

**TDMS No.** 20107 - 04  
**Test Type:** CHRONIC  
**Route:** GAVAGE  
**Species/Strain:** MICE/B6C3F1

**E05: CLINICAL OBSERVATIONS SUMMARY**

N,N-Dimethyl-p-toluidine

**CAS Number:** 99-97-8

**Date Report Requested:** 03/10/2011

**Time Report Requested:** 11:43:19

**First Dose M/F:** 10/26/04 / 10/25/04

**Lab:** BAT

**C Number:** C20107  
**Lock Date:** 02/26/2008  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 2.3.0  
**PWG Approval Date:** NONE

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 Lab: BAT

| SEX: MALE             |          | WEEK: 105         |         |                   |          |                   |          |                   |  |
|-----------------------|----------|-------------------|---------|-------------------|----------|-------------------|----------|-------------------|--|
| OBSERVATION           | 0 MG/KG  |                   | 6 MG/KG |                   | 20 MG/KG |                   | 60 MG/KG |                   |  |
|                       | CURRENT* | TOTAL+            | CURRENT | TOTAL             | CURRENT  | TOTAL             | CURRENT  | TOTAL             |  |
| Diarrhea              | 0 / 0    | 0/50              | 0 / 0   | 0/50              | 0 / 0    | 1 / 50<br>DAY 673 | 0 / 0    | 0/50              |  |
| Eye Abnormality       | 0 / 0    | 5 / 50<br>DAY 533 | 0 / 0   | 2 / 50<br>DAY 477 | 0 / 0    | 1 / 50<br>DAY 365 | 0 / 0    | 1 / 50<br>DAY 673 |  |
| Mass<br>Appendage     | 0 / 0    | 1 / 50<br>DAY 701 | 0 / 0   | 1 / 50<br>DAY 617 | 0 / 0    | 0/50              | 0 / 0    | 0/50              |  |
| Mass<br>Head          | 0 / 0    | 2 / 50<br>DAY 617 | 0 / 0   | 2 / 50<br>DAY 589 | 0 / 0    | 1 / 50<br>DAY 701 | 0 / 0    | 1 / 50<br>DAY 645 |  |
| Mass<br>Torso/Dorsal  | 0 / 0    | 0/50              | 0 / 0   | 0/50              | 0 / 0    | 1 / 50<br>DAY 561 | 0 / 0    | 0/50              |  |
| Mass<br>Torso/Ventral | 0 / 0    | 7 / 50<br>DAY 477 | 0 / 0   | 6 / 50<br>DAY 281 | 0 / 0    | 7 / 50<br>DAY 449 | 0 / 0    | 5 / 50<br>DAY 505 |  |
| Nasal/Eye Discharge   | 0 / 0    | 2 / 50<br>DAY 617 | 0 / 0   | 1 / 50<br>DAY 701 | 0 / 0    | 0/50              | 0 / 0    | 0/50              |  |
| Ruffled Fur           | 0 / 0    | 3 / 50<br>DAY 533 | 0 / 0   | 4 / 50<br>DAY 533 | 0 / 0    | 4 / 50<br>DAY 589 | 0 / 0    | 1 / 50<br>DAY 561 |  |

\* ANIMALS WITH OBSERVATION IN CURRENT PERIOD / TOTAL ANIMALS OBSERVED IN CURRENT PERIOD (WITHIN 30 DAYS OF RUN DATE)  
 + ROW 1 = CUMULATIVE NO. OF ANIMALS WITH OBSERVATION / TOTAL ANIMALS STARTED ON STUDY  
 ROW 2 = DAY OF ONSET

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Lab: BAT

| SEX: MALE                      |          | WEEK: 105         |         |                   |          |                   |          |                   |  |
|--------------------------------|----------|-------------------|---------|-------------------|----------|-------------------|----------|-------------------|--|
| OBSERVATION                    | 0 MG/KG  |                   | 6 MG/KG |                   | 20 MG/KG |                   | 60 MG/KG |                   |  |
|                                | CURRENT* | TOTAL+            | CURRENT | TOTAL             | CURRENT  | TOTAL             | CURRENT  | TOTAL             |  |
| Thin                           | 0 / 0    | 0/50              | 0 / 0   | 2 / 50<br>DAY 533 | 0 / 0    | 6 / 50<br>DAY 589 | 0 / 0    | 1 / 50<br>DAY 561 |  |
| Ulcer/Abscess<br>Head          | 0 / 0    | 3 / 50<br>DAY 85  | 0 / 0   | 1 / 50<br>DAY 85  | 0 / 0    | 1 / 50<br>DAY 617 | 0 / 0    | 1 / 50<br>DAY 673 |  |
| Ulcer/Abscess<br>Torso/Dorsal  | 0 / 0    | 1 / 50<br>DAY 645 | 0 / 0   | 0/50              | 0 / 0    | 1 / 50<br>DAY 561 | 0 / 0    | 1 / 50<br>DAY 673 |  |
| Ulcer/Abscess<br>Torso/Lateral | 0 / 0    | 0/50              | 0 / 0   | 0/50              | 0 / 0    | 0/50              | 0 / 0    | 1 / 50<br>DAY 673 |  |
| Ulcer/Abscess<br>Torso/Ventral | 0 / 0    | 0/50              | 0 / 0   | 2 / 50<br>DAY 505 | 0 / 0    | 0/50              | 0 / 0    | 0/50              |  |

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

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First Dose M/F: 10/26/04 / 10/25/04

Lab: BAT

| SEX: FEMALE           |          | WEEK: 105         |         |                   |          |                   |          |                   |  |
|-----------------------|----------|-------------------|---------|-------------------|----------|-------------------|----------|-------------------|--|
| OBSERVATION           | 0 MG/KG  |                   | 6 MG/KG |                   | 20 MG/KG |                   | 60 MG/KG |                   |  |
|                       | CURRENT* | TOTAL+            | CURRENT | TOTAL             | CURRENT  | TOTAL             | CURRENT  | TOTAL             |  |
| Abnormal Breathing    | 0 / 0    | 0/50              | 0 / 0   | 0/50              | 0 / 0    | 0/50              | 0 / 0    | 1 / 50<br>DAY 645 |  |
| Diarrhea              | 0 / 0    | 0/50              | 0 / 0   | 2 / 50<br>DAY 505 | 0 / 0    | 2 / 50<br>DAY 505 | 0 / 0    | 0/50              |  |
| Eye Abnormality       | 0 / 0    | 0/50              | 0 / 0   | 0/50              | 0 / 0    | 1 / 50<br>DAY 477 | 0 / 0    | 1 / 50<br>DAY 505 |  |
| Mass<br>Appendage     | 0 / 0    | 1 / 50<br>DAY 617 | 0 / 0   | 1 / 50<br>DAY 505 | 0 / 0    | 2 / 50<br>DAY 505 | 0 / 0    | 0/50              |  |
| Mass<br>Head          | 0 / 0    | 0/50              | 0 / 0   | 0/50              | 0 / 0    | 2 / 50<br>DAY 645 | 0 / 0    | 1 / 50<br>DAY 645 |  |
| Mass<br>Torso/Dorsal  | 0 / 0    | 0/50              | 0 / 0   | 0/50              | 0 / 0    | 0/50              | 0 / 0    | 1 / 50<br>DAY 701 |  |
| Mass<br>Torso/Lateral | 0 / 0    | 1 / 50<br>DAY 645 | 0 / 0   | 1 / 50<br>DAY 701 | 0 / 0    | 1 / 50<br>DAY 701 | 0 / 0    | 0/50              |  |
| Mass<br>Torso/Ventral | 0 / 0    | 1 / 50<br>DAY 477 | 0 / 0   | 1 / 50<br>DAY 645 | 0 / 0    | 1 / 50<br>DAY 645 | 0 / 0    | 0/50              |  |

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|--------------------------------|-----------|-------------------|---------|-------------------|----------|-------------------|----------|-------------------|
|                                | 0 MG/KG   |                   | 6 MG/KG |                   | 20 MG/KG |                   | 60 MG/KG |                   |
|                                | CURRENT*  | TOTAL+            | CURRENT | TOTAL             | CURRENT  | TOTAL             | CURRENT  | TOTAL             |
| Nasal/Eye Discharge            | 0 / 0     | 0/50              | 0 / 0   | 0/50              | 0 / 0    | 0/50              | 0 / 0    | 1 / 50<br>DAY 673 |
| Ruffled Fur                    | 0 / 0     | 0/50              | 0 / 0   | 0/50              | 0 / 0    | 0/50              | 0 / 0    | 2 / 50<br>DAY 589 |
| Thin                           | 0 / 0     | 1 / 50<br>DAY 645 | 0 / 0   | 0/50              | 0 / 0    | 1 / 50<br>DAY 449 | 0 / 0    | 2 / 50<br>DAY 617 |
| Ulcer/Abscess<br>Appendage     | 0 / 0     | 0/50              | 0 / 0   | 1 / 50<br>DAY 701 | 0 / 0    | 0/50              | 0 / 0    | 0/50              |
| Ulcer/Abscess<br>Torso/Dorsal  | 0 / 0     | 0/50              | 0 / 0   | 1 / 50<br>DAY 673 | 0 / 0    | 4 / 50<br>DAY 477 | 0 / 0    | 1 / 50<br>DAY 477 |
| Ulcer/Abscess<br>Torso/Lateral | 0 / 0     | 0/50              | 0 / 0   | 1 / 50<br>DAY 701 | 0 / 0    | 1 / 50<br>DAY 701 | 0 / 0    | 0/50              |
| Ulcer/Abscess<br>Torso/Ventral | 0 / 0     | 0/50              | 0 / 0   | 0/50              | 0 / 0    | 1 / 50<br>DAY 701 | 0 / 0    | 0/50              |

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

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