

APPENDIX C
SUMMARY OF LESIONS IN MALE MICE
IN THE 2-YEAR FEED STUDY
OF FUMONISIN B₁

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in the 2-Year Feed Study of Fumonisin B₁ **C-2**

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TABLE C1
Summary of the Incidence of Neoplasms in Male Mice in the 2-Year Feed Study of Fumonisin B₁^a

	0 ppm	5 ppm	15 ppm	80 ppm	150 ppm
Disposition Summary					
3-Week evaluation	4	4	4	4	4
7-Week evaluation	4	4	4	4	4
9-Week evaluation	4	4	4	4	4
24-Week evaluation	4	4	4	4	4
Animals initially in 2-year study	48	48	48	48	48
Early deaths					
Removed from study		1			
Moribund	4	3	1	5	4
Natural deaths	3	5	2	6	2
Survivors					
Terminal sacrifice	41	39	45	37	42
Animals examined microscopically	64	64	64	64	64

Tissues Examined at 3 Weeks with No Neoplasms Observed

Kidney
Liver

Tissues Examined at 7 Weeks with No Neoplasms Observed

Kidney
Liver
Preputial gland
Seminal vesicle

Tissues Examined at 9 and 24 Weeks with No Neoplasms Observed

Kidney
Liver
Preputial gland

2-Year Study

Adrenal gland	(46)	(8)	(1)	(9)	(48)
Lymph mal	1 (2%)				1 (2%)
Pheochrom bgn	1 (2%)				
Blood vessel, aorta	(46)	(9)	(3)	(11)	(48)
Lymph mal		1 (11%)		1 (9%)	
Bone, femur	(48)	(9)	(2)	(11)	(48)
Histio sarc				1 (9%)	
Lymph mal	1 (2%)			1 (9%)	2 (4%)
Bone, sternum	(47)	(9)	(2)	(11)	(48)
Histio sarc				1 (9%)	
Lymph mal	1 (2%)	1 (11%)		1 (9%)	1 (2%)
Bone marrow	(47)	(9)	(2)	(11)	(47)
Hemangiosarc, metastatic, spleen				1 (9%)	
Histio sarc			1 (50%)	2 (18%)	1 (2%)
Lymph mal	1 (2%)	1 (11%)		1 (9%)	2 (4%)
Brain, cerebellum	(47)	(8)	(2)	(8)	(46)
Lymph mal		1 (13%)			

TABLE C1
Summary of the Incidence of Neoplasms in Male Mice in the 2-Year Feed Study of Fumonisin B₁

	0 ppm	5 ppm	15 ppm	80 ppm	150 ppm
2-Year Study (continued)					
Brain, cerebrum	(47)	(9)	(2)	(10)	(48)
Lymph mal		1 (11%)			
Coagulating gland	(46)	(7)	(1)	(10)	(47)
Lymph mal	1 (2%)			1 (10%)	1 (2%)
Ear	(45)	(5)	(2)	(9)	(48)
Lymph mal	1 (2%)				
Epididymis	(48)	(8)	(2)	(8)	(48)
Adenoma, interstit cell			1 (50%)		
Histio sarc				1 (13%)	
Lymph mal	2 (4%)			1 (13%)	1 (2%)
Eye	(44)	(6)	(1)	(7)	(45)
Lymph mal	1 (2%)				
Gallbladder	(40)	(3)	(1)	(7)	(42)
Lymph mal	1 (3%)			1 (14%)	
Harderian gland	(46)	(8)	(1)	(9)	(44)
Adenoma	1 (2%)				5 (11%)
Carcinoma		1 (13%)			
Lymph mal	1 (2%)			1 (11%)	2 (5%)
Heart	(48)	(9)	(3)	(11)	(48)
Lymph mal		1 (11%)		1 (9%)	
Intestine large, cecum	(46)	(5)	(1)	(6)	(46)
Lymph mal					1 (2%)
Intestine large, colon	(46)	(6)	(1)	(8)	(46)
Lymph mal	1 (2%)				1 (2%)
Intestine large, rectum	(45)	(8)	(1)	(7)	(47)
Lymph mal	1 (2%)				
Intestine small, ileum	(46)	(6)	(1)	(7)	(46)
Lymph mal				1 (14%)	1 (2%)
Kidney	(47)	(48)	(45)	(47)	(48)
Histio sarc				1 (2%)	
Lymph mal	1 (2%)	2 (4%)		2 (4%)	3 (6%)
Lacrimal gland	(44)	(8)	(2)	(8)	(47)
Lymph mal	2 (5%)				1 (2%)
Liver	(47)	(47)	(48)	(48)	(48)
Hemangiosarc		1 (2%)		1 (2%)	
Hepatoclr aden	9 (19%)	7 (15%)	7 (15%)	6 (13%)	8 (17%)
Hepatoclr carc	4 (9%)	3 (6%)	4 (8%)	3 (6%)	2 (4%)
Histio sarc			1 (2%)	2 (4%)	1 (2%)
Ito cl tm mal		1 (2%)			
Lymph mal	1 (2%)	1 (2%)		1 (2%)	4 (8%)
Lung	(48)	(9)	(2)	(11)	(48)
Adenocarc, multiple					1 (2%)
Alv bron aden	6 (13%)				6 (13%)
Histio sarc			1 (50%)	2 (18%)	1 (2%)
Lymph mal	3 (6%)	1 (11%)		1 (9%)	2 (4%)
Lymph node	(48)	(9)	(3)	(15)	(48)
Lymph mal, inguinal				1 (7%)	
Lymph node, mandibular	(46)	(8)	(2)	(10)	(48)
Fibrosarc, metastatic, skin	1 (2%)				
Histio sarc					1 (2%)
Lymph mal	3 (7%)			1 (10%)	3 (6%)
Lymph node, mesenteric	(48)	(7)	(3)	(15)	(45)
Histio sarc			1 (33%)	2 (13%)	1 (2%)
Lymph mal	4 (8%)		1 (33%)	5 (33%)	5 (11%)

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Summary of the Incidence of Neoplasms in Male Mice in the 2-Year Feed Study of Fumonisin B₁

	0 ppm	5 ppm	15 ppm	80 ppm	150 ppm
2-Year Study (continued)					
Mammary gland	(4)	(2)		(1)	(10)
Lymph mal	1 (25%)				1 (10%)
Nose	(48)	(9)	(1)	(11)	(48)
Histio sarc				1 (9%)	
Lymph mal	2 (4%)	1 (11%)		1 (9%)	4 (8%)
Pancreas	(47)	(8)	(1)	(10)	(47)
Lymph mal	1 (2%)			1 (10%)	2 (4%)
Peripheral nerve	(46)	(8)	(3)	(11)	(46)
Lymph mal	1 (2%)				1 (2%)
Preputial gland	(46)	(9)	(4)	(17)	(46)
Lymph mal	1 (2%)			1 (6%)	1 (2%)
Prostate	(46)	(8)		(10)	(47)
Lymph mal	2 (4%)			1 (10%)	
Salivary glands	(48)	(11)	(1)	(10)	(48)
Fibrosarc, metastatic, skin	2 (4%)				
Lymph mal	2 (4%)	1 (9%)		1 (10%)	5 (10%)
Seminal vesicle	(46)	(8)	(1)	(9)	(47)
Lymph mal	1 (2%)			1 (11%)	
Skeletal muscle	(47)	(9)	(2)	(12)	(48)
Fibrosarc				1 (8%)	
Fibrosarc, metastatic, thoracic, skin					1 (2%)
Skin	(48)	(11)	(7)	(14)	(47)
Fib histiocyt		1 (9%)			
Fibroma				1 (7%)	
Fibrosarc	5 (10%)	1 (9%)	5 (71%)	4 (29%)	5 (11%)
Hemangioma		1 (9%)			
Lymph mal				1 (7%)	1 (2%)
Sarcoma	1 (2%)				
Squam cel carc		1 (9%)			
Spleen	(47)	(8)	(1)	(13)	(48)
Hemangiosarc				1 (8%)	
Histio sarc				2 (15%)	1 (2%)
Lymph mal	2 (4%)			3 (23%)	6 (13%)
Stomach, forestomach	(47)	(7)	(1)	(11)	(48)
Lymph mal	1 (2%)			1 (9%)	
Papilloma squa	1 (2%)			1 (9%)	
Stomach, glandular	(45)	(7)	(2)	(10)	(45)
Adenocarc			1 (50%)		
Lymph mal	1 (2%)				
Testes	(48)	(9)	(1)	(12)	(48)
Histio sarc				1 (8%)	
Thymus	(33)	(6)	(2)	(7)	(26)
Lymph mal		1 (17%)		1 (14%)	2 (8%)
Thyroid gland	(44)	(7)	(1)	(7)	(46)
Lymph mal				1 (14%)	
Trachea	(40)	(7)	(1)	(9)	(43)
Lymph mal				1 (11%)	
Urinary bladder	(46)	(9)		(10)	(46)
Lymph mal	3 (7%)			1 (10%)	4 (9%)
Zymbal's gland	(31)	(5)	(2)	(8)	(34)
Lymph mal				1 (13%)	

TABLE C1
Summary of the Incidence of Neoplasms in Male Mice in the 2-Year Feed Study of Fumonisin B₁

	0 ppm	5 ppm	15 ppm	80 ppm	150 ppm
Neoplasm Summary					
Total animals with primary neoplasms ^b					
2-Year study	24	16	16	21	27
Total primary neoplasms					
2-Year study	73	30	23	71	91
Total animals with benign neoplasms					
2-Year study	15	8	8	8	17
Total benign neoplasms					
2-Year study	18	8	8	8	19
Total animals with malignant neoplasms					
2-Year study	13	10	11	16	16
Total malignant neoplasms					
2-Year study	55	22	15	63	72
Total animals with metastatic neoplasms					
2-Year study	2			1	1
Total metastatic neoplasms					
2-Year study	3			1	1

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

^b Primary neoplasms: all neoplasms except metastatic neoplasms