

**APPENDIX B**  
**SUMMARY OF LESIONS IN FEMALE RATS**  
**IN THE 2-YEAR FEED STUDY**  
**OF FUMONISIN B<sub>1</sub>**

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**TABLE B1****Summary of the Incidence of Neoplasms in Female Rats in the 2-Year Feed Study of Fumonisin B<sub>1</sub><sup>a</sup>**

	<b>0 ppm</b>	<b>5 ppm</b>	<b>15 ppm</b>	<b>50 ppm</b>	<b>100 ppm</b>
<b>Disposition Summary</b>					
6-Week evaluation	4	4	4	4	4
10-Week evaluation	4	4	4	4	4
14-Week evaluation	4	4	4	4	4
26-Week evaluation	4	4	4	4	4
Animals initially in 2-year study	48	40	48	48	48
Early deaths					
Removed from study	1	2		2	
Moribund	20	15	23	16	16
Natural deaths	2	1	1		3
Survivors					
Terminal sacrifice	25	22	24	30	29
Animals examined microscopically	64	56	64	64	64

**Tissues Examined at 6 Weeks with No Neoplasms Observed**Kidney  
Liver**Tissues Examined at 10 Weeks with No Neoplasms Observed**Kidney  
Liver  
Mesentery  
Ovary**Tissues Examined at 14 Weeks with No Neoplasms Observed**Intestine large  
Kidney  
Liver  
Ovary  
Uterus**Tissues Examined at 26 Weeks with No Neoplasms Observed**Kidney  
Liver  
Ovary  
Uterus**2-Year Study**

Adrenal gland	(48)	(20)	(24)	(19)	(47)
Adenoma, cortex	1 (2%)				1 (2%)
Leukemia monuc	5 (10%)	2 (10%)	8 (33%)	2 (11%)	6 (13%)
Osteosarc, metastatic, bone	1 (2%)				
Pheochrom bgn, medulla	2 (4%)		1 (4%)	1 (5%)	2 (4%)
Bone	(48)	(18)	(24)	(18)	(48)
Sarcoma, maxilla				1 (6%)	

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**Summary of the Incidence of Neoplasms in Female Rats in the 2-Year Feed Study of Fumonisins B<sub>1</sub>**

	<b>0 ppm</b>	<b>5 ppm</b>	<b>15 ppm</b>	<b>50 ppm</b>	<b>100 ppm</b>
<b>2-Year Study (continued)</b>					
Bone, femur	(48)	(18)	(24)	(18)	(48)
Osteosarc	1 (2%)				
Bone marrow	(46)	(18)	(23)	(18)	(48)
Leukemia monuc	6 (13%)	6 (33%)	10 (43%)	5 (28%)	10 (21%)
Brain	(48)	(18)	(24)	(18)	(48)
Carcinoma, metastatic, pituitary gland					1 (2%)
Leukemia monuc		1 (6%)	1 (4%)		1 (2%)
Brain, cerebrum	(48)	(18)	(24)	(18)	(48)
Astrocyto mal	1 (2%)				
Meningioma mal					1 (2%)
Clitoral gland	(41)	(19)	(25)	(22)	(40)
Adenoma	9 (22%)	2 (11%)	7 (28%)	6 (27%)	8 (20%)
Adenoma, bilateral	1 (2%)		2 (8%)		2 (5%)
Carcinoma	1 (2%)				1 (3%)
Leukemia monuc	1 (2%)	1 (5%)	1 (4%)		
Esophagus	(48)	(18)	(23)	(17)	(48)
Leukemia monuc			1 (4%)		
Osteosarc, metastatic, bone	1 (2%)				
Harderian gland	(48)	(18)	(24)	(18)	(48)
Leukemia monuc			1 (4%)		1 (2%)
Heart	(48)	(18)	(24)	(18)	(48)
Alv bron carc, metastatic, lung					1 (2%)
Leukemia monuc	3 (6%)	1 (6%)	6 (25%)	2 (11%)	5 (10%)
Mesothelio mal, metastatic, unc pri site	1 (2%)				
Intestine large, cecum	(47)	(16)	(24)	(16)	(47)
Leukemia monuc			1 (4%)		
Intestine large, colon	(47)	(18)	(24)	(18)	(47)
Leukemia monuc			1 (4%)		
Intestine large, rectum	(47)	(18)	(24)	(18)	(48)
Histiocytoma, metastatic, skin					1 (2%)
Leukemia monuc			1 (4%)		
Schwannoma mal, metastatic, uterus			1 (4%)		
Intestine small, duodenum	(47)	(18)	(24)	(18)	(48)
Leiomyosar				1 (6%)	
Leukemia monuc			1 (4%)		
Intestine small, ileum	(44)	(18)	(24)	(18)	(46)
Leukemia monuc			2 (8%)		
Intestine small, jejunum	(47)	(18)	(24)	(18)	(46)
Leukemia monuc			1 (4%)		
Kidney	(48)	(40)	(48)	(48)	(48)
Adenoma, renal tubule				1 (2%)	
Carcinoma, renal tubule					1 (2%)
Leukemia monuc	2 (4%)	1 (3%)	6 (13%)	3 (6%)	5 (10%)
Lacrimal gland	(47)	(22)	(26)	(19)	(48)
Leukemia monuc	2 (4%)		3 (12%)		6 (13%)
Liver	(48)	(40)	(48)	(48)	(48)
Hepatocell aden			1 (2%)		
Histiocytoma, metastatic, skin					1 (2%)
Leukemia monuc	12 (25%)	13 (33%)	15 (31%)	8 (17%)	16 (33%)
Lung	(47)	(40)	(48)	(48)	(48)
Alv bron aden		1 (3%)		1 (2%)	2 (4%)
Alv bron carc					1 (2%)
Histiocytoma, metastatic, skin					1 (2%)
Leukemia monuc	8 (17%)	10 (25%)	11 (23%)	6 (13%)	6 (13%)
Osteosarc, metastatic, bone	1 (2%)				

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	<b>0 ppm</b>	<b>5 ppm</b>	<b>15 ppm</b>	<b>50 ppm</b>	<b>100 ppm</b>
<b>2-Year Study (continued)</b>					
Lung, bronchus	(47)	(40)	(48)	(48)	(48)
Carcinoma			1 (2%)		
Lymph node	(48)	(20)	(25)	(18)	(48)
Leukemia monuc	1 (2%)			1 (6%)	
Leukemia monuc, inguinal		1 (5%)			
Leukemia monuc, pancreatic			1 (4%)		
Leukemia monuc, renal	1 (2%)				
Leukemia monuc, thoracic				1 (6%)	
Lymph node, mandibular	(48)	(17)	(24)	(17)	(48)
Leukemia monuc	9 (19%)	5 (29%)	8 (33%)	4 (24%)	10 (21%)
Lymph node, mesenteric	(48)	(19)	(25)	(18)	(48)
Leukemia monuc	8 (17%)	5 (26%)	10 (40%)	4 (22%)	7 (15%)
Mammary gland	(47)	(28)	(33)	(30)	(48)
Adenoma	1 (2%)		1 (3%)		
Carcinoma	2 (4%)	3 (11%)	3 (9%)		3 (6%)
Carcinoma, multiple			1 (3%)		
Fibroadenoma	15 (32%)	11 (39%)	12 (36%)	11 (37%)	8 (17%)
Fibroadenoma, multiple	3 (6%)	2 (7%)	4 (12%)	5 (17%)	3 (6%)
Fibroma	1 (2%)				
Leukemia monuc		1 (4%)	1 (3%)		
Mesentery	(2)	(5)	(5)	(3)	(2)
Leukemia monuc	1 (50%)	1 (20%)	1 (20%)		
Ovary	(47)	(19)	(25)	(22)	(47)
Gra cl tum bgn	2 (4%)				
Leukemia monuc	1 (2%)	1 (5%)	3 (12%)		
Pancreas	(48)	(18)	(24)	(18)	(48)
Leukemia monuc	1 (2%)	1 (6%)	6 (25%)	1 (6%)	
Pituitary gland	(47)	(30)	(35)	(34)	(48)
Adenoma, pars distalis	32 (68%)	20 (67%)	25 (71%)	23 (68%)	29 (60%)
Adenoma, pars intermed				1 (3%)	
Carcinoma, pars distalis					1 (2%)
Leukemia monuc	1 (2%)	3 (10%)	4 (11%)	2 (6%)	
Salivary glands	(48)	(18)	(25)	(18)	(48)
Leukemia monuc		1 (6%)	2 (8%)		
Skeletal muscle	(48)	(18)	(24)	(18)	(48)
Histiocytoma, metastatic, skin				1 (2%)	
Skeletal muscle, thigh	(48)	(18)	(24)	(18)	(48)
Osteosarc, metastatic, bone	1 (2%)				
Skin	(48)	(18)	(27)	(21)	(48)
Fibroma, subcut tiss	1 (2%)		1 (4%)		
Histiocytoma, subcut tiss				2 (4%)	
Keratoacanthoma			1 (4%)		1 (2%)
Lipoma, subcut tiss	1 (2%)			2 (10%)	
Liposarc, subcut tiss				1 (5%)	
Melanoma mal, subcut tiss, head					1 (2%)
Schwannoma mal, subcut tiss	1 (2%)				
Squamous cel carc				1 (5%)	
Spleen	(48)	(25)	(30)	(21)	(48)
Histiocytoma, metastatic, skin					1 (2%)
Leukemia monuc	13 (27%)	12 (48%)	15 (50%)	8 (38%)	16 (33%)
Stomach, forestomach	(48)	(17)	(24)	(18)	(48)
Leukemia monuc	1 (2%)	1 (6%)	2 (8%)		1 (2%)
Stomach, glandular	(48)	(18)	(24)	(18)	(48)
Leukemia monuc		1 (6%)	3 (13%)		1 (2%)

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	<b>0 ppm</b>	<b>5 ppm</b>	<b>15 ppm</b>	<b>50 ppm</b>	<b>100 ppm</b>
<b>2-Year Study (continued)</b>					
Thymus	(41)	(15)	(22)	(18)	(40)
Leukemia monuc	4 (10%)	4 (27%)	9 (41%)	2 (11%)	7 (18%)
Thyroid gland	(48)	(18)	(25)	(19)	(48)
Adenoma, c cell	2 (4%)		3 (12%)		6 (13%)
Adenoma, multiple, c cell	1 (2%)				
Carcinoma, c cell	1 (2%)		1 (4%)	1 (5%)	1 (2%)
Leukemia monuc		1 (6%)	2 (8%)		
Tongue	(48)	(18)	(24)	(20)	(48)
Papilloma squa				2 (10%)	
Trachea	(48)	(18)	(24)	(18)	(48)
Leukemia monuc			1 (4%)		
Urinary bladder	(45)	(17)	(24)	(18)	(47)
Leukemia monuc	1 (2%)	1 (6%)	6 (25%)		
Papilloma, transit epithel					1 (2%)
Schwannoma mal, metastatic, uterus			1 (4%)		
Uterus	(47)	(23)	(30)	(23)	(48)
Carcinoma, endometrium					1 (2%)
Deciduoma bgn	1 (2%)				
Leiomyosar	1 (2%)				
Leukemia monuc	1 (2%)	1 (4%)	3 (10%)		
Leukemia monuc, cervix				1 (4%)	
Polyp stromal, endometrium	10 (21%)	4 (17%)	5 (17%)	3 (13%)	7 (15%)
Sarc stromal					1 (2%)
Sarcoma, cervix		1 (4%)			
Schwannoma mal			1 (3%)		
Vagina	(47)	(17)	(25)	(18)	(47)
Leukemia monuc	1 (2%)	1 (6%)	3 (12%)	2 (11%)	1 (2%)
Liposarc					1 (2%)
Papilloma squa	1 (2%)				
Polyp			1 (4%)		
Schwannoma mal, metastatic, uterus			1 (4%)		
Zymbal's gland	(34)	(15)	(18)	(14)	(38)
Adenoma				1 (7%)	
Carcinoma		1 (7%)			

### Neoplasm Summary

Total animals with primary neoplasms				
2-Year study	43	32	44	43
Total primary neoplasms				46
2-Year study	175	121	221	114
Total animals with benign neoplasms				184
2-Year study	41	26	37	38
Total benign neoplasms				42
2-Year study	84	40	64	57
Total animals with malignant neoplasms				71
2-Year study	18	17	22	14
Total malignant neoplasms				25
2-Year study	91	81	157	57
Total animals with metastatic neoplasms				113
2-Year study	2		1	3
Total metastatic neoplasms				7
2-Year study	5		3	

<sup>a</sup> Number of animals examined microscopically at the site and the number of animals with neoplasm

<sup>b</sup> Primary neoplasms: all neoplasms except metastatic neoplasms