

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

**P02: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (a)**  
**Test Compound:** Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)  
**CAS Number:** INIT/PROM

**Date Report Requested:** 10/20/2014  
**Time Report Requested:** 23:50:29  
**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

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**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)

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

b - Primary tumors: all tumors except metastatic tumors

\* Number of animals with any tissue examined microscopically

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**Lab:** BAT

B6C3F1 Mouse MALE	VEHICLE CONTROL	DMBA 2.5/ACETONE	DMBA 25 /ACETONE	DMBA 50 /ACETONE	DMBA2.5/COMPLETE E	TPA 5/ COMPLETE
Melanoma Nos						
Subcut Tiss, Sarcoma						1 (100%)
Skin, Control	(0)	(0)	(0)	(1)	(2)	(6)
Skin, SOA-Mass	(0)	(0)	(1)	(0)	(30)	(0)
Basal Cell Carcinoma					1 (3%)	
Keratoacanthoma					4 (13%)	
Keratoacanthoma, Multiple					1 (3%)	
Sebaceous GI, Adenoma			1 (100%)		1 (3%)	
Sebaceous GI, Adenoma, Multiple					1 (3%)	
Squamous Cell Carcinoma					10 (33%)	
Squamous Cell Carcinoma, Multiple					14 (47%)	
Squamous Cell Papilloma					7 (23%)	
Squamous Cell Papilloma, Multiple					5 (17%)	
Subcut Tiss, Fibrosarcoma					1 (3%)	
Subcut Tiss, Sarcoma					1 (3%)	
Skin, SOA-No Mass	(0)	(0)	(8)	(7)	(23)	(30)
Melanoma Nos					1 (4%)	
Melanoma Nos, Multiple						
<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 - Primary tumors: all tumors except metastatic tumors

\* Number of animals with any tissue examined microscopically

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**B6C3F1 Mouse MALE**

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

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URINARY SYSTEM

None

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

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**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>						
<b>Animals Initially In Study</b>	30	30	30	30	30	30
<b>Early Deaths</b>						
<b>Accidentally Killed</b>				1		
<b>Moribund Sacrifice</b>			1	3	2	
<b>Natural Death</b>					1	
<b>Survivors</b>						
<b>Terminal Sacrifice</b>	30	30	29	26	27	30
<b>Missing</b>						
<b>Animals Examined Microscopically</b>	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)
Melanoma Nos		1 (50%)				

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

b - Primary tumors: all tumors except metastatic tumors

\* Number of animals with any tissue examined microscopically

Experiment Number: 05117-01

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**P02: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (a)**

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

CAS Number: INIT/PROM

Date Report Requested: 10/20/2014

Time Report Requested: 23:50:29

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
Subcut Tiss, Sarcoma						
Skin, Control	(9)	(12)	(9)	(4)	(14)	(10)
Skin, SOA-Mass	(0)	(10)	(12)	(20)	(1)	(2)
Basal Cell Carcinoma						
Keratoacanthoma			2 (17%)	2 (10%)		1 (50%)
Keratoacanthoma, Multiple			1 (8%)			
Sebaceous GI, Adenoma		1 (10%)	1 (8%)	2 (10%)	1 (100%)	1 (50%)
Sebaceous GI, Adenoma, Multiple						
Squamous Cell Carcinoma		1 (10%)	1 (8%)	2 (10%)		1 (50%)
Squamous Cell Carcinoma, Multiple				1 (5%)		
Squamous Cell Papilloma		4 (40%)	7 (58%)	7 (35%)		
Squamous Cell Papilloma, Multiple		4 (40%)	3 (25%)	9 (45%)		
Subcut Tiss, Fibrosarcoma				1 (5%)		
Subcut Tiss, Sarcoma						
Skin, SOA-No Mass	(27)	(29)	(29)	(30)	(27)	(30)
Melanoma Nos			2 (7%)	6 (20%)		1 (3%)
Melanoma Nos, Multiple			2 (7%)	4 (13%)		

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 - Primary tumors: all tumors except metastatic tumors

\* Number of animals with any tissue examined microscopically

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**First Dose M/F:** NA / NA  
**Lab:** BAT

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<b>B6C3F1 Mouse MALE</b>	<b>BPO 20/ COMPLETE</b>	<b>DMBA 2.5/ TPA 5</b>	<b>DMBA 25/ TPA 5</b>	<b>DMBA 50/ TPA 5</b>	<b>DMBA 2.5/BPO 20</b>	<b>DMBA 25/ BPO 20</b>
None						

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

b - Primary tumors: all tumors except metastatic tumors

\* Number of animals with any tissue examined microscopically

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B6C3F1 Mouse MALE	VEHICLE CONTROL	DMBA 2.5/ACETONE	DMBA 25 /ACETONE	DMBA 50 /ACETONE	DMBA2.5/COMPLETE E	TPA 5/ COMPLETE
<b>Tumor Summary for MALE</b>						
Total Animals with Primary Neoplasms (b)			1		29	1
Total Primary Neoplasms			1		46	1
Total Animals with Benign Neoplasms			1		17	
Total Benign Neoplasms			1		19	
Total Animals with Malignant Neoplasms					26	1
Total Malignant Neoplasms					26	1
Total Animals with Metastatic Neoplasms						
Total Metastatic Neoplasms						
Total Animals with Malignant Neoplasms Uncertain Primary Site						
Total Animals with Neoplasms Uncertain - Benign or Malignant					1	
Total Uncertain Neoplasms					1	

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

b - Primary tumors: all tumors except metastatic tumors

\* Number of animals with any tissue examined microscopically

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**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>Tumor Summary for MALE</b>						
<b>Total Animals with Primary Neoplasms (b)</b>		11	14	21	1	3
<b>Total Primary Neoplasms</b>		11	19	34	1	4
<b>Total Animals with Benign Neoplasms</b>		9	11	16	1	2
<b>Total Benign Neoplasms</b>		9	14	20	1	2
<b>Total Animals with Malignant Neoplasms</b>		1	1	4		1
<b>Total Malignant Neoplasms</b>		1	1	4		1
<b>Total Animals with Metastatic Neoplasms</b>						
<b>Total Metastatic Neoplasms</b>						
<b>Total Animals with Malignant Neoplasms Uncertain Primary Site</b>						
<b>Total Animals with Neoplasms Uncertain - Benign or Malignant</b>		1	4	10		1
<b>Total Uncertain Neoplasms</b>		1	4	10		1

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

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

b - Primary tumors: all tumors except metastatic tumors

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**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)
Squamous Cell Carcinoma						

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

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\* Number of animals with any tissue examined microscopically

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**Lab:** BAT

B6C3F1 Mouse FEMALE	VEHICLE CONTROL	DMBA 2.5/ACETONE	DMBA 25 /ACETONE	DMBA 50 /ACETONE	DMBA2.5/COMPLETE E	TPA 5/ COMPLETE
Skin, Control	(0)	(0)	(0)	(3)	(9)	(22)
Skin, SOA-Mass	(0)	(0)	(0)	(0)	(29)	(1)
Basal Cell Adenoma					1 (3%)	
Basal Cell Carcinoma					1 (3%)	
Keratoacanthoma						
Melanoma Nos						
Sebaceous GI, Adenoma					8 (28%)	
Sebaceous GI, Adenoma, Multiple					1 (3%)	
Squamous Cell Carcinoma					16 (55%)	1 (100%)
Squamous Cell Carcinoma, Multiple					8 (28%)	
Squamous Cell Papilloma					3 (10%)	
Squamous Cell Papilloma, Multiple					8 (28%)	
Subcut Tiss, Hemangiosarcoma						
Skin, SOA-No Mass	(0)	(0)	(5)	(18)	(24)	(30)
Melanoma Nos						
Melanoma Nos, Multiple						

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

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\* Number of animals with any tissue examined microscopically

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**Lab:** BAT

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**B6C3F1 Mouse FEMALE**

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

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None

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

b - Primary tumors: all tumors except metastatic tumors

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**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>						
<b>Animals Initially In Study</b>	30	30	30	30	30	30
<b>Early Deaths</b>						
<b>Accidentally Killed</b>	1					
<b>Moribund Sacrifice</b>	2		1	2	1	1
<b>Natural Death</b>			1	1	1	
<b>Survivors</b>						
<b>Terminal Sacrifice</b>	27	30	28	27	28	29
<b>Animals Examined Microscopically</b>	30	30	30	30	30	30
<b>ALIMENTARY SYSTEM</b>						
None						
<b>CARDIOVASCULAR SYSTEM</b>						
None						
<b>ENDOCRINE SYSTEM</b>						
None						
<b>GENERAL BODY SYSTEM</b>						
None						
<b>GENITAL SYSTEM</b>						
None						
<b>HEMATOPOIETIC SYSTEM</b>						
None						
<b>INTEGUMENTARY SYSTEM</b>						
Skin	(3)	(1)	(2)	(2)	(3)	(1)
Squamous Cell Carcinoma			1 (50%)			
Skin, Control	(26)	(26)	(19)	(23)	(23)	(25)

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

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\* Number of animals with any tissue examined microscopically

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**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
Skin, SOA-Mass	(0)	(4)	(7)	(19)	(5)	(1)
Basal Cell Adenoma						
Basal Cell Carcinoma						
Keratoacanthoma				1 (5%)		
Melanoma Nos				1 (5%)		
Sebaceous GI, Adenoma		2 (50%)	3 (43%)	11 (58%)		
Sebaceous GI, Adenoma, Multiple				2 (11%)		
Squamous Cell Carcinoma			3 (43%)	1 (5%)	2 (40%)	
Squamous Cell Carcinoma, Multiple						
Squamous Cell Papilloma		1 (25%)	3 (43%)	5 (26%)	3 (60%)	1 (100%)
Squamous Cell Papilloma, Multiple		2 (50%)	1 (14%)	5 (26%)		
Subcut Tiss, Hemangiosarcoma				1 (5%)		
Skin, SOA-No Mass	(29)	(30)	(30)	(30)	(29)	(30)
Melanoma Nos		2 (7%)	5 (17%)	10 (33%)	1 (3%)	4 (13%)
Melanoma Nos, Multiple			4 (13%)	9 (30%)		
<b>MUSCULOSKELETAL SYSTEM</b>						
None						
<b>NERVOUS SYSTEM</b>						
None						
<b>RESPIRATORY SYSTEM</b>						
None						
<b>SPECIAL SENSES SYSTEM</b>						
None						
<b>URINARY SYSTEM</b>						
None						

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

b - Primary tumors: all tumors except metastatic tumors

\* Number of animals with any tissue examined microscopically

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**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>Tumor Summary for FEMALE</b>						
<b>Total Animals with Primary Neoplasms (b)</b>					<b>29</b>	<b>1</b>
<b>Total Primary Neoplasms</b>					<b>46</b>	<b>1</b>
<b>Total Animals with Benign Neoplasms</b>					<b>14</b>	
<b>Total Benign Neoplasms</b>					<b>21</b>	
<b>Total Animals with Malignant Neoplasms</b>					<b>25</b>	<b>1</b>
<b>Total Malignant Neoplasms</b>					<b>25</b>	<b>1</b>
<b>Total Animals with Metastatic Neoplasms</b>						
<b>Total Metastatic Neoplasms</b>						
<b>Total Animals with Malignant Neoplasms Uncertain Primary Site</b>						
<b>Total Animals with Neoplasms Uncertain - Benign or Malignant</b>						
<b>Total Uncertain Neoplasms</b>						

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

b - Primary tumors: all tumors except metastatic tumors

\* Number of animals with any tissue examined microscopically

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**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>Tumor Summary for FEMALE</b>						
<b>Total Animals with Primary Neoplasms (b)</b>		<b>6</b>	<b>13</b>	<b>24</b>	<b>6</b>	<b>5</b>
<b>Total Primary Neoplasms</b>		<b>7</b>	<b>20</b>	<b>46</b>	<b>6</b>	<b>5</b>
<b>Total Animals with Benign Neoplasms</b>		<b>4</b>	<b>7</b>	<b>17</b>	<b>3</b>	<b>1</b>
<b>Total Benign Neoplasms</b>		<b>5</b>	<b>7</b>	<b>24</b>	<b>3</b>	<b>1</b>
<b>Total Animals with Malignant Neoplasms</b>			<b>3</b>	<b>2</b>	<b>2</b>	
<b>Total Malignant Neoplasms</b>			<b>4</b>	<b>2</b>	<b>2</b>	
<b>Total Animals with Metastatic Neoplasms</b>						
<b>Total Metastatic Neoplasms</b>						
<b>Total Animals with Malignant Neoplasms Uncertain Primary Site</b>						
<b>Total Animals with Neoplasms Uncertain - Benign or Malignant</b>		<b>2</b>	<b>9</b>	<b>19</b>	<b>1</b>	<b>4</b>
<b>Total Uncertain Neoplasms</b>		<b>2</b>	<b>9</b>	<b>19</b>	<b>1</b>	<b>4</b>

**\*\* END OF REPORT \*\***

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

b - Primary tumors: all tumors except metastatic tumors

\* Number of animals with any tissue examined microscopically