

**TDMS No.** 20008 - 04  
**Test Type:** CHRONIC  
**Route:** DOSED FEED  
**Species/Strain:** MICE/B6C3F1

**E05: CLINICAL OBSERVATIONS SUMMARY**

Milk thistle extract  
**CAS Number:** 84604-20-6

**Date Report Requested:** 09/30/2008  
**Time Report Requested:** 13:16:42  
**First Dose M/F:** 03/25/03 / 03/25/03  
**Lab:** SRI

**C Number:** C20008  
**Lock Date:** 06/29/2006  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 2.0.0

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| OBSERVATION                           | 0 PPM            |                   | 12500 PPM |                   | 25000 PPM |                   | 50000 PPM |                   |
|---------------------------------------|------------------|-------------------|-----------|-------------------|-----------|-------------------|-----------|-------------------|
|                                       | CURRENT*         | TOTAL+            | CURRENT   | TOTAL             | CURRENT   | TOTAL             | CURRENT   | TOTAL             |
|                                       | <b>SEX:</b> MALE | <b>WEEK:</b> 105  |           |                   |           |                   |           |                   |
| <b>Eye Abnormality</b>                | 0 / 0            | 3 / 50<br>DAY 562 | 0 / 0     | 3 / 50<br>DAY 478 | 0 / 0     | 3 / 50<br>DAY 590 | 0 / 0     | 1 / 50<br>DAY 590 |
| <b>Mass</b><br>Torso/Ventral          | 0 / 0            | 0 / 50            | 0 / 0     | 0 / 50            | 0 / 0     | 0 / 50            | 0 / 0     | 2 / 50<br>DAY 534 |
| <b>Mass</b><br>Appendage              | 0 / 0            | 4 / 50<br>DAY 366 | 0 / 0     | 2 / 50<br>DAY 506 | 0 / 0     | 0 / 50            | 0 / 0     | 0 / 50            |
| <b>Mass</b><br>Head                   | 0 / 0            | 3 / 50<br>DAY 534 | 0 / 0     | 3 / 50<br>DAY 58  | 0 / 0     | 2 / 50<br>DAY 478 | 0 / 0     | 0 / 50            |
| <b>Nasal/Eye Discharge</b>            | 0 / 0            | 2 / 50<br>DAY 534 | 0 / 0     | 3 / 50<br>DAY 478 | 0 / 0     | 3 / 50<br>DAY 590 | 0 / 0     | 0 / 50            |
| <b>Ulcer/Abscess</b><br>Appendage     | 0 / 0            | 2 / 50<br>DAY 590 | 0 / 0     | 0 / 50            | 0 / 0     | 0 / 50            | 0 / 0     | 0 / 50            |
| <b>Ulcer/Abscess</b><br>Torso/Ventral | 0 / 0            | 0 / 50            | 0 / 0     | 0 / 50            | 0 / 0     | 1 / 50<br>DAY 590 | 0 / 0     | 1 / 50<br>DAY 590 |

\* 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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**SEX:** MALE

**WEEK:** 105

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

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| SEX: FEMALE           |          | WEEK: 105         |           |                   |           |                   |           |                   |  |
|-----------------------|----------|-------------------|-----------|-------------------|-----------|-------------------|-----------|-------------------|--|
| OBSERVATION           | 0 PPM    |                   | 12500 PPM |                   | 25000 PPM |                   | 50000 PPM |                   |  |
|                       | CURRENT* | TOTAL+            | CURRENT   | TOTAL             | CURRENT   | TOTAL             | CURRENT   | TOTAL             |  |
| Abnormal Breathing    | 0 / 0    | 0/50              | 0 / 0     | 1 / 50<br>DAY 449 | 0 / 0     | 0/50              | 0 / 0     | 0/50              |  |
| Eye Abnormality       | 0 / 0    | 2 / 50<br>DAY 589 | 0 / 0     | 1 / 50<br>DAY 477 | 0 / 0     | 1 / 50<br>DAY 589 | 0 / 0     | 0/50              |  |
| Head Tilt             | 0 / 0    | 3 / 50<br>DAY 589 | 0 / 0     | 1 / 50<br>DAY 645 | 0 / 0     | 1 / 50<br>DAY 645 | 0 / 0     | 0/50              |  |
| Lethargic             | 0 / 0    | 0/50              | 0 / 0     | 0/50              | 0 / 0     | 1 / 50<br>DAY 645 | 0 / 0     | 0/50              |  |
| Mass<br>Torso/Ventral | 0 / 0    | 1 / 50<br>DAY 533 | 0 / 0     | 0/50              | 0 / 0     | 1 / 50<br>DAY 645 | 0 / 0     | 1 / 50<br>DAY 645 |  |
| Mass<br>Torso/Dorsal  | 0 / 0    | 1 / 50<br>DAY 673 | 0 / 0     | 0/50              | 0 / 0     | 1 / 50<br>DAY 701 | 0 / 0     | 1 / 50<br>DAY 617 |  |
| Mass<br>Head          | 0 / 0    | 2 / 50<br>DAY 617 | 0 / 0     | 1 / 50<br>DAY 589 | 0 / 0     | 2 / 50<br>DAY 589 | 0 / 0     | 0/50              |  |
| Mass<br>Torso/Lateral | 0 / 0    | 0/50              | 0 / 0     | 2 / 50<br>DAY 533 | 0 / 0     | 0/50              | 0 / 0     | 1 / 50<br>DAY 673 |  |

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| OBSERVATION                           | 0 PPM                      |                   | 12500 PPM         |                   | 25000 PPM         |                   | 50000 PPM         |        |
|---------------------------------------|----------------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|--------|
|                                       | CURRENT*                   | TOTAL+            | CURRENT           | TOTAL             | CURRENT           | TOTAL             | CURRENT           | TOTAL  |
|                                       | <b>Nasal/Eye Discharge</b> | 0 / 0             | 2 / 50<br>DAY 589 | 0 / 0             | 1 / 50<br>DAY 505 | 0 / 0             | 3 / 50<br>DAY 589 | 0 / 0  |
| <b>Ruffled Fur</b>                    | 0 / 0                      | 0 / 50            | 0 / 0             | 0 / 50            | 0 / 0             | 1 / 50<br>DAY 673 | 0 / 0             | 0 / 50 |
| <b>Thin</b>                           | 0 / 0                      | 2 / 50<br>DAY 533 | 0 / 0             | 3 / 50<br>DAY 57  | 0 / 0             | 1 / 50<br>DAY 477 | 0 / 0             | 0 / 50 |
| <b>Ulcer/Abscess</b><br>Torso/Ventral | 0 / 0                      | 0 / 50            | 0 / 0             | 0 / 50            | 0 / 0             | 1 / 50<br>DAY 673 | 0 / 0             | 0 / 50 |
| <b>Ulcer/Abscess</b><br>Torso/Dorsal  | 0 / 0                      | 1 / 50<br>DAY 673 | 0 / 0             | 0 / 50            | 0 / 0             | 0 / 50            | 0 / 0             | 0 / 50 |
| <b>Ulcer/Abscess</b><br>Torso/Lateral | 0 / 0                      | 0 / 50            | 0 / 0             | 1 / 50<br>DAY 673 | 0 / 0             | 0 / 50            | 0 / 0             | 0 / 50 |

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**SEX:** FEMALE

**WEEK:** 105

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