

DBP Chronic Perinatal Study-Rats

Table 2: PND 4 and 21 Live Litter Size and Survival

Parameter	Control	300 ppm	1000 ppm	3000 ppm	10000 ppm	Trend
Live Per Litter^{a,b}						
PND 4 Precull Male ^c	5.77 ± 0.40 [31]	6.04 ± 0.46 [23]	5.66 ± 0.42 [32]	5.84 ± 0.26 [32]	5.60 ± 0.48 [20]	0.726-
PND 4 Precull Female ^c	5.65 ± 0.37 [31]	6.70 ± 0.46 [23]	6.47 ± 0.38 [32]	6.28 ± 0.25 [32]	6.55 ± 0.51 [20]	0.390+
PND 4 Precull Total ^g	11.34 ± 0.34 [35]	12.77 ± 0.39 [26]*	12.15 ± 0.35 [33]	12.12 ± 0.26 [33]	11.88 ± 0.46 [32]	0.732+
PND 4 Postcull Male	4.00 ± 0.10 [28]	3.88 ± 0.09 [25]	3.89 ± 0.15 [27]	4.00 ± 0.00 [30]	3.85 ± 0.12 [27]	0.977-
PND 4 Postcull Female	4.00 ± 0.10 [28]	4.12 ± 0.09 [25]	4.11 ± 0.15 [27]	4.00 ± 0.00 [30]	4.15 ± 0.12 [27]	0.977+
PND 4 Postcull Total	8.00 ± 0.00 [28]	8.00 ± 0.00 [25]	8.00 ± 0.00 [27]	8.00 ± 0.00 [30]	8.00 ± 0.00 [27]	1.000+
PND 7 Male + Female	8.00 ± 0.00 [28]	8.00 ± 0.00 [25]	8.00 ± 0.00 [27]	8.00 ± 0.00 [30]	8.00 ± 0.00 [27]	1.000+
PND 10 Male + Female	8.00 ± 0.00 [28]	8.00 ± 0.00 [25]	8.00 ± 0.00 [27]	8.00 ± 0.00 [30]	7.96 ± 0.04 [27]	0.156-
PND 14 Male + Female	8.00 ± 0.00 [28]	7.96 ± 0.04 [25]	8.00 ± 0.00 [27]	8.00 ± 0.00 [30]	7.96 ± 0.04 [27]	0.621-
PND 17 Male + Female	8.00 ± 0.00 [28]	7.96 ± 0.04 [25]	7.96 ± 0.04 [27]	8.00 ± 0.00 [30]	7.96 ± 0.04 [27]	0.707-
PND 21 Male	4.00 ± 0.10 [28]	3.88 ± 0.09 [25]	3.85 ± 0.16 [27]	4.00 ± 0.00 [30]	3.85 ± 0.12 [27]	0.988-
PND 21 Female	4.00 ± 0.10 [28]	4.08 ± 0.10 [25]	4.11 ± 0.15 [27]	4.00 ± 0.00 [30]	4.11 ± 0.10 [27]	0.877+
PND 21 Male + Female	8.00 ± 0.00 [28]	7.96 ± 0.04 [25]	7.96 ± 0.04 [27]	8.00 ± 0.00 [30]	7.96 ± 0.04 [27]	0.707-
% Male PND 4 Precull						
% Male in Group ^{d,e}	50.6 [354]	47.4 [293]	46.6 [388]	48.2 [388]	46.1 [243]	
% Male in Litter ^a	50.3 ± 3.1 [31]	47.7 ± 3.2 [23]	46.1 ± 3.1 [32]	48.1 ± 1.7 [32]	46.1 ± 2.5 [20]	0.560-
Survival^{a,b,f,g}						
Total Dead PND 1-4 ^{e,g,j}	5 [35]	2 [26]	2 [33]	6 [33]	7 [32]	
Total Dead PND 4-21 ^{e,j}	0 [28]	1 [25]	1 [27]	0 [30]	1 [27]	
Dead/Litter PND 1-4 ^g	0.14 ± 0.07 [35]	0.08 ± 0.05 [26]	0.06 ± 0.04 [33]	0.18 ± 0.11 [33]	0.22 ± 0.10 [32]	0.548+
Dead/Litter PND 4-21	0.00 ± 0.00 [28]	0.04 ± 0.04 [25]	0.04 ± 0.04 [27]	0.00 ± 0.00 [30]	0.04 ± 0.04 [27]	0.707+
Survival 1-4 ^{g,h}	0.998 ± 0.002 [35]	1.000 ± 0.000 [26]	0.997 ± 0.003 [33]	1.000 ± 0.000 [33]	0.997 ± 0.003 [32]	1.000+
Survival 4-21 ⁱ	1.000 ± 0.000 [28]	0.995 ± 0.005 [25]	0.995 ± 0.005 [27]	1.000 ± 0.000 [30]	0.995 ± 0.005 [27]	0.707-

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- a: Each dose was compared to the control with Shirley's test when a trend was present ($P < .01$ from Jonckheere's trend test), or with Dunn's test when no trend was present [$* = P < 0.05$, $** = P < 0.01$]
- b: Results shown as mean \pm standard error [number of litters] unless otherwise noted.
- c: Litters where the male/female pup counts were inconsistent between PND 1 and PND 4 were excluded from the male/female-specific endpoints.
- d: $100 \times (\text{Number of live males in dose group}) / (\text{Number of live males and females in dose group})$ [Number of pups]
- e: No statistics were performed on this endpoint.
- f: There was one non-sexed dead pup on PND1 in the 1000 ppm group.
- g: PND 1-4 litter size, dead, and survival endpoints do not include litters where the pup count increased from PND 1 to PND 4
- h: $(\text{Number alive on PND 4 precull}) / (\text{Number alive on PND 1})$
- i: $(\text{Number alive on PND 21}) / (\text{Number alive on PND 4 postcull})$
- j: Number of dead pups in dose [Number of litters]