

TDMS No. 20006 - 02
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

INDOLE-3-CARBINOL
CAS Number: 700-06-1

Date Report Reqsted: 06/05/2007
Time Report Reqsted: 07:56:47
First Dose M/F: 09/01/04 / 09/02/04
Lab: SRI

F1_M3

C Number: C20006
Lock Date: 03/07/2006
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
TDMSE Version: 1.7.0

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SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF INDOLE-3-CARBINOL

MALE MICE

Organ

Lymph Node, Mesenteric
Spleen

Morphology

Necrosis Lymphoid
Hematopoietic Cell Proliferation

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

| DOSE | Males | | | | | |
|------|---------|------------|-------------|------------|-----------|-----------|
| | 0 MG/KG | 15.6 MG/KG | 31.25 MG/KG | 62.5 MG/KG | 125 MG/KG | 250 MG/KG |

**Adrenal Cortex
 Accessory Adrenal Cortical Nodule**

LESION RATES

| | | | | | | |
|--------------------|------------|----------|----------|----------|----------|-----------|
| OVERALL (a) | 3/10 (30%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 3/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/10.00 |
| POLY-3 PERCENT (g) | 30% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 3/10 (30%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| FIRST INCIDENCE | 94 (T) | --- | --- | --- | --- | --- |

STATISTICAL TESTS

| | | | | | | |
|---------------------|----------|-----|-----|-----|-----|----------|
| LIFE TABLE | P=0.064N | (e) | (e) | (e) | (e) | P=0.111N |
| POLY 3 | (e) | (e) | (e) | (e) | (e) | P=0.095N |
| POLY 1.5 | (e) | (e) | (e) | (e) | (e) | P=0.095N |
| POLY 6 | (e) | (e) | (e) | (e) | (e) | P=0.095N |
| LOGISTIC REGRESSION | P=0.064N | (e) | (e) | (e) | (e) | (e) |
| COCH-ARM / FISHERS | P=0.059N | (e) | (e) | (e) | (e) | P=0.105N |
| ORDER RESTRICTED | (e) | (e) | (e) | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | (e) |

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 TERMINAL SACRIFICE AT 14 WEEKS**

| DOSE | Males | | | | | |
|------|---------|------------|-------------|------------|-----------|-----------|
| | 0 MG/KG | 15.6 MG/KG | 31.25 MG/KG | 62.5 MG/KG | 125 MG/KG | 250 MG/KG |

**Adrenal Cortex: Capsule
 Hyperplasia**

LESION RATES

| | | | | | | |
|--------------------|------------|----------|----------|----------|----------|------------|
| OVERALL (a) | 5/10 (50%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 5/10 (50%) |
| POLY-3 RATE (b) | 5/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/0.00 | 5/10.00 |
| POLY-3 PERCENT (g) | 50% | 0% | 0% | 0% | 0% | 50% |
| TERMINAL (d) | 5/10 (50%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 5/10 (50%) |
| FIRST INCIDENCE | 94 (T) | --- | --- | --- | --- | 94 (T) |

STATISTICAL TESTS

| | | | | | | |
|---------------------|---------|-----|-----|-----|-----|----------|
| LIFE TABLE | P=0.586 | (e) | (e) | (e) | (e) | P=0.669 |
| POLY 3 | (e) | (e) | (e) | (e) | (e) | P=0.664 |
| POLY 1.5 | (e) | (e) | (e) | (e) | (e) | P=0.664 |
| POLY 6 | (e) | (e) | (e) | (e) | (e) | P=0.664 |
| LOGISTIC REGRESSION | P=0.586 | (e) | (e) | (e) | (e) | P=0.669 |
| COCH-ARM / FISHERS | P=0.588 | (e) | (e) | (e) | (e) | P=0.672N |
| ORDER RESTRICTED | (e) | (e) | (e) | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | (e) |

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 First Dose M/F: 09/01/04 / 09/02/04
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

| DOSE | Males | | | | | |
|------|---------|------------|-------------|------------|-----------|-----------|
| | 0 MG/KG | 15.6 MG/KG | 31.25 MG/KG | 62.5 MG/KG | 125 MG/KG | 250 MG/KG |

**Esophagus
 Inflammation Chronic**

LESION RATES

| | | | | | | |
|--------------------|------------|----------|----------|----------|----------|------------|
| OVERALL (a) | 3/10 (30%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 3/10 (30%) |
| POLY-3 RATE (b) | 3/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/0.00 | 3/10.00 |
| POLY-3 PERCENT (g) | 30% | 0% | 0% | 0% | 0% | 30% |
| TERMINAL (d) | 3/10 (30%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 3/10 (30%) |
| FIRST INCIDENCE | 94 (T) | --- | --- | --- | --- | 94 (T) |

STATISTICAL TESTS

| | | | | | | |
|---------------------|---------|-----|-----|-----|-----|----------|
| LIFE TABLE | P=0.594 | (e) | (e) | (e) | (e) | P=0.683 |
| POLY 3 | (e) | (e) | (e) | (e) | (e) | P=0.678 |
| POLY 1.5 | (e) | (e) | (e) | (e) | (e) | P=0.678 |
| POLY 6 | (e) | (e) | (e) | (e) | (e) | P=0.678 |
| LOGISTIC REGRESSION | P=0.594 | (e) | (e) | (e) | (e) | P=0.683 |
| COCH-ARM / FISHERS | P=0.596 | (e) | (e) | (e) | (e) | P=0.686N |
| ORDER RESTRICTED | (e) | (e) | (e) | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | (e) |

TDMS No. 20006 - 02
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 INDOLE-3-CARBINOL
 CAS Number: 700-06-1

Date Report Reqsted: 06/05/2007
 Time Report Reqsted: 07:56:47
 First Dose M/F: 09/01/04 / 09/02/04
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

| DOSE | Males | | | | | |
|------|---------|------------|-------------|------------|-----------|-----------|
| | 0 MG/KG | 15.6 MG/KG | 31.25 MG/KG | 62.5 MG/KG | 125 MG/KG | 250 MG/KG |

**Harderian Gland
 Inflammation Chronic**

LESION RATES

| | | | | | | |
|--------------------|------------|----------|----------|----------|----------|------------|
| OVERALL (a) | 1/10 (10%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 2/10 (20%) |
| POLY-3 RATE (b) | 1/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/0.00 | 2/10.00 |
| POLY-3 PERCENT (g) | 10% | 0% | 0% | 0% | 0% | 20% |
| TERMINAL (d) | 1/10 (10%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 2/10 (20%) |
| FIRST INCIDENCE | 94 (T) | --- | --- | --- | --- | 94 (T) |

STATISTICAL TESTS

| | | | | | | |
|---------------------|---------|-----|-----|-----|-----|---------|
| LIFE TABLE | P=0.380 | (e) | (e) | (e) | (e) | P=0.500 |
| POLY 3 | (e) | (e) | (e) | (e) | (e) | P=0.500 |
| POLY 1.5 | (e) | (e) | (e) | (e) | (e) | P=0.500 |
| POLY 6 | (e) | (e) | (e) | (e) | (e) | P=0.500 |
| LOGISTIC REGRESSION | P=0.380 | (e) | (e) | (e) | (e) | P=0.500 |
| COCH-ARM / FISHERS | P=0.377 | (e) | (e) | (e) | (e) | P=0.500 |
| ORDER RESTRICTED | (e) | (e) | (e) | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | (e) |

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P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

| DOSE | Males | | | | | |
|------|---------|------------|-------------|------------|-----------|-----------|
| | 0 MG/KG | 15.6 MG/KG | 31.25 MG/KG | 62.5 MG/KG | 125 MG/KG | 250 MG/KG |

**Lymph Node, Mandibular
 Hyperplasia**

LESION RATES

| | | | | | | |
|--------------------|-----------|----------|----------|----------|----------|------------|
| OVERALL (a) | 3/9 (33%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 4/10 (40%) |
| POLY-3 RATE (b) | 3/9.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/0.00 | 4/10.00 |
| POLY-3 PERCENT (g) | 33.3% | 0% | 0% | 0% | 0% | 40% |
| TERMINAL (d) | 3/9 (33%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 4/10 (40%) |
| FIRST INCIDENCE | 94 (T) | --- | --- | --- | --- | 94 (T) |

STATISTICAL TESTS

| | | | | | | |
|---------------------|---------|-----|-----|-----|-----|---------|
| LIFE TABLE | P=0.476 | (e) | (e) | (e) | (e) | P=0.568 |
| POLY 3 | (e) | (e) | (e) | (e) | (e) | P=0.566 |
| POLY 1.5 | (e) | (e) | (e) | (e) | (e) | P=0.566 |
| POLY 6 | (e) | (e) | (e) | (e) | (e) | P=0.566 |
| LOGISTIC REGRESSION | P=0.476 | (e) | (e) | (e) | (e) | P=0.568 |
| COCH-ARM / FISHERS | P=0.475 | (e) | (e) | (e) | (e) | P=0.570 |
| ORDER RESTRICTED | (e) | (e) | (e) | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | (e) |

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

| DOSE | Males | | | | | |
|------|---------|------------|-------------|------------|-----------|-----------|
| | 0 MG/KG | 15.6 MG/KG | 31.25 MG/KG | 62.5 MG/KG | 125 MG/KG | 250 MG/KG |

**Lymph Node, Mandibular
 Infiltration Cellular**

LESION RATES

| | | | | | | |
|--------------------|-----------|----------|----------|----------|----------|------------|
| OVERALL (a) | 4/9 (44%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 3/10 (30%) |
| POLY-3 RATE (b) | 4/9.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/0.00 | 3/10.00 |
| POLY-3 PERCENT (g) | 44.4% | 0% | 0% | 0% | 0% | 30% |
| TERMINAL (d) | 4/9 (44%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 3/10 (30%) |
| FIRST INCIDENCE | 94 (T) | --- | --- | --- | --- | 94 (T) |

STATISTICAL TESTS

| | | | | | | |
|---------------------|----------|-----|-----|-----|-----|----------|
| LIFE TABLE | P=0.344N | (e) | (e) | (e) | (e) | P=0.432N |
| POLY 3 | (e) | (e) | (e) | (e) | (e) | P=0.433N |
| POLY 1.5 | (e) | (e) | (e) | (e) | (e) | P=0.433N |
| POLY 6 | (e) | (e) | (e) | (e) | (e) | P=0.433N |
| LOGISTIC REGRESSION | P=0.344N | (e) | (e) | (e) | (e) | P=0.432N |
| COCH-ARM / FISHERS | P=0.340N | (e) | (e) | (e) | (e) | P=0.430N |
| ORDER RESTRICTED | (e) | (e) | (e) | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | (e) |

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 TERMINAL SACRIFICE AT 14 WEEKS**

| DOSE | Males | | | | | |
|------|---------|------------|-------------|------------|-----------|-----------|
| | 0 MG/KG | 15.6 MG/KG | 31.25 MG/KG | 62.5 MG/KG | 125 MG/KG | 250 MG/KG |

Lymph Node, Mesenteric
 Necrosis Lymphoid

LESION RATES

| | | | | | | |
|--------------------|-----------|----------|----------|----------|----------|-----------|
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 3/8 (38%) |
| POLY-3 RATE (b) | 0/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/0.00 | 3/8.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 37.5% |
| TERMINAL (d) | 0/10 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 3/8 (38%) |
| FIRST INCIDENCE | --- | --- | --- | --- | --- | 94 (T) |

STATISTICAL TESTS

| | | | | | | |
|---------------------|----------|-----|-----|-----|-----|---------|
| LIFE TABLE | P=0.040* | (e) | (e) | (e) | (e) | P=0.074 |
| POLY 3 | (e) | (e) | (e) | (e) | (e) | P=0.053 |
| POLY 1.5 | (e) | (e) | (e) | (e) | (e) | P=0.053 |
| POLY 6 | (e) | (e) | (e) | (e) | (e) | P=0.053 |
| LOGISTIC REGRESSION | (e) | (e) | (e) | (e) | (e) | P=0.074 |
| COCH-ARM / FISHERS | P=0.036* | (e) | (e) | (e) | (e) | P=0.069 |
| ORDER RESTRICTED | (e) | (e) | (e) | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | (e) |

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 TERMINAL SACRIFICE AT 14 WEEKS**

| DOSE | Males | | | | | |
|------|---------|------------|-------------|------------|-----------|-----------|
| | 0 MG/KG | 15.6 MG/KG | 31.25 MG/KG | 62.5 MG/KG | 125 MG/KG | 250 MG/KG |

**Salivary Glands
 Hyperplasia Lymphoid**

LESION RATES

| | | | | | | |
|--------------------|-----------|----------|----------|----------|----------|-----------|
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/10 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| FIRST INCIDENCE | --- | --- | --- | --- | --- | --- |

STATISTICAL TESTS

| | | | | | | |
|---------------------|-----|-----|-----|-----|-----|-----|
| LIFE TABLE | (e) | (e) | (e) | (e) | (e) | (e) |
| POLY 3 | (e) | (e) | (e) | (e) | (e) | (e) |
| POLY 1.5 | (e) | (e) | (e) | (e) | (e) | (e) |
| POLY 6 | (e) | (e) | (e) | (e) | (e) | (e) |
| LOGISTIC REGRESSION | (e) | (e) | (e) | (e) | (e) | (e) |
| COCH-ARM / FISHERS | (e) | (e) | (e) | (e) | (e) | (e) |
| ORDER RESTRICTED | (e) | (e) | (e) | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | (e) |

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 TERMINAL SACRIFICE AT 14 WEEKS**

| DOSE | Males | | | | | |
|------|---------|------------|-------------|------------|-----------|-----------|
| | 0 MG/KG | 15.6 MG/KG | 31.25 MG/KG | 62.5 MG/KG | 125 MG/KG | 250 MG/KG |

**Spleen
 Hematopoietic Cell Proliferation**

LESION RATES

| | | | | | | |
|--------------------|-----------|-----------|----------|----------|----------|-----------|
| OVERALL (a) | 0/10 (0%) | 2/3 (67%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/10.00 | 2/3.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/10.00 |
| POLY-3 PERCENT (g) | 0% | 66.7% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/10 (0%) | 2/3 (67%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| FIRST INCIDENCE | --- | 94 (T) | --- | --- | --- | --- |

STATISTICAL TESTS

| | | | | | | |
|---------------------|----------|-----------|-----|-----|-----|-----|
| LIFE TABLE | P=0.225N | P=0.034* | (e) | (e) | (e) | (e) |
| POLY 3 | (e) | P=0.003** | (e) | (e) | (e) | (e) |
| POLY 1.5 | (e) | P=0.003** | (e) | (e) | (e) | (e) |
| POLY 6 | (e) | P=0.003** | (e) | (e) | (e) | (e) |
| LOGISTIC REGRESSION | (e) | P=0.034* | (e) | (e) | (e) | (e) |
| COCH-ARM / FISHERS | P=0.220N | P=0.038* | (e) | (e) | (e) | (e) |
| ORDER RESTRICTED | (e) | (e) | (e) | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | (e) |

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 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

| DOSE | Females | | | | | |
|------|---------|------------|-------------|------------|-----------|-----------|
| | 0 MG/KG | 15.6 MG/KG | 31.25 MG/KG | 62.5 MG/KG | 125 MG/KG | 250 MG/KG |

**Adrenal Cortex
 Accessory Adrenal Cortical Nodule**

LESION RATES

| | | | | | | |
|--------------------|-----------|----------|----------|----------|----------|-----------|
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 0/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 0/10 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| FIRST INCIDENCE | --- | --- | --- | --- | --- | --- |

STATISTICAL TESTS

| | | | | | | |
|---------------------|-----|-----|-----|-----|-----|-----|
| LIFE TABLE | (e) | (e) | (e) | (e) | (e) | (e) |
| POLY 3 | (e) | (e) | (e) | (e) | (e) | (e) |
| POLY 1.5 | (e) | (e) | (e) | (e) | (e) | (e) |
| POLY 6 | (e) | (e) | (e) | (e) | (e) | (e) |
| LOGISTIC REGRESSION | (e) | (e) | (e) | (e) | (e) | (e) |
| COCH-ARM / FISHERS | (e) | (e) | (e) | (e) | (e) | (e) |
| ORDER RESTRICTED | (e) | (e) | (e) | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | (e) |

TDMS No. 20006 - 02
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 INDOLE-3-CARBINOL
 CAS Number: 700-06-1

Date Report Reqsted: 06/05/2007
 Time Report Reqsted: 07:56:47
 First Dose M/F: 09/01/04 / 09/02/04
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

| DOSE | Females | | | | | |
|------|---------|------------|-------------|------------|-----------|-----------|
| | 0 MG/KG | 15.6 MG/KG | 31.25 MG/KG | 62.5 MG/KG | 125 MG/KG | 250 MG/KG |

**Adrenal Cortex: Capsule
 Hyperplasia**

LESION RATES

| | | | | | | |
|--------------------|--------------|----------|----------|----------|----------|--------------|
| OVERALL (a) | 10/10 (100%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 10/10 (100%) |
| POLY-3 RATE (b) | 10/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/0.00 | 10/10.00 |
| POLY-3 PERCENT (g) | 100% | 0% | 0% | 0% | 0% | 100% |
| TERMINAL (d) | 10/10 (100%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 10/10 (100%) |
| FIRST INCIDENCE | 94 (T) | --- | --- | --- | --- | 94 (T) |

STATISTICAL TESTS

| | | | | | | |
|---------------------|-----|-----|-----|-----|-----|-----|
| LIFE TABLE | (e) | (e) | (e) | (e) | (e) | (e) |
| POLY 3 | (e) | (e) | (e) | (e) | (e) | (e) |
| POLY 1.5 | (e) | (e) | (e) | (e) | (e) | (e) |
| POLY 6 | (e) | (e) | (e) | (e) | (e) | (e) |
| LOGISTIC REGRESSION | (e) | (e) | (e) | (e) | (e) | (e) |
| COCH-ARM / FISHERS | (e) | (e) | (e) | (e) | (e) | (e) |
| ORDER RESTRICTED | (e) | (e) | (e) | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | (e) |

TDMS No. 20006 - 02
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 INDOLE-3-CARBINOL
 CAS Number: 700-06-1

Date Report Reqsted: 06/05/2007
 Time Report Reqsted: 07:56:47
 First Dose M/F: 09/01/04 / 09/02/04
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

| DOSE | Females | | | | | |
|------|---------|------------|-------------|------------|-----------|-----------|
| | 0 MG/KG | 15.6 MG/KG | 31.25 MG/KG | 62.5 MG/KG | 125 MG/KG | 250 MG/KG |

**Esophagus
 Inflammation Chronic**

LESION RATES

| | | | | | | |
|--------------------|------------|----------|----------|----------|----------|------------|
| OVERALL (a) | 2/10 (20%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 5/10 (50%) |
| POLY-3 RATE (b) | 2/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/0.00 | 5/10.00 |
| POLY-3 PERCENT (g) | 20% | 0% | 0% | 0% | 0% | 50% |
| TERMINAL (d) | 2/10 (20%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 5/10 (50%) |
| FIRST INCIDENCE | 94 (T) | --- | --- | --- | --- | 94 (T) |

STATISTICAL TESTS

| | | | | | | |
|---------------------|---------|-----|-----|-----|-----|---------|
| LIFE TABLE | P=0.127 | (e) | (e) | (e) | (e) | P=0.180 |
| POLY 3 | (e) | (e) | (e) | (e) | (e) | P=0.174 |
| POLY 1.5 | (e) | (e) | (e) | (e) | (e) | P=0.174 |
| POLY 6 | (e) | (e) | (e) | (e) | (e) | P=0.174 |
| LOGISTIC REGRESSION | P=0.127 | (e) | (e) | (e) | (e) | P=0.180 |
| COCH-ARM / FISHERS | P=0.121 | (e) | (e) | (e) | (e) | P=0.175 |
| ORDER RESTRICTED | (e) | (e) | (e) | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | (e) |

TDMS No. 20006 - 02
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 INDOLE-3-CARBINOL
 CAS Number: 700-06-1

Date Report Reqsted: 06/05/2007
 Time Report Reqsted: 07:56:47
 First Dose M/F: 09/01/04 / 09/02/04
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

| DOSE | Females | | | | | |
|------|---------|------------|-------------|------------|-----------|-----------|
| | 0 MG/KG | 15.6 MG/KG | 31.25 MG/KG | 62.5 MG/KG | 125 MG/KG | 250 MG/KG |

**Harderian Gland
 Inflammation Chronic**

LESION RATES

| | | | | | | |
|--------------------|-----------|----------|----------|----------|----------|------------|
| OVERALL (a) | 0/10 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 1/10 (10%) |
| POLY-3 RATE (b) | 0/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/0.00 | 1/10.00 |
| POLY-3 PERCENT (g) | 0% | 0% | 0% | 0% | 0% | 10% |
| TERMINAL (d) | 0/10 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 1/10 (10%) |
| FIRST INCIDENCE | --- | --- | --- | --- | --- | 94 (T) |

STATISTICAL TESTS

| | | | | | | |
|---------------------|---------|-----|-----|-----|-----|---------|
| LIFE TABLE | P=0.309 | (e) | (e) | (e) | (e) | P=0.500 |
| POLY 3 | (e) | (e) | (e) | (e) | (e) | P=0.500 |
| POLY 1.5 | (e) | (e) | (e) | (e) | (e) | P=0.500 |
| POLY 6 | (e) | (e) | (e) | (e) | (e) | P=0.500 |
| LOGISTIC REGRESSION | (e) | (e) | (e) | (e) | (e) | P=0.500 |
| COCH-ARM / FISHERS | P=0.304 | (e) | (e) | (e) | (e) | P=0.500 |
| ORDER RESTRICTED | (e) | (e) | (e) | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | (e) |

TDMS No. 20006 - 02
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 INDOLE-3-CARBINOL
 CAS Number: 700-06-1

Date Report Reqsted: 06/05/2007
 Time Report Reqsted: 07:56:47
 First Dose M/F: 09/01/04 / 09/02/04
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

| DOSE | Females | | | | | |
|------|---------|------------|-------------|------------|-----------|-----------|
| | 0 MG/KG | 15.6 MG/KG | 31.25 MG/KG | 62.5 MG/KG | 125 MG/KG | 250 MG/KG |

**Lymph Node, Mandibular
 Hyperplasia**

LESION RATES

| | | | | | | |
|--------------------|------------|----------|----------|----------|----------|------------|
| OVERALL (a) | 3/10 (30%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 4/10 (40%) |
| POLY-3 RATE (b) | 3/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/0.00 | 4/10.00 |
| POLY-3 PERCENT (g) | 30% | 0% | 0% | 0% | 0% | 40% |
| TERMINAL (d) | 3/10 (30%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 4/10 (40%) |
| FIRST INCIDENCE | 94 (T) | --- | --- | --- | --- | 94 (T) |

STATISTICAL TESTS

| | | | | | | |
|---------------------|---------|-----|-----|-----|-----|---------|
| LIFE TABLE | P=0.410 | (e) | (e) | (e) | (e) | P=0.500 |
| POLY 3 | (e) | (e) | (e) | (e) | (e) | P=0.500 |
| POLY 1.5 | (e) | (e) | (e) | (e) | (e) | P=0.500 |
| POLY 6 | (e) | (e) | (e) | (e) | (e) | P=0.500 |
| LOGISTIC REGRESSION | P=0.410 | (e) | (e) | (e) | (e) | P=0.500 |
| COCH-ARM / FISHERS | P=0.407 | (e) | (e) | (e) | (e) | P=0.500 |
| ORDER RESTRICTED | (e) | (e) | (e) | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | (e) |

TDMS No. 20006 - 02
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 INDOLE-3-CARBINOL
 CAS Number: 700-06-1

Date Report Reqsted: 06/05/2007
 Time Report Reqsted: 07:56:47
 First Dose M/F: 09/01/04 / 09/02/04
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

| DOSE | Females | | | | | |
|------|---------|------------|-------------|------------|-----------|-----------|
| | 0 MG/KG | 15.6 MG/KG | 31.25 MG/KG | 62.5 MG/KG | 125 MG/KG | 250 MG/KG |

**Lymph Node, Mandibular
 Infiltration Cellular**

LESION RATES

| | | | | | | |
|--------------------|------------|----------|----------|----------|----------|------------|
| OVERALL (a) | 3/10 (30%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 3/10 (30%) |
| POLY-3 RATE (b) | 3/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/0.00 | 3/10.00 |
| POLY-3 PERCENT (g) | 30% | 0% | 0% | 0% | 0% | 30% |
| TERMINAL (d) | 3/10 (30%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 3/10 (30%) |
| FIRST INCIDENCE | 94 (T) | --- | --- | --- | --- | 94 (T) |

STATISTICAL TESTS

| | | | | | | |
|---------------------|---------|-----|-----|-----|-----|----------|
| LIFE TABLE | P=0.594 | (e) | (e) | (e) | (e) | P=0.683 |
| POLY 3 | (e) | (e) | (e) | (e) | (e) | P=0.678 |
| POLY 1.5 | (e) | (e) | (e) | (e) | (e) | P=0.678 |
| POLY 6 | (e) | (e) | (e) | (e) | (e) | P=0.678 |
| LOGISTIC REGRESSION | P=0.594 | (e) | (e) | (e) | (e) | P=0.683 |
| COCH-ARM / FISHERS | P=0.596 | (e) | (e) | (e) | (e) | P=0.686N |
| ORDER RESTRICTED | (e) | (e) | (e) | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | (e) |

TDMS No. 20006 - 02
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 INDOLE-3-CARBINOL
 CAS Number: 700-06-1

Date Report Reqsted: 06/05/2007
 Time Report Reqsted: 07:56:47
 First Dose M/F: 09/01/04 / 09/02/04
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

| DOSE | Females | | | | | |
|------|---------|------------|-------------|------------|-----------|-----------|
| | 0 MG/KG | 15.6 MG/KG | 31.25 MG/KG | 62.5 MG/KG | 125 MG/KG | 250 MG/KG |

Lymph Node, Mesenteric
 Necrosis Lymphoid

LESION RATES

| | | | | | | |
|--------------------|------------|-----------|----------|-----------|-----------|-----------|
| OVERALL (a) | 1/10 (10%) | 0/10 (0%) | 0/9 (0%) | 0/10 (0%) | 0/10 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 1/10.00 | 0/10.00 | 0/9.00 | 0/10.00 | 0/10.00 | 0/10.00 |
| POLY-3 PERCENT (g) | 10% | 0% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 1/10 (10%) | 0/10 (0%) | 0/9 (0%) | 0/10 (0%) | 0/10 (0%) | 0/10 (0%) |
| FIRST INCIDENCE | 94 (T) | --- | --- | --- | --- | --- |

STATISTICAL TESTS

| | | | | | | |
|---------------------|----------|----------|----------|----------|----------|----------|
| LIFE TABLE | P=0.413N | P=0.500N | P=0.521N | P=0.500N | P=0.500N | P=0.500N |
| POLY 3 | P=0.413N | P=0.500N | P=0.521N | P=0.500N | P=0.500N | P=0.500N |
| POLY 1.5 | P=0.413N | P=0.500N | P=0.521N | P=0.500N | P=0.500N | P=0.500N |
| POLY 6 | P=0.413N | P=0.500N | P=0.521N | P=0.500N | P=0.500N | P=0.500N |
| LOGISTIC REGRESSION | P=0.413N | (e) | (e) | (e) | (e) | (e) |
| COCH-ARM / FISHERS | P=0.412N | P=0.500N | P=0.526N | P=0.500N | P=0.500N | P=0.500N |
| ORDER RESTRICTED | P=0.065N | (e) | (e) | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | P=0.076N | (e) | (e) | (e) | (e) | (e) |

TDMS No. 20006 - 02
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 INDOLE-3-CARBINOL
 CAS Number: 700-06-1

Date Report Reqsted: 06/05/2007
 Time Report Reqsted: 07:56:47
 First Dose M/F: 09/01/04 / 09/02/04
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

| DOSE | Females | | | | | |
|------|---------|------------|-------------|------------|-----------|-----------|
| | 0 MG/KG | 15.6 MG/KG | 31.25 MG/KG | 62.5 MG/KG | 125 MG/KG | 250 MG/KG |

**Salivary Glands
 Hyperplasia Lymphoid**

LESION RATES

| | | | | | | |
|--------------------|------------|----------|----------|----------|----------|------------|
| OVERALL (a) | 2/10 (20%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 2/10 (20%) |
| POLY-3 RATE (b) | 2/10.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/0.00 | 2/10.00 |
| POLY-3 PERCENT (g) | 20% | 0% | 0% | 0% | 0% | 20% |
| TERMINAL (d) | 2/10 (20%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 2/10 (20%) |
| FIRST INCIDENCE | 94 (T) | --- | --- | --- | --- | 94 (T) |

STATISTICAL TESTS

| | | | | | | |
|---------------------|---------|-----|-----|-----|-----|----------|
| LIFE TABLE | P=0.607 | (e) | (e) | (e) | (e) | P=0.707 |
| POLY 3 | (e) | (e) | (e) | (e) | (e) | P=0.702 |
| POLY 1.5 | (e) | (e) | (e) | (e) | (e) | P=0.702 |
| POLY 6 | (e) | (e) | (e) | (e) | (e) | P=0.702 |
| LOGISTIC REGRESSION | P=0.607 | (e) | (e) | (e) | (e) | P=0.707 |
| COCH-ARM / FISHERS | P=0.610 | (e) | (e) | (e) | (e) | P=0.709N |
| ORDER RESTRICTED | (e) | (e) | (e) | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | (e) |

TDMS No. 20006 - 02
 Test Type: 90-DAY
 Route: GAVAGE
 Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 INDOLE-3-CARBINOL
 CAS Number: 700-06-1

Date Report Reqsted: 06/05/2007
 Time Report Reqsted: 07:56:47
 First Dose M/F: 09/01/04 / 09/02/04
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1)
 TERMINAL SACRIFICE AT 14 WEEKS**

| DOSE | Females | | | | | |
|------|---------|------------|-------------|------------|-----------|-----------|
| | 0 MG/KG | 15.6 MG/KG | 31.25 MG/KG | 62.5 MG/KG | 125 MG/KG | 250 MG/KG |

**Spleen
 Hematopoietic Cell Proliferation**

LESION RATES

| | | | | | | |
|--------------------|------------|------------|----------|----------|----------|-----------|
| OVERALL (a) | 2/10 (20%) | 1/1 (100%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| POLY-3 RATE (b) | 2/10.00 | 1/1.00 | 0/0.00 | 0/0.00 | 0/0.00 | 0/10.00 |
| POLY-3 PERCENT (g) | 20% | 100% | 0% | 0% | 0% | 0% |
| TERMINAL (d) | 2/10 (20%) | 1/1 (100%) | 0/0 (0%) | 0/0 (0%) | 0/0 (0%) | 0/10 (0%) |
| FIRST INCIDENCE | 94 (T) | 94 (T) | --- | --- | --- | --- |

STATISTICAL TESTS

| | | | | | | |
|---------------------|----------|---------|-----|-----|-----|----------|
| LIFE TABLE | P=0.084N | P=0.305 | (e) | (e) | (e) | P=0.234N |
| POLY 3 | (e) | P=0.286 | (e) | (e) | (e) | P=0.227N |
| POLY 1.5 | (e) | P=0.286 | (e) | (e) | (e) | P=0.227N |
| POLY 6 | (e) | P=0.286 | (e) | (e) | (e) | P=0.227N |
| LOGISTIC REGRESSION | P=0.084N | P=0.305 | (e) | (e) | (e) | (e) |
| COCH-ARM / FISHERS | P=0.079N | P=0.273 | (e) | (e) | (e) | P=0.237N |
| ORDER RESTRICTED | (e) | (e) | (e) | (e) | (e) | (e) |
| MAX-ISO-POLY-3 | (e) | (e) | (e) | (e) | (e) | (e) |

TDMS No. 20006 - 02

Test Type: 90-DAY

Route: GAVAGE

Species/Strain: MICE/B6C3F1

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

INDOLE-3-CARBINOL

CAS Number: 700-06-1

Date Report Reqsted: 06/05/2007

Time Report Reqsted: 07:56:47

First Dose M/F: 09/01/04 / 09/02/04

Lab: SRI

LEGEND

- (a) Number of tumor-bearing animals/number of animals examined at site.
 - (b) Number of tumor-bearing animals/Poly-3 number
 - (d) Observed incidence at terminal kill.
 - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group. The life table analysis regards tumors in animals dying prior to terminal kill as being (directly or indirectly) the cause of death.
 - (e) Value of Statistic cannot be computed.
 - (g) Poly-3 adjusted lifetime tumor incidence.
 - (I) Interim sacrifice
 - (T) Terminal sacrifice
 - # Tumor rates based on numbers of animals necropsied.
 - * To the right of any statistical result, indicates significance at ($P \leq 0.05$).
 - ** To the right of any statistical result, indicates significance at ($P \leq 0.01$).
 - N Indicates a negative trend for all tests
- Logistic regression is an alternative method for analyzing the incidence of non-fatal tumors.
The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

*** END OF REPORT ***