Test Type: MOG
Route: Dosing in Feed

Species/Strain: Rat/Sprague-Dawley

C Number:

Study Gender:

PWG Approval Date

R14: Developmental Markers Summary

Test Compound: 2-Hydroxy-4-methoxybenzophenone

CAS Number: 131-57-7

MOG002B

Both

See web page for date of PWG Approval

Date Report Requested: 03/20/2019

Time Report Requested: 13:55:46

Lab: RTI

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F1 Male

Generation	Litter	Cohort		Treatment Groups (ppm)					
				0	3000	10000	30000	0.05 ppm EE	
F1	Α		PND 13						
			No. Examined (litters)	85 (22)	80 (20)	82 (21)	82 (20)	57 (15)	
			No. of areolae/nipples per litter ^a	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	
			No. pups with areolae/nipples (%) ^b	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	
			No. litters with areolae/nipples (%) ^b	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	
			Testicular Descent						
			No. Examined (litters)	85 (22)	80 (20)	82 (21)	80 (20)	57 (15)	
			No. Removed (litters) ^c	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	
			No. Not Attaining Testes Descent (litters) ^d	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	
			Day of Testes Descent						
			Mean Analysis ^e						
			Litter Mean ± SE ^f	19.1 ± 0.3 **	19.2 ± 0.3	19.0 ± 0.3	18.0 ± 0.2 *	19.4 ± 0.2	
			Proportional Hazards Analysis ⁹						
			Litter-based Model ^h	p<0.001	p=0.778	p=0.929	p=0.026	p=0.058	

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F2 Male

Generation	Litter	Cohort		Treatment Groups (ppm)					
				0	3000	10000	30000	0.05 ppm EE	
F2	Α		PND 13						
			No. Examined (litters)	91 (30)	112 (34)	103 (32)	92 (30)	89 (27)	
			No. of areolae/nipples per litter ^a	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	
			No. pups with areolae/nipples (%) ^b	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	
			No. litters with areolae/nipples (%) ^b	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	
			Testicular Descent						
			No. Examined (litters)	91 (30)	110 (34)	101 (32)	88 (30)	88 (27)	
			No. Removed (litters) ^c	0 (0)	2 (2)	0 (0)	2 (1)	1 (1)	
			No. Not Attaining Testes Descent (litters) ^d	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)	
			Day of Testes Descent						
			Mean Analysis ^e						
			Litter Mean ± SE ^f	17.1 ± 0.4	17.6 ± 0.3	17.0 ± 0.3	17.5 ± 0.3	17.3 ± 0.5	
			Proportional Hazards Analysis ⁹						
			Litter-based Model ^h	p=0.065	p=0.264	p=0.570	p=0.352	p=0.164	

Test Type: MOG

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LEGEND

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

No. Examined (litters) = the number of animals or pups examined (number of litters represented)

The number of areolae/nipples per litter are shown as mean ± SEM

No. of pups with areolae/ nipples reported as number of affected pups (%)

No. of litters with areolae/ nipples reported as number of affected litters (%)

If measured, the No. of areolae/nipples at terminal sacrifice are shown as mean ± SEM

^aStatistical analysis for the F1 generation performed by Jonckheere (trend) and Shirley or Dunn (pairwise) tests. Statistical analysis for the F2 generation performed using a bootstrapped Jonckheere trend test; pairwise comparisons were done using the Datta-Satten modified Wilcoxon tests with Hommel adjustment for multiple comparisons.

^bStatistical analysis for the F1 generation was performed using Cochran-Armitage (trend) and Fisher Exact (pairwise) tests. Statistical analysis for the F2 generation was performed using a Rao-Scott Cochran-Armitage test for both trend and pairwise tests.

^cAnimals that died or were removed prior to the end of the observation period and did not attain. These animals were excluded from all analyses.

^dAnimals that survived to the end of the observation period without attaining.

^eSummary statistics and mixed model results are presented for animals that attained during the observation period.

Means of litter means presented. Trend and pairwise tests were based on mixed models for day of attainment with dose as a covariate and a random effect for litter. The Dunnett-Hsu adjustment was used for multiple comparisons.

⁹Animals that did not attain by the end of the observation period were included in the proportional hazards analysis.

^hP-values for trend and pairwise comparisons were calculated from a Cox proportional hazards model with random effect for litter and a 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 <= 0.05
- ** Statistically significant at P <= 0.01

The EE group was not included in any trend analysis, it was included in the pairwise analysis to the control group.

EE = Ethinyl estradiol

** END OF REPORT **