

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

**TABLE A1** Summary of the Incidence of Neoplasms in Male Rats  
in the 2-Year Feed Study of Fumonisin B<sub>1</sub> . . . . . **A-3**

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in the 2-Year Feed Study of Fumonisin B<sub>1</sub> . . . . . **A-32**

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in the 2-Year Feed Study of Fumonisin B<sub>1</sub> . . . . . **A-36**



**TABLE A1**  
**Summary of the Incidence of Neoplasms in Male Rats in the 2-Year Feed Study of Fumonisin B<sub>1</sub><sup>a</sup>**

	0 ppm	5 ppm	15 ppm	50 ppm	150 ppm
<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	2			2	
Moribund	24	19	19	19	21
Natural deaths	6	4	4	9	2
Survivors					
Terminal sacrifice	16	17	25	18	25
Animals examined microscopically	64	56	64	64	64
<b>Tissues Examined at 6 Weeks with No Neoplasms Observed</b>					
Kidney					
Liver					
<b>Tissues Examined at 10 Weeks with No Neoplasms Observed</b>					
Kidney					
Liver					
Mesentery					
<b>Tissues Examined at 14 Weeks with No Neoplasms Observed</b>					
Kidney					
Liver					
Testes					
<b>Tissues Examined at 26 Weeks with No Neoplasms Observed</b>					
Intestine large					
Kidney					
Liver					
<b>2-Year Study</b>					
Adrenal gland	(47)	(22)	(25)	(31)	(47)
Adenoma, cortex				1 (3%)	2 (4%)
Carcinoma, cortex					1 (2%)
Leukemia monoc	9 (19%)	3 (14%)	5 (20%)	3 (10%)	4 (9%)
Pheochrom bgn, bilateral, medulla					2 (4%)
Pheochrom bgn, medulla	11 (23%)	4 (18%)	6 (24%)	3 (10%)	6 (13%)
Pheochrom mal, medulla	1 (2%)		1 (4%)		
Bone	(48)	(23)	(23)	(30)	(48)
Osteoma, scapula	1 (2%)				
Sarcoma, synovial tiss			1 (4%)		
Bone marrow	(47)	(23)	(23)	(30)	(48)
Leukemia monoc	15 (32%)	12 (52%)	10 (43%)	10 (33%)	10 (21%)

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

	0 ppm	5 ppm	15 ppm	50 ppm	150 ppm
<b>2-Year Study</b> (continued)					
Brain	(48)	(24)	(23)	(31)	(48)
Leukemia monuc	2 (4%)		4 (17%)	2 (6%)	
Leukemia monuc, medulla					1 (2%)
Oligodendr mal, pons	1 (2%)				
Brain, cerebellum	(48)	(24)	(23)	(31)	(47)
Gra cl tum bgn, meninges	2 (4%)				
Brain, cerebrum	(48)	(24)	(23)	(31)	(48)
Astrocyto mal			1 (4%)		
Oligodendr mal				1 (3%)	
Ear				(1)	
Keratoacanthma				1 (100%)	
Epididymis	(48)	(23)	(22)	(28)	(47)
Leukemia monuc			1 (5%)		
Mesothelio mal	2 (4%)				3 (6%)
Eye	(47)	(24)	(26)	(35)	(48)
Leukemia monuc, retrobulbar		1 (4%)			
Harderian gland	(48)	(23)	(23)	(30)	(48)
Carcinoma			1 (4%)		
Leukemia monuc		1 (4%)	1 (4%)		
Heart	(48)	(23)	(24)	(30)	(48)
Leukemia monuc	6 (13%)	3 (13%)	6 (25%)	3 (10%)	4 (8%)
Schwannoma mal				1 (3%)	
Intestine large, cecum	(45)	(23)	(23)	(25)	(47)
Leukemia monuc		1 (4%)	1 (4%)		
Intestine large, colon	(47)	(23)	(23)	(28)	(47)
Leukemia monuc	1 (2%)	1 (4%)			
Intestine small, duodenum	(47)	(23)	(23)	(30)	(47)
Leukemia monuc	1 (2%)		1 (4%)		
Mesothelio mal				1 (3%)	
Intestine small, ileum	(45)	(23)	(22)	(26)	(47)
Leukemia monuc	2 (4%)		1 (5%)		
Intestine small, jejunum	(44)	(21)	(21)	(26)	(47)
Carcinoma				1 (4%)	
Leukemia monuc			1 (5%)		
Sarcoma				1 (4%)	
Kidney	(48)	(40)	(48)	(48)	(48)
Adenoma, bilateral, renal tubule				1 (2%)	
Adenoma, renal tubule				1 (2%)	5 (10%)
Carcinoma, bilateral, renal tubule				1 (2%)	
Carcinoma, renal tubule				6 (13%)	10 (21%)
Leukemia monuc	6 (13%)	4 (10%)	9 (19%)	4 (8%)	3 (6%)
Liposarc	1 (2%)				
Mesothelio mal	1 (2%)				1 (2%)
Nephroblastoma				1 (2%)	
Lacrimal gland	(47)	(23)	(22)	(30)	(48)
Leukemia monuc	3 (6%)		1 (5%)	1 (3%)	
Liver	(48)	(40)	(48)	(48)	(48)
Carcinoma, metastatic, thyroid gland			1 (2%)		
Fib histiocyt, metastatic, skin					1 (2%)
Hepatoclr aden		2 (5%)	2 (4%)		1 (2%)
Hepatoclr carc		1 (3%)	1 (2%)		
Histio sarc, metastatic, skin					1 (2%)
Leukemia monuc	20 (42%)	20 (50%)	17 (35%)	18 (38%)	12 (25%)
Mesothelio mal					1 (2%)

**TABLE A1**  
**Summary of the Incidence of Neoplasms in Male Rats in the 2-Year Feed Study of Fumonisin B<sub>1</sub>**

	0 ppm	5 ppm	15 ppm	50 ppm	150 ppm
<b>2-Year Study</b> (continued)					
Lung	(48)	(24)	(23)	(32)	(48)
Alv bron aden		1 (4%)		1 (3%)	
Alv bron carc		1 (4%)			
Carcinoma, metastatic, adrenal gland				2 (6%)	1 (2%)
Carcinoma, metastatic, kidney					4 (8%)
Carcinoma, metastatic, thyroid gland			1 (4%)		
Fib histiocyt, metastatic, skin					1 (2%)
Histio sarc, metastatic, skin					1 (2%)
Leukemia monuc	16 (33%)	9 (38%)	8 (35%)	9 (28%)	7 (15%)
Sarcoma, metastatic, skin	1 (2%)				
Lung, bronchus	(48)	(24)	(23)	(31)	(48)
Squam cel carc		1 (4%)		1 (3%)	1 (2%)
Lymph node	(48)	(24)	(27)	(33)	(48)
Carcinoma, metastatic, kidney					1 (2%)
Carcinoma, metastatic, mediastinal, kidney					1 (2%)
Carcinoma, metastatic, mediastinal, lung		1 (4%)			
Carcinoma, metastatic, renal, kidney					1 (2%)
Leukemia monuc	1 (2%)	2 (8%)			
Leukemia monuc, axillary			1 (4%)		
Leukemia monuc, deep cervical			1 (4%)		
Leukemia monuc, thoracic		1 (4%)			
Lymph node, mandibular	(48)	(23)	(26)	(32)	(48)
Leukemia monuc	16 (33%)	11 (48%)	7 (27%)	8 (25%)	10 (21%)
Lymph node, mesenteric	(47)	(23)	(23)	(30)	(48)
Leukemia monuc	12 (26%)	11 (48%)	8 (35%)	9 (30%)	7 (15%)
Mammary gland	(40)	(20)	(24)	(24)	(42)
Carcinoma			1 (4%)		
Fibroadenoma	2 (5%)				4 (10%)
Mesentery	(4)	(3)	(3)	(4)	(4)
Carcinoma, metastatic, kidney					1 (25%)
Fibroma				1 (25%)	
Mesothelio mal	1 (25%)				
Nose	(48)	(23)	(23)	(29)	(48)
Leukemia monuc		1 (4%)			
Pancreas	(47)	(24)	(25)	(30)	(48)
Adenoma	4 (9%)			2 (7%)	3 (6%)
Adenoma, acinar cell	2 (4%)		2 (8%)	2 (7%)	2 (4%)
Adenoma, duct					1 (2%)
Carcinoma	3 (6%)	2 (8%)	2 (8%)		3 (6%)
Carcinoma, metastatic, kidney					1 (2%)
Histio sarc, metastatic, skin					1 (2%)
Leukemia monuc	1 (2%)	1 (4%)	2 (8%)	1 (3%)	2 (4%)
Mesothelio mal				1 (3%)	1 (2%)
Mixd tumor bgn					1 (2%)
Parathyroid gland	(46)	(21)	(22)	(26)	(47)
Adenoma	1 (2%)				
Pituitary gland	(43)	(28)	(33)	(33)	(45)
Adenoma, pars distalis	30 (70%)	18 (64%)	23 (70%)	18 (55%)	24 (53%)
Adenoma, pars intermed				1 (3%)	
Carcinoma, pars distalis		1 (4%)			1 (2%)
Leukemia monuc	5 (12%)	3 (11%)	1 (3%)	1 (3%)	1 (2%)
Preputial gland	(43)	(19)	(20)	(30)	(44)
Adenoma	2 (5%)	2 (11%)	1 (5%)	2 (7%)	2 (5%)
Carcinoma			1 (5%)		1 (2%)
Prostate	(48)	(22)	(23)	(30)	(48)
Adenoma	1 (2%)			1 (3%)	1 (2%)
Histio sarc, metastatic, skin					1 (2%)
Leukemia monuc				2 (7%)	

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

	0 ppm	5 ppm	15 ppm	50 ppm	150 ppm
<b>2-Year Study</b> (continued)					
Salivary glands	(48)	(23)	(23)	(30)	(48)
Leukemia monuc				1 (3%)	
Seminal vesicle	(48)	(23)	(24)	(30)	(48)
Leukemia monuc	1 (2%)				
Mesothelio mal					1 (2%)
Skeletal muscle	(48)	(23)	(24)	(30)	(48)
Fibrosarc			1 (4%)		
Mesothelio mal, abdominal					1 (2%)
Skin	(48)	(27)	(28)	(32)	(48)
Adenoma, sebaceous gland			1 (4%)		
Basal cel aden	3 (6%)			1 (3%)	3 (6%)
Fib histiocy, subcut tiss					1 (2%)
Fibroma, subcut tiss	3 (6%)	3 (11%)	2 (7%)	2 (6%)	
Hemangioma				1 (3%)	
Hemangioma, subcut tiss			1 (4%)		
Histio sarc					1 (2%)
Histio sarc, subcut tiss				1 (3%)	1 (2%)
Keratoacanthma	2 (4%)		3 (11%)		1 (2%)
Keratoacanthma, multiple		1 (4%)			
Lipoma, subcut tiss	1 (2%)	1 (4%)	1 (4%)	1 (3%)	1 (2%)
Papilloma squa	1 (2%)				
Papilloma squa, tail				1 (3%)	
Sarcoma, subcut tiss	1 (2%)		1 (4%)		
Trichoepithel		1 (4%)	1 (4%)		1 (2%)
Spinal cord, thoracic	(47)	(23)	(23)	(30)	(48)
Leukemia monuc	1 (2%)		1 (4%)		
Spleen	(48)	(29)	(33)	(41)	(48)
Carcinoma, metastatic, kidney					1 (2%)
Histio sarc, metastatic, skin					1 (2%)
Leukemia monuc	24 (50%)	20 (69%)	20 (61%)	18 (44%)	16 (33%)
Liposarc		1 (3%)			
Mesothelio mal				1 (2%)	1 (2%)
Stomach, forestomach	(48)	(23)	(23)	(30)	(48)
Leukemia monuc	2 (4%)		1 (4%)	1 (3%)	1 (2%)
Papilloma squa	1 (2%)	1 (4%)			
Stomach, glandular	(48)	(23)	(23)	(30)	(48)
Mesothelio mal	1 (2%)			1 (3%)	
Testes	(48)	(39)	(46)	(46)	(48)
Adenoma, bilateral, interstit cell	19 (40%)	24 (62%)	20 (43%)	22 (48%)	26 (54%)
Adenoma, interstit cell	14 (29%)	6 (15%)	14 (30%)	13 (28%)	11 (23%)
Mesothelio mal	1 (2%)			2 (4%)	4 (8%)
Thymus	(37)	(19)	(21)	(24)	(41)
Leukemia monuc	8 (22%)	6 (32%)	5 (24%)	4 (17%)	3 (7%)
Thyroid gland	(48)	(24)	(25)	(31)	(48)
Adenoma, c cell	9 (19%)	2 (8%)	4 (16%)	2 (6%)	10 (21%)
Adenoma, multiple, c cell					1 (2%)
Carcinoma, c cell	1 (2%)	1 (4%)	2 (8%)	2 (6%)	
Carcinoma, follicular cel		1 (4%)			
Leukemia monuc			1 (4%)	1 (3%)	
Tissue NOS	(2)		(2)	(1)	(1)
Chordoma			1 (50%)		
Mesothelio mal, pelvic	1 (50%)				
Mesothelio mal, scrotal				1 (100%)	

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	0 ppm	5 ppm	15 ppm	50 ppm	150 ppm
<b>2-Year Study</b> (continued)					
Tongue	(48)	(23)	(23)	(30)	(48)
Leukemia monuc			1 (4%)		
Urinary bladder	(47)	(22)	(23)	(30)	(48)
Leukemia monuc	1 (2%)			2 (7%)	
Mesothelio mal				1 (3%)	1 (2%)
Zymbal's gland	(33)	(19)	(17)	(21)	(33)
Carcinoma	1 (3%)	1 (5%)	1 (6%)	1 (5%)	
<b>Neoplasm Summary</b>					
Total animals with primary neoplasms <sup>b</sup>					
2-Year study	46	38	48	46	44
Total primary neoplasms					
2-Year study	278	187	211	201	223
Total animals with benign neoplasms					
2-Year study	45	36	45	44	43
Total benign neoplasms					
2-Year study	109	66	81	78	108
Total animals with malignant neoplasms					
2-Year study	30	26	28	30	30
Total malignant neoplasms					
2-Year study	169	121	130	123	115
Total animals with metastatic neoplasms					
2-Year study	1	1	1	2	7
Total metastatic neoplasms					
2-Year study	1	1	2	2	18

<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