

**TABLE B3**  
**Statistical Analysis of Primary Neoplasms in Female Rats in the 2-Year Feed Study of Fumonisin B<sub>1</sub>**

	0 ppm	5 ppm	15 ppm	50 ppm	100 ppm
<b>Clitoral Gland: Adenoma</b>					
Overall rate <sup>a</sup>	10/41 (24%)	2/19 (11%)	9/25 (36%)	6/22 (27%)	10/40 (25%)
Adjusted rate <sup>b</sup>	27.8%	17.8%	48.9%	37.0%	27.6%
Terminal rate <sup>c</sup>	5/24 (21%)	2/5 (40%)	4/5 (80%)	4/7 (57%)	5/24 (21%)
First incidence (days)	574	740 (T)	509	642	659
Poly-3 test <sup>d</sup>	P= 0.5089N	P= 0.3240N	P= 0.0967	P= 0.3948	P= 0.5840
<b>Lung: Alveolar/Bronchiolar Adenoma or Carcinoma</b>					
Overall rate	0/47 (0%)	1/40 (3%)	0/48 (0%)	1/48 (2%)	3/48 (6%)
Adjusted rate	0.0%	3.2%	0.0%	2.5%	7.1%
Terminal rate	0/26 (0%)	1/24 (4%)	0/24 (0%)	1/32 (3%)	2/29 (7%)
First incidence (days)	— <sup>e</sup>	740 (T)	—	740 (T)	680
Poly-3 test	P= 0.0340	P= 0.4534	— <sup>f</sup>	P= 0.5032	P= 0.1218
<b>Mammary Gland: Fibroadenoma</b>					
Overall rate	18/47 (38%)	13/28 (46%)	16/33 (49%)	16/30 (53%)	11/48 (23%)
Adjusted rate	43.6%	59.8%	61.8%	67.2%	26.0%
Terminal rate	10/25 (40%)	6/12 (50%)	9/10 (90%)	11/14 (79%)	9/29 (31%)
First incidence (days)	321	498	509	539	673
Poly-3 test	P= 0.0112N	P= 0.2318	P= 0.0914	P= 0.0841	P= 0.0803N
<b>Mammary Gland: Carcinoma</b>					
Overall rate	2/47 (4%)	3/28 (11%)	4/33 (12%)	0/30 (0%)	3/48 (6%)
Adjusted rate	5.0%	15.1%	15.8%	0.0%	7.2%
Terminal rate	0/25 (0%)	1/12 (8%)	0/10 (0%)	0/14 (0%)	3/29 (10%)
First incidence (days)	706	509	406	—	740 (T)
Poly-3 test	P= 0.3600N	P= 0.2319	P= 0.1487	P= 0.3613N	P= 0.5147
<b>Mammary Gland: Adenoma or Carcinoma</b>					
Overall rate	3/47 (6%)	3/28 (11%)	4/33 (12%)	0/30 (0%)	3/48 (6%)
Adjusted rate	7.6%	15.1%	15.8%	0.0%	7.2%
Terminal rate	1/25 (4%)	1/12 (8%)	0/10 (0%)	0/14 (0%)	3/29 (10%)
First incidence (days)	706	509	406	—	740 (T)
Poly-3 test	P= 0.2642N	P= 0.3579	P= 0.2561	P= 0.2286N	P= 0.6481N
<b>Mammary Gland: Fibroadenoma, Adenoma, or Carcinoma</b>					
Overall rate	21/47 (45%)	15/28 (54%)	20/33 (61%)	16/30 (53%)	13/48 (27%)
Adjusted rate	50.5%	66.9%	71.9%	67.2%	30.7%
Terminal rate	11/25 (44%)	7/12 (58%)	9/10 (90%)	11/14 (79%)	11/29 (38%)
First incidence (days)	321	498	406	539	673
Poly-3 test	P= 0.0032N	P= 0.2285	P= 0.0436	P= 0.2078	P= 0.0578N
<b>Pituitary Gland (Pars Distalis): Adenoma</b>					
Overall rate	32/47 (68%)	20/30 (67%)	25/35 (71%)	23/34 (68%)	29/48 (60%)
Adjusted rate	75.6%	78.6%	83.3%	80.4%	63.6%
Terminal rate	19/26 (73%)	11/15 (73%)	12/12 (100%)	15/19 (79%)	19/29 (66%)
First incidence (days)	574	460	509	400	477
Poly-3 test	P= 0.0761N	P= 0.5933N	P= 0.2375	P= 0.5455	P= 0.2003N

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	0 ppm	5 ppm	15 ppm	50 ppm	100 ppm
<b>Pituitary Gland (Pars Distalis): Adenoma or Carcinoma</b>					
Overall rate	32/47 (68%)	20/30 (67%)	25/35 (71%)	23/34 (68%)	30/48 (63%)
Adjusted rate	75.6%	78.6%	83.3%	80.4%	65.4%
Terminal rate	19/26 (73%)	11/15 (73%)	12/12 (100%)	15/19 (79%)	19/29 (66%)
First incidence (days)	574	460	509	400	477
Poly-3 test	P= 0.1126N	P= 0.5933N	P= 0.2375	P= 0.5455	P= 0.2550N
<b>Skin (Subcutaneous Tissue): Fibroma, Fibrous Histiocytoma, Histiocytic Sarcoma, or Sarcoma</b>					
Overall rate	1/48 (2%)	0/18 (0%)	1/27 (4%)	0/21 (0%)	3/48 (6%)
Adjusted rate	2.4%	0.0%	5.8%	0.0%	7.1%
Terminal rate	0/26 (0%)	0/2 (0%)	1/3 (33%)	0/5 (0%)	2/29 (7%)
First incidence (days)	587	—	740 (T)	—	671
Poly-3 test	P= 0.1878	P= 0.7444N	P= 0.5497	P= 0.6956N	P= 0.3074
<b>Thyroid Gland (C-cell): Adenoma</b>					
Overall rate	3/48 (6%)	0/18 (0%)	3/25 (12%)	0/19 (0%)	6/48 (13%)
Adjusted rate	7.4%	0.0%	17.9%	0.0%	14.1%
Terminal rate	3/26 (12%)	0/2 (0%)	0/1 (0%)	0/3 (0%)	3/29 (10%)
First incidence (days)	740 (T)	—	453	—	659
Poly-3 test	P= 0.1990	P= 0.4401N	P= 0.2428	P= 0.3896N	P= 0.2559
<b>Thyroid Gland (C-cell): Adenoma or Carcinoma</b>					
Overall rate	4/48 (8%)	0/18 (0%)	4/25 (16%)	1/19 (5%)	7/48 (15%)
Adjusted rate	9.9%	0.0%	23.9%	9.0%	16.4%
Terminal rate	4/26 (15%)	0/2 (0%)	1/1 (100%)	1/3 (33%)	4/29 (14%)
First incidence (days)	740 (T)	—	453	740 (T)	659
Poly-3 test	P= 0.2383	P= 0.3563N	P= 0.1684	P= 0.6243N	P= 0.2771
<b>Uterus: Stromal Polyp</b>					
Overall rate	10/47 (21%)	4/23 (17%)	5/30 (17%)	3/23 (13%)	7/48 (15%)
Adjusted rate	24.6%	28.3%	23.6%	19.4%	16.2%
Terminal rate	7/26 (27%)	3/7 (43%)	3/6 (50%)	2/7 (29%)	4/29 (14%)
First incidence (days)	537	659	453	649	477
Poly-3 test	P= 0.1723N	P= 0.5979	P= 0.6056N	P= 0.4175N	P= 0.2645N
<b>Uterus: Stromal Polyp, Stromal Sarcoma, or Carcinoma</b>					
Overall rate	10/47 (21%)	4/23 (17%)	5/30 (17%)	3/23 (13%)	8/48 (17%)
Adjusted rate	24.6%	28.3%	23.6%	19.4%	18.5%
Terminal rate	7/26 (27%)	3/7 (43%)	3/6 (50%)	2/7 (29%)	5/29 (17%)
First incidence (days)	537	659	453	649	477
Poly-3 test	P= 0.2631N	P= 0.5979	P= 0.6056N	P= 0.4175N	P= 0.3614N
<b>All Organs: Mononuclear Cell Leukemia</b>					
Overall rate	13/48 (27%)	13/40 (33%)	16/48 (33%)	9/48 (19%)	16/48 (33%)
Adjusted rate	30.6%	39.0%	38.8%	21.8%	35.9%
Terminal rate	6/26 (23%)	7/24 (29%)	6/24 (25%)	4/32 (13%)	7/29 (24%)
First incidence (days)	574	468	495	580	477
Poly-3 test	P= 0.4956N	P= 0.3354	P= 0.2612	P= 0.2350N	P= 0.3542

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**Statistical Analysis of Primary Neoplasms in Female Rats in the 2-Year Feed Study of Fumonisin B<sub>1</sub>**

	0 ppm	5 ppm	15 ppm	50 ppm	100 ppm
<b>All Organs: Benign Neoplasms</b>					
Overall rate	41/48 (85%)	26/40 (65%)	37/48 (77%)	38/48 (79%)	42/48 (88%)
Adjusted rate	89.9%	73.5%	81.9%	86.2%	88.5%
Terminal rate	22/26 (85%)	15/24 (63%)	19/24 (79%)	26/32 (81%)	25/29 (86%)
First incidence (days)	321	460	453	400	477
Poly-3 test	P= 0.1454	P= 0.0282N	P= 0.2859N	P= 0.3275N	P= 0.6053
<b>All Organs: Malignant Neoplasms</b>					
Overall rate	18/48 (38%)	17/40 (43%)	22/48 (46%)	14/48 (29%)	25/48 (52%)
Adjusted rate	41.6%	49.0%	50.3%	33.0%	55.3%
Terminal rate	7/26 (27%)	8/24 (33%)	7/24 (29%)	6/32 (19%)	13/29 (45%)
First incidence (days)	574	468	406	580	477
Poly-3 test	P= 0.2318	P= 0.3806	P= 0.2439	P= 0.2508N	P= 0.1168
<b>All Organs: Benign or Malignant Neoplasms</b>					
Overall rate	43/48 (90%)	32/40 (80%)	44/48 (92%)	43/48 (90%)	46/48 (96%)
Adjusted rate	92.5%	85.5%	92.8%	95.0%	95.8%
Terminal rate	22/26 (85%)	17/24 (71%)	21/24 (88%)	28/32 (88%)	27/29 (93%)
First incidence (days)	321	460	406	400	477
Poly-3 test	P= 0.0788	P= 0.1774N	P= 0.4964	P= 0.5927	P= 0.2681

(T)Terminal sacrifice

<sup>a</sup> Number of neoplasm-bearing animals/number of animals examined microscopically

<sup>b</sup> Poly-3 estimated neoplasm incidence after adjustment for intercurrent mortality

<sup>c</sup> Observed incidence at terminal kill

<sup>d</sup> Beneath the control incidence are the P values associated with the trend test. Beneath the exposed group incidence are the P values corresponding to pairwise comparisons between the controls and that exposed group. For all tissues except the lung, only the pairwise comparisons between the 100 ppm group and control group are unbiased; overall rates and all other pairwise comparisons may not be valid. The Poly-3 test accounts for differential mortality in animals that do not reach terminal sacrifice. A negative trend or a lower incidence in an exposure group is indicated by N.

<sup>e</sup> Not applicable; no neoplasms in animal group

<sup>f</sup> Value of statistic cannot be computed.