P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/16/2014 AVERAGE SEVERITY GRADES[b]

**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)

Species/Strain: Mouse/CD-1 CRL

Route: DERMAL, SOLUTION | SKIN APPLICATION

First Dose M/F: NA / NA **CAS Number: INIT/PROM** 

Time Report Requested: 17:47:31

Lab: BAT

C Number: C61994B

Lock Date: 04/07/1992

**Cage Range:** ΑII

**Date Range:** ΑII

**Reasons For Removal:** ΑII

**Removal Date Range:** ΑII

**Treatment Groups:** ΑII

**Study Gender:** Both

**PWG Approval Date** 04/27/1994

Species/Strain: Mouse/CD-1 CRL

Route: DERMAL, SOLUTION | SKIN APPLICATION

## P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/16/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 17:47:31

**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)

CAS Number: INIT/PROM

Time Report Requested: 17:47:31

First Dose M/F: NA / NA

CD-1 CRL Mouse MALE	VEHICLE CONTROL	DMBA0.25/ACETON E	DMBA 2.5/ACETONE	DMBA 25/ACETONE	DMBA2.5/COMPLET	TPA 5/ COMPLETE
Disposition Summary						
Animals Initially In Study	30	30	30	30	30	30
Early Deaths						
Moribund Sacrifice	1	2	1	1	7	9
Natural Death	2	3		1	4	
Survivors						
Terminal Sacrifice	27	25	29	28	19	21
Animals Examined Microscopically	30	30	30	30	30	30
ALIMENTARY SYSTEM None						
CARDIOVASCULAR SYSTEM None						
ENDOCRINE SYSTEM None						
GENERAL BODY SYSTEM None						
GENITAL SYSTEM None						
HEMATOPOIETIC SYSTEM None						
INTEGUMENTARY SYSTEM						
Skin	(25)	(22)	(25)	(23)	(5)	(10)
Acanthosis	2 [3.0]	4 [3.0]	2 [3.0]	3 [2.7]	2 [2.0]	10 [2.7]
Alopecia					1	1
Cyst Epithelial Inclusion						

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: Mouse/CD-1 CRL

Route: DERMAL, SOLUTION | SKIN APPLICATION

## P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/16/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 17:47:32

**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)

CAS Number: INIT/PROM

Time Report Requested: 17:47:32

First Dose M/F: NA / NA

Lab: BAT

CD-1 CRL Mouse MALE	VEHICLE CONTROL	DMBA0.25/ACETON E	DMBA 2.5/ACETONE	DMBA 25/ACETONE	DMBA2.5/COMPLET E	TPA 5/ COMPLETE
Hair Follicle, Cyst						
Inflammation, Chronic Active	2 [4.0]	4 [4.0]	2 [4.0]	3 [4.0]	5 [4.0]	10 [4.0]
Ulcer	1 [4.0]	1 [4.0]		2 [4.0]	5 [4.0]	1 [4.0]
Ulcer, Multiple	1 [4.0]	3 [4.0]	2 [4.0]			9 [4.0]
Skin, Control	(2)	(1)	(1)	(1)	(9)	(23)
Acanthosis	1 [1.0]		1 [1.0]	1 [2.0]	7 [1.1]	19 [1.8]
Inflammation, Chronic Active	1 [1.0]	1 [3.0]		1 [1.0]	7 [1.1]	22 [1.5]
Ulcer						
Skin, SOA-Mass	(0)	(1)	(0)	(1)	(24)	(3)
Acanthosis					1 [3.0]	
Skin, SOA-No Mass	(4)	(8)	(5)	(7)	(28)	(30)
Acanthosis	4 [2.0]	8 [2.5]	4 [2.0]	5 [1.8]	26 [2.4]	31 [2.7]
Alopecia						
Hair Follicle, Cyst						
Inflammation, Chronic Active	4 [2.5]	7 [2.4]	5 [2.2]	5 [1.2]	25 [2.4]	30 [2.9]
Ulcer	1 [4.0]				9 [4.0]	7 [4.0]
Ulcer, Multiple	1 [4.0]	2 [4.0]			1 [4.0]	7 [4.0]
MUSCULOSKELETAL SYSTEM None						
NERVOUS SYSTEM None						
RESPIRATORY SYSTEM None						
SPECIAL SENSES SYSTEM						

None

**URINARY SYSTEM** 

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH

AVERAGE SEVERITY GRADES[b]

Date Report Requested: 10/16/2014

Route: DERMAL, SOLUTION | SKIN APPLICATION

Time Report Requested: 17:47:32
First Dose M/F: NA / NA

**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)

Lab: BAT

Species/Strain: Mouse/CD-1 CRL

CAS Number: INIT/PROM

**CD-1 CRL Mouse MALE** 

VEHICLE CONTROL DMBA0.25/ACETON DMBA 2.5/ACETONE DMBA 25/ACETONE DMBA2.5/COMPLET TPA 5/ COMPLETE E

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: Mouse/CD-1 CRL

Route: DERMAL, SOLUTION | SKIN APPLICATION

## P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/16/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 17:47:32

**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)

CAS Number: INIT/PROM

Time Report Requested: 17:47:32

First Dose M/F: NA / NA

CD-1 CRL Mouse MALE	BPO 20/ COMPLETE	DMBA0.25/ TPA 5	DMBA 2.5/ TPA 5	DMBA 25/ TPA 5	DMBA 2.5/ BPO 20	DMBA 25/ BPO 20
Disposition Summary						
Animals Initially In Study	30	30	30	30	30	30
Early Deaths			_	40		
Moribund Sacrifice	2	6	8	13	2	6
Natural Death	3	4	7	2	1	
Survivors Terminal Sacrifice	25	20	15	15	27	24
Animals Examined Microscopically	25 30	20 30	30	30	27 30	30
Animais Examined Microscopically	30	30	30	30	30	30
LIMENTARY SYSTEM  None						
ARDIOVASCULAR SYSTEM None						
NDOCRINE SYSTEM None						
SENERAL BODY SYSTEM  None						
GENITAL SYSTEM None						
IEMATOPOIETIC SYSTEM None						
NTEGUMENTARY SYSTEM						
Skin	(5)	(9)	(9)	(10)	(5)	(9)
Acanthosis						7 [3.1]
Alopecia		1		1		
-		1		1		
Hair Follicle, Cyst						1
Alopecia Cyst Epithelial Inclusion	3 [3.0]	8 [2.6] 1 1	8 [2.8]	•	3 [3.3]	

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: Mouse/CD-1 CRL

Route: DERMAL, SOLUTION | SKIN APPLICATION

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/16/2014 Time Report Requested: 17:47:32

**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)

CAS Number: INIT/PROM

Time Report Requested: 17:47:32

First Dose M/F: NA / NA

Lab: BAT

CD-1 CRL Mouse MALE	<b>BPO 20/ COMPLETE</b>	DMBA0.25/ TPA 5	DMBA 2.5/ TPA 5	DMBA 25/ TPA 5	DMBA 2.5/ BPO 20	DMBA 25/ BPO 20
Inflammation, Chronic Active	3 [4.0]	8 [4.0]	8 [3.8]	10 [4.0]	3 [3.7]	7 [4.0]
Ulcer	1 [4.0]	4 [4.0]	5 [4.0]	2 [4.0]		2 [4.0]
Ulcer, Multiple	2 [4.0]	3 [4.0]	2 [4.0]	8 [4.0]	2 [4.0]	5 [4.0]
Skin, Control	(11)	(14)	(10)	(19)	(10)	(12)
Acanthosis	9 [1.2]	13 [1.8]	9 [1.6]	18 [1.7]	7 [1.1]	9 [1.0]
Inflammation, Chronic Active	11 [1.4]	12 [1.6]	8 [1.5]	19 [1.5]	7 [1.0]	8 [1.0]
Ulcer	1 [4.0]			1 [4.0]		
Skin, SOA-Mass Acanthosis	(1)	(16)	(21)	(22) 1 [3.0]	(3)	(9)
Skin, SOA-No Mass	(28)	(30)	(30)	(30)	(26)	(29)
Acanthosis	27 [1.9]	30 [2.5]	30 [2.8]	30 [2.8]	25 [1.8]	29 [1.9]
Alopecia				1		
Hair Follicle, Cyst				1	1	
Inflammation, Chronic Active	28 [2.1]	30 [2.6]	29 [3.2]	30 [2.9]	24 [1.9]	28 [1.9]
Ulcer	6 [4.0]	5 [4.0]	11 [4.0]	7 [4.0]	5 [4.0]	2 [4.0]
Ulcer, Multiple	4 [4.0]	10 [4.0]	8 [4.0]	8 [4.0]	2 [4.0]	5 [4.0]
MUSCULOSKELETAL SYSTEM None						
NERVOUS SYSTEM None						
RESPIRATORY SYSTEM None						
SPECIAL SENSES SYSTEM None						
URINARY SYSTEM						

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

**Experiment Number:** 05117-02

Test Type: INIT/PROMOT

Route: DERMAL, SOLUTION | SKIN APPLICATION

Species/Strain: Mouse/CD-1 CRL

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/16/2014 AVERAGE SEVERITY GRADES[b]

**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)

CAS Number: INIT/PROM

Time Report Requested: 17:47:32

First Dose M/F: NA / NA

Lab: BAT

\*\*\*END OF MALE DATA\*\*\*

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

## P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/16/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 17:47:32

**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)

Species/Strain: Mouse/CD-1 CRL

Route: DERMAL, SOLUTION | SKIN APPLICATION

CAS Number: INIT/PROM

Time Report Requested: 17:47:32

First Dose M/F: NA / NA

Lab: BAT

CD-1 CRL Mouse FEMALE	VEHICLE CONTROL	DMBA0.25/ACETON E	DMBA 2.5/ACETONE	DMBA 25/ACETONE	DMBA2.5/COMPLET E	TPA 5/ COMPLETE
Disposition Summary						
Animals Initially In Study	30	30	30	30	30	30
Early Deaths						
Drowned						1
Moribund Sacrifice	1				7	4
Natural Death	1	1	1	1	3	1
Survivors						
Accidentally Killed				1		
Moribund Sacrifice	1					
Natural Death						1
Terminal Sacrifice	27	29	29	28	20	23
Animals Examined Microscopically	30	30	30	30	30	30
ALIMENTARY SYSTEM						
None						
CARDIOVASCULAR SYSTEM						
None						
ENDOCRINE SYSTEM						
None						
GENERAL BODY SYSTEM						
None						
				,		
GENITAL SYSTEM						
None						
HEMATOPOIETIC SYSTEM						
None						

a - Number of animals examined microscopically at site and number of animals with lesion

**INTEGUMENTARY SYSTEM** 

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: Mouse/CD-1 CRL

Route: DERMAL, SOLUTION | SKIN APPLICATION

## P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/16/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 17:47:32

**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)

CAS Number: INIT/PROM

Time Report Requested: 17:47:32

First Dose M/F: NA / NA

Lab: BAT

CD-1 CRL Mouse FEMALE	VEHICLE CONTROL	DMBA0.25/ACETON E	DMBA 2.5/ACETONE	DMBA 25/ACETONE	DMBA2.5/COMPLET E	TPA 5/ COMPLETE
Skin	(22)	(25)	(19)	(24)	(0)	(8)
Acanthosis	2 [3.0]		1 [3.0]			7 [2.6]
Alopecia						
Hair Follicle, Cyst			1			
Inflammation, Chronic Active	2 [4.0]		1 [4.0]			7 [4.0]
Metaplasia, Osseous	1 [3.0]					
Ulcer	2 [4.0]					2 [4.0]
Ulcer, Multiple			1 [4.0]			6 [4.0]
Skin, Control	(3)	(3)	(6)	(1)	(15)	(26)
Acanthosis					7 [1.1]	21 [1.7]
Inflammation, Chronic Active	3 [1.0]	3 [1.0]	6 [1.0]	1 [1.0]	14 [1.1]	27 [1.7]
Ulcer						
Skin, SOA-Mass	(0)	(0)	(0)	(0)	(25)	(7)
Acanthosis					1 [4.0]	1 [2.0]
Skin, SOA-No Mass	(9)	(5)	(10)	(5)	(28)	(30)
Acanthosis	5 [1.6]	1 [2.0]	3 [1.7]		25 [2.1]	31 [2.5]
Hair Follicle, Cyst						
Inflammation, Chronic Active	9 [1.4]	5 [1.2]	10 [1.0]	5 [1.2]	27 [2.3]	29 [2.6]
Ulcer	1 [4.0]				5 [4.0]	4 [4.0]
Ulcer, Multiple	1 [4.0]				2 [4.0]	5 [4.0]
IUSCULOSKELETAL SYSTEM						
None						
ERVOUS SYSTEM						
None						

SPECIAL SENSES SYSTEM

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: Mouse/CD-1 CRL

Route: DERMAL, SOLUTION | SKIN APPLICATION

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]

Date Report Requested: 10/16/2014
Time Report Requested: 17:47:32

**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)

CAS Number: INIT/PROM

Time Report Requested: 17:47:32

First Dose M/F: NA / NA

	CD-1 CRL Mouse FEMALE	VEHICLE CONTROL	DMBA0.25/ACETON E	DMBA 2.5/ACETONE	DMBA 25/ACETONE	DMBA2.5/COMPLET E	TPA 5/ COMPLETE
None							
URINARY	YSYSTEM						
None				,			

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: Mouse/CD-1 CRL

Route: DERMAL, SOLUTION | SKIN APPLICATION

## P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/16/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 17:47:32

**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)

CAS Number: INIT/PROM

Time Report Requested: 17:47:32

First Dose M/F: NA / NA

CD-1 CRL Mouse FEMALE	BPO 20/ COMPLETE	DMBA0.25/ TPA 5	DMBA 2.5/ TPA 5	DMBA 25/ TPA 5	DMBA 2.5/ BPO 20	DMBA 25/ BPO 20
Disposition Summary						
Animals Initially In Study	30	30	30	30	30	30
Early Deaths						
Drowned						
Moribund Sacrifice		6	7	10	1	
Natural Death		2	3	4	1	
Survivors						
Accidentally Killed						
Moribund Sacrifice			_			
Natural Death			1	4.0		
Terminal Sacrifice	30	22	19	16	28	30
Animals Examined Microscopically	30	30	30	30	30	30
ALIMENTARY SYSTEM						
None						
CARDIOVASCULAR SYSTEM						
None						
ENDOCRINE SYSTEM						
None						
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
None		,	,	,	,	
HEMATOPOIETIC SYSTEM						
None						
					·	
INTEGUMENTARY SYSTEM Skin	(1)	<i>(</i> 5)	(4)	(4)	(1)	(1)
SKIII	(1)	(5)	(4)	(4)	(1)	(1)

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

Species/Strain: Mouse/CD-1 CRL

Route: DERMAL, SOLUTION | SKIN APPLICATION

### P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/16/2014 Time Report Requested: 17:47:32

**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)

CAS Number: INIT/PROM

Time Report Requested: 17:47:32

First Dose M/F: NA / NA

Lab: BAT

CD-1 CRL Mouse FEMALE	BPO 20/ COMPLETE	DMBA0.25/ TPA 5	DMBA 2.5/ TPA 5	DMBA 25/ TPA 5	DMBA 2.5/ BPO 20	DMBA 25/ BPO 20
Acanthosis	1 [3.0]	4 [3.0]	4 [3.0]	4 [2.3]	1 [3.0]	
Alopecia		1		1		
Hair Follicle, Cyst						
Inflammation, Chronic Active	1 [4.0]	5 [3.8]	4 [3.8]	4 [3.3]	1 [4.0]	
Metaplasia, Osseous						
Ulcer	1 [4.0]	2 [4.0]	1 [4.0]	2 [4.0]		
Ulcer, Multiple			2 [4.0]		1 [4.0]	
Skin, Control	(30)	(22)	(25)	(19)	(19)	(20)
Acanthosis	20 [1.2]	19 [1.9]	21 [2.0]	16 [1.8]	11 [1.0]	19 [1.0]
Inflammation, Chronic Active	30 [1.3]	21 [1.5]	25 [1.9]	19 [1.5]	18 [1.1]	19 [1.0]
Ulcer			1 [4.0]			
Skin, SOA-Mass	(0)	(18)	(20)	(28)	(5)	(6)
Acanthosis				1 [2.0]		
Skin, SOA-No Mass	(30)	(29)	(30)	(30)	(30)	(28)
Acanthosis	30 [1.4]	29 [2.5]	30 [2.7]	30 [2.8]	30 [1.6]	28 [1.4]
Hair Follicle, Cyst				1		
Inflammation, Chronic Active	30 [1.8]	29 [2.3]	30 [2.8]	30 [3.1]	30 [1.6]	28 [1.4]
Ulcer			3 [4.0]	4 [4.0]	1 [4.0]	
Ulcer, Multiple	1 [4.0]	5 [4.0]	5 [4.0]	11 [4.0]	2 [4.0]	

MUSCULOSKELETAL SYSTEM

None

**NERVOUS SYSTEM** 

None

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

**Experiment Number:** 05117-02

Test Type: INIT/PROMOT

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/16/2014 AVERAGE SEVERITY GRADES[b]

**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG) **CAS Number: INIT/PROM** 

First Dose M/F: NA / NA

Time Report Requested: 17:47:32

Lab: BAT

Species/Strain: Mouse/CD-1 CRL

**CD-1 CRL Mouse FEMALE** 

Route: DERMAL, SOLUTION | SKIN APPLICATION

BPO 20/ COMPLETE DMBA0.25/ TPA 5

**DMBA 2.5/ TPA 5** 

**DMBA 25/ TPA 5** 

DMBA 2.5/ BPO 20

DMBA 25/ BPO 20

**URINARY SYSTEM** 

None

\*\* END OF REPORT \*\*

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)