

**APPENDIX A
SUMMARY OF LESIONS IN MALE RATS
IN THE 2-YEAR FEED STUDY
OF FUMONISIN B₁**

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TABLE A1
Summary of the Incidence of Neoplasms in Male Rats in the 2-Year Feed Study of Fumonisins B₁^a

	0 ppm	5 ppm	15 ppm	50 ppm	150 ppm
Disposition Summary					
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
Tissues Examined at 6 Weeks with No Neoplasms Observed					
Kidney					
Liver					
Tissues Examined at 10 Weeks with No Neoplasms Observed					
Kidney					
Liver					
Mesentery					
Tissues Examined at 14 Weeks with No Neoplasms Observed					
Kidney					
Liver					
Testes					
Tissues Examined at 26 Weeks with No Neoplasms Observed					
Intestine large					
Kidney					
Liver					
2-Year Study					
Adrenal gland	(47)	(22)	(25)	(31)	(47)
Adenoma, cortex				1 (3%)	2 (4%)
Carcinoma, cortex					1 (2%)
Leukemia monuc	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 monuc	15 (32%)	12 (52%)	10 (43%)	10 (33%)	10 (21%)

TABLE A1
Summary of the Incidence of Neoplasms in Male Rats in the 2-Year Feed Study of Fumonisin B₁

	0 ppm	5 ppm	15 ppm	50 ppm	150 ppm
2-Year Study (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 (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%)		
Histo sarc, metastatic, skin					1 (2%)
Leukemia monuc	20 (42%)	20 (50%)	17 (35%)	18 (38%)	12 (25%)
Mesothelio mal					1 (2%)

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Summary of the Incidence of Neoplasms in Male Rats in the 2-Year Feed Study of Fumonisins B₁

	0 ppm	5 ppm	15 ppm	50 ppm	150 ppm
2-Year Study (continued)					
Lung	(48)	(24)	(23)	(32)	(48)
Alv bron aden		1 (4%)		1 (3%)	
Alv bron carc		1 (4%)			
Carcinoma, metastatic, adrenal gland					1 (2%)
Carcinoma, metastatic, kidney				2 (6%)	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%)
Mixed 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%)
Histo sarc, metastatic, skin					1 (2%)
Leukemia monuc				2 (7%)	

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	0 ppm	5 ppm	15 ppm	50 ppm	150 ppm
2-Year Study (continued)					
Salivary glands	(48)	(23)	(23)	(30)	(48)
Leukemia monuc				1 (3%)	
Seminal vesicle	(48)	(23)	(24)	(30)	(48)
Leukemia monuc	1 (2%)				
Mesothilio mal					1 (2%)
Skeletal muscle	(48)	(23)	(24)	(30)	(48)
Fibrosarc			1 (4%)		
Mesothilio 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 histiocyt, 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%)
Histo sarc, metastatic, skin					1 (2%)
Leukemia monuc	24 (50%)	20 (69%)	20 (61%)	18 (44%)	16 (33%)
Liposarc		1 (3%)			
Mesothilio 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)
Mesothilio 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%)
Mesothilio 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%)		
Mesothilio mal, pelvic	1 (50%)				
Mesothilio mal, scrotal				1 (100%)	

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	0 ppm	5 ppm	15 ppm	50 ppm	150 ppm
2-Year Study (continued)					
Tongue	(48)	(23)	(23) 1 (4%)	(30)	(48)
Leukemia monuc					
Urinary bladder	(47)	(22)	(23)	(30)	(48)
Leukemia monuc	1 (2%)			2 (7%)	
Mesothelio mal				1 (3%)	
Zymbal's gland	(33)	(19)	(17) 1 (6%)	(21)	(33) 1 (2%)
Carcinoma	1 (3%)	1 (5%)		1 (5%)	
Neoplasm Summary					
Total animals with primary neoplasms ^b					
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

^a Number of animals examined microscopically at the site and the number of animals with neoplasm

^b Primary neoplasms: all neoplasms except metastatic neoplasms