Experiment Number: 05117-04 Test Type: INIT/PROMOT Route: SKIN APPLICATION Species/Strain: Mouse/B6C3F1	P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a) Test Compound: Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG) CAS Number: INIT/PROM	Date Report Requested: 10/21/2014 Time Report Requested: 06:25:33 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	

All

Both

04/27/1994

Treatment Groups:

PWG Approval Date

Study Gender:

Test Type: INIT/PROMOT

Route: SKIN APPLICATION

Species/Strain: Mouse/B6C3F1

P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

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

CAS Number: INIT/PROM

Date Report Requested: 10/21/2014 Time Report Requested: 06:25:33 First Dose M/F: NA / NA Lab: BAT

B6C3F1 Mouse MALE	VEHICLE CONTROL	MNNG 100/ACETONE	MNNG 500/ACETONE	MNNG1000/ACETON E	TPA 5 COMPLETE	MNNG100/COMPLET E
Disposition Summary						
Animals Initially In Study Early Deaths	30	30	30	30	30	30
Moribund Sacrifice Natural Death			1	2		12 2
Survivors	22	20				10
Terminal Sacrifice <u>Animals Examined Microscopically</u>	30 30	30 30	29 30	28 30	30 30	16 30
ALIMENTARY SYSTEM None						
CARDIOVASCULAR SYSTEM						
ENDOCRINE SYSTEM None						
GENERAL BODY SYSTEM None						
GENITAL SYSTEM None						
HEMATOPOIETIC SYSTEM						
INTEGUMENTARY SYSTEM						
Skin	(30)	(28)	(11)	(6)	(0)	(0)
Skin, Control Skin, SOA-Mass	(0) (0)	(0) (0)	(1) (1)	(0) (10)	(20) (0)	(10) (29)

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

b - Primary tumors: all tumors except metastatic tumors

Test Type: INIT/PROMOT **Route:** SKIN APPLICATION

Species/Strain: Mouse/B6C3F1

P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

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

CAS Number: INIT/PROM

Date Report Requested: 10/21/2014 Time Report Requested: 06:25:33 First Dose M/F: NA / NA Lab: BAT

B6C3F1 Mouse MALE	VEHICLE CONTROL	MNNG 100/ACETONE	MNNG 500/ACETONE	MNNG1000/ACETON E	TPA 5 COMPLETE	MNNG100/COMPLET E
Keratoacanthoma				1 (10%)		
Squamous Cell Carcinoma				3 (30%)		16 (55%)
Squamous Cell Carcinoma, Multiple						13 (45%)
Squamous Cell Papilloma				1 (10%)		2 (7%)
Squamous Cell Papilloma, Multiple						
Subcut Tiss, Fibrosarcoma				1 (10%)		
Subcut Tiss, Hemangiosarcoma						
Subcut Tiss, Sarcoma			1 (100%)	3 (30%)		
Subcut Tiss, Sarcoma, Multiple						
Subcut Tiss, Squamous Cell Carcinoma						1 (3%)
Trichoepithelioma						
Skin, SOA-No Mass	(0)	(2)	(18)	(22)	(30)	(23)
Subcut Tiss, Lymphangioma						
Subcut Tiss, Lymphangiosarcoma						
Subcut Tiss, Sarcoma				1 (5%)		
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 - Primary tumors: all tumors except metastatic tumors

Experiment Number: 05117-04		P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS					Date Report Requested: 10/21/2014	
Test Type: INIT/PROMOT		ABRIDGED) (a)					Time Report Requested: 06:25:33	
Route: SKIN APPLICATION		Test Compound: Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)					First Dose M/F: NA / NA	
Species/Strain: Mouse/B6C3F1		CAS Number: INIT/PROM					Lab: BAT	
B6C3F1 Mouse MALE	VEHICLE CONTROL	MNNG 100/ACETONE	MNNG 500/ACETONE	MNNG1000/ACETON E	TPA 5(COMPLETE	MNNG100/COMPLET E	

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: 05117-04 Test Type: INIT/PROMOT Route: SKIN APPLICATION Species/Strain: Mouse/B6C3F1	P05: INCIDENCE F	Date Report Requested: 10/21/2014 Time Report Requested: 06:25:33 First Dose M/F: NA / NA Lab: BAT				
B6C3F1 Mouse MALE	BPO 20 COMPLETE	MNNG 100/BPO 20	MNNG 500/BPO 20	MNNG1000/BPO 20	MNNG 100/TPA 5	MNNG1000/TPA 5
Disposition Summary						-
Animals Initially In Study Early Deaths	30	30	30	30	30	30
Moribund Sacrifice Natural Death Survivors			1	2	1	14
Terminal Sacrifice Animals Examined Microscopically	30 30	30 30	29 30	28 30	29 30	16 30
ALIMENTARY SYSTEM None						
CARDIOVASCULAR SYSTEM None						
ENDOCRINE SYSTEM None						
GENERAL BODY SYSTEM None						
GENITAL SYSTEM None						
HEMATOPOIETIC SYSTEM None						
INTEGUMENTARY SYSTEM Skin Skin, Control Skin, SOA-Mass Keratoacanthoma	(6) (12) (0)	(8) (6) (0)	(2) (3) (4)	(3) (3) (12)	(1) (7) (9)	(0) (9) (22)

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

b - Primary tumors: all tumors except metastatic tumors

Route: SKIN APPLICATION Species/Strain: Mouse/B6C3F1 B6C3F1 Mouse MALE	Test Com	pound: Init/prom compara CAS Num	First Dose M/F: NA / NA Lab: BAT			
	BPO 20 COMPLETE	MNNG 100/BPO 20	MNNG 500/BPO 20	MNNG1000/BPO 20	MNNG 100/TPA 5	MNNG1000/TPA 5
Squamous Cell Carcinoma			2 (50%)	1 (8%)		4 (18%)
Squamous Cell Carcinoma, Multiple				1 (8%)		1 (5%)
Squamous Cell Papilloma				3 (25%)	5 (56%)	3 (14%)
Squamous Cell Papilloma, Multiple				1 (8%)	2 (22%)	3 (14%)
Subcut Tiss, Fibrosarcoma						
Subcut Tiss, Hemangiosarcoma			1 (25%)			
Subcut Tiss, Sarcoma			1 (25%)	3 (25%)	1 (11%)	10 (45%)
Subcut Tiss, Sarcoma, Multiple				1 (8%)		2 (9%)
Subcut Tiss, Squamous Cell Carcinoma						
Trichoepithelioma						2 (9%)
Skin, SOA-No Mass	(24)	(22)	(27)	(26)	(29)	(28)
Subcut Tiss, Lymphangioma						1 (4%)
Subcut Tiss, Lymphangiosarcoma						1 (4%)
Subcut Tiss, Sarcoma						
MUSCULOSKELETAL SYSTEM						
None						
NERVOUS SYSTEM						
None						
RESPIRATORY SYSTEM						
None						
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
None						

P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

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Date Report Requested: 10/21/2014

Time Report Requested: 06:25:33

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

b - Primary tumors: all tumors except metastatic tumors

Experiment Number: 05117-04

Test Type: INIT/PROMOT

Test Type: INIT/PROMOT **Route:** SKIN APPLICATION

Species/Strain: Mouse/B6C3F1

P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

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

CAS Number: INIT/PROM

Date Report Requested: 10/21/2014 Time Report Requested: 06:25:33 First Dose M/F: NA / NA Lab: BAT

B6C3F1 Mouse MALE	VEHICLE CONTROL	MNNG 100/ACETONE	MNNG 500/ACETONE	MNNG1000/ACETON E	TPA 5 COMPLETE	MNNG100/COMPLET E
Tumor Summary for MALE						
Total Animals with Primary Neoplasms (b)			1	10		29
Total Primary Neoplasms			1	10		32
Total Animals with Benign Neoplasms				2		2
Total Benign Neoplasms				2		2
Total Animals with Malignant Neoplasms			1	8		29
Total Malignant Neoplasms			1	8		30
Total Animals with Metastatic Neoplasms						
Total Metastatic Neoplasms						
Total Animals with Malignant Neoplasms Uncertain Primary Site						
Total Animals with Neoplasms Uncertain - Benign or Malignant						
Total Uncertain Neoplasms						

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

b - Primary tumors: all tumors except metastatic tumors

Experiment Number: 05117-04 Test Type: INIT/PROMOT Route: SKIN APPLICATION Species/Strain: Mouse/B6C3F1		ATES OF NEOPLASM ABRI bound: Init/prom compara CAS Num	Date Report Requested: 10/21/2014 Time Report Requested: 06:25:33 First Dose M/F: NA / NA Lab: BAT			
B6C3F1 Mouse MALE	BPO 20 COMPLETE	MNNG 100/BPO 20	MNNG 500/BPO 20	MNNG1000/BPO 20	MNNG 100/TPA 5	MNNG1000/TPA 5
Tumor Summary for MALE						
Total Animals with Primary Neoplasms (b) Total Primary Neoplasms			4 4	9 10	8 8	22 27
Total Animals with Benign Neoplasms Total Benign Neoplasms				4 4	7 7	8 9
Total Animals with Malignant Neoplasms Total Malignant Neoplasms			4 4	6 6	1 1	16 18
Total Animals with Metastatic Neoplasms Total Metastatic Neoplasms						
Total Animals with Malignant Neoplasms Uncertain Primary Site						
Total Animals with Neoplasms Uncertain - Benign or Malignant Total Uncertain Neoplasms						

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

Test Type: INIT/PROMOT

Species/Strain: Mouse/B6C3F1

Route: SKIN APPLICATION

P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

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

CAS Number: INIT/PROM

Date Report Requested: 10/21/2014 Time Report Requested: 06:25:33 First Dose M/F: NA / NA Lab: BAT

B6C3F1 Mouse FEMALE	VEHICLE CONTROL	MNNG 100/ACETONE	MNNG 500/ACETONE	MNNG1000/ACETON E	TPA 5 COMPLETE	MNNG100/COMPLET E
Disposition Summary						
Animals Initially In Study Early Deaths Drowned	30	30	30	30	30	30
Moribund Sacrifice Natural Death				6 1		13 4
Survivors Terminal Sacrifice Missing	30	30	30	23	30	13
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)	(28)	(9)	(8)	(0)	(2)

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

b - Primary tumors: all tumors except metastatic tumors

Test Type: INIT/PROMOT **Route:** SKIN APPLICATION

Species/Strain: Mouse/B6C3F1

P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

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

CAS Number: INIT/PROM

Date Report Requested: 10/21/2014 Time Report Requested: 06:25:33 First Dose M/F: NA / NA Lab: BAT

B6C3F1 Mouse FEMALE	VEHICLE CONTROL	MNNG 100/ACETONE	MNNG 500/ACETONE	MNNG1000/ACETON E	TPA 5 COMPLETE	MNNG100/COMPLET E
Sarcoma				1 (13%)		
Squamous Cell Carcinoma				1 (13%)		
Skin, Control	(0)	(0)	(0)	(2)	(23)	(10)
Subcut Tiss, Sarcoma				1 (50%)		
Skin, SOA-Mass	(0)	(0)	(0)	(9)	(1)	(30)
Sebaceous GI, Adenoma						
Squamous Cell Carcinoma				5 (56%)		24 (80%)
Squamous Cell Carcinoma, Multiple						6 (20%)
Squamous Cell Papilloma						1 (3%)
Squamous Cell Papilloma, Multiple						
Subcut Tiss, Sarcoma				4 (44%)		1 (3%)
Subcut Tiss, Sarcoma, Multiple				1 (11%)		
Skin, SOA-No Mass	(0)	(2)	(21)	(19)	(30)	(26)
Subcut Tiss, Lymphangioma						
Subcut Tiss, Mast Cell Tumor Benign						1 (4%)
Subcut Tiss, Sarcoma						
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

Experiment Number: 05117-04 Test Type: INIT/PROMOT Route: SKIN APPLICATION Species/Strain: Mouse/B6C3F1		RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a) pound: Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG) CAS Number: INIT/PROM			Date Report Requested: 10/21/2014 Time Report Requested: 06:25:33 First Dose M/F: NA / NA Lab: BAT	
B6C3F1 Mouse FEMALE	VEHICLE CONTROL	MNNG 100/ACETONE	MNNG 500/ACETONE	MNNG1000/ACETON E	TPA 5 COMPLETE	MNNG100/COMPLET E
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

Experiment Number: 05117-04 Test Type: INIT/PROMOT	P05: INCIDENCE F	Date Report Requested: 10/21/2014 Time Report Requested: 06:25:33				
Route: SKIN APPLICATION Species/Strain: Mouse/B6C3F1 B6C3F1 Mouse FEMALE	Test Com	First Dose M/F: NA / NA Lab: BAT				
	BPO 20 COMPLETE	MNNG 100/BPO 20	MNNG 500/BPO 20	MNNG1000/BPO 20	MNNG 100/TPA 5	MNNG1000/TPA 5
Disposition Summary						
Animals Initially In Study Early Deaths	30	30	30	30	30	30
Drowned Moribund Sacrifice Natural Death Survivors	1		1 2	5		5 3
Terminal Sacrifice Missing	29 30	30 30	27	25 30	29 1 29	22 30
Animals Examined Microscopically ALIMENTARY SYSTEM None		30	30	30	29	30
CARDIOVASCULAR SYSTEM None						
ENDOCRINE SYSTEM None						
GENERAL BODY SYSTEM None						
GENITAL SYSTEM None						
HEMATOPOIETIC SYSTEM None						
INTEGUMENTARY SYSTEM Skin Sarcoma	(13)	(8)	(3)	(2)	(0)	(0)

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

b - Primary tumors: all tumors except metastatic tumors

Experiment Number: 05117-04	P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS	Date Report Requested: 10/21/2014
Test Type: INIT/PROMOT	ABRIDGED) (a)	Time Report Requested: 06:25:33
Route: SKIN APPLICATION	Test Compound: Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG)	First Dose M/F: NA / NA

Species/Strain: Mouse/B6C3F1

CAS Number: INIT/PROM

Lab: BAT

B6C3F1 Mouse FEMALE	BPO 20 COMPLETE	MNNG 100/BPO 20	MNNG 500/BPO 20	MNNG1000/BPO 20	MNNG 100/TPA 5	MNNG1000/TPA 5
Squamous Cell Carcinoma						
Skin, Control	(8)	(2)	(3)	(4)	(10)	(12)
Subcut Tiss, Sarcoma						
Skin, SOA-Mass	(0)	(1)	(2)	(10)	(1)	(10)
Sebaceous GI, Adenoma				1 (10%)		
Squamous Cell Carcinoma				4 (40%)		1 (10%)
Squamous Cell Carcinoma, Multiple						
Squamous Cell Papilloma		1 (100%)		2 (20%)	1 (100%)	1 (10%)
Squamous Cell Papilloma, Multiple						1 (10%)
Subcut Tiss, Sarcoma			1 (50%)	3 (30%)		7 (70%)
Subcut Tiss, Sarcoma, Multiple						1 (10%)
Skin, SOA-No Mass	(18)	(22)	(27)	(27)	(29)	(28)
Subcut Tiss, Lymphangioma						1 (4%)
Subcut Tiss, Mast Cell Tumor Benign						
Subcut Tiss, Sarcoma				1 (4%)		
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 - Primary tumors: all tumors except metastatic tumors

Experiment Number: 05117-04 Test Type: INIT/PROMOT Route: SKIN APPLICATION Species/Strain: Mouse/B6C3F1		ATES OF NEOPLASM ABRI ound: Init/prom compara CAS Num	Date Report Requested: 10/21/2014 Time Report Requested: 06:25:33 First Dose M/F: NA / NA Lab: BAT			
B6C3F1 Mouse FEMALE	VEHICLE CONTROL	MNNG 100/ACETONE	MNNG 500/ACETONE	MNNG1000/ACETON E	TPA 5 COMPLETE	MNNG100/COMPLET E
Tumor Summary for FEMALE						
Total Animals with Primary Neoplasms (b) Total Primary Neoplasms				9 13		30 33
Total Animals with Benign Neoplasms Total Benign Neoplasms						2 2
Total Animals with Malignant Neoplasms Total Malignant Neoplasms				9 13		30 31
Total Animals with Metastatic Neoplasms Total Metastatic Neoplasms						
Total Animals with Malignant Neoplasms Uncertain Primary Site						
Total Animals with Neoplasms Uncertain - Benign or Malignant Total Uncertain Neoplasms						

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

b - Primary tumors: all tumors except metastatic tumors

Experiment Number: 05117-04 Test Type: INIT/PROMOT Route: SKIN APPLICATION Species/Strain: Mouse/B6C3F1	P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a) Test Compound: Init/prom comparative mouse study (DMBA/TPA/BPO/MNNG) CAS Number: INIT/PROM				Date Report Requested: 10/21/2014 Time Report Requested: 06:25:33 First Dose M/F: NA / NA Lab: BAT	
B6C3F1 Mouse FEMALE	BPO 20 COMPLETE	MNNG 100/BPO 20	MNNG 500/BPO 20	MNNG1000/BPO 20	MNNG 100/TPA 5	MNNG1000/TPA 5
Tumor Summary for FEMALE						
Total Animals with Primary Neoplasms (b) Total Primary Neoplasms		1 1	1 1	11 11	1 1	10 12
Total Animals with Benign Neoplasms Total Benign Neoplasms		1 1		3 3	1 1	3 3
Total Animals with Malignant Neoplasms Total Malignant Neoplasms			1 1	8 8		8 9
Total Animals with Metastatic Neoplasms Total Metastatic Neoplasms						
Total Animals with Malignant Neoplasms Uncertain Primary Site						
Total Animals with Neoplasms Uncertain - Benign or Malignant Total Uncertain Neoplasms						

** 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