

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

R06: Andrology Summary
Test Compound: Diisobutyl Phthalate
CAS Number: 84-69-5

Date Report Requested: 01/09/2020
Time Report Requested: 09:09:23
Lab: RTI

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

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Male

Generation	Litter ID	Terminal Sac	Cohort	Treatment Groups (ppm)				
				0	1000	5000	10000	
F0	SD 139 - 141			No. Examined	23	23	23	23
				Testis Weight (g)	1.974 ± 0.028	1.899 ± 0.041	1.896 ± 0.033	2.001 ± 0.039
				Spermatid Head Count (millions)	246.4 ± 8.8	235.5 ± 11.6	239.5 ± 10.5	241.1 ± 12.6
				Spermatid Head Concentration (millions/gram tissue)	125.4 ± 4.8	124.1 ± 6.2	126.2 ± 5.0	121.8 ± 7.0
				Percent Motile Sperm	85.7 ± 1.1	82.5 ± 1.9	87.5 ± 1.0	84.4 ± 1.1
				Epididymis Weight (g)	0.639 ± 0.008	0.623 ± 0.011	0.617 ± 0.010	0.631 ± 0.010
				Cauda Epididymis Weight (g)	0.241 ± 0.004	0.241 ± 0.006	0.231 ± 0.005	0.244 ± 0.004
				Cauda Epididymis Sperm Count (millions)	160.9 ± 6.1	171.9 ± 8.2	157.4 ± 6.9	161.7 ± 6.1
				Cauda Epididymis Sperm Concentration (millions/gram tissue)	671.9 ± 25.6	710.2 ± 26.1	679.9 ± 22.1	665.3 ± 26.6

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Generation	Litter ID	Terminal Sac	Cohort	Treatment Groups (ppm)				
				0	1000	5000	10000	
F1	C	PND 90 - 92	F1c NonParent Males	No. Examined (Litters)	45 (17)	31 (13)	39 (17)	39 (15)
				Testis Weight (g)	1.904 ± 0.026	1.912 ± 0.044	1.943 ± 0.048	1.903 ± 0.054
				Spermatid Head Count (millions)	260.1 ± 7.2	243.7 ± 11.2	279.1 ± 13.1	254.8 ± 16.3
				Spermatid Head Concentration (millions/gram tissue)	137.0 ± 3.7	127.0 ± 4.0	143.7 ± 5.5	131.8 ± 7.1
				Percent Motile Sperm	74.2 ± 1.8 *	72.6 ± 1.7	66.7 ± 2.8 *	64.2 ± 5.1
				Percent Progressively Motile Sperm	57.5 ± 1.4 *	56.1 ± 1.6	51.2 ± 2.3	50.4 ± 4.0
				Epididymis Weight (g)	0.551 ± 0.011 **	0.548 ± 0.013	0.529 ± 0.011	0.495 ± 0.017 **
				Cauda Epididymis Weight (g)	0.225 ± 0.004 **	0.223 ± 0.007	0.205 ± 0.005 *	0.191 ± 0.007 **
				Cauda Epididymis Sperm Count (millions)	197.0 ± 8.1 **	180.0 ± 7.4	170.6 ± 8.5	158.9 ± 11.4 *
				Cauda Epididymis Sperm Concentration (millions/gram tissue)	874.0 ± 27.5	807.3 ± 24.1	822.2 ± 28.8	809.3 ± 47.7

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Generation	Litter ID	Terminal Sac	Cohort	Treatment Groups (ppm)				
				0	1000	5000	10000	
F1	C	PND 213 - 223	F1c Parental Males	No. Examined (Litters)	40 (21)	39 (20)	37 (19)	40 (18)
				Testis Weight (g)	2.129 ± 0.038 **	2.095 ± 0.030	2.126 ± 0.055	1.961 ± 0.070 *
				Spermatid Head Count (millions)	304.8 ± 8.3	316.8 ± 8.1	314.4 ± 10.3	283.5 ± 14.0
				Spermatid Head Concentration (millions/gram tissue)	144.1 ± 3.7	151.1 ± 2.9	145.2 ± 4.5	139.6 ± 6.0
				Percent Motile Sperm	69.5 ± 2.7	71.5 ± 2.3	66.1 ± 3.3	65.3 ± 2.7
				Percent Progressively Motile Sperm	58.0 ± 2.6	60.7 ± 2.0	54.5 ± 3.0	54.5 ± 2.2
				Epididymis Weight (g)	0.684 ± 0.008 **	0.684 ± 0.009	0.673 ± 0.012	0.609 ± 0.021 **
				Cauda Epididymis Weight (g)	0.274 ± 0.004 **	0.280 ± 0.005	0.267 ± 0.007	0.240 ± 0.010 **
				Cauda Epididymis Sperm Count (millions)	221.8 ± 8.4 *	227.3 ± 7.1	210.7 ± 10.1	183.8 ± 13.7
				Cauda Epididymis Sperm Concentration (millions/gram tissue)	805.7 ± 20.6	808.2 ± 17.3	770.3 ± 28.2	728.8 ± 39.0

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LEGEND

Data are displayed as mean \pm SEM for the F0 animals. Data are displayed as the mean of the litter mean \pm SEM of litter means for the F1 and/or F2 animals.

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.

Statistical analysis of the F0 organ weight endpoints performed using Jonckheere trend test and Williams or Dunnett for pairwise tests. Statistical analysis for all other F0 endpoints performed using Jonckheere trend test and Shirley or Dunn for pairwise tests.

Statistical analysis of F1 and/or F2 organ weight endpoints performed using linear mixed models with the dam ID as the random effect for both trend and pairwise test, and using the Dunnett-Hsu adjustment for multiple comparisons. For all other F1 and/or F2 endpoints, a bootstrapped Jonckheere trend test was used, and pairwise comparisons were done using the Datta-Satten modified Wilcoxon test with Hommel adjustment for multiple comparisons.

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 $P \leq 0.01$

PND - Postnatal Day, adults post-weaning; SD - Study Day

**** END OF REPORT ****