

**TDMS No.** 20008 - 03  
**Test Type:** CHRONIC  
**Route:** DOSED FEED  
**Species/Strain:** RATS/F 344/N

**E05: CLINICAL OBSERVATIONS SUMMARY**

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

**Date Report Requested:** 10/09/2008  
**Time Report Requested:** 11:00:21  
**First Dose M/F:** 03/04/03 / 03/04/03  
**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

SEX: MALE		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 DAY 646	0 / 0	1 / 50 DAY 86	0 / 0	0 / 50	
Ataxia	0 / 0	1 / 50 DAY 590	0 / 0	0 / 50	0 / 0	0 / 50	0 / 0	0 / 50	
Eye Abnormality	0 / 0	5 / 50 DAY 254	0 / 0	2 / 50 DAY 394	0 / 0	2 / 50 DAY 86	0 / 0	4 / 50 DAY 310	
Head Tilt	0 / 0	5 / 50 DAY 254	0 / 0	2 / 50 DAY 450	0 / 0	2 / 50 DAY 170	0 / 0	4 / 50 DAY 422	
Lethargic	0 / 0	2 / 50 DAY 590	0 / 0	2 / 50 DAY 590	0 / 0	2 / 50 DAY 310	0 / 0	0 / 50	
Mass Torso/Ventral	0 / 0	5 / 50 DAY 394	0 / 0	7 / 50 DAY 506	0 / 0	3 / 50 DAY 618	0 / 0	1 / 50 DAY 702	
Mass Torso/Dorsal	0 / 0	5 / 50 DAY 450	0 / 0	4 / 50 DAY 618	0 / 0	0 / 50	0 / 0	2 / 50 DAY 618	
Mass Torso/Lateral	0 / 0	3 / 50 DAY 590	0 / 0	2 / 50 DAY 646	0 / 0	2 / 50 DAY 254	0 / 0	1 / 50 DAY 674	

\* 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

OBSERVATION	0 PPM		12500 PPM		25000 PPM		50000 PPM	
	CURRENT*	TOTAL+	CURRENT	TOTAL	CURRENT	TOTAL	CURRENT	TOTAL
	SEX: MALE	WEEK: 105						
Mass Head	0 / 0	1 / 50 DAY 590	0 / 0	1 / 50 DAY 590	0 / 0	0 / 50	0 / 0	1 / 50 DAY 534
Mass Appendage	0 / 0	4 / 50 DAY 310	0 / 0	2 / 50 DAY 618	0 / 0	1 / 50 DAY 590	0 / 0	1 / 50 DAY 618
Nasal/Eye Discharge	0 / 0	12 / 50 DAY 394	0 / 0	9 / 50 DAY 86	0 / 0	5 / 50 DAY 86	0 / 0	11 / 50 DAY 282
Paralysis	0 / 0	0 / 50	0 / 0	1 / 50 DAY 702	0 / 0	0 / 50	0 / 0	0 / 50
Ruffled Fur	0 / 0	0 / 50	0 / 0	2 / 50 DAY 366	0 / 0	0 / 50	0 / 0	0 / 50
Thin	0 / 0	4 / 50 DAY 590	0 / 0	6 / 50 DAY 562	0 / 0	5 / 50 DAY 86	0 / 0	1 / 50 DAY 702
Ulcer/Abscess Torso/Dorsal	0 / 0	5 / 50 DAY 450	0 / 0	1 / 50 DAY 674	0 / 0	0 / 50	0 / 0	2 / 50 DAY 618
Ulcer/Abscess Torso/Ventral	0 / 0	5 / 50 DAY 394	0 / 0	3 / 50 DAY 590	0 / 0	1 / 50 DAY 618	0 / 0	0 / 50

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	CURRENT*	TOTAL+	CURRENT	TOTAL	CURRENT	TOTAL	CURRENT	TOTAL
	SEX: MALE	WEEK: 105						
Ulcer/Abscess Torso/Lateral	0 / 0	3 / 50 DAY 562	0 / 0	0 / 50	0 / 0	1 / 50 DAY 282	0 / 0	0 / 50
Ulcer/Abscess Head	0 / 0	1 / 50 DAY 702	0 / 0	0 / 50	0 / 0	0 / 50	0 / 0	1 / 50 DAY 534
Ulcer/Abscess Appendage	0 / 0	2 / 50 DAY 338	0 / 0	1 / 50 DAY 618	0 / 0	2 / 50 DAY 366	0 / 0	1 / 50 DAY 394

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**SEX:** MALE

**WEEK:** 105

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

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	0/50	0 / 0	1 / 50 DAY 31	0 / 0	0/50
Ataxia	0 / 0	0/50	0 / 0	0/50	0 / 0	1 / 50 DAY 451	0 / 0	0/50
Eye Abnormality	0 / 0	0/50	0 / 0	4 / 50 DAY 59	0 / 0	3 / 50 DAY 59	0 / 0	4 / 50 DAY 171
Head Tilt	0 / 0	0/50	0 / 0	5 / 50 DAY 87	0 / 0	4 / 50 DAY 115	0 / 0	3 / 50 DAY 171
Impaired Gait	0 / 0	0/50	0 / 0	0/50	0 / 0	1 / 50 DAY 451	0 / 0	0/50
Lethargic	0 / 0	0/50	0 / 0	0/50	0 / 0	2 / 50 DAY 563	0 / 0	3 / 50 DAY 647
Mass Torso/Ventral	0 / 0	11 / 50 DAY 479	0 / 0	11 / 50 DAY 479	0 / 0	10 / 50 DAY 339	0 / 0	9 / 50 DAY 423
Mass Torso/Dorsal	0 / 0	0/50	0 / 0	2 / 50 DAY 535	0 / 0	2 / 50 DAY 451	0 / 0	0/50

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ROW 2 = DAY OF ONSET

SEX: FEMALE

WEEK: 105

OBSERVATION	0 PPM		12500 PPM		25000 PPM		50000 PPM	
	CURRENT*	TOTAL+	CURRENT	TOTAL	CURRENT	TOTAL	CURRENT	TOTAL
<b>Mass</b> Torso/Lateral	0 / 0	7 / 50 DAY 619	0 / 0	5 / 50 DAY 479	0 / 0	4 / 50 DAY 255	0 / 0	5 / 50 DAY 367
<b>Mass</b> Head	0 / 0	1 / 50 DAY 675	0 / 0	0 / 50	0 / 0	3 / 50 DAY 647	0 / 0	0 / 50
<b>Mass</b> Appendage	0 / 0	0 / 50	0 / 0	0 / 50	0 / 0	0 / 50	0 / 0	1 / 50 DAY 423
<b>Nasal/Eye Discharge</b>	0 / 0	13 / 50 DAY 87	0 / 0	21 / 50 DAY 87	0 / 0	10 / 50 DAY 87	0 / 0	16 / 50 DAY 59
<b>Ruffled Fur</b>	0 / 0	0 / 50	0 / 0	1 / 50 DAY 535	0 / 0	0 / 50	0 / 0	0 / 50
<b>Thin</b>	0 / 0	0 / 50	0 / 0	2 / 50 DAY 591	0 / 0	7 / 50 DAY 31	0 / 0	5 / 50 DAY 143
<b>Ulcer/Abscess</b> Torso/Dorsal	0 / 0	0 / 50	0 / 0	0 / 50	0 / 0	1 / 50 DAY 647	0 / 0	0 / 50
<b>Ulcer/Abscess</b> Torso/Ventral	0 / 0	1 / 50 DAY 479	0 / 0	1 / 50 DAY 647	0 / 0	2 / 50 DAY 367	0 / 0	0 / 50

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	CURRENT*	TOTAL+	CURRENT	TOTAL	CURRENT	TOTAL	CURRENT	TOTAL
Ulcer/Abscess Head	0 / 0	0/50	0 / 0	0/50	0 / 0	3 / 50 DAY 675	0 / 0	0/50
Ulcer/Abscess Appendage	0 / 0	0/50	0 / 0	0/50	0 / 0	0/50	0 / 0	1 / 50 DAY 507

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