

**APPENDIX B
SUMMARY OF LESIONS IN FEMALE RATS
IN THE 2-YEAR FEED STUDY
OF FUMONISIN B₁**

TABLE B1 **Summary of the Incidence of Neoplasms in Female Rats
in the 2-Year Feed Study of Fumonisin B₁** **B-2**

TABLE B2 **Individual Animal Tumor Pathology of Female Rats
in the 2-Year Feed Study of Fumonisin B₁** **B-6**

TABLE B3 **Statistical Analysis of Primary Neoplasms in Female Rats
in the 2-Year Feed Study of Fumonisin B₁** **B-26**

TABLE B4 **Summary of the Incidence of Nonneoplastic Lesions in Female Rats
in the 2-Year Feed Study of Fumonisin B₁** **B-29**

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

	0 ppm	5 ppm	15 ppm	50 ppm	100 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	1	2		2	
Moribund	20	15	23	16	16
Natural deaths	2	1	1		3
Survivors					
Terminal sacrifice	25	22	24	30	29
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
Ovary

Tissues Examined at 14 Weeks with No Neoplasms Observed

Intestine large
Kidney
Liver
Ovary
Uterus

Tissues Examined at 26 Weeks with No Neoplasms Observed

Kidney
Liver
Ovary
Uterus

2-Year Study

Adrenal gland	(48)	(20)	(24)	(19)	(47)
Adenoma, cortex	1 (2%)				1 (2%)
Leukemia monuc	5 (10%)	2 (10%)	8 (33%)	2 (11%)	6 (13%)
Osteosarc, metastatic, bone	1 (2%)				
Pheochrom bgn, medulla	2 (4%)		1 (4%)	1 (5%)	2 (4%)
Bone	(48)	(18)	(24)	(18)	(48)
Sarcoma, maxilla				1 (6%)	

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

	0 ppm	5 ppm	15 ppm	50 ppm	100 ppm
2-Year Study (continued)					
Bone, femur	(48)	(18)	(24)	(18)	(48)
Osteosarc	1 (2%)				
Bone marrow	(46)	(18)	(23)	(18)	(48)
Leukemia monuc	6 (13%)	6 (33%)	10 (43%)	5 (28%)	10 (21%)
Brain	(48)	(18)	(24)	(18)	(48)
Carcinoma, metastatic, pituitary gland					1 (2%)
Leukemia monuc		1 (6%)	1 (4%)		1 (2%)
Brain, cerebrum	(48)	(18)	(24)	(18)	(48)
Astrocyto mal	1 (2%)				
Meningioma mal					1 (2%)
Clitoral gland	(41)	(19)	(25)	(22)	(40)
Adenoma	9 (22%)	2 (11%)	7 (28%)	6 (27%)	8 (20%)
Adenoma, bilateral	1 (2%)		2 (8%)		2 (5%)
Carcinoma	1 (2%)				1 (3%)
Leukemia monuc	1 (2%)	1 (5%)	1 (4%)		
Esophagus	(48)	(18)	(23)	(17)	(48)
Leukemia monuc			1 (4%)		
Osteosarc, metastatic, bone	1 (2%)				
Harderian gland	(48)	(18)	(24)	(18)	(48)
Leukemia monuc			1 (4%)		1 (2%)
Heart	(48)	(18)	(24)	(18)	(48)
Alv bron carc, metastatic, lung					1 (2%)
Leukemia monuc	3 (6%)	1 (6%)	6 (25%)	2 (11%)	5 (10%)
Mesothelio mal, metastatic, unc pri site	1 (2%)				
Intestine large, cecum	(47)	(16)	(24)	(16)	(47)
Leukemia monuc			1 (4%)		
Intestine large, colon	(47)	(18)	(24)	(18)	(47)
Leukemia monuc			1 (4%)		
Intestine large, rectum	(47)	(18)	(24)	(18)	(48)
Histio sarc, metastatic, skin					1 (2%)
Leukemia monuc			1 (4%)		
Schwannoma mal, metastatic, uterus			1 (4%)		
Intestine small, duodenum	(47)	(18)	(24)	(18)	(48)
Leiomyosar				1 (6%)	
Leukemia monuc			1 (4%)		
Intestine small, ileum	(44)	(18)	(24)	(18)	(46)
Leukemia monuc			2 (8%)		
Intestine small, jejunum	(47)	(18)	(24)	(18)	(46)
Leukemia monuc			1 (4%)		
Kidney	(48)	(40)	(48)	(48)	(48)
Adenoma, renal tubule				1 (2%)	
Carcinoma, renal tubule					1 (2%)
Leukemia monuc	2 (4%)	1 (3%)	6 (13%)	3 (6%)	5 (10%)
Lacrimal gland	(47)	(22)	(26)	(19)	(48)
Leukemia monuc	2 (4%)		3 (12%)		6 (13%)
Liver	(48)	(40)	(48)	(48)	(48)
Hepatocl aden			1 (2%)		
Histio sarc, metastatic, skin					1 (2%)
Leukemia monuc	12 (25%)	13 (33%)	15 (31%)	8 (17%)	16 (33%)
Lung	(47)	(40)	(48)	(48)	(48)
Alv bron aden		1 (3%)		1 (2%)	2 (4%)
Alv bron carc					1 (2%)
Histio sarc, metastatic, skin					1 (2%)
Leukemia monuc	8 (17%)	10 (25%)	11 (23%)	6 (13%)	6 (13%)
Osteosarc, metastatic, bone	1 (2%)				

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

	0 ppm	5 ppm	15 ppm	50 ppm	100 ppm
2-Year Study (continued)					
Lung, bronchus	(47)	(40)	(48)	(48)	(48)
Carcinoma			1 (2%)		
Lymph node	(48)	(20)	(25)	(18)	(48)
Leukemia monuc	1 (2%)			1 (6%)	
Leukemia monuc, inguinal		1 (5%)			
Leukemia monuc, pancreatic			1 (4%)		
Leukemia monuc, renal	1 (2%)				
Leukemia monuc, thoracic				1 (6%)	
Lymph node, mandibular	(48)	(17)	(24)	(17)	(48)
Leukemia monuc	9 (19%)	5 (29%)	8 (33%)	4 (24%)	10 (21%)
Lymph node, mesenteric	(48)	(19)	(25)	(18)	(48)
Leukemia monuc	8 (17%)	5 (26%)	10 (40%)	4 (22%)	7 (15%)
Mammary gland	(47)	(28)	(33)	(30)	(48)
Adenoma	1 (2%)		1 (3%)		
Carcinoma	2 (4%)	3 (11%)	3 (9%)		3 (6%)
Carcinoma, multiple			1 (3%)		
Fibroadenoma	15 (32%)	11 (39%)	12 (36%)	11 (37%)	8 (17%)
Fibroadenoma, multiple	3 (6%)	2 (7%)	4 (12%)	5 (17%)	3 (6%)
Fibroma	1 (2%)				
Leukemia monuc		1 (4%)	1 (3%)		
Mesentery	(2)	(5)	(5)	(3)	(2)
Leukemia monuc	1 (50%)	1 (20%)	1 (20%)		
Ovary	(47)	(19)	(25)	(22)	(47)
Gra cl tum bgn	2 (4%)				
Leukemia monuc	1 (2%)	1 (5%)	3 (12%)		
Pancreas	(48)	(18)	(24)	(18)	(48)
Leukemia monuc	1 (2%)	1 (6%)	6 (25%)	1 (6%)	
Pituitary gland	(47)	(30)	(35)	(34)	(48)
Adenoma, pars distalis	32 (68%)	20 (67%)	25 (71%)	23 (68%)	29 (60%)
Adenoma, pars intermed				1 (3%)	
Carcinoma, pars distalis					1 (2%)
Leukemia monuc	1 (2%)	3 (10%)	4 (11%)	2 (6%)	
Salivary glands	(48)	(18)	(25)	(18)	(48)
Leukemia monuc		1 (6%)	2 (8%)		
Skeletal muscle	(48)	(18)	(24)	(18)	(48)
Histo sarc, metastatic, skin					1 (2%)
Skeletal muscle, thigh	(48)	(18)	(24)	(18)	(48)
Osteosarc, metastatic, bone	1 (2%)				
Skin	(48)	(18)	(27)	(21)	(48)
Fibroma, subcut tiss	1 (2%)		1 (4%)		2 (4%)
Histo sarc, subcut tiss					1 (2%)
Keratoacanthma			1 (4%)		
Lipoma, subcut tiss	1 (2%)			2 (10%)	
Liposarc, subcut tiss				1 (5%)	
Melanoma mal, subcut tiss, head					1 (2%)
Schwannoma mal, subcut tiss	1 (2%)				
Squam cel carc				1 (5%)	
Spleen	(48)	(25)	(30)	(21)	(48)
Histo sarc, metastatic, skin					1 (2%)
Leukemia monuc	13 (27%)	12 (48%)	15 (50%)	8 (38%)	16 (33%)
Stomach, forestomach	(48)	(17)	(24)	(18)	(48)
Leukemia monuc	1 (2%)	1 (6%)	2 (8%)		1 (2%)
Stomach, glandular	(48)	(18)	(24)	(18)	(48)
Leukemia monuc		1 (6%)	3 (13%)		1 (2%)

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

	0 ppm	5 ppm	15 ppm	50 ppm	100 ppm
2-Year Study (continued)					
Thymus	(41)	(15)	(22)	(18)	(40)
Leukemia monuc	4 (10%)	4 (27%)	9 (41%)	2 (11%)	7 (18%)
Thyroid gland	(48)	(18)	(25)	(19)	(48)
Adenoma, c cell	2 (4%)		3 (12%)		6 (13%)
Adenoma, multiple, c cell	1 (2%)				
Carcinoma, c cell	1 (2%)		1 (4%)	1 (5%)	1 (2%)
Leukemia monuc		1 (6%)	2 (8%)		
Tongue	(48)	(18)	(24)	(20)	(48)
Papilloma squa				2 (10%)	
Trachea	(48)	(18)	(24)	(18)	(48)
Leukemia monuc			1 (4%)		
Urinary bladder	(45)	(17)	(24)	(18)	(47)
Leukemia monuc	1 (2%)	1 (6%)	6 (25%)		
Papilloma, transit epithe					1 (2%)
Schwannoma mal, metastatic, uterus			1 (4%)		
Uterus	(47)	(23)	(30)	(23)	(48)
Carcinoma, endometrium					1 (2%)
Deciduoma bgn	1 (2%)				
Leiomyosar	1 (2%)				
Leukemia monuc	1 (2%)	1 (4%)	3 (10%)		
Leukemia monuc, cervix				1 (4%)	
Polyp stromal, endometrium	10 (21%)	4 (17%)	5 (17%)	3 (13%)	7 (15%)
Sarc stromal					1 (2%)
Sarcoma, cervix		1 (4%)			
Schwannoma mal			1 (3%)		
Vagina	(47)	(17)	(25)	(18)	(47)
Leukemia monuc	1 (2%)	1 (6%)	3 (12%)	2 (11%)	1 (2%)
Liposarc					1 (2%)
Papilloma squa	1 (2%)				
Polyp			1 (4%)		
Schwannoma mal, metastatic, uterus			1 (4%)		
Zymbal's gland	(34)	(15)	(18)	(14)	(38)
Adenoma				1 (7%)	
Carcinoma		1 (7%)			

Neoplasm Summary

Total animals with primary neoplasms ^b					
2-Year study	43	32	44	43	46
Total primary neoplasms					
2-Year study	175	121	221	114	184
Total animals with benign neoplasms					
2-Year study	41	26	37	38	42
Total benign neoplasms					
2-Year study	84	40	64	57	71
Total animals with malignant neoplasms					
2-Year study	18	17	22	14	25
Total malignant neoplasms					
2-Year study	91	81	157	57	113
Total animals with metastatic neoplasms					
2-Year study	2		1		3
Total metastatic neoplasms					
2-Year study	5		3		7

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

^b Primary neoplasms: all neoplasms except metastatic neoplasms