

APPENDIX D
SUMMARY OF LESIONS IN FEMALE MICE
IN THE 2-YEAR FEED STUDY
OF FUMONISIN B₁

TABLE D1 **Summary of the Incidence of Neoplasms in Female Mice**
in the 2-Year Feed Study of Fumonisin B₁ **D-2**

TABLE D2 **Individual Animal Tumor Pathology of Female Mice**
in the 2-Year Feed Study of Fumonisin B₁ **D-6**

TABLE D3 **Statistical Analysis of Primary Neoplasms in Female Mice**
in the 2-Year Feed Study of Fumonisin B₁ **D-28**

TABLE D4 **Summary of the Incidence of Nonneoplastic Lesions in Female Mice**
in the 2-Year Feed Study of Fumonisin B₁ **D-30**

TABLE D1
Summary of the Incidence of Neoplasms in Female Mice in the 2-Year Feed Study of Fumonisin B₁^a

	0 ppm	5 ppm	15 ppm	50 ppm	80 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	4				
Moribund	7	3	2	3	6
Natural deaths	1	1		6	14
Survivors					
Terminal sacrifice	35	44	46	39	28
Missing	1				
Animals examined microscopically	63	64	64	64	64
Tissues Examined at 3 Weeks with No Neoplasms Observed					
Kidney					
Liver					
Tissues Examined at 7 Weeks with No Neoplasms Observed					
Eye					
Heart					
Kidney					
Liver					
Tissues Examined at 9 Weeks with No Neoplasms Observed					
Intestine small					
Kidney					
Liver					
Tissues Examined at 24 Weeks with No Neoplasms Observed					
Kidney					
Liver					
Ovary					
Oviduct					
Thymus					
Uterus					
2-Year Study					
Adrenal gland	(45)	(3)	(3)	(9)	(40)
Histio sarc			1 (33%)		
Histio sarc, metastatic, spleen					1 (3%)
Lymph mal				3 (33%)	
Blood vessel, aorta	(43)	(4)	(2)	(7)	(48)
Lymph mal				1 (14%)	
Bone, femur	(47)	(3)	(2)	(8)	(47)
Lymph mal					1 (2%)

TABLE D1
Summary of the Incidence of Neoplasms in Female Mice in the 2-Year Feed Study of Fumonisin B₁

	0 ppm	5 ppm	15 ppm	50 ppm	80 ppm
2-Year Study (continued)					
Bone marrow	(47)	(4)	(2)	(8)	(45)
Histio sarc	1 (2%)				
Lymph mal	2 (4%)			1 (13%)	1 (2%)
Brain, cerebellum	(45)	(4)	(2)	(9)	(42)
Lymph mal	1 (2%)			1 (11%)	
Meningioma mal					1 (2%)
Brain, cerebrum	(47)	(4)	(2)	(9)	(47)
Lymph mal				1 (11%)	
Meningioma mal					2 (4%)
Clitoral gland	(34)	(3)		(2)	(34)
Adenoma	1 (3%)				
Lymph mal	1 (3%)			1 (50%)	3 (9%)
Ear	(46)	(3)	(2)	(6)	(41)
Lymph mal				1 (17%)	
Esophagus	(46)	(4)	(2)	(8)	(46)
Lymph mal	1 (2%)			3 (38%)	1 (2%)
Eye	(45)	(3)	(2)	(4)	(36)
Lymph mal				1 (25%)	
Gallbladder	(42)	(3)	(2)	(5)	(26)
Lymph mal	2 (5%)			1 (20%)	2 (8%)
Harderian gland	(46)	(5)	(3)	(8)	(44)
Adenoma	4 (9%)	1 (20%)	1 (33%)	2 (25%)	
Carcinoma	1 (2%)				
Histio sarc	1 (2%)				
Lymph mal	7 (15%)			3 (38%)	3 (7%)
Heart	(47)	(4)	(2)	(9)	(47)
Lymph mal	2 (4%)			2 (22%)	
Intestine large, cecum	(47)	(3)	(2)	(6)	(35)
Lymph mal	2 (4%)			1 (17%)	4 (11%)
Intestine large, colon	(47)	(4)	(2)	(5)	(36)
Lymph mal	1 (2%)				2 (6%)
Intestine large, rectum	(47)	(4)	(2)	(6)	(34)
Lymph mal	1 (2%)				
Intestine small, duodenum	(47)	(3)	(2)	(5)	(34)
Lymph mal	2 (4%)				
Intestine small, ileum	(47)	(3)	(2)	(6)	(35)
Lymph mal				1 (17%)	2 (6%)
Intestine small, jejunum	(47)	(3)	(3)	(5)	(35)
Lymph mal			1 (33%)		
Kidney	(47)	(48)	(48)	(48)	(42)
Histio sarc	2 (4%)		1 (2%)		
Histio sarc, metastatic, spleen					1 (2%)
Lymph mal	13 (28%)	8 (17%)	4 (8%)	7 (15%)	13 (31%)
Lacrimal gland	(46)	(4)	(1)	(7)	(40)
Lymph mal	14 (30%)			4 (57%)	9 (23%)
Liver	(47)	(48)	(48)	(47)	(45)
Hemangiosarc	1 (2%)				2 (4%)
Hepatoclr aden	5 (11%)	3 (6%)	1 (2%)	16 (34%)	31 (69%)
Hepatoclr carc				10 (21%)	9 (20%)
Histio sarc	2 (4%)		1 (2%)		
Histio sarc, metastatic, spleen	1 (2%)			1 (2%)	1 (2%)
Lymph mal	16 (34%)	6 (13%)	4 (8%)	7 (15%)	7 (16%)

TABLE D1
Summary of the Incidence of Neoplasms in Female Mice in the 2-Year Feed Study of Fumonisin B₁

	0 ppm	5 ppm	15 ppm	50 ppm	80 ppm
2-Year Study (continued)					
Lung	(47)	(4)	(2)	(9)	(47)
Adenocarc, metastatic, mammary gland	1 (2%)				
Alv bron aden	2 (4%)			1 (11%)	
Hepatoclr carc, metastatic, liver					2 (4%)
Histio sarc	2 (4%)				
Histio sarc, metastatic, spleen	1 (2%)			1 (11%)	
Lymph mal	15 (32%)			5 (56%)	11 (23%)
Lymph mal hist					1 (2%)
Squam cel carc, metastatic, skin		1 (25%)			
Lymph node	(47)	(6)	(7)	(11)	(45)
Lymph mal, lumbar	2 (4%)			1 (9%)	
Lymph mal, renal	2 (4%)		1 (14%)		1 (2%)
Squam cel carc, metastatic, axillary, skin		1 (17%)			
Lymph node, deep cervical		(1)			(1)
Lymph mal					1 (100%)
Squam cel carc, metastatic, skin		1 (100%)			
Lymph node, mandibular	(46)	(5)	(3)	(8)	(44)
Lymph mal	13 (28%)	1 (20%)		4 (50%)	10 (23%)
Lymph mal hist					1 (2%)
Squam cel carc, metastatic, skin		1 (20%)			
Lymph node, mesenteric	(47)	(5)	(5)	(8)	(39)
Histio sarc	1 (2%)		1 (20%)		
Histio sarc, metastatic, spleen	1 (2%)				
Lymph mal	17 (36%)	1 (20%)	2 (40%)	3 (38%)	10 (26%)
Lymph mal hist					1 (3%)
Mammary gland	(46)	(2)	(2)	(9)	(38)
Adenocarc	1 (2%)		1 (50%)	1 (11%)	
Adenocarc, inguinal				1 (11%)	
Lymph mal	5 (11%)			3 (33%)	4 (11%)
Nose	(47)	(4)	(2)	(9)	(48)
Adenoma, glands					1 (2%)
Lymph mal	5 (11%)			3 (33%)	4 (8%)
Ovary	(46)	(15)	(15)	(22)	(42)
Hemangioma				1 (5%)	
Histio sarc	1 (2%)				
Histio sarc, metastatic, spleen					1 (2%)
Lymph mal	9 (20%)			5 (23%)	11 (26%)
Lymph mal hist					1 (2%)
Pancreas	(47)	(5)	(2)	(8)	(39)
Histio sarc, metastatic, spleen	1 (2%)				1 (3%)
Lymph mal	6 (13%)			2 (25%)	4 (10%)
Salivary glands	(47)	(4)	(2)	(8)	(47)
Lymph mal	14 (30%)			4 (50%)	12 (26%)
Lymph mal hist					1 (2%)
Skeletal muscle	(47)	(4)	(2)	(9)	(48)
Lymph mal					1 (2%)
Skin	(47)	(4)	(1)	(9)	(42)
Carc adenosqua	1 (2%)				
Fibrosarc	1 (2%)	1 (25%)			
Lymph mal				2 (22%)	
Papilloma					1 (2%)
Squam cel carc		1 (25%)			
Spinal cord, thoracic	(47)	(4)	(2)	(8)	(46)
Lymph mal	1 (2%)			1 (13%)	

TABLE D1
Summary of the Incidence of Neoplasms in Female Mice in the 2-Year Feed Study of Fumonisin B₁

	0 ppm	5 ppm	15 ppm	50 ppm	80 ppm
2-Year Study (continued)					
Spleen	(47)	(10)	(13)	(17)	(42)
Hemangiosarc					1 (2%)
Hemangiosarc, metastatic, liver					1 (2%)
Histio sarc	2 (4%)		1 (8%)	1 (6%)	1 (2%)
Lymph mal	17 (36%)	5 (50%)	9 (69%)	9 (53%)	12 (29%)
Stomach, forestomach	(46)	(4)	(2)	(9)	(43)
Lymph mal	1 (2%)			2 (22%)	
Stomach, glandular	(46)	(4)	(2)	(6)	(39)
Lymph mal	1 (2%)			1 (17%)	1 (3%)
Thymus	(37)	(4)	(2)	(5)	(34)
Lymph mal	7 (19%)			2 (40%)	6 (18%)
Thyroid gland	(46)	(3)	(1)	(7)	(41)
Adenoma	1 (2%)			1 (14%)	1 (2%)
Tongue	(47)	(4)	(2)	(9)	(46)
Lymph mal	2 (4%)			1 (11%)	
Trachea	(43)	(3)	(1)	(5)	(38)
Lymph mal					1 (3%)
Urinary bladder	(45)	(4)	(2)	(8)	(35)
Histio sarc	2 (4%)				
Lymph mal	13 (29%)			4 (50%)	10 (29%)
Uterus	(47)	(38)	(32)	(38)	(42)
Hemangioma	1 (2%)				
Hemangiosarc		1 (3%)			
Histio sarc	2 (4%)			1 (3%)	
Histio sarc, metastatic, spleen					1 (2%)
Leiomyoma	1 (2%)				
Lymph mal	2 (4%)			4 (11%)	
Polyp			1 (3%)	1 (3%)	
Sarc stromal		1 (3%)			1 (2%)
Vagina	(47)	(3)	(2)	(8)	(38)
Histio sarc	2 (4%)				
Histio sarc, metastatic, spleen					1 (3%)
Lymph mal	3 (6%)			4 (50%)	2 (5%)
Neoplasm Summary					
Total animals with primary neoplasms ^b					
2-Year study	32	16	13	30	44
Total primary neoplasms					
2-Year study	238	29	30	135	205
Total animals with benign neoplasms					
2-Year study	13	4	3	21	31
Total benign neoplasms					
2-Year study	15	4	3	22	34
Total animals with malignant neoplasms					
2-Year study	28	13	12	19	24
Total malignant neoplasms					
2-Year study	223	25	27	113	171
Total animals with metastatic neoplasms					
2-Year study	2	1		1	4
Total metastatic neoplasms					
2-Year study	5	4		2	10

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

^b Primary neoplasms: all neoplasms except metastatic neoplasms