

**Study Number:** R88007B  
**Test Type:** RACB  
**Route:** Dosing in Feed  
**Species/Strain:** Rat/Sprague-Dawley

**R03: Summary of Litter Data**  
**Test Compound:** Butyl Paraben  
**CAS Number:** 94-26-8

**Date Report Requested:** 12/03/2018  
**Time Report Requested:** 13:30:31  
**Lab:** RTI

**C Number:** R88007B  
**Study Gender:** Both  
**PWG Approval Date** See web page for date of PWG Approval

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**F1 Pups**

**Treatment Groups (ppm)**

Litter ID	Treatment Groups (ppm)				
	0	5000	15000	40000	
A	Total Litter Size <sup>a</sup>				
	PND 0	13.3 ± 1.0 (19) **	14.1 ± 0.6 (18)	12.9 ± 0.7 (19)	11.7 ± 0.6 (19) **
	Live Litter Size <sup>a</sup>				
	PND 0	12.1 ± 1.0 (19) *	13.4 ± 0.6 (18)	12.3 ± 0.7 (19)	10.9 ± 0.7 (19)
	PND 1	11.9 ± 1.0 (19) *	13.3 ± 0.6 (18)	12.1 ± 0.7 (19)	10.8 ± 0.7 (19)
	PND 4	11.9 ± 1.0 (19) *	13.3 ± 0.6 (18)	12.1 ± 0.7 (19)	10.6 ± 0.7 (19)
	Total Dead <sup>a</sup>				
	PND 0	1.21 ± 0.26 (19)	0.61 ± 0.24 (18)	0.68 ± 0.20 (19)	0.79 ± 0.27 (19)
	PND 1 - 4	0.22 ± 0.10 (18)	0.11 ± 0.08 (18)	0.21 ± 0.10 (19)	0.32 ± 0.13 (19)
	Live Birth Ratio				
	PND 0	0.85 ± 0.05 (19)	0.96 ± 0.02 (18)	0.95 ± 0.01 (19)	0.93 ± 0.02 (19)
	Survival Ratio <sup>a</sup>				
	PND 1 - 4	0.93 ± 0.06 (18)	0.99 ± 0.01 (18)	0.98 ± 0.01 (19)	0.97 ± 0.01 (19)

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**Treatment Groups (ppm)**

Litter ID	Treatment Groups (ppm)				
	0	5000	15000	40000	
B	Total Litter Size <sup>a</sup>				
	PND 0	12.8 ± 1.0 (20) *	14.0 ± 0.9 (17)	14.0 ± 0.6 (21)	11.8 ± 0.4 (19)
	Live Litter Size <sup>a</sup>				
	PND 0	11.8 ± 1.0 (20)	12.8 ± 0.9 (17)	12.5 ± 0.6 (21)	11.1 ± 0.7 (19)
	PND 1	11.8 ± 1.0 (20)	12.5 ± 1.0 (17)	12.2 ± 0.6 (21)	10.7 ± 0.7 (19)
	PND 4	11.6 ± 1.0 (20)	12.4 ± 1.1 (17)	12.2 ± 0.6 (21)	10.6 ± 0.7 (19)
	Total Dead <sup>a</sup>				
	PND 0	0.95 ± 0.22 (20)	1.24 ± 0.42 (17)	1.48 ± 0.35 (21)	0.74 ± 0.34 (19)
	PND 1 - 4	0.21 ± 0.10 (19)	0.41 ± 0.30 (17)	0.29 ± 0.16 (21)	0.42 ± 0.12 (19)
	Live Birth Ratio				
	PND 0	0.87 ± 0.05 (20)	0.91 ± 0.03 (17)	0.90 ± 0.02 (21)	0.92 ± 0.05 (19)
	Survival Ratio <sup>a</sup>				
	PND 1 - 4	0.99 ± 0.01 (19)	0.96 ± 0.04 (17)	0.97 ± 0.02 (21)	0.96 ± 0.01 (19)

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F1 Pups

Treatment Groups (ppm)

Litter ID	0	5000	15000	40000
C				
Total Litter Size <sup>a</sup>				
PND 0	11.4 ± 0.8 (20)	13.6 ± 0.7 (14)	11.4 ± 0.9 (20)	9.4 ± 1.0 (17)
Live Litter Size <sup>a</sup>				
PND 0	10.4 ± 0.9 (20)	12.6 ± 0.6 (14)	11.0 ± 0.8 (20)	9.2 ± 1.0 (17)
PND 1	10.4 ± 0.9 (20)	12.5 ± 0.6 (14)	11.0 ± 0.8 (20)	9.0 ± 1.0 (17)
PND 4 pre-cull	10.3 ± 0.9 (20)	12.3 ± 0.6 (14)	10.9 ± 0.8 (20)	9.0 ± 1.0 (17)
PND 4 post-cull	9.6 ± 0.7 (20)	11.4 ± 0.3 (14)	10.1 ± 0.7 (20)	8.7 ± 0.9 (17)
PND 7	9.4 ± 0.7 (20)	11.1 ± 0.3 (14)	9.9 ± 0.7 (20)	8.3 ± 0.9 (17)
PND 10	9.4 ± 0.7 (20)	11.1 ± 0.3 (14)	9.8 ± 0.7 (20)	8.0 ± 0.9 (17)
PND 13	9.4 ± 0.7 (20)	11.0 ± 0.3 (14)	9.9 ± 0.7 (19)	7.9 ± 0.9 (17)
PND 16	9.4 ± 0.7 (20)	10.9 ± 0.3 (14)	9.9 ± 0.7 (19)	7.8 ± 0.9 (17)
PND 19	9.4 ± 0.7 (20)	10.9 ± 0.3 (14)	9.9 ± 0.7 (19)	7.8 ± 0.9 (17)
PND 21	9.4 ± 0.7 (20)	10.9 ± 0.3 (14)	9.9 ± 0.7 (19)	7.7 ± 0.9 (17)
Total Dead <sup>a</sup>				
PND 0	1.00 ± 0.36 (20) *	1.00 ± 0.30 (14)	0.40 ± 0.13 (20)	0.18 ± 0.13 (17)
PND 1 - 4	0.15 ± 0.11 (20)	0.36 ± 0.17 (14)	0.10 ± 0.07 (20)	0.18 ± 0.13 (17)
PND 5 - 21	0.20 ± 0.16 (20)	0.43 ± 0.20 (14)	0.32 ± 0.15 (19)	1.00 ± 0.52 (17)
Live Birth Ratio				
PND 0	0.91 ± 0.04 (20) *	0.93 ± 0.02 (14)	0.97 ± 0.01 (20)	0.99 ± 0.01 (17)
Survival Ratio <sup>a</sup>				
PND 1 - 4	0.99 ± 0.01 (20)	0.97 ± 0.01 (14)	0.99 ± 0.01 (20)	0.96 ± 0.03 (17)
PND 5 - 21	0.98 ± 0.01 (20)	0.96 ± 0.02 (14)	0.97 ± 0.01 (19)	0.91 ± 0.05 (17)

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**F1 Pups**

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**Treatment Groups (ppm)**

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<b>Litter ID</b>		<b>40000</b>	<b>40000 NF</b>
D	Total Litter Size <sup>a</sup>		
	PND 0	9.4 ± 1.0 (15)	13.1 ± 1.0 (17)
	Live Litter Size <sup>a</sup>		
	PND 0	8.7 ± 1.0 (15)	11.9 ± 0.9 (17)
	PND 1	8.5 ± 0.9 (15)	11.6 ± 0.9 (17)
	PND 4	8.4 ± 0.9 (15)	11.6 ± 1.0 (17)
	Total Dead <sup>a</sup>		
	PND 0	0.67 ± 0.27 (15)	1.18 ± 0.63 (17)
	PND 1 - 4	0.33 ± 0.16 (15)	0.29 ± 0.14 (17)
	Live Birth Ratio		
	PND 0	0.91 ± 0.04 (15)	0.92 ± 0.03 (17)
	Survival Ratio <sup>a</sup>		
	PND 1 - 4	0.97 ± 0.02 (15)	0.96 ± 0.02 (17)

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**F2 Pups: Fertility Female**

Litter ID		Treatment Groups (ppm)			
		0	5000	15000	40000
A	Total Litter Size <sup>a</sup>				
	PND 0	13.8 ± 0.9 (17) *	14.3 ± 0.7 (13)	13.1 ± 0.7 (17)	11.9 ± 0.4 (8) *
	Live Litter Size <sup>a</sup>				
	PND 0	11.9 ± 0.8 (17)	12.4 ± 0.8 (13)	12.2 ± 0.6 (17)	10.9 ± 0.6 (8)
	PND 1	11.6 ± 0.9 (17)	12.3 ± 0.8 (13)	11.7 ± 0.7 (17)	10.5 ± 0.7 (8)
	PND 4	11.3 ± 0.9 (17)	11.9 ± 0.8 (13)	11.5 ± 0.7 (17)	10.2 ± 0.6 (8)
	Total Dead <sup>a</sup>				
	PND 0	1.94 ± 0.64 (17)	1.85 ± 0.58 (13)	0.95 ± 0.28 (17)	1.00 ± 0.58 (8)
	PND 1 - 4	0.62 ± 0.36 (17)	0.57 ± 0.26 (13)	0.68 ± 0.20 (17)	0.70 ± 0.12 (8)
	Live Birth Ratio				
	PND 0	0.88 ± 0.04 (17)	0.87 ± 0.04 (13)	0.93 ± 0.02 (17)	0.92 ± 0.04 (8)
	Survival Ratio <sup>a</sup>				
	PND 1 - 4	0.94 ± 0.03 (17)	0.94 ± 0.03 (13)	0.93 ± 0.03 (17)	0.93 ± 0.01 (8)

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**F2 Pups: Fertility Female**

Litter ID		Treatment Groups (ppm)			
		0	5000	15000	40000
B	Total Litter Size <sup>a</sup>				
	PND 0	13.4 ± 0.9 (20)	12.1 ± 1.0 (14)	12.5 ± 0.9 (16)	12.0 ± 0.6 (8)
	Live Litter Size <sup>a</sup>				
	PND 0	11.1 ± 0.9 (20)	10.7 ± 1.1 (14)	11.4 ± 1.0 (16)	11.1 ± 0.7 (8)
	PND 1	10.8 ± 0.9 (20)	10.6 ± 1.1 (14)	10.7 ± 1.0 (16)	11.0 ± 0.7 (8)
	PND 4	10.5 ± 0.8 (20)	10.5 ± 1.1 (14)	10.5 ± 1.0 (16)	10.9 ± 0.7 (8)
	Total Dead <sup>a</sup>				
	PND 0	2.35 ± 0.52 (20)	1.40 ± 0.39 (14)	1.13 ± 0.39 (16)	0.83 ± 0.29 (8) *
	PND 1 - 4	0.58 ± 0.20 (20)	0.15 ± 0.08 (13)	0.85 ± 0.36 (16)	0.27 ± 0.11 (8)
	Live Birth Ratio				
	PND 0	0.81 ± 0.04 (20)	0.85 ± 0.07 (14)	0.91 ± 0.03 (16) *	0.93 ± 0.02 (8)
	Survival Ratio <sup>a</sup>				
	PND 1 - 4	0.93 ± 0.03 (20)	0.96 ± 0.02 (13)	0.92 ± 0.04 (16)	0.97 ± 0.01 (8)

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**F2 Pups: Fertility Female**

Litter ID	Treatment Groups (ppm)				
	0	5000	15000	40000	
C	Total Litter Size <sup>a</sup>				
	PND 0	12.0 ± 1.0 (18)	11.4 ± 0.9 (14)	10.2 ± 1.0 (17)	8.6 ± 0.8 (8)
	Live Litter Size <sup>a</sup>				
	PND 0	10.4 ± 0.9 (18)	10.4 ± 0.9 (14)	9.2 ± 0.9 (17)	8.1 ± 0.8 (8)
	PND 1	10.3 ± 0.8 (18)	10.2 ± 0.9 (14)	8.7 ± 1.0 (17)	7.8 ± 0.7 (8)
	PND 4 pre-cull	10.0 ± 0.8 (18)	10.1 ± 0.9 (14)	8.4 ± 0.9 (17)	7.8 ± 0.7 (8)
	PND 4 post-cull	9.2 ± 0.7 (18)	9.0 ± 0.7 (14)	8.2 ± 0.8 (17)	7.7 ± 0.7 (8)
	PND 7	9.3 ± 0.6 (18)	8.9 ± 0.7 (14)	8.1 ± 0.8 (17)	7.4 ± 0.6 (8)
	PND 10	9.2 ± 0.7 (18)	8.9 ± 0.7 (14)	8.0 ± 0.8 (17)	7.3 ± 0.6 (8)
	PND 13	9.1 ± 0.7 (18)	8.8 ± 0.6 (14)	8.0 ± 0.8 (17)	7.0 ± 0.6 (8)
	PND 16	9.1 ± 0.7 (18)	8.8 ± 0.6 (14)	8.0 ± 0.8 (17)	7.0 ± 0.6 (8) *
	PND 19	9.1 ± 0.7 (18)	8.8 ± 0.7 (14)	8.0 ± 0.8 (17)	6.9 ± 0.6 (8) *
	PND 21	9.1 ± 0.7 (18)	8.8 ± 0.7 (14)	8.0 ± 0.8 (17)	6.9 ± 0.6 (8) *
	Total Dead <sup>a</sup>				
	PND 0	1.56 ± 0.35 (18)	1.02 ± 0.31 (14)	0.93 ± 0.23 (17)	0.56 ± 0.19 (8)
	PND 1 - 4	0.33 ± 0.16 (18)	0.31 ± 0.15 (14)	0.78 ± 0.38 (17)	0.31 ± 0.17 (8)
	PND 5 - 21	0.39 ± 0.20 (18)	0.23 ± 0.10 (14)	0.23 ± 0.10 (17)	0.81 ± 0.24 (8)
	Live Birth Ratio				
	PND 0	0.86 ± 0.04 (18)	0.91 ± 0.04 (14)	0.91 ± 0.02 (17)	0.94 ± 0.02 (8)
	Survival Ratio <sup>a</sup>				
	PND 1 - 4	0.98 ± 0.01 (18)	0.97 ± 0.01 (14)	0.92 ± 0.04 (17)	0.97 ± 0.01 (8)
	PND 5 - 21	0.97 ± 0.02 (18)	0.97 ± 0.01 (14)	0.95 ± 0.03 (17)	0.92 ± 0.03 (8)



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## LEGEND

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Data are displayed as the means and standard errors of the litter means, N is number of litters

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

<sup>a</sup>F1 litter size and survival endpoints were analyzed using Jonckheere's test for trend and Shirley's or Dunn's methods for pairwise comparison of controls to dose groups. F2 litter size and survival endpoints were analyzed using the bootstrapped Jonckheere trend test. Pairwise comparisons were done using the Datta-Satten modified Wilcoxon tests with the Hommel adjustment for multiple comparisons.

No analysis was performed on the D litter and F0-N group because there were no D litter control groups.

\* Statistically significant at  $P \leq 0.05$

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

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

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

D Litter is crossover mating of F0 40000 ppm Females with F0 control Males and F0 naive Females with F0 40000 ppm Males (dose listed as 40000 NF are the F0 naive Females)

NF = Naive Females

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