

**Study Number:** R10997  
**Test Type:** RACB  
**Route:** Dosing in Feed  
**Species/Strain:** Rat/Sprague-Dawley

**R03: Summary of Litter Data**  
**Test Compound:** Diisobutyl Phthalate  
**CAS Number:** 84-69-5

**Date Report Requested:** 01/15/2020  
**Time Report Requested:** 06:35:59  
**Lab:** RTI

**C Number:** R10997  
**Study Gender:** Both  
**PWG Approval Date** See web page for date of PWG Approval

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**F1 Pups from F0 Females**

Litter ID		Treatment Groups (ppm)			
		0	1000	5000	10000
A	No. F0 Dams				
	PND 0	21	23	21	22
	Total No. Pups				
	PND 0	285	298	279	264
	Total Pups per Litter				
	PND 0	13.6 ± 0.4 (21) *	13.0 ± 0.6 (23)	13.3 ± 0.6 (21)	12.0 ± 0.5 (22)
	Total No. Live				
	PND 0	265	281	266	243
	Live per Litter				
	PND 0	12.6 ± 0.5 (21)	12.2 ± 0.7 (23)	12.7 ± 0.6 (21)	11.0 ± 0.7 (22)
	PND 1	12.9 ± 0.4 (20)	11.9 ± 0.8 (23)	12.3 ± 0.8 (21)	10.8 ± 0.7 (22)
	PND 4	12.9 ± 0.4 (20)	11.6 ± 0.8 (23)	12.3 ± 0.8 (21)	10.7 ± 0.7 (22)
	Dead per Litter				
	PND 0	0.95 ± 0.26 (21)	0.74 ± 0.20 (23)	0.62 ± 0.23 (21)	0.95 ± 0.36 (22)
	PND 1 - 4	0.38 ± 0.29 (21)	0.61 ± 0.21 (23)	0.38 ± 0.21 (21)	0.32 ± 0.12 (22)
	Number of Dead				
	PND 0	20 (13)	17 (12)	13 (7)	21 (9)
	PND 1 - 4	8 (3)	14 (8)	8 (4)	7 (6)
	% Live Male Pups per Litter				
	PND 0	47.49 ± 3.92 (21)	51.08 ± 3.16 (23)	47.86 ± 2.85 (21)	44.59 ± 3.01 (22)
Survival Ratio					
PND 0	0.93 ± 0.02 (21)	0.93 ± 0.02 (23)	0.95 ± 0.02 (21)	0.91 ± 0.03 (22)	
PND 1 - 4	0.95 ± 0.05 (21)	0.93 ± 0.03 (23)	0.95 ± 0.03 (21)	0.97 ± 0.01 (22)	

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Litter ID		Treatment Groups (ppm)			
		0	1000	5000	10000
B	No. F0 Dams				
	PND 0	21	23	21	22
	Total No. Pups				
	PND 0	267	305	287	282
	Total Pups per Litter				
	PND 0	12.7 ± 0.7 (21)	13.3 ± 0.6 (23)	13.7 ± 0.5 (21)	12.8 ± 0.7 (22)
	Total No. Live				
	PND 0	250	292	268	279
	Live per Litter				
	PND 0	11.9 ± 0.7 (21)	12.7 ± 0.5 (23)	12.8 ± 0.7 (21)	12.7 ± 0.7 (22)
	PND 1	11.8 ± 0.7 (21)	12.5 ± 0.6 (23)	12.6 ± 0.7 (21)	12.3 ± 0.7 (22)
	PND 4	11.8 ± 0.7 (21)	12.2 ± 0.6 (23)	12.5 ± 0.7 (21)	12.2 ± 0.7 (22)
	Dead per Litter				
	PND 0	0.81 ± 0.25 (21) *	0.57 ± 0.18 (23)	0.90 ± 0.28 (21)	0.14 ± 0.10 (22) *
	PND 1 - 4	0.14 ± 0.08 (21)	0.52 ± 0.28 (23)	0.29 ± 0.12 (21)	0.50 ± 0.18 (22)
	Number of Dead				
	PND 0	17 (9)	13 (9)	19 (10)	3 (2)
	PND 1 - 4	3 (3)	12 (4)	6 (5)	11 (7)
	% Live Male Pups per Litter				
	PND 0	48.61 ± 2.81 (21)	45.27 ± 3.53 (23)	45.58 ± 4.21 (21)	55.37 ± 2.99 (22)
Survival Ratio					
PND 0	0.94 ± 0.02 (21) *	0.96 ± 0.01 (23)	0.92 ± 0.03 (21)	0.99 ± 0.01 (22) *	
PND 1 - 4	0.99 ± 0.01 (21)	0.96 ± 0.02 (23)	0.95 ± 0.03 (21)	0.96 ± 0.02 (22)	

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Litter ID		Treatment Groups (ppm)			
		0	1000	5000	10000
C	No. F0 Dams				
	PND 0	21	22	20	21
	Total No. Pups				
	PND 0	209	224	211	222
	Total Pups per Litter				
	PND 0	10.0 ± 0.8 (21)	10.2 ± 0.9 (22)	10.6 ± 0.6 (20)	10.6 ± 1.0 (21)
	Total No. Live				
	PND 0	191	202	200	211
	Live per Litter				
	PND 0	9.1 ± 0.7 (21)	9.2 ± 0.9 (22)	10.0 ± 0.7 (20)	10.6 ± 0.9 (20)
	PND 1	9.0 ± 0.7 (21)	9.0 ± 1.0 (22)	9.9 ± 0.7 (20)	10.4 ± 0.9 (20)
	PND 4 pre-cull	8.8 ± 0.7 (21)	8.8 ± 1.0 (21)	9.9 ± 0.7 (20)	10.2 ± 0.9 (20)
	PND 4 post-cull	8.4 ± 0.6 (21) *	8.1 ± 0.8 (21)	9.5 ± 0.6 (20)	9.6 ± 0.8 (20)
	PND 7	8.2 ± 0.6 (21)	7.9 ± 0.8 (21)	9.4 ± 0.6 (20)	8.7 ± 0.8 (19)
	PND 10	8.1 ± 0.6 (21)	7.6 ± 0.8 (21)	9.3 ± 0.6 (20)	8.6 ± 0.8 (19)
	PND 13	8.1 ± 0.6 (21)	7.4 ± 0.8 (21)	9.2 ± 0.6 (20)	8.5 ± 0.8 (19)
	PND 16	8.1 ± 0.6 (21)	7.4 ± 0.8 (21)	9.2 ± 0.6 (20)	8.5 ± 0.8 (19)
	PND 19	8.1 ± 0.6 (21)	7.4 ± 0.8 (21)	9.2 ± 0.6 (20)	8.5 ± 0.8 (19)
	PND 21	8.1 ± 0.6 (21)	7.4 ± 0.8 (21)	9.2 ± 0.6 (20)	8.5 ± 0.8 (19)
	Dead per Litter				
	PND 0	0.86 ± 0.30 (21)	1.00 ± 0.33 (22)	0.55 ± 0.26 (20)	0.52 ± 0.18 (21)
PND 1 - 4	0.33 ± 0.11 (21)	0.82 ± 0.33 (22)	0.15 ± 0.08 (20)	0.40 ± 0.18 (20)	
PND 5 - 21	0.33 ± 0.16 (21)	0.71 ± 0.29 (21)	0.35 ± 0.18 (20)	1.45 ± 0.67 (20)	
Number of Dead					
PND 0	18 (10)	22 (9)	11 (7)	11 (8)	
PND 1 - 4	7 (7)	18 (10)	3 (3)	8 (5)	
PND 5 - 21	7 (5)	15 (7)	7 (4)	29 (6)	

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**F1 Pups from F0 Females**

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Litter ID	Treatment Groups (ppm)			
	0	1000	5000	10000
% Live Male Pups per Litter				
PND 0	56.75 ± 3.60 (21)	45.72 ± 4.27 (22)	48.88 ± 4.53 (20)	57.90 ± 3.87 (20)
Survival Ratio				
PND 0	0.93 ± 0.02 (21)	0.89 ± 0.04 (22)	0.94 ± 0.03 (20)	0.91 ± 0.05 (21)
PND 1 - 4	0.97 ± 0.01 (21)	0.88 ± 0.05 (22)	0.98 ± 0.01 (20)	0.95 ± 0.03 (20)
PND 5 - 21	0.95 ± 0.02 (21)	0.91 ± 0.04 (21)	0.97 ± 0.02 (20)	0.87 ± 0.06 (20)

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F2 Pups from F1c Parental Females

Litter ID		Treatment Groups (ppm)			
		0	1000	5000	10000
A	No. F0 Dams				
	PND 0	18	16	19	16
	No. F1 Dams				
	PND 0	32	31	32	29
	Total No. Pups				
	PND 0	466	380	404	315
	Total Pups per Litter				
	PND 0	14.5 ± 0.5 (18) **	12.3 ± 0.7 (16) *	12.7 ± 0.7 (19) *	11.0 ± 0.7 (16) **
	Total No. Live				
	PND 0	415	364	384	287
	Live per Litter				
	PND 0	13.0 ± 0.6 (18) **	11.7 ± 0.7 (16)	12.1 ± 0.6 (19)	10.0 ± 0.8 (16) *
	PND 1	12.6 ± 0.6 (18) *	11.6 ± 0.7 (16)	11.9 ± 0.7 (19)	9.8 ± 0.9 (16) *
	PND 4	12.5 ± 0.5 (18) **	11.5 ± 0.6 (16)	11.6 ± 0.7 (19)	9.7 ± 0.8 (16) *
	Dead per Litter				
	PND 0	1.53 ± 0.27 (18)	0.57 ± 0.25 (16) *	0.61 ± 0.16 (19) *	1.03 ± 0.33 (16)
	PND 1 - 4	0.47 ± 0.17 (18)	0.47 ± 0.19 (16)	0.47 ± 0.23 (19)	0.24 ± 0.09 (16)
	Number of Dead				
	PND 0	51 (23)	16 (11)	20 (13)	28 (15)
	PND 1 - 4	20 (13)	15 (9)	15 (7)	6 (6)
% Live Male Pups per Litter					
PND 0	48.19 ± 1.88 (18)	48.58 ± 3.76 (16)	46.77 ± 4.06 (19)	46.11 ± 4.03 (16)	
Survival Ratio					
PND 0	0.89 ± 0.02 (18)	0.95 ± 0.02 (16) *	0.95 ± 0.01 (19) *	0.89 ± 0.04 (16)	
PND 1 - 4	0.96 ± 0.01 (18)	0.93 ± 0.03 (16)	0.96 ± 0.02 (19)	0.97 ± 0.01 (16)	

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F2 Pups from F1c Parental Females

Litter ID		Treatment Groups (ppm)			
		0	1000	5000	10000
B	No. F0 Dams				
	PND 0	20	17	19	18
	No. F1 Dams				
	PND 0	35	31	31	33
	Total No. Pups				
	PND 0	511	433	407	382
	Total Pups per Litter				
	PND 0	14.8 ± 0.5 (20) **	14.0 ± 0.7 (17)	13.4 ± 0.6 (19)	11.8 ± 0.6 (18) **
	Total No. Live				
	PND 0	452	391	377	353
	Live per Litter				
	PND 0	13.6 ± 0.5 (19) **	12.5 ± 0.7 (17)	12.4 ± 0.5 (19)	11.0 ± 0.6 (18) *
	PND 1	13.1 ± 0.5 (19) **	12.3 ± 0.7 (17)	12.3 ± 0.5 (19)	10.8 ± 0.6 (18) *
	PND 4	13.0 ± 0.5 (19) **	12.1 ± 0.7 (17)	12.2 ± 0.5 (19)	10.6 ± 0.6 (18) *
	Dead per Litter				
	PND 0	1.84 ± 0.50 (20) *	1.44 ± 0.48 (17)	0.97 ± 0.22 (19)	0.78 ± 0.26 (18) *
	PND 1 - 4	0.57 ± 0.13 (19)	0.46 ± 0.21 (17)	0.21 ± 0.10 (19)	0.36 ± 0.15 (18)
	Number of Dead				
	PND 0	59 (23)	42 (17)	30 (13)	29 (12)
	PND 1 - 4	16 (13)	16 (9)	6 (5)	13 (9)
% Live Male Pups per Litter					
PND 0	49.31 ± 2.68 (19)	47.58 ± 2.23 (17)	49.73 ± 3.48 (19)	51.58 ± 3.03 (18)	
Survival Ratio					
PND 0	0.86 ± 0.05 (20)	0.90 ± 0.03 (17)	0.93 ± 0.01 (19)	0.94 ± 0.02 (18)	
PND 1 - 4	0.96 ± 0.01 (19)	0.97 ± 0.02 (17)	0.98 ± 0.01 (19)	0.97 ± 0.01 (18)	

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F2 Pups from F1c Parental Females

Litter ID	Treatment Groups (ppm)			
	0	1000	5000	10000
C	No. F0 Dams			
	PND 0	19	18	20
	No. F1 Dams			
	PND 0	33	37	30
	Total No. Pups			
	PND 0	466	470	379
	Total Pups per Litter			
	PND 0	14.3 ± 0.6 (19) **	12.5 ± 0.6 (18)	13.1 ± 0.7 (20)
	Total No. Live			
	PND 0	412	418	362
	Live per Litter			
	PND 0	13.1 ± 0.6 (19) *	11.1 ± 0.8 (18)	12.8 ± 0.6 (20)
	PND 1	12.9 ± 0.6 (19) *	10.8 ± 0.8 (18)	12.6 ± 0.6 (20)
	PND 4 pre-cull	12.7 ± 0.6 (19) *	10.6 ± 0.8 (18)	12.0 ± 0.5 (19)
	PND 4 post-cull	10.9 ± 0.3 (19)	9.6 ± 0.6 (18)	11.1 ± 0.4 (19)
	PND 7	10.1 ± 0.4 (19)	9.4 ± 0.6 (18)	10.5 ± 0.4 (19)
	PND 10	9.8 ± 0.4 (19)	9.1 ± 0.7 (18)	10.2 ± 0.5 (19)
	PND 13	9.6 ± 0.4 (19)	9.0 ± 0.7 (18)	10.1 ± 0.5 (19)
	PND 16	9.5 ± 0.4 (19)	9.0 ± 0.7 (18)	10.1 ± 0.5 (19)
	PND 19	9.5 ± 0.4 (19)	9.0 ± 0.7 (18)	10.1 ± 0.5 (19)
	PND 21	9.5 ± 0.4 (19)	9.0 ± 0.7 (18)	10.1 ± 0.5 (19)
	Dead per Litter			
	PND 0	1.64 ± 0.36 (19) *	1.72 ± 0.50 (18)	0.58 ± 0.15 (20)
	PND 1 - 4	0.44 ± 0.14 (19)	0.47 ± 0.13 (18)	1.33 ± 0.79 (20)
	PND 5 - 21	1.37 ± 0.35 (19)	0.62 ± 0.25 (18)	1.03 ± 0.42 (19)
	Number of Dead			

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**F2 Pups from F1c Parental Females**

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Litter ID	Treatment Groups (ppm)			
	0	1000	5000	10000
PND 0	54 (20)	52 (23)	17 (13)	25 (17)
PND 1 - 4	15 (10)	16 (13)	32 (11)	13 (9)
PND 5 - 21	40 (15)	23 (12)	32 (9)	31 (12)
% Live Male Pups per Litter				
PND 0	52.32 ± 1.86 (19) *	47.99 ± 2.37 (18)	48.97 ± 3.73 (20)	43.35 ± 3.15 (18)
Survival Ratio				
PND 0	0.87 ± 0.03 (19)	0.84 ± 0.04 (18)	0.93 ± 0.03 (20)	0.93 ± 0.02 (18)
PND 1 - 4	0.96 ± 0.02 (19)	0.94 ± 0.02 (18)	0.90 ± 0.05 (20)	0.96 ± 0.02 (18)
PND 5 - 21	0.88 ± 0.03 (19)	0.95 ± 0.02 (18)	0.91 ± 0.04 (19)	0.92 ± 0.03 (18)

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## LEGEND

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Total No. of Pups and Total Pups per Litter is inclusive of nonviable pups.

For the endpoints of Total Pups per Litter, Live per Litter, Dead per Litter, % Live Male Pups per Litter, and Survival Ratio for the F1 and F2 pups, data are displayed as the mean of litter values  $\pm$  SEM of litter values (number of litters produced by F0 dams). For F2 pups, N is number of litters produced by the F0 generation where generally two F1 offspring/sex/litter were selected to produce F2 pups through non-sibling mating.

F1 Total Pups per Litter, Live per Litter, Dead per Litter, % Live Male Pups per Litter, and Survival Ratio endpoints were analyzed using Jonckheere (trend) and Shirley or Dunn (pairwise) tests. The same endpoints for the F2 litters were analyzed using a bootstrapped Jonckheere test for trend, and a Datta-Satten modified Wilcoxon test with Hommel adjustment for pairwise comparisons.

For Number of Dead, N is displayed as the number of pups (number of litters contributing dead pups).

In multiple breeding/littering studies Litter A is the default designation for the first litter; subsequent litters of the same pair would be B, C etc.

All calculations are based on the last litter observation of the day

Survival ratio on PND 0 is live pup count at the last PND 0 litter observation relative to the total number of pups upon completion of parturition.

C litters were culled to 12 pups (6 males and 6 females when possible).

Statistical significance for the control group indicates a significant trend test

Statistical significance for a treatment group indicates a significant pairwise test compared to the vehicle control group

\* Statistically significant at  $P \leq 0.05$

\*\* Statistically significant at  $P \leq 0.01$

**\*\* END OF REPORT \*\***