

**TABLE C4**  
**Summary of the Incidence of Nonneoplastic Lesions in Male Mice in the 2-Year Feed Study of Fumonisin B<sub>1</sub><sup>a</sup>**

	0 ppm	5 ppm	15 ppm	80 ppm	150 ppm
<b>Disposition Summary</b>					
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
<b>3-Week Evaluation</b>					
Kidney	(4)	(4)	(4)	(4)	(4)
Inflammation, subacute, unilateral	1 (25%)				
Liver	(4)	(4)	(4)	(4)	(4)
Inflammation, subacute, multifocal	1 (25%)				
<b>7-Week Evaluation</b>					
Preputial gland		(1)		(1)	(1)
Cyst, focal				1 (100%)	
Cyst, multifocal		1 (100%)			1 (100%)
<b>Tissues Examined with No Lesions Observed</b>					
Kidney					
Liver					
Seminal vesicle					
<b>9-Week Evaluation</b>					
Kidney	(4)	(4)	(4)	(4)	(4)
Fatty change, multifocal, bilateral, renal tubule		1 (25%)			
Inflammation, unilateral, perirenal tiss			1 (25%)		
Vacuoliz cyto, multifocal, bilateral, renal tubule			1 (25%)		
Liver	(4)	(4)	(4)	(4)	(4)
Inflammation, granulomatous, focal				1 (25%)	
Preputial gland		(1)			(1)
Cyst, focal		1 (100%)			1 (100%)

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

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<b>24-Week Evaluation</b>					
Kidney	(4)	(4)	(4)	(4)	(4)
Fatty change, multifocal, bilateral, renal tubule	1 (25%)		2 (50%)		
Inflammation, subacute, focal, unilateral			1 (25%)		
Vacuoliz cyto, multifocal, bilateral, renal tubule	2 (50%)	4 (100%)	1 (25%)		
Preputial gland	(1)		(1)	(1)	
Cyst, focal	1 (100%)				
Cyst, multifocal			1 (100%)	1 (100%)	
<b>Tissues Examined with No Lesions Observed</b>					
Liver					
<b>2-Year Study</b>					
Adrenal gland	(46)	(8)	(1)	(9)	(48)
Hyperplasia, bilateral, cortex, spindle cell	29 (63%)	2 (25%)	1 (100%)	3 (33%)	27 (56%)
Hyperplasia, unilateral, cortex, spindle cell	12 (26%)	2 (25%)		3 (33%)	18 (38%)
Hyperplasia, unilateral, medulla					2 (4%)
Blood vessel, aorta	(46)	(9)	(3)	(11)	(48)
Mineralization, focal					1 (2%)
Bone, femur	(48)	(9)	(2)	(11)	(48)
Proliferation, focal					1 (2%)
Bone, sternum	(47)	(9)	(2)	(11)	(48)
Proliferation, focal					2 (4%)
Proliferation, multifocal					1 (2%)
Bone marrow	(47)	(9)	(2)	(11)	(47)
Hyperplasia, diffuse	21 (45%)	3 (33%)	1 (50%)	4 (36%)	25 (53%)
Hyperplasia, multifocal		2 (22%)			2 (4%)
Brain, cerebellum	(47)	(8)	(2)	(8)	(46)
Mineralization, multifocal	1 (2%)				
Brain, cerebrum	(47)	(9)	(2)	(10)	(48)
Cyst, focal		1 (11%)			
Mineralization, focal				1 (10%)	
Mineralization, multifocal	8 (17%)	1 (11%)	1 (50%)		17 (35%)
Coagulating gland	(46)	(7)	(1)	(10)	(47)
Inflammation, chronic, focal	2 (4%)				
Inflammation, subacute, focal	1 (2%)				
Epididymis	(48)	(8)	(2)	(8)	(48)
Inflammation, chronic, focal	1 (2%)				
Inflammation, chronic, focal, bilateral	1 (2%)				1 (2%)
Inflammation, chronic, focal, unilateral	1 (2%)	1 (13%)			1 (2%)
Inflammation, subacute, focal, unilateral	1 (2%)			1 (13%)	1 (2%)
Mineralization, focal, unilateral	1 (2%)				
Esophagus	(47)	(7)	(2)	(11)	(45)
Hyperkeratosis, diffuse		1 (14%)			
Hyperkeratosis, multifocal		1 (14%)			
Inflammation, subacute, focal	1 (2%)				
Eye	(44)	(6)	(1)	(7)	(45)
Hyperplasia, melanocyte, focal, unilateral		1 (17%)			

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<b>2-Year Study</b> (continued)					
Gallbladder	(40)	(3)	(1)	(7)	(42)
Edema, multifocal					1 (2%)
Fibrosis, diffuse					1 (2%)
Harderian gland	(46)	(8)	(1)	(9)	(44)
Degen, focal	1 (2%)				
Hyperplasia	1 (2%)				1 (2%)
Inflammation, chronic	3 (7%)	1 (13%)			7 (16%)
Inflammation, subacute	3 (7%)			3 (33%)	3 (7%)
Heart	(48)	(9)	(3)	(11)	(48)
Cardiomyopathy, diffuse					1 (2%)
Intestine large, cecum	(46)	(5)	(1)	(6)	(46)
Hyperplasia, lymphoid, focal	3 (7%)				2 (4%)
Intestine large, colon	(46)	(6)	(1)	(8)	(46)
Hyperplasia, lymphoid, focal	2 (4%)				2 (4%)
Intestine large, rectum	(45)	(8)	(1)	(7)	(47)
Cyst, multifocal, anus, mucosa		1 (13%)			
Hyperplasia, lymphoid, focal					1 (2%)
Inflammation, chronic, multifocal, anus		1 (13%)			
Intestine small, ileum	(46)	(6)	(1)	(7)	(46)
Hyperplasia, lymphoid, focal	1 (2%)	1 (17%)			3 (7%)
Intestine small, jejunum	(46)	(5)	(2)	(6)	(46)
Cyst, focal			1 (50%)		
Kidney	(47)	(48)	(45)	(47)	(48)
Cyst	1 (2%)	5 (10%)	3 (7%)	5 (11%)	1 (2%)
Degen, focal, cortex, renal tubule			1 (2%)	4 (9%)	1 (2%)
Degen, multifocal, cortex, renal tubule		2 (4%)			
Dilatation, diffuse, right, pelvis				1 (2%)	
Glmsclerosis, diffuse		1 (2%)			1 (2%)
Glmsclerosis, multifocal	14 (30%)	19 (40%)	22 (49%)	14 (30%)	13 (27%)
Hyperplasia, focal, cortex, renal tubule	6 (13%)	2 (4%)	4 (9%)	1 (2%)	8 (17%)
Hyperplasia, lymphoid, focal				1 (2%)	
Hyperplasia, multifocal, cortex, renal tubule	14 (30%)	14 (29%)	21 (47%)	7 (15%)	4 (8%)
Infarct				1 (2%)	
Inflammation, chronic, focal	7 (15%)	1 (2%)	6 (13%)	6 (13%)	6 (13%)
Inflammation, chronic, focal, pelvis					2 (4%)
Inflammation, chronic, multifocal	12 (26%)	18 (38%)	18 (40%)	20 (43%)	6 (13%)
Inflammation, focal		1 (2%)			
Inflammation, multifocal	1 (2%)				
Inflammation, subacute, focal			1 (2%)		
Inflammation, subacute, multifocal	5 (11%)	5 (10%)	9 (20%)	3 (6%)	5 (10%)
Mineralization, multifocal, renal tubule		1 (2%)	3 (7%)		
Nephropathy, chronic, multifocal		1 (2%)			3 (6%)
Proliferation, focal, renal tubule			2 (4%)	2 (4%)	
Proliferation, multifocal, renal tubule		2 (4%)	4 (9%)		
Lacrimal gland	(44)	(8)	(2)	(8)	(47)
Hyperplasia, focal, duct					1 (2%)
Hyperplasia, multifocal, duct	1 (2%)				
Inflammation, chronic, focal	6 (14%)				5 (11%)
Inflammation, chronic, multifocal	1 (2%)				1 (2%)
Inflammation, subacute, focal	2 (5%)	1 (13%)			1 (2%)

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<b>2-Year Study</b> (continued)					
Liver	(47)	(47)	(48)	(48)	(48)
Amyloid dep, multifocal				1 (2%)	
Apoptosis, hepatocyte					3 (6%)
Basoph focus	2 (4%)	1 (2%)		2 (4%)	2 (4%)
Clear cl focus	1 (2%)				1 (2%)
Cyst, focal			1 (2%)		
Cyst, multifocal	1 (2%)				1 (2%)
Eosin focus					1 (2%)
Granuloma	5 (11%)	5 (11%)	3 (6%)	6 (13%)	18 (38%)
Hypertrophy, diffuse, hepatocyte	10 (21%)	3 (6%)	16 (33%)	24 (50%)	30 (63%)
Hypertrophy, focal, hepatocyte		6 (13%)	8 (17%)	1 (2%)	
Infiltrat cell, lymphocytic, multifocal	2 (4%)	3 (6%)	3 (6%)	5 (10%)	8 (17%)
Mineralization, multifocal		1 (2%)		1 (2%)	
Necrosis, multifocal	1 (2%)	1 (2%)		4 (8%)	14 (29%)
Pigment, multifocal				2 (4%)	18 (38%)
Tension lipoid	3 (6%)	5 (11%)	4 (8%)	3 (6%)	9 (19%)
Vacuoliz cyto, centrilobular	7 (15%)	12 (26%)	21 (44%)	9 (19%)	9 (19%)
Vacuoliz cyto, diffuse			1 (2%)		
Lung	(48)	(9)	(2)	(11)	(48)
Degen, cystic, alveolar epith	1 (2%)				
Hyperplasia, focal, alveolar epith	1 (2%)			1 (9%)	1 (2%)
Inflammation, chronic, multifocal	7 (15%)				12 (25%)
Inflammation, subacute, focal	2 (4%)	1 (11%)			
Inflammation, subacute, multifocal	2 (4%)				3 (6%)
Inflammation, subacute, multifocal, perivascular		1 (11%)			
Lymph node, mandibular	(46)	(8)	(2)	(10)	(48)
Hyperplasia, lymphoid	6 (13%)				11 (23%)
Inflammation, focal					1 (2%)
Pigment, hemosiderin, multifocal		1 (13%)			
Pigment, multifocal	8 (17%)	2 (25%)	1 (50%)		8 (17%)
Lymph node, mesenteric	(48)	(7)	(3)	(15)	(45)
Angiectasis		1 (14%)			
Cyst, multifocal					1 (2%)
Deplet lymph, multifocal	2 (4%)				
Hemorrhage, focal	1 (2%)	1 (14%)			
Hemorrhage, multifocal	5 (10%)	1 (14%)			1 (2%)
Hyperplasia, lymphoid	7 (15%)	1 (14%)			18 (40%)
Hyperplasia, mononuclear cl, multifocal			1 (33%)		
Pigment, multifocal	6 (13%)				1 (2%)
Mesentery		(1)			
Granuloma, focal		1 (100%)			
Nose	(48)	(9)	(1)	(11)	(48)
Cytoplas alter, olfactory epi					1 (2%)
Exudate, focal, nasolacrim duct	2 (4%)				
Inflammation, chronic, focal	1 (2%)				2 (4%)
Inflammation, chronic, multifocal				1 (9%)	3 (6%)
Inflammation, subacute, focal	2 (4%)				
Inflammation, subacute, multifocal	2 (4%)				3 (6%)
Proliferation, multifocal				1 (9%)	
Pancreas	(47)	(8)	(1)	(10)	(47)
Atrophy, focal, acinar cell					1 (2%)
Cyst, focal					1 (2%)
Inflammation, chronic, focal					1 (2%)
Inflammation, subacute, focal				1 (10%)	
Parathyroid gland	(39)	(3)	(1)	(5)	(39)
Cyst, focal	1 (3%)				1 (3%)

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<b>2-Year Study</b> (continued)					
Preputial gland	(46)	(9)	(4)	(17)	(46)
Abscess, focal	1 (2%)				1 (2%)
Cyst, focal, right			1 (25%)		
Cyst, multifocal	9 (20%)	4 (44%)	2 (50%)	9 (53%)	18 (39%)
Cyst, multifocal, bilateral	9 (20%)	1 (11%)		2 (12%)	6 (13%)
Hyperplasia, diffuse, bilateral	1 (2%)				
Hyperplasia, diffuse, unilateral	1 (2%)				
Hypertrophy, diffuse, bilateral	1 (2%)				
Inflammation, chronic			2 (50%)	2 (12%)	2 (4%)
Inflammation, subacute	2 (4%)	1 (11%)			1 (2%)
Prostate	(46)	(8)		(10)	(47)
Inflammation, chronic	7 (15%)	2 (25%)		1 (10%)	7 (15%)
Inflammation, subacute	4 (9%)				
Salivary glands	(48)	(11)	(1)	(10)	(48)
Cyst, focal		1 (9%)			
Inflammation, chronic	19 (40%)	1 (9%)		2 (20%)	22 (46%)
Inflammation, subacute	4 (8%)	2 (18%)		3 (30%)	1 (2%)
Seminal vesicle	(46)	(8)	(1)	(9)	(47)
Inflammation, chronic, focal	1 (2%)	1 (13%)			
Inflammation, subacute, multifocal	1 (2%)				
Skeletal muscle	(47)	(9)	(2)	(12)	(48)
Degen	4 (9%)				3 (6%)
Skin	(48)	(11)	(7)	(14)	(47)
Hyperkeratosis, focal	1 (2%)				
Hyperplasia, focal	1 (2%)				
Hyperplasia, focal, sebaceous gland	1 (2%)				
Hyperplasia, lymphoid, focal	1 (2%)				
Hyperplasia, multifocal, dermis	1 (2%)				
Inflammation, chronic	1 (2%)	2 (18%)	3 (43%)	1 (7%)	4 (9%)
Necrosis, focal	1 (2%)				
Spinal cord, thoracic	(47)	(8)	(2)	(10)	(48)
Atrophy, focal					1 (2%)
Cyst, focal	1 (2%)				
Spleen	(47)	(8)	(1)	(13)	(48)
Congestion, multifocal	1 (2%)				
Cyst, focal	1 (2%)				
Deplet lymph, multifocal				1 (8%)	1 (2%)
Edema, multifocal		1 (13%)			
Hema cell prol	1 (2%)	2 (25%)		1 (8%)	2 (4%)
Hemorrhage, multifocal		1 (13%)			1 (2%)
Hyperplasia, lymphoid	14 (30%)	1 (13%)	1 (100%)	2 (15%)	15 (31%)
Stomach, forestomach	(47)	(7)	(1)	(11)	(48)
Hyperkeratosis, diffuse	1 (2%)	1 (14%)			
Hyperplasia, diffuse	1 (2%)	1 (14%)			
Necrosis, focal	1 (2%)				
Stomach, glandular	(45)	(7)	(2)	(10)	(45)
Hyperplasia, focal	1 (2%)				
Testes	(48)	(9)	(1)	(12)	(48)
Atrophy, unilateral, seminif tub	1 (2%)				
Degen, diffuse, bilateral, seminif tub	1 (2%)				
Degen, diffuse, unilateral, seminif tub		1 (11%)			
Degen, focal, unilateral, seminif tub	1 (2%)				
Degen, multifocal, bilateral, seminif tub	1 (2%)				
Degen, multifocal, unilateral, seminif tub	1 (2%)			1 (8%)	
Inflammation, subacute, multifocal, bilateral		1 (11%)			
Mineralization, multifocal, unilateral		1 (11%)		2 (16%)	1 (2%)

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<b>2-Year Study</b> (continued)					
Thymus	(33)	(6)	(2)	(7)	(26)
Atrophy	1 (3%)			1 (14%)	
Cyst		1 (17%)		1 (14%)	
Hyperplasia, lymphoid					1 (4%)
Thyroid gland	(44)	(7)	(1)	(7)	(46)
Cyst	2 (5%)				6 (13%)
Urinary bladder	(46)	(9)		(10)	(46)
Dilatation		1 (11%)		1 (10%)	
Inflammation, chronic	17 (37%)	3 (33%)		2 (20%)	22 (48%)
Inflammation, subacute	1 (2%)				1 (2%)

