P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/22/2014 AVERAGE SEVERITY GRADES[b]

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

Species/Strain: Mouse/SENCAR

Route: SKIN APPLICATION|DERMAL, SOLUTION

**CAS Number: INIT/PROM** 

Lab: BAT

Time Report Requested: 18:08:43

First Dose M/F: NA / NA

C Number: C61994C

Lock Date: 04/09/1992

**Cage Range:** ΑII

**Date Range:** ΑII

**Reasons For Removal:** ΑII

**Removal Date Range:** ΑII

**Treatment Groups:** ΑII

**Study Gender:** Both

**PWG Approval Date** 04/29/1994

Species/Strain: Mouse/SENCAR

Route: SKIN APPLICATION|DERMAL, SOLUTION

## P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/22/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 18:08:43

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

CAS Number: INIT/PROM

Time Report Requested: 18:08:43

First Dose M/F: NA / NA

| SENCAR Mouse MALE                | VEHICLE CONTROL | DMBA0.25 /TPA 1 | DMBA 2.5 /TPA 1 | DMBA 25 /TPA 1 | TPA 1/ COMPLETE | MNNG 100 /TPA 1 |
|----------------------------------|-----------------|-----------------|-----------------|----------------|-----------------|-----------------|
| Disposition Summary              |                 |                 |                 |                |                 |                 |
| Animals Initially In Study       | 30              | 30              | 30              | 30             | 30              | 30              |
| Early Deaths                     |                 |                 |                 |                |                 |                 |
| Moribund Sacrifice               | 1               | 22              | 22              | 25             | 17              | 20              |
| Natural Death                    |                 | 2               | 6               | 4              | 4               | 2               |
| Survivors                        |                 |                 |                 |                |                 |                 |
| Terminal Sacrifice               | 29              | 6               | 2               | 1              | 9               | 8               |
| 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                             | (28)            | (6)             | (5)             | (6)            | (2)             | (7)             |
| Acanthosis                       | ,               | 12 [2.8]        | 10 [3.2]        | 10 [3.2]       | 2 [3.0]         | ,               |
| Alopecia                         |                 |                 |                 |                |                 |                 |
| Epithelium, Hyperplasia          |                 |                 |                 |                |                 | 2 [3.0]         |
| Hair Follicle, Cyst              |                 |                 |                 |                |                 | 2               |

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: 10/22/2014 Time Report Requested: 18:08:43

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

Species/Strain: Mouse/SENCAR

Route: SKIN APPLICATION|DERMAL, SOLUTION

CAS Number: INIT/PROM

Time Report Requested: 18:08:43

First Dose M/F: NA / NA

Lab: BAT

| SENCAR Mouse MALE            | VEHICLE CONTROL | DMBA0.25 /TPA 1 | DMBA 2.5 /TPA 1 | DMBA 25 /TPA 1 | TPA 1/ COMPLETE | MNNG 100 /TPA 1 |
|------------------------------|-----------------|-----------------|-----------------|----------------|-----------------|-----------------|
| Inflammation, Chronic Active |                 | 12 [3.8]        | 10 [4.0]        | 12 [4.0]       | 2 [4.0]         | 10 [3.0]        |
| Ulcer                        |                 | 6 [4.0]         | 6 [4.0]         | 6 [4.0]        | 2 [4.0]         | 10 [4.0]        |
| Ulcer, Multiple              |                 | 6 [4.0]         | 4 [4.0]         | 4 [4.0]        |                 |                 |
| Skin, Control                | (0)             | (23)            | (23)            | (20)           | (20)            | (21)            |
| Acanthosis                   |                 | 46 [2.1]        | 46 [2.2]        | 40 [2.3]       | 19 [2.5]        | 42 [2.2]        |
| Hair Follicle, Cyst          |                 |                 | 2               |                |                 |                 |
| Inflammation, Chronic Active |                 | 34 [1.6]        | 32 [1.8]        | 34 [1.6]       | 11 [1.6]        | 32 [1.2]        |
| Ulcer                        |                 | 4 [4.0]         | 4 [4.0]         | 4 [4.0]        | 2 [4.0]         |                 |
| Ulcer, Multiple              |                 |                 | 2 [4.0]         |                |                 |                 |
| Skin, SOA-Mass               | (0)             | (8)             | (14)            | (21)           | (1)             | (10)            |
| Acanthosis                   |                 |                 |                 |                |                 | 2 [2.0]         |
| Ulcer                        |                 |                 |                 |                |                 | 2 [4.0]         |
| Skin, SOA-No Mass            | (2)             | (30)            | (30)            | (29)           | (30)            | (30)            |
| Acanthosis                   | 2 [1.5]         | 60 [3.0]        | 60 [3.2]        | 58 [3.1]       | 30 [3.3]        | 46 [3.1]        |
| Alopecia                     |                 |                 |                 |                |                 |                 |
| Hair Follicle, Cyst          |                 | 10              | 12              | 18             | 15              | 20              |
| Inflammation, Chronic Active | 2 [1.0]         | 60 [3.4]        | 60 [3.5]        | 56 [3.4]       | 30 [3.1]        | 58 [2.8]        |
| Ulcer                        |                 | 18 [4.0]        | 28 [4.0]        | 12 [4.0]       | 5 [4.0]         | 42 [3.9]        |
| Ulcer, Multiple              |                 | 24 [4.0]        | 18 [4.0]        | 30 [4.0]       | 13 [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)

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/22/2014 AVERAGE SEVERITY GRADES[b]

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

VEHICLE CONTROL DMBA0.25 /TPA 1

Time Report Requested: 18:08:43

First Dose M/F: NA / NA

Lab: BAT

Species/Strain: Mouse/SENCAR

Route: SKIN APPLICATION|DERMAL, SOLUTION

**SENCAR Mouse MALE** 

CAS Number: INIT/PROM

DMBA 2.5 /TPA 1

DMBA 25 /TPA 1 TPA 1/ COMPLETE MNNG 100 /TPA 1

**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)

Species/Strain: Mouse/SENCAR

Route: SKIN APPLICATION|DERMAL, SOLUTION

Test Type: INIT/PROMOT

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/22/2014 Time Report Requested: 18:08:43

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

CAS Number: INIT/PROM

Time Report Requested: 18:08:43

First Dose M/F: NA / NA

| SENCAR Mouse MALE   | MNNG1000 /TPA 1 |
|---|-----------------|
| Disposition Summary   |                 |
| Animals Initially In Study<br>Early Deaths                      | 30              |
| Moribund Sacrifice Natural Death                                | 26<br>3         |
| Survivors   |                 |
| Terminal Sacrifice Animals Examined Microscopically             | 1<br>30         |
| ALIMENTARY SYSTEM None  |                 |
| CARDIOVASCULAR SYSTEM None                                      |                 |
| ENDOCRINE SYSTEM None   |                 |
| GENERAL BODY SYSTEM None  |                 |
| GENITAL SYSTEM None   |                 |
| HEMATOPOIETIC SYSTEM None                                       |                 |
| INTEGUMENTARY SYSTEM  |                 |
| Skin<br>Acanthosis  | (6)             |
| Acanthosis Alopecia Epithelium, Hyperplasia Hair Follicle, Cyst | 4               |

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/SENCAR

Route: SKIN APPLICATION|DERMAL, SOLUTION

Test Type: INIT/PROMOT

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/22/2014 Time Report Requested: 18:08:43

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

CAS Number: INIT/PROM

Time Report Requested: 18:08:43

First Dose M/F: NA / NA

Lab: BAT

| SENCAR Mouse MALE            | MNNG1000 /TPA 1 |
|------------------------------|-----------------|
| Inflammation, Chronic Active | 8 [3.0]         |
| Ulcer                        | 8 [3.8]         |
| Ulcer, Multiple              |                 |
| Skin, Control                | (12)            |
| Acanthosis                   | 24 [1.7]        |
| Hair Follicle, Cyst          |                 |
| Inflammation, Chronic Active | 14 [1.3]        |
| Ulcer                        | 2 [4.0]         |
| Ulcer, Multiple              |                 |
| Skin, SOA-Mass               | (20)            |
| Acanthosis                   |                 |
| Ulcer                        |                 |
| Skin, SOA-No Mass            | (29)            |
| Acanthosis                   | 42 [2.4]        |
| Alopecia                     | 2               |
| Hair Follicle, Cyst          | 6               |
| Inflammation, Chronic Active | 58 [2.7]        |
| Ulcer                        | 42 [4.0]        |
| Ulcer, Multiple              |                 |
| MUSCULOSKELETAL SYSTEM       |                 |
| None                         |                 |
|                              |                 |
| NERVOUS SYSTEM               |                 |
| None                         |                 |
| RESPIRATORY SYSTEM           |                 |
| None                         |                 |
| ODEOLAL OFFICES OVOTERA      |                 |

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)

Test Type: INIT/PROMOT

P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/22/2014 AVERAGE SEVERITY GRADES[b]

Route: SKIN APPLICATION|DERMAL, SOLUTION

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

Species/Strain: Mouse/SENCAR

CAS Number: INIT/PROM

Time Report Requested: 18:08:43

First Dose M/F: NA / NA

Lab: BAT

**SENCAR Mouse MALE** MNNG1000 /TPA 1 **URINARY SYSTEM** None

\*\*\*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)

Species/Strain: Mouse/SENCAR

Route: SKIN APPLICATION|DERMAL, SOLUTION

## P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/22/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 18:08:43

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

CAS Number: INIT/PROM

Time Report Requested: 18:08:43

First Dose M/F: NA / NA

| SENCAR Mouse FEMALE              | VEHICLE CONTROL | DMBA0.25 /TPA 1 | DMBA 2.5 /TPA 1 | DMBA 25 /TPA 1 | TPA 1/ COMPLETE | MNNG 100 /TPA |
|----------------------------------|-----------------|-----------------|-----------------|----------------|-----------------|---------------|
| Disposition Summary              |                 |                 |                 |                |                 |               |
| Animals Initially In Study       | 30              | 30              | 30              | 30             | 30              | 30            |
| Early Deaths                     |                 |                 |                 |                |                 |               |
| Moribund Sacrifice               | 1               | 18              | 19              | 23             | 19              | 15            |
| Natural Death                    | 2               | 4               | 5               | 6              | 1               | 2             |
| Survivors                        |                 |                 |                 |                |                 |               |
| Terminal Sacrifice               | 27              | 8               | 6               | 1              | 10              | 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             |                 |                 |                 |                |                 |               |
| Mammary Gland                    | (1)             | (0)             | (0)             | (0)            | (0)             | (0)           |
| Skin                             | (29)            | (3)             | (4)             | (2)            | (2)             | (3)           |
| Acanthosis                       | ,               | 4 [3.5]         | 6 [3.0]         | 2 [4.0]        | 1 [2.0]         | . ,           |
| Alopecia                         |                 |                 |                 |                | 1               | 2             |
| Inflammation, Chronic Active     | 1 [3.0]         | 4 [4.0]         | 6 [4.0]         | 4 [4.0]        | 1 [4.0]         | 4 [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)

Species/Strain: Mouse/SENCAR

None

None

**URINARY SYSTEM** 

Route: SKIN APPLICATION|DERMAL, SOLUTION

## P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/22/2014 AVERAGE SEVERITY GRADES[b] Time Report Requested: 18:08:43

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

CAS Number: INIT/PROM

Time Report Requested: 18:08:43

First Dose M/F: NA / NA

| SENCAR Mouse FEMALE          | VEHICLE CONTROL | DMBA0.25 /TPA 1 | DMBA 2.5 /TPA 1 | DMBA 25 /TPA 1 | TPA 1/ COMPLETE | MNNG 100 /TPA 1 |
|------------------------------|-----------------|-----------------|-----------------|----------------|-----------------|-----------------|
| Ulcer                        | 1 [4.0]         | 4 [4.0]         | 6 [4.0]         | 2 [4.0]        | 1 [4.0]         | 2 [4.0]         |
| Skin, Control                | (0)             | (25)            | (26)            | (19)           | (24)            | (16)            |
| Acanthosis                   |                 | 48 [2.2]        | 52 [2.6]        | 38 [1.9]       | 24 [2.3]        | 32 [2.3]        |
| Hair Follicle, Cyst          |                 | 4               | 2               |                | 1               |                 |
| Inflammation, Chronic Active |                 | 46 [1.6]        | 46 [1.8]        | 18 [1.9]       | 19 [1.7]        | 30 [1.1]        |
| Ulcer                        |                 | 2 [4.0]         | 4 [4.0]         |                |                 |                 |
| Ulcer, Multiple              |                 |                 | 2 [4.0]         |                |                 |                 |
| Skin, SOA-Mass               | (0)             | (9)             | (20)            | (25)           | (2)             | (16)            |
| Acanthosis                   |                 |                 | 2 [3.0]         | 2 [3.0]        | 1 [4.0]         | 2 [2.0]         |
| Cyst Epithelial Inclusion    |                 |                 |                 |                |                 |                 |
| Skin, SOA-No Mass            | (1)             | (30)            | (30)            | (28)           | (30)            | (29)            |
| Acanthosis                   |                 | 60 [3.1]        | 60 [3.1]        | 56 [3.3]       | 30 [3.3]        | 48 [3.3]        |
| Hair Follicle, Cyst          |                 | 24              | 16              | 18             | 16              | 10              |
| Inflammation, Chronic Active | 1 [3.0]         | 60 [3.3]        | 60 [3.4]        | 54 [3.5]       | 30 [3.0]        | 56 [2.7]        |
| Ulcer                        | 1 [4.0]         | 16 [4.0]        | 30 [4.0]        | 26 [4.0]       | 5 [4.0]         | 38 [3.8]        |
| Ulcer, Multiple              |                 | 24 [4.0]        | 12 [4.0]        | 18 [4.0]       | 11 [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)

Test Type: INIT/PROMOT

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/22/2014 Time Report Requested: 18:08:43

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

Species/Strain: Mouse/SENCAR

Route: SKIN APPLICATION|DERMAL, SOLUTION

CAS Number: INIT/PROM

Time Report Requested: 18:08:43

First Dose M/F: NA / NA

| SENCAR Mouse FEMALE                        | MNNG1000 /TPA 1 |
|--|-----------------|
| Disposition Summary                        |                 |
| Animals Initially In Study<br>Early Deaths | 30              |
| Moribund Sacrifice                         | 24              |
| Natural Death<br>Survivors                 | 4               |
| Terminal Sacrifice                         | 2               |
| Animals Examined Microscopically           | 30              |
| ALIMENTARY SYSTEM None                     |                 |
| CARDIOVASCULAR SYSTEM None                 |                 |
| ENDOCRINE SYSTEM None                      |                 |
| GENERAL BODY SYSTEM None                   |                 |
| GENITAL SYSTEM None                        |                 |
| HEMATOPOIETIC SYSTEM None                  |                 |
| INTEGUMENTARY SYSTEM                       |                 |
| Mammary Gland                              | (0)             |
| Skin                                       | (6)             |
| Acanthosis<br>Alopecia                     | 6 [3.0]         |
| Inflammation, Chronic Active               | 12 [2.8]        |

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)

Route: SKIN APPLICATION|DERMAL, SOLUTION

Test Type: INIT/PROMOT

# P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH AVERAGE SEVERITY GRADES[b] Date Report Requested: 10/22/2014 Time Report Requested: 18:08:43

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

Species/Strain: Mouse/SENCAR CAS Number: INIT/PROM

Time Report Requested: 18:08:43

First Dose M/F: NA / NA

| SENCAR Mouse FEMALE          | MNNG1000 /TPA 1 |
|------------------------------|-----------------|
| Ulcer                        | 10 [3.8]        |
| Skin, Control                | (14)            |
| Acanthosis                   | 22 [2.2]        |
| Hair Follicle, Cyst          | 2               |
| Inflammation, Chronic Active | 20 [1.5]        |
| Ulcer                        | 4 [4.0]         |
| Ulcer, Multiple              |                 |
| Skin, SOA-Mass               | (16)            |
| Acanthosis                   | 4 [2.0]         |
| Cyst Epithelial Inclusion    | 2               |
| Skin, SOA-No Mass            | (28)            |
| Acanthosis                   | 48 [3.1]        |
| Hair Follicle, Cyst          | 6               |
| Inflammation, Chronic Active | 46 [2.7]        |
| Ulcer                        | 34 [3.8]        |
| Ulcer, Multiple              |                 |
| 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)

Test Type: INIT/PROMOT

Route: SKIN APPLICATION|DERMAL, SOLUTION

Species/Strain: Mouse/SENCAR

#### P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH Date Report Requested: 10/22/2014 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: 18:08:43

Lab: BAT

\*\* 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)