

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

	0 ppm	5 ppm	15 ppm	50 ppm	80 ppm
Harderian Gland: Adenoma					
Overall rate ^a	4/46 (9%)	1/5 (20%)	1/3 (33%)	2/8 (25%)	0/44 (0%)
Adjusted rate ^b	9.3%	30.7%	42.1%	35.9%	0.0%
Terminal rate ^c	4/39 (10%)	1/1 (100%)	1/1 (100%)	0/0	0/28 (0%)
First incidence (days)	630	740 (T)	740 (T)	636	— ^e
Poly-3 test ^d	P= 0.0839N	P= 0.4035	P= 0.3148	P= 0.1546	P= 0.0914N
Harderian Gland: Adenoma or Carcinoma					
Overall rate	4/46 (9%)	1/5 (20%)	1/3 (33%)	2/8 (25%)	0/44 (0%)
Adjusted rate	9.3%	30.7%	42.1%	35.9%	0.0%
Terminal rate	4/39 (10%)	1/1 (100%)	1/1 (100%)	0/0	0/28 (0%)
First incidence (days)	630	740 (T)	740 (T)	—	—
Poly-3 test	P= 0.0839N	P= 0.4035	P= 0.3148	P= 0.1546	P= 0.0914N
Liver: Hepatocellular Adenoma					
Overall rate	5/47 (11%)	3/48 (6%)	1/48 (2%)	16/47 (34%)	31/45 (69%)
Adjusted rate	11.7%	6.5%	2.1%	36.3%	73.7%
Terminal rate	5/39 (13%)	3/44 (7%)	1/46 (2%)	14/39 (36%)	21/28 (75%)
First incidence (days)	740 (T)	740 (T)	740 (T)	703	391
Poly-3 test	P= 0.0001	P= 0.3314N	P= 0.0862N	P= 0.0047	P= 0.0001
Liver: Hepatocellular Carcinoma					
Overall rate	0/47 (0%)	0/48 (0%)	0/48 (0%)	10/47 (21%)	9/45 (20%)
Adjusted rate	0.0%	0.0%	0.0%	22.5%	23.0%
Terminal rate	0/39 (0%)	0/44 (0%)	0/46 (0%)	8/39 (21%)	3/28 (11%)
First incidence (days)	—	—	—	636	437
Poly-3 test	P= 0.0001	— ^f	—	P= 0.0007	P= 0.0007
Liver: Hepatocellular Adenoma or Carcinoma					
Overall rate	5/47 (11%)	3/48 (6%)	1/48 (2%)	19/47 (40%)	39/45 (87%)
Adjusted rate	11.7%	6.5%	2.1%	42.7%	88.3%
Terminal rate	5/39 (13%)	3/44 (7%)	1/46 (2%)	16/39 (41%)	24/28 (86%)
First incidence (days)	740 (T)	740 (T)	740 (T)	636	391
Poly-3 test	P= 0.0001	P= 0.3314N	P= 0.0862N	P= 0.0005	P= 0.0001
All Organs: Malignant Lymphoma					
Overall rate	20/47 (43%)	9/48 (19%)	10/48 (21%)	9/48 (19%)	14/48 (29%)
Adjusted rate	46.6%	19.5%	21.1%	19.5%	36.9%
Terminal rate	19/39 (49%)	9/44 (21%)	10/46 (22%)	4/39 (10%)	12/28 (43%)
First incidence (days)	668	740 (T)	740 (T)	481	641
Poly-3 test	P= 0.5023N	P= 0.0070N	P= 0.0115N	P= 0.0070N	P= 0.3020N
All Organs: Benign Neoplasms					
Overall rate	13/47 (28%)	4/48 (8%)	3/48 (6%)	21/48 (44%)	31/48 (65%)
Adjusted rate	29.7%	8.6%	6.3%	46.1%	72.5%
Terminal rate	11/39 (28%)	4/44 (9%)	3/46 (7%)	16/39 (41%)	21/28 (75%)
First incidence (days)	619	740 (T)	740 (T)	572	391
Poly-3 test	P= 0.0001	P= 0.0114N	P= 0.0036N	P= 0.0691	P= 0.0001

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	0 ppm	5 ppm	15 ppm	50 ppm	80 ppm
All Organs: Malignant Neoplasms					
Overall rate	28/47 (60%)	13/48 (27%)	12/48 (25%)	19/48 (40%)	25/48 (52%)
Adjusted rate	62.0%	27.5%	25.0%	40.0%	60.2%
Terminal rate	21/39 (54%)	10/44 (23%)	11/46 (24%)	11/39 (28%)	15/28 (54%)
First incidence (days)	436	475	555	454	437
Poly-3 test	P= 0.0512	P= 0.0009N	P= 0.0003N	P= 0.0405N	P= 0.5742
All Organs: Benign or Malignant Neoplasms					
Overall rate	32/47 (68%)	16/48 (33%)	13/48 (27%)	30/48 (63%)	44/48 (92%)
Adjusted rate	69.8%	33.8%	27.1%	62.5%	96.3%
Terminal rate	24/39 (62%)	13/44 (30%)	12/46 (26%)	21/39 (54%)	27/28 (96%)
First incidence (days)	436	475	555	454	391
Poly-3 test	P= 0.0001	P= 0.0005N	P= 0.0001N	P= 0.3621N	P= 0.0002

(T)Terminal sacrifice

^a Number of neoplasm-bearing animals/number of animals examined microscopically

^b Poly-3 estimated neoplasm incidence after adjustment for intercurrent mortality

^c Observed incidence at terminal kill

^d 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 liver, only the pairwise comparisons between the 80 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**.

^e Not applicable; no neoplasms in animal group

^f Value of statistic cannot be computed.