DOSE	vehicle	6.25%	12.5%	25%	50%	
Liver Inflammation Chronic						
LESION RATES						
OVERALL (a)	5/10 (50%)	7/10 (70%)	9/10 (90%)	5/10 (50%)	5/10 (50%)	
POLY-3 RATE (b)	5/10.00	7/10.00	9/10.00	5/10.00	5/10.00	
POLY-3 PERCENT (g)	50%	70%	90%	50%	50%	
TERMINAL (d)	5/10 (50%)	7/10 (70%)	9/10 (90%)	5/10 (50%)	5/10 (50%)	
FIRST INCIDENCE	92 (T)					
STATISTICAL TESTS						
POLY 3	P=0.267N	P=0.329	P=0.061	P=0.664	P=0.664	
POLY 1.5	P=0.267N	P=0.329	P=0.061	P=0.664	P=0.664	
POLY 6	P=0.267N	P=0.329	P=0.061	P=0.664	P=0.664	
COCH-ARM / FISHERS	P=0.268N	P=0.325	P=0.070	P=0.672N	P=0.672N	
MAX-ISO-POLY-3	P=0.177N	P=0.188	P=0.020*	P=1.000	P=1.000	

Test Type: 90-DAY

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION

Species/Strain: RATS/F344/N Tac

CAS Number: 54464-57-2

Time Report Requested: 14:54:57

Date Report Requested: 03/30/2016

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

	Females							
DOSE	vehicle	6.25%	12.5%	25%	50%			
Lung Inflammation Chronic								
LESION RATES								
OVERALL (a)	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)			
POLY-3 RATE (b)	3/10.00	0/0.00	0/0.00	0/0.00	0/0.00			
POLY-3 PERCENT (g)	30%	0%	0%	0%	0%			
TERMINAL (d)	3/10 (30%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)			
FIRST INCIDENCE	92 (T)							
STATISTICAL TESTS								
POLY 3	(e)	(e)	(e)	(e)	(e)			
POLY 1.5	(e)	(e)	(e)	(e)	(e)			
POLY 6	(e)	(e)	(e)	(e)	(e)			
COCH-ARM / FISHERS	P=1.000N	(e)	(e)	(e)	(e)			
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)			

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION

Test Type: 90-DAY

Species/Strain: RATS/F344/N Tac

CAS Number: 54464-57-2

Date Report Requested: 03/30/2016 Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

	Females						
DOSE	vehicle	6.25%	12.5%	25%	50%		
Lung Mineralization							
LESION RATES							
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)		
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00		
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%		
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)		
FIRST INCIDENCE	92 (T)						
STATISTICAL TESTS							
POLY 3	(e)	(e)	(e)	(e)	(e)		
POLY 1.5	(e)	(e)	(e)	(e)	(e)		
POLY 6	(e)	(e)	(e)	(e)	(e)		
COCH-ARM / FISHERS	P=1.000N	(e)	(e)	(e)	(e)		
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)		

Test Type: 90-DAY

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION

Species/Strain: RATS/F344/N Tac

CAS Number: 54464-57-2

First Dose M/F: 12/12/06 / 12/13/06

Time Report Requested: 14:54:57

Date Report Requested: 03/30/2016

Lab: MBA

	Females							
DOSE	vehicle	6.25%	12.5%	25%	50%			
Lung: Interstitium								
Inflammation Focal								
LESION RATES								
OVERALL (a)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)			
POLY-3 RATE (b)	1/10.00	0/0.00	0/0.00	0/0.00	0/0.00			
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%			
TERMINAL (d)	1/10 (10%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)			
FIRST INCIDENCE	92 (T)							
STATISTICAL TESTS								
POLY 3	(e)	(e)	(e)	(e)	(e)			
POLY 1.5	(e)	(e)	(e)	(e)	(e)			
POLY 6	(e)	(e)	(e)	(e)	(e)			
COCH-ARM / FISHERS	P=1.000N	(e)	(e)	(e)	(e)			
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)			

Test Type: 90-DAY

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

CAS Number: 54464-57-2 **Route: SKIN APPLICATION**

Species/Strain: RATS/F344/N Tac

Date Report Requested: 03/30/2016

First Dose M/F: 12/12/06 / 12/13/06

Time Report Requested: 14:54:57

Lab: MBA

	Females							
DOSE	vehicle	6.25%	12.5%	25%	50%			
Lymph Node, Mesenteric Infiltration Cellular Histiocyt	e							
LESION RATES								
OVERALL (a)	6/10 (60%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)			
POLY-3 RATE (b)	6/10.00	0/0.00	0/0.00	0/0.00	0/0.00			
POLY-3 PERCENT (g)	60%	0%	0%	0%	0%			
TERMINAL (d)	6/10 (60%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)			
FIRST INCIDENCE	92 (T)							
STATISTICAL TESTS								
POLY 3	(e)	(e)	(e)	(e)	(e)			
POLY 1.5	(e)	(e)	(e)	(e)	(e)			
POLY 6	(e)	(e)	(e)	(e)	(e)			
COCH-ARM / FISHERS	P=1.000N	(e)	(e)	(e)	(e)			
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)			

Test Type: 90-DAY

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION CAS Number: 54464-57-2

Species/Strain: RATS/F344/N Tac

Date Report Requested: 03/30/2016 Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

	Females							
DOSE	vehicle	6.25%	12.5%	25%	50%			
Lymph Node: Iliac Hyperplasia Diffuse								
LESION RATES								
OVERALL (a)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)			
POLY-3 RATE (b)	1/1.00	0/0.00	0/0.00	0/0.00	0/0.00			
POLY-3 PERCENT (g)	100%	0%	0%	0%	0%			
TERMINAL (d)	1/1 (100%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)			
FIRST INCIDENCE	92 (T)							
STATISTICAL TESTS								
POLY 3	(e)	(e)	(e)	(e)	(e)			
POLY 1.5	(e)	(e)	(e)	(e)	(e)			
POLY 6	(e)	(e)	(e)	(e)	(e)			
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)	(e)			
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)	(e)			

Test Type: 90-DAY

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION

Species/Strain: RATS/F344/N Tac

CAS Number: 54464-57-2

Date Report Requested: 03/30/2016 Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

			Females			
DOSE	vehicle	6.25%	12.5%	25%	50%	
Pancreas: Acinus						
Atrophy						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	
POLY-3 RATE (b)	0/10.00	0/0.00	0/0.00	0/0.00	0/0.00	
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%	
TERMINAL (d)	0/10 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	
FIRST INCIDENCE						
STATISTICAL TESTS						
POLY 3	(n)	(n)	(n)	(n)	(n)	
POLY 1.5	(n)	(n)	(n)	(n)	(n)	
POLY 6	(n)	(n)	(n)	(n)	(n)	
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)	
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)	

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION

Test Type: 90-DAY

Species/Strain: RATS/F344/N Tac

CAS Number: 54464-57-2

Date Report Requested: 03/30/2016

Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

	Females							
DOSE	vehicle	6.25%	12.5%	25%	50%			
Skin Hyperplasia								
LESION RATES								
OVERALL (a)	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			
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%			
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)			
FIRST INCIDENCE								
STATISTICAL TESTS								
POLY 3	(n)	(n)	(n)	(n)	(n)			
POLY 1.5	(n)	(n)	(n)	(n)	(n)			
POLY 6	(n)	(n)	(n)	(n)	(n)			
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)			
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)			

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION

Test Type: 90-DAY

Species/Strain: RATS/F344/N Tac

CAS Number: 54464-57-2

Date Report Requested: 03/30/2016

Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

	Females							
DOSE	vehicle	6.25%	12.5%	25%	50%			
Skin								
Inflammation								
LESION RATES								
OVERALL (a)	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			
POLY-3 PERCENT (g)	0%	0%	0%	0%	0%			
TERMINAL (d)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)			
FIRST INCIDENCE								
STATISTICAL TESTS								
POLY 3	(n)	(n)	(n)	(n)	(n)			
POLY 1.5	(n)	(n)	(n)	(n)	(n)			
POLY 6	(n)	(n)	(n)	(n)	(n)			
COCH-ARM / FISHERS	(n)	(n)	(n)	(n)	(n)			
MAX-ISO-POLY-3	(n)	(n)	(n)	(n)	(n)			

Species/Strain: RATS/F344/N Tac

Route: SKIN APPLICATION

Test Type: 90-DAY

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

CAS Number: 54464-57-2

Date Report Requested: 03/30/2016 Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

			Females			
DOSE	vehicle	6.25%	12.5%	25%	50%	
Skin, Site of Application Hyperkeratosis						
LESION RATES						
OVERALL (a)	0/10 (0%)	0/10 (0%)	4/10 (40%)	5/10 (50%)	7/10 (70%)	
POLY-3 RATE (b)	0/10.00	0/10.00	4/10.00	5/10.00	7/10.00	
POLY-3 PERCENT (g)	0%	0%	40%	50%	70%	
TERMINAL (d)	0/10 (0%)	0/10 (0%)	4/10 (40%)	5/10 (50%)	7/10 (70%)	
FIRST INCIDENCE			92 (T)	92 (T)	92 (T)	
STATISTICAL TESTS						
POLY 3	P<0.001**	(e)	P=0.033*	P=0.008**	P<0.001**	
POLY 1.5	P<0.001**	(e)	P=0.033*	P=0.008**	P<0.001**	
POLY 6	P<0.001**	(e)	P=0.033*	P=0.008**	P<0.001**	
COCH-ARM / FISHERS	P<0.001**	(e)	P=0.043*	P=0.016*	P=0.002**	
MAX-ISO-POLY-3	P<0.001**	(e)	P=0.007**	P<0.001**	P<0.001**	

Test Type: 90-DAY

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E Super®; OTNE)

Route: SKIN APPLICATION Species/Strain: RATS/F344/N Tac **CAS Number:** 54464-57-2

Date Report Requested: 03/30/2016

Time Report Requested: 14:54:57

First Dose M/F: 12/12/06 / 12/13/06

Lab: MBA

Females							
DOSE	vehicle	6.25%	12.5%	25%	50%		
Skin, Site of Application Hyperplasia							
LESION RATES							
OVERALL (a)	0/10 (0%)	1/10 (10%)	5/10 (50%)	7/10 (70%)	7/10 (70%)		
POLY-3 RATE (b)	0/10.00	1/10.00	5/10.00	7/10.00	7/10.00		
POLY-3 PERCENT (g)	0%	10%	50%	70%	70%		
TERMINAL (d)	0/10 (0%)	1/10 (10%)	5/10 (50%)	7/10 (70%)	7/10 (70%)		
FIRST INCIDENCE		92 (T)	92 (T)	92 (T)	92 (T)		
STATISTICAL TESTS							
POLY 3	P<0.001**	P=0.500	P=0.008**	P<0.001**	P<0.001**		
POLY 1.5	P<0.001**	P=0.500	P=0.008**	P<0.001**	P<0.001**		
POLY 6	P<0.001**	P=0.500	P=0.008**	P<0.001**	P<0.001**		
COCH-ARM / FISHERS	P<0.001**	P=0.500	P=0.016*	P=0.002**	P=0.002**		
MAX-ISO-POLY-3	P<0.001**	P=0.158	P<0.001**	P<0.001**	P<0.001**		

Experiment Number: 20307 - 03 P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Ethanone, 1-(1,2,3,4,5,6,7,8-Octahydro-2,3,8,8-Tetramethyl-2-Naphthalenyl)- (Iso-E

Date Report Requested: 03/30/2016

Time Report Requested: 14:54:57

Super®; OTNE)

Route: SKIN APPLICATION **CAS Number:** 54464-57-2 **First Dose M/F:** 12/12/06 / 12/13/06

Species/Strain: RATS/F344/N Tac Lab: MBA

LEGEND

Test Type: 90-DAY

/ -	\	Number of tumor-	I	. 1 - / 1 6	' ' 	
12	1	NIIIMAAT AT TIIMAT-	.naarina anima	aic/niimnar at	· animaic avam	NINAM ST CITA
(a	1	HULLIDEL OF FULLOF	vealliu allilli	มอ/เเนเเมษา บเ	ariiriais exair	iii icu ai siic.

- (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.
- (n) No statistics are calculated if all dose groups have fewer than two tumors.
- (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<=0.05).</p>
- ** To the right of any statistical result, indicates significance at (P<=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 ***