

**Experiment Number:** 05117-01  
**Test Type:** INIT/PROMOT  
**Route:** DERMAL,SOLUTION  
**Species/Strain:** Mouse/B6C3F1

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

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

**Date Report Requested:** 10/20/2014  
**Time Report Requested:** 23:48:55  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**C Number:** C61994A  
**Lock Date:** 04/07/1992  
**Cage Range:** All  
**Date Range:** All  
**Reasons For Removal:** All  
**Removal Date Range:** All  
**Treatment Groups:** All  
**Study Gender:** Both  
**PWG Approval Date** 04/26/1994

Experiment Number: 05117-01  
 Test Type: INIT/PROMOT  
 Route: DERMAL,SOLUTION  
 Species/Strain: Mouse/B6C3F1

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]**  
 Test Compound: Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)  
 CAS Number: INIT/PROM

Date Report Requested: 10/20/2014  
 Time Report Requested: 23:48:55  
 First Dose M/F: NA / NA  
 Lab: BAT

B6C3F1 Mouse MALE	VEHICLE CONTROL	DMBA 2.5/ACETONE	DMBA 25 /ACETONE	DMBA 50 /ACETONE	DMBA2.5/COMPLETE E	TPA 5/ COMPLETE
<b>Disposition Summary</b>						
Animals Initially In Study	30	30	30	30	30	30
Early Deaths						
Accidentally Killed						
Moribund Sacrifice	3				3	1
Natural Death	1				1	
Survivors						
Terminal Sacrifice	26	30	29	30	26	29
Missing			1			
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	(30)	(30)	(22)	(23)	(0)	(1)
Acanthosis						

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:** 05117-01  
**Test Type:** INIT/PROMOT  
**Route:** DERMAL,SOLUTION  
**Species/Strain:** Mouse/B6C3F1

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]**  
**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)  
**CAS Number:** INIT/PROM

**Date Report Requested:** 10/20/2014  
**Time Report Requested:** 23:48:55  
**First Dose M/F:** NA / NA  
**Lab:** BAT

B6C3F1 Mouse MALE	VEHICLE CONTROL	DMBA 2.5/ACETONE	DMBA 25 /ACETONE	DMBA 50 /ACETONE	DMBA2.5/COMPLETE E	TPA 5/ COMPLETE
Inflammation, Chronic Active Ulcer Ulcer, Multiple						
Skin, Control	(0)	(0)	(0)	(1)	(2)	(6)
Acanthosis				1 [1.0]	2 [1.0]	6 [1.3]
Inflammation, Chronic Active Pigmentation, Melanin Ulcer						4 [1.3] 2 [1.0]
Skin, SOA-Mass	(0)	(0)	(1)	(0)	(30)	(0)
Acanthosis					2 [2.5]	
Skin, SOA-No Mass	(0)	(0)	(8)	(7)	(23)	(30)
Acanthosis			8 [1.0]	7 [1.0]	23 [1.8]	30 [1.9]
Cyst Epithelial Inclusion Granuloma					1	
Inflammation, Chronic Active Pigmentation, Melanin Ulcer Ulcer, Multiple			1 [1.0]		5 [2.0]	29 [1.9] 23 [1.4] 1 [4.0] 2 [4.0]
<b>MUSCULOSKELETAL SYSTEM</b>						
None						
<b>NERVOUS SYSTEM</b>						
None						
<b>RESPIRATORY SYSTEM</b>						
None						
<b>SPECIAL SENSES SYSTEM</b>						
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)

**Experiment Number:** 05117-01  
**Test Type:** INIT/PROMOT  
**Route:** DERMAL,SOLUTION  
**Species/Strain:** Mouse/B6C3F1

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

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

**Date Report Requested:** 10/20/2014  
**Time Report Requested:** 23:48:55  
**First Dose M/F:** NA / NA  
**Lab:** BAT

---

**B6C3F1 Mouse MALE**

**VEHICLE CONTROL DMBA 2.5/ACETONE DMBA 25 /ACETONE DMBA 50 /ACETONE DMBA2.5/COMPLET TPA 5/ COMPLETE  
E**

---

URINARY SYSTEM

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)

Experiment Number: 05117-01  
 Test Type: INIT/PROMOT  
 Route: DERMAL,SOLUTION  
 Species/Strain: Mouse/B6C3F1

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH  
 AVERAGE SEVERITY GRADES[b]**  
 Test Compound: Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)  
 CAS Number: INIT/PROM

Date Report Requested: 10/20/2014  
 Time Report Requested: 23:48:55  
 First Dose M/F: NA / NA  
 Lab: BAT

B6C3F1 Mouse MALE	BPO 20/ COMPLETE	DMBA 2.5/ TPA 5	DMBA 25/ TPA 5	DMBA 50/ TPA 5	DMBA 2.5/BPO 20	DMBA 25/ BPO 20
<b>Disposition Summary</b>						
Animals Initially In Study	30	30	30	30	30	30
Early Deaths						
Accidentally Killed				1		
Moribund Sacrifice			1	3	2	
Natural Death					1	
Survivors						
Terminal Sacrifice	30	30	29	26	27	30
Missing						
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	(3)	(2)	(0)	(0)	(5)	(1)
Acanthosis					3 [2.7]	1 [3.0]
Inflammation, Chronic Active					3 [4.0]	1 [4.0]

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:** 05117-01  
**Test Type:** INIT/PROMOT  
**Route:** DERMAL,SOLUTION  
**Species/Strain:** Mouse/B6C3F1

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]**  
**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)  
**CAS Number:** INIT/PROM

**Date Report Requested:** 10/20/2014  
**Time Report Requested:** 23:48:55  
**First Dose M/F:** NA / NA  
**Lab:** BAT

B6C3F1 Mouse MALE	BPO 20/ COMPLETE	DMBA 2.5/ TPA 5	DMBA 25/ TPA 5	DMBA 50/ TPA 5	DMBA 2.5/BPO 20	DMBA 25/ BPO 20
Ulcer					2 [4.0]	
Ulcer, Multiple					1 [4.0]	1 [4.0]
Skin, Control	(9)	(12)	(9)	(4)	(14)	(10)
Acanthosis	9 [1.0]	12 [1.1]	9 [1.1]	4 [1.0]	14 [1.1]	10 [1.0]
Inflammation, Chronic Active		9 [1.0]	5 [1.2]	1 [1.0]	8 [1.0]	4 [1.8]
Pigmentation, Melanin		2 [1.0]	2 [1.0]			
Ulcer						1 [4.0]
Skin, SOA-Mass	(0)	(10)	(12)	(20)	(1)	(2)
Acanthosis			2 [2.0]	1 [4.0]		
Skin, SOA-No Mass	(27)	(29)	(29)	(30)	(27)	(30)
Acanthosis	27 [1.2]	28 [1.8]	29 [1.9]	30 [1.9]	27 [1.7]	30 [1.7]
Cyst Epithelial Inclusion						
Granuloma	1 [3.0]					
Inflammation, Chronic Active	26 [1.2]	28 [1.6]	28 [1.6]	28 [1.5]	27 [1.5]	27 [1.4]
Pigmentation, Melanin		10 [1.1]	17 [2.3]	14 [2.4]	3 [1.3]	
Ulcer		1 [4.0]		1 [4.0]	2 [4.0]	1 [4.0]
Ulcer, Multiple					1 [4.0]	2 [4.0]

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

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)

**Experiment Number:** 05117-01  
**Test Type:** INIT/PROMOT  
**Route:** DERMAL,SOLUTION  
**Species/Strain:** Mouse/B6C3F1

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

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

**Date Report Requested:** 10/20/2014  
**Time Report Requested:** 23:48:55  
**First Dose M/F:** NA / NA  
**Lab:** BAT

---

**B6C3F1 Mouse MALE**

**BPO 20/ COMPLETE**

**DMBA 2.5/ TPA 5**

**DMBA 25/ TPA 5**

**DMBA 50/ TPA 5**

**DMBA 2.5/BPO 20**

**DMBA 25/ BPO 20**

---

\*\*\*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)

Experiment Number: 05117-01  
 Test Type: INIT/PROMOT  
 Route: DERMAL,SOLUTION  
 Species/Strain: Mouse/B6C3F1

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH  
 AVERAGE SEVERITY GRADES[b]**  
 Test Compound: Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)  
 CAS Number: INIT/PROM

Date Report Requested: 10/20/2014  
 Time Report Requested: 23:48:55  
 First Dose M/F: NA / NA  
 Lab: BAT

B6C3F1 Mouse FEMALE	VEHICLE CONTROL	DMBA 2.5/ACETONE	DMBA 25 /ACETONE	DMBA 50 /ACETONE	DMBA2.5/COMPLETE E	TPA 5/ COMPLETE
<b>Disposition Summary</b>						
Animals Initially In Study	30	30	30	30	30	30
Early Deaths						
Accidentally Killed						
Moribund Sacrifice					2	
Natural Death		1			2	
Survivors						
Terminal Sacrifice	30	29	30	30	26	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	(30)	(30)	(25)	(11)	(1)	(0)
Acanthosis					1 [1.0]	
Alopecia						

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: 05117-01  
 Test Type: INIT/PROMOT  
 Route: DERMAL,SOLUTION  
 Species/Strain: Mouse/B6C3F1

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]**  
 Test Compound: Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)  
 CAS Number: INIT/PROM

Date Report Requested: 10/20/2014  
 Time Report Requested: 23:48:55  
 First Dose M/F: NA / NA  
 Lab: BAT

B6C3F1 Mouse FEMALE	VEHICLE CONTROL	DMBA 2.5/ACETONE	DMBA 25 /ACETONE	DMBA 50 /ACETONE	DMBA2.5/COMPLETE E	TPA 5/ COMPLETE
Hair Follicle, Cyst, Multiple Inflammation, Chronic Active Pigmentation, Melanin Ulcer Ulcer, Multiple					1 [4.0] 1 [4.0]	
Skin, Control	(0)	(0)	(0)	(3)	(9)	(22)
Acanthosis Inflammation, Chronic Active Pigmentation, Melanin				3 [1.0]	8 [1.0] 2 [1.0]	14 [1.1] 22 [1.3] 14 [1.3]
Skin, SOA-Mass	(0)	(0)	(0)	(0)	(29)	(1)
Acanthosis Sebaceous GI, Hyperplasia					1 [3.0] 1 [1.0]	
Skin, SOA-No Mass	(0)	(0)	(5)	(18)	(24)	(30)
Acanthosis Granuloma Inflammation, Chronic Active Mineralization Pigmentation, Melanin Ulcer Ulcer, Multiple			5 [1.2] 1 [2.0]	18 [1.0] 2 [1.0]	24 [1.9] 1 [2.0] 9 [2.8] 7 [2.3] 3 [4.0] 2 [4.0]	30 [1.8] 30 [2.5] 29 [2.4] 1 [4.0] 1 [4.0]
<b>MUSCULOSKELETAL SYSTEM</b>						
None						
<b>NERVOUS SYSTEM</b>						
None						
<b>RESPIRATORY SYSTEM</b>						
None						
<b>SPECIAL SENSES SYSTEM</b>						

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:** 05117-01  
**Test Type:** INIT/PROMOT  
**Route:** DERMAL,SOLUTION  
**Species/Strain:** Mouse/B6C3F1

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

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

**Date Report Requested:** 10/20/2014  
**Time Report Requested:** 23:48:55  
**First Dose M/F:** NA / NA  
**Lab:** BAT

---

<b>B6C3F1 Mouse FEMALE</b>	<b>VEHICLE CONTROL</b>	<b>DMBA 2.5/ACETONE</b>	<b>DMBA 25 /ACETONE</b>	<b>DMBA 50 /ACETONE</b>	<b>DMBA2.5/COMPLET E</b>	<b>TPA 5/ COMPLETE</b>
None						
URINARY SYSTEM						
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)

Experiment Number: 05117-01  
 Test Type: INIT/PROMOT  
 Route: DERMAL,SOLUTION  
 Species/Strain: Mouse/B6C3F1

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH  
 AVERAGE SEVERITY GRADES[b]**  
 Test Compound: Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)  
 CAS Number: INIT/PROM

Date Report Requested: 10/20/2014  
 Time Report Requested: 23:48:55  
 First Dose M/F: NA / NA  
 Lab: BAT

B6C3F1 Mouse FEMALE	BPO 20/ COMPLETE	DMBA 2.5/ TPA 5	DMBA 25/ TPA 5	DMBA 50/ TPA 5	DMBA 2.5/ BPO 20	DMBA 25/ BPO 20
<b>Disposition Summary</b>						
Animals Initially In Study	30	30	30	30	30	30
Early Deaths						
Accidentally Killed	1					
Moribund Sacrifice	2		1	2	1	1
Natural Death			1	1	1	
Survivors						
Terminal Sacrifice	27	30	28	27	28	29
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	(3)	(1)	(2)	(2)	(3)	(1)
Acanthosis	1 [4.0]			1 [4.0]	2 [3.0]	1 [1.0]
Alopecia		1		1		1
Hair Follicle, Cyst, Multiple	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)

**Experiment Number:** 05117-01  
**Test Type:** INIT/PROMOT  
**Route:** DERMAL,SOLUTION  
**Species/Strain:** Mouse/B6C3F1

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b]**  
**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)  
**CAS Number:** INIT/PROM

**Date Report Requested:** 10/20/2014  
**Time Report Requested:** 23:48:55  
**First Dose M/F:** NA / NA  
**Lab:** BAT

B6C3F1 Mouse FEMALE	BPO 20/ COMPLETE	DMBA 2.5/ TPA 5	DMBA 25/ TPA 5	DMBA 50/ TPA 5	DMBA 2.5/ BPO 20	DMBA 25/ BPO 20
Inflammation, Chronic Active	2 [2.5]		1 [4.0]	1 [4.0]	2 [4.0]	1 [1.0]
Pigmentation, Melanin	1 [1.0]					
Ulcer				1 [4.0]	1 [4.0]	
Ulcer, Multiple	1 [4.0]		1 [4.0]		1 [4.0]	
Skin, Control	(26)	(26)	(19)	(23)	(23)	(25)
Acanthosis	25 [1.0]	26 [1.0]	17 [1.1]	23 [1.1]	22 [1.0]	20 [1.0]
Inflammation, Chronic Active	25 [1.2]	24 [1.1]	18 [1.1]	19 [1.1]	21 [1.0]	24 [1.0]
Pigmentation, Melanin		20 [1.2]	14 [1.1]	14 [1.4]	3 [1.0]	1 [2.0]
Skin, SOA-Mass	(0)	(4)	(7)	(19)	(5)	(1)
Acanthosis		1 [4.0]				
Sebaceous GI, Hyperplasia						
Skin, SOA-No Mass	(29)	(30)	(30)	(30)	(29)	(30)
Acanthosis	29 [1.5]	30 [1.9]	30 [2.1]	30 [2.2]	29 [1.7]	28 [1.3]
Granuloma						
Inflammation, Chronic Active	27 [1.9]	30 [2.1]	30 [2.4]	30 [2.4]	29 [1.8]	30 [1.3]
Mineralization			1 [1.0]			
Pigmentation, Melanin	6 [1.3]	28 [2.5]	21 [2.6]	11 [2.3]	8 [1.4]	2 [1.0]
Ulcer			1 [4.0]	1 [4.0]	2 [4.0]	
Ulcer, Multiple	1 [4.0]	1 [4.0]	3 [4.0]	3 [4.0]	2 [4.0]	

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

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)

**Experiment Number:** 05117-01  
**Test Type:** INIT/PROMOT  
**Route:** DERMAL,SOLUTION  
**Species/Strain:** Mouse/B6C3F1

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

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

**Date Report Requested:** 10/20/2014  
**Time Report Requested:** 23:48:55  
**First Dose M/F:** NA / NA  
**Lab:** BAT

---

**B6C3F1 Mouse FEMALE**

**BPO 20/ COMPLETE**

**DMBA 2.5/ TPA 5**

**DMBA 25/ TPA 5**

**DMBA 50/ 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)