Test Type: 26-WEEK

Route: DOSED FEED

### P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

Chitosan

**CAS Number:** 9012-76-4

Species/Strain: RATS/SD

**3 Number:** 9012-76-4

Lab: BAT

Date Report Requested: 05/28/2009

Time Report Requested: 08:46:11

First Dose M/F: 08/31/06 / 09/01/06

F1\_R8

**C Number:** C20226

**Lock Date:** 05/07/2008

Cage Range: ALL

Date Range: ALL

**Reasons For Removal:** ALL

Removal Date Range: ALL

Treatment Groups: Include ALL

Study Gender: Both

**TDMSE Version:** 2.1.0

Test Type: 26-WEEK

Route: DOSED FEED

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Chitosan

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First Dose M/F: 08/31/06 / 09/01/06

Species/Strain: RATS/SD

| SPRAGUE-DAWLEY RATS MALE  | 0 %                          | 1 %                       | 3 %                       | 9 %                          |  |
|---|------------------------------|---------------------------|---------------------------|------------------------------|--|
| Disposition Summary   |                              |                           |                           |                              |  |
| Animals Initially in Study<br>Early Deaths                              | 10                           | 10                        | 10                        | 10                           |  |
| Survivors<br>Terminal Sacrifice<br>Animals Examined Microscopically     | 10<br>10                     | 10<br>10                  | 10<br>10                  | 10<br>10                     |  |
| ALIMENTARY SYSTEM   |                              |                           |                           |                              |  |
| Liver<br>Pancreas<br>Stomach, Forestomach                               | (10)<br>(10)<br>(10)         | (10)<br>(0)<br>(0)        | (10)<br>(0)<br>(0)        | (10)<br>(10)<br>(10)         |  |
| CARDIOVASCULAR SYSTEM   |                              |                           |                           |                              |  |
| Blood Vessel<br>Heart   | (10)<br>(10)                 | (0)<br>(0)                | (0)<br>(0)                | (10)<br>(10)                 |  |
| ENDOCRINE SYSTEM  |                              |                           |                           |                              |  |
| Adrenal Cortex<br>Parathyroid Gland<br>Pituitary Gland<br>Thyroid Gland | (10)<br>(10)<br>(10)<br>(10) | (1)<br>(10)<br>(0)<br>(0) | (0)<br>(10)<br>(0)<br>(0) | (10)<br>(10)<br>(10)<br>(10) |  |
| GENERAL BODY SYSTEM   |                              |                           |                           |                              |  |
| None  |                              |                           |                           |                              |  |
| GENITAL SYSTEM  |                              |                           |                           |                              |  |
| Preputial Gland<br>Prostate<br>Testes                                   | (10)<br>(10)<br>(10)         | (0)<br>(10)<br>(0)        | (0)<br>(10)<br>(0)        | (10)<br>(10)<br>(10)         |  |

a - Number of animals examined microscopically at site and number of animals with lesion

Test Type: 26-WEEK

Route: DOSED FEED
Species/Strain: RATS/SD

# P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)

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Date Report Requested: 05/28/2009

Lab: BAT

| SPRAGUE-DAWLEY RATS MALE             | 0 %                  | 1 %               | 3 %               | 9 %                  |  |
|--------------------------------------|----------------------|-------------------|-------------------|----------------------|--|
| HEMATOPOIETIC SYSTEM                 |                      |                   |                   |                      |  |
| Lymph Node, Mandibular Spleen Thymus | (10)<br>(10)<br>(10) | (0)<br>(0)<br>(0) | (0)<br>(0)<br>(0) | (10)<br>(10)<br>(10) |  |
| INTEGUMENTARY SYSTEM                 |                      |                   |                   |                      |  |
| Skin                                 | (10)                 | (0)               | (0)               | (10)                 |  |
| MUSCULOSKELETAL SYSTEM               |                      |                   |                   |                      |  |
| Skeletal Muscle                      | (0)                  | (0)               | (0)               | (1)                  |  |
| NERVOUS SYSTEM                       |                      |                   |                   |                      |  |
| None                                 |                      |                   |                   |                      |  |
| RESPIRATORY SYSTEM                   |                      |                   |                   |                      |  |
| Lung<br>Nose                         | (10)<br>(10)         | (0)<br>(0)        | (0)<br>(0)        | (10)<br>(10)         |  |
| SPECIAL SENSES SYSTEM                |                      |                   |                   |                      |  |
| Eye<br>Harderian Gland               | (10)<br>(10)         | (1)<br>(0)        | (0)<br>(0)        | (10)<br>(10)         |  |
| URINARY SYSTEM                       |                      |                   |                   |                      |  |
| Kidney<br>Urinary Bladder            | (10)<br>(10)         | (10)<br>(0)       | (10)<br>(0)       | (10)<br>(10)         |  |

a - Number of animals examined microscopically at site and number of animals with lesion

Test Type: 26-WEEK

Route: DOSED FEED Species/Strain: RATS/SD

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Lab: BAT

SPRAGUE-DAWLEY RATS MALE

0 %

1 %

3 %

9 %

### **Tumor Summary for Males**

Total Animals with Primary Neoplasms (b)
Total Primary Neoplasms

Total Animals with Benign Neoplasms

Total Benign Neoplasms

Total Animals with Malignant Neoplasms

**Total Malignant Neoplasms** 

Total Animals with Metastatic Neoplasms Total Metastatic Neoplasms

Total Animals with Malignant

Total Animals with Malignant Neoplasms Uncertain Primary Site

Total Animals with Neoplasms Uncertain-Benign or Malignant Total Uncertain Neoplasms

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

a - Number of animals examined microscopically at site and number of animals with lesion

b - Primary tumors: all tumors except metastatic tumors

Test Type: 26-WEEK

Route: DOSED FEED
Species/Strain: RATS/SD

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Lab: BAT

| SPRAGUE-DAWLEY RATS FEMALE                                    | 0 %          | 1 %         | 3 %         | 9 %          |  |
|---|--------------|-------------|-------------|--------------|--|
| Disposition Summary   |              |             |             |              |  |
| Animals Initially in Study<br>Early Deaths                    | 10           | 10          | 10          | 10           |  |
| Survivors Terminal Sacrifice Animals Examined Microscopically | 10<br>10     | 10<br>10    | 10<br>10    | 10<br>10     |  |
| ALIMENTARY SYSTEM   |              |             |             |              |  |
| Liver<br>Pancreas   | (10)<br>(10) | (10)<br>(0) | (10)<br>(0) | (10)<br>(10) |  |
| CARDIOVASCULAR SYSTEM   |              |             |             |              |  |
| Heart   | (10)         | (0)         | (0)         | (10)         |  |
| ENDOCRINE SYSTEM  |              |             |             |              |  |
| Pituitary Gland   | (10)         | (0)         | (0)         | (10)         |  |
| GENERAL BODY SYSTEM   |              |             |             |              |  |
| None  |              |             |             |              |  |
| GENITAL SYSTEM  |              |             |             |              |  |
| Clitoral Gland  | (10)         | (0)         | (0)         | (10)         |  |
| HEMATOPOIETIC SYSTEM  |              |             |             |              |  |
| Spleen<br>Thymus  | (10)<br>(10) | (0)<br>(0)  | (0)<br>(0)  | (10)<br>(10) |  |

#### **INTEGUMENTARY SYSTEM**

a - Number of animals examined microscopically at site and number of animals with lesion

Test Type: 26-WEEK

Route: DOSED FEED
Species/Strain: RATS/SD

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Lab: BAT

| SPRAGUE-DAWLEY RATS FEMALE             | 0 %          | 1 %        | 3 %        | 9 %             |  |
|--|--------------|------------|------------|-----------------|--|
| Mammary Gland<br>Adenoma               | (10)         | (0)        | (0)        | (10)<br>1 (10%) |  |
| MUSCULOSKELETAL SYSTEM                 |              |            |            |                 |  |
| None                                   |              |            |            |                 |  |
| NERVOUS SYSTEM                         |              |            |            |                 |  |
| Brain                                  | (10)         | (0)        | (0)        | (10)            |  |
| RESPIRATORY SYSTEM                     |              |            |            |                 |  |
| Lung<br>Nose                           | (10)<br>(10) | (0)<br>(0) | (0)<br>(0) | (10)<br>(10)    |  |
|  |              |            | . ,        | . ,             |  |
| SPECIAL SENSES SYSTEM  Harderian Gland | (10)         | (0)        | (0)        | (10)            |  |
|  | (10)         | (0)        | (0)        | (10)            |  |
| URINARY SYSTEM                         |              |            |            |                 |  |
| Kidney                                 | (10)         | (10)       | (10)       | (10)            |  |

a - Number of animals examined microscopically at site and number of animals with lesion

Test Type: 26-WEEK

Route: DOSED FEED
Species/Strain: RATS/SD

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Lab: BAT

| SPRAGUE-DAWLEY RATS FEMALE                                       | 0 % | 1 % | 3 % | 9 % |  |
|--|-----|-----|-----|-----|--|
| umor Summary for Females   |     |     |     |     |  |
| Total Animals with Primary Neoplasms (b)                         |     |     |     | 1   |  |
| Total Primary Neoplasms  |     |     |     | 1   |  |
| Total Animals with Benign Neoplasms                              |     |     |     | 1   |  |
| Total Benign Neoplasms   |     |     |     | 1   |  |
| Total Animals with Malignant<br>Neoplasms                        |     |     |     |     |  |
| Total Malignant Neoplasms  |     |     |     |     |  |
| Total Animals with Metastatic<br>Neoplasms                       |     |     |     |     |  |
| Total Metastatic Neoplasms                                       |     |     |     |     |  |
| Total Animals with Malignant<br>Neoplasms Uncertain Primary Site |     |     |     |     |  |
| Total Animals with Neoplasms<br>Uncertain-Benign or Malignant    |     |     |     |     |  |
| Total Uncertain Neoplasms  |     |     |     |     |  |

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

a - Number of animals examined microscopically at site and number of animals with lesion

b - Primary tumors: all tumors except metastatic tumors