Test Type: INIT/PROMOT

Route: DERMAL, SOLUTION | SKIN APPLICATION

Species/Strain: Mouse/CD-1 CRL

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

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

CAS Number: INIT/PROM

Date Report Requested: 10/16/2014 Time Report Requested: 17:49:13

First Dose M/F: NA / NA

Lab: BAT

C Number: C61994B

**Lock Date:** 04/07/1992

Cage Range: All

Date Range: All

Reasons For Removal:

Removal Date Range:

Treatment Groups: All

Study Gender: Both

PWG Approval Date 04/27/1994

### P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

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

Route: DERMAL, SOLUTION | SKIN APPLICATION

Species/Strain: Mouse/CD-1 CRL

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

Lab: BAT

Date Report Requested: 10/16/2014

Time Report Requested: 17:49:13

CD-1 CRL Mouse MALE	VEHICLE CONTROL	DMBA0.25/ACETON E	DMBA 2.5/ACETONE	DMBA 25/ACETONE	DMBA2.5/COMPLET	TPA 5/ COMPLE
Disposition Summary						
Animals Initially In Study Early Deaths	30	30	30	30	30	30
Moribund Sacrifice Natural Death	1 2	2 3	1	1 1	7 4	9
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 Acanthosis Alopecia Cyst Epithelial Inclusion Hair Follicle, Cyst	(25) 2 (8%)	(22) 4 (18%)	(25) 2 (8%)	(23) 3 (13%)	(5) 2 (40%) 1 (20%)	(10) 10 (100%) 1 (10%)

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

Species/Strain: Mouse/CD-1 CRL

Route: DERMAL, SOLUTION | SKIN APPLICATION

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

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

CAS Number: INIT/PROM

Date Report Requested: 10/16/2014 Time Report Requested: 17:49:13

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 E	TPA 5/ COMPLETI
Inflammation, Chronic Active	2 (8%)	4 (18%)	2 (8%)	3 (13%)	5 (100%)	10 (100%)
Ulcer	1 (4%)	1 (5%)		2 (9%)	5 (100%)	1 (10%)
Ulcer, Multiple	1 (4%)	3 (14%)	2 (8%)			9 (90%)
Skin, Control	(2)	(1)	(1)	(1)	(9)	(23)
Acanthosis	1 (50%)		1 (100%)	1 (100%)	7 (78%)	19 (83%)
Inflammation, Chronic Active	1 (50%)	1 (100%)		1 (100%)	7 (78%)	22 (96%)
Ulcer						
Skin, SOA-Mass Acanthosis	(0)	(1)	(0)	(1)	(24) 1 (4%)	(3)
Skin, SOA-No Mass	(4)	(8)	(5)	(7)	(28)	(30)
Acanthosis Alopecia	4 (100%)	8 (100%)	4 (80%)	5 (71%)	26 (93%)	31 (103%)
Hair Follicle, Cyst		_ ()			/	
Inflammation, Chronic Active	4 (100%)	7 (88%)	5 (100%)	5 (71%)	25 (89%)	30 (100%)
Ulcer	1 (25%)	- (()			9 (32%)	7 (23%)
Ulcer, Multiple	1 (25%)	2 (25%)			1 (4%)	7 (23%)
MUSCULOSKELETAL SYSTEM None						
NERVOUS SYSTEM None						
RESPIRATORY SYSTEM None						
SPECIAL SENSES SYSTEM None						
URINARY SYSTEM						
None						

Test Type: INIT/PROMOT

## P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

Route: DERMAL, SOLUTION | SKIN APPLICATION

Species/Strain: Mouse/CD-1 CRL

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

CAS Number: INIT/PROM

Date Report Requested: 10/16/2014 Time Report Requested: 17:49:13

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 2
Disposition Summary						
Animals Initially In Study	30	30	30	30	30	30
Early Deaths						
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	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	(5)	(9)	(9)	(10)	(5)	(9)
Acanthosis	3 (60%)	8 (89%)	8 (89%)	10 (100%)	3 (60%)	7 (78%)
Alopecia	` ,	1 (11%)	` ,	1 (10%)	, ,	, ,
Cyst Epithelial Inclusion		1 (11%)		1 (10%)		
Hair Follicle, Cyst						1 (11%)

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

Route: DERMAL, SOLUTION | SKIN APPLICATION

Species/Strain: Mouse/CD-1 CRL

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

CAS Number: INIT/PROM

Date Report Requested: 10/16/2014 Time Report Requested: 17:49:13

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 (60%)	8 (89%)	8 (89%)	10 (100%)	3 (60%)	7 (78%)
Ulcer	1 (20%)	4 (44%)	5 (56%)	2 (20%)		2 (22%)
Ulcer, Multiple	2 (40%)	3 (33%)	2 (22%)	8 (80%)	2 (40%)	5 (56%)
Skin, Control	(11)	(14)	(10)	(19)	(10)	(12)
Acanthosis	9 (82%)	13 (93%)	9 (90%)	18 (95%)	7 (70%)	9 (75%)
Inflammation, Chronic Active	11 (100%)	12 (86%)	8 (80%)	19 (100%)	7 (70%)	8 (67%)
Ulcer	1 (9%)			1 (5%)		
Skin, SOA-Mass	(1)	(16)	(21)	(22)	(3)	(9)
Acanthosis				1 (5%)		
Skin, SOA-No Mass	(28)	(30)	(30)	(30)	(26)	(29)
Acanthosis	27 (96%)	30 (100%)	30 (100%)	30 (100%)	25 (96%)	29 (100%)
Alopecia				1 (3%)		
Hair Follicle, Cyst				1 (3%)	1 (4%)	
Inflammation, Chronic Active	28 (100%)	30 (100%)	29 (97%)	30 (100%)	24 (92%)	28 (97%)
Ulcer	6 (21%)	5 (17%)	11 (37%)	7 (23%)	5 (19%)	2 (7%)
Ulcer, Multiple	4 (14%)	10 (33%)	8 (27%)	8 (27%)	2 (8%)	5 (17%)
MUSCULOSKELETAL SYSTEM						
None				,	···	
NERVOUS SYSTEM						
None						
RESPIRATORY SYSTEM						
None						
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
None						

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

Species/Strain: Mouse/CD-1 CRL

Route: DERMAL, SOLUTION | SKIN APPLICATION

Test Type: INIT/PROMOT

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

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

CAS Number: INIT/PROM

Date Report Requested: 10/16/2014
Time Report Requested: 17:49:13

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
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						
INTEGUMENTARY SYSTEM Skin	(22)	(25)	(19)	(24)	(0)	(8)

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

Species/Strain: Mouse/CD-1 CRL

RESPIRATORY SYSTEM

SPECIAL SENSES SYSTEM

None

None

Route: DERMAL, SOLUTION | SKIN APPLICATION

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

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

CAS Number: INIT/PROM

Date Report Requested: 10/16/2014
Time Report Requested: 17:49:13

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
Acanthosis	2 (9%)		1 (5%)			7 (88%)
Alopecia						
Hair Follicle, Cyst			1 (5%)			
Inflammation, Chronic Active	2 (9%)		1 (5%)			7 (88%)
Metaplasia, Osseous	1 (5%)					
Ulcer	2 (9%)					2 (25%)
Ulcer, Multiple			1 (5%)			6 (75%)
Skin, Control	(3)	(3)	(6)	(1)	(15)	(26)
Acanthosis					7 (47%)	21 (81%)
Inflammation, Chronic Active	3 (100%)	3 (100%)	6 (100%)	1 (100%)	14 (93%)	27 (104%)
Ulcer						
Skin, SOA-Mass	(0)	(0)	(0)	(0)	(25)	(7)
Acanthosis					1 (4%)	1 (14%)
Skin, SOA-No Mass	(9)	(5)	(10)	(5)	(28)	(30)
Acanthosis	5 (56%)	1 (20%)	3 (30%)		25 (89%)	31 (103%)
Hair Follicle, Cyst						
Inflammation, Chronic Active	9 (100%)	5 (100%)	10 (100%)	5 (100%)	27 (96%)	29 (97%)
Ulcer	1 (11%)				5 (18%)	4 (13%)
Ulcer, Multiple	1 (11%)				2 (7%)	5 (17%)
IUSCULOSKELETAL SYSTEM						
None						
IERVOUS SYSTEM						
None						

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

Species/Strain: Mouse/CD-1 CRL

Test Type: INIT/PROMOT

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

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

CAS Number: INIT/PROM

Date Report Requested: 10/16/2014 Time Report Requested: 17:49:13

First Dose M/F: NA / NA

Lab: BAT

**CD-1 CRL Mouse FEMALE** 

Route: DERMAL, SOLUTION | SKIN APPLICATION

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

**URINARY SYSTEM** 

None

Species/Strain: Mouse/CD-1 CRL

Route: DERMAL, SOLUTION | SKIN APPLICATION

Test Type: INIT/PROMOT

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

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

CAS Number: INIT/PROM

Date Report Requested: 10/16/2014
Time Report Requested: 17:49:13

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 Early Deaths	30	30	30	30	30	30
Drowned Moribund Sacrifice Natural Death		6 2	7 3	10 4	1 1	
Survivors Accidentally Killed Moribund Sacrifice						
Natural Death Terminal Sacrifice Animals Examined Microscopically	30 30	22 30	1 19 30	16 30	28 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)	(5)	(4)	(4)	(1)	(1)

Species/Strain: Mouse/CD-1 CRL

Route: DERMAL, SOLUTION | SKIN APPLICATION

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

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

CAS Number: INIT/PROM

Date Report Requested: 10/16/2014
Time Report Requested: 17:49:13

First Dose M/F: NA / NA

Lab: BAT

CD-1 CRL Mouse FEMALE	<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
Acanthosis	1 (100%)	4 (80%)	4 (100%)	4 (100%)	1 (100%)	
Alopecia		1 (20%)		1 (25%)		
Hair Follicle, Cyst						
Inflammation, Chronic Active	1 (100%)	5 (100%)	4 (100%)	4 (100%)	1 (100%)	
Metaplasia, Osseous						
Ulcer	1 (100%)	2 (40%)	1 (25%)	2 (50%)		
Ulcer, Multiple			2 (50%)		1 (100%)	
Skin, Control	(30)	(22)	(25)	(19)	(19)	(20)
Acanthosis	20 (67%)	19 (86%)	21 (84%)	16 (84%)	11 (58%)	19 (95%)
Inflammation, Chronic Active	30 (100%)	21 (95%)	25 (100%)	19 (100%)	18 (95%)	19 (95%)
Ulcer			1 (4%)			
Skin, SOA-Mass	(0)	(18)	(20)	(28)	(5)	(6)
Acanthosis				1 (4%)		
Skin, SOA-No Mass	(30)	(29)	(30)	(30)	(30)	(28)
Acanthosis	30 (100%)	29 (100%)	30 (100%)	30 (100%)	30 (100%)	28 (100%)
Hair Follicle, Cyst				1 (3%)		
Inflammation, Chronic Active	30 (100%)	29 (100%)	30 (100%)	30 (100%)	30 (100%)	28 (100%)
Ulcer			3 (10%)	4 (13%)	1 (3%)	
Ulcer, Multiple	1 (3%)	5 (17%)	5 (17%)	11 (37%)	2 (7%)	
MUSCULOSKELETAL SYSTEM						
None						
NERVOUS SYSTEM						
None						

**URINARY SYSTEM** 

None

None

RESPIRATORY SYSTEM

SPECIAL SENSES SYSTEM

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

Species/Strain: Mouse/CD-1 CRL

Route: DERMAL, SOLUTION | SKIN APPLICATION

Test Type: INIT/PROMOT

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

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

CAS Number: INIT/PROM

Date Report Requested: 10/16/2014 Time Report Requested: 17:49:13

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 2.5/ TPA 5 DMBA 2.5/ BPO 20 DMBA 25/ BPO 20

None

\*\* END OF REPORT \*\*