

Estrous Cycling and Natural Delivery/Litter Observation Data

F1 Estrous Cycling Data, From Data Analysis Presented at EPA on August 30, 2002^a

	APFO Dose Group (mg/kg/day)				
	0	1	3	10	30
All 4-Day Cycles	14/30	19/29	9/30	15/29	15/30
3-5 Day Cycles	24/30	26/29	21/30	25/29	27/30

Cycle Length (Days)	Incidence of Cycle Length Per Group				
2	1	0	5	2	5
3	2	1	7	5	5
4	75	80	57	84	86
5	18	16	32	14	17
6	5	2	5	3	0
7	1	1	0	0	0
8	2	0	1	0	2
Mean Cycle Length (Days) ± S.D.	4.3 ± 0.8	4.2 ± 0.5	4.3 ± 0.9	4.1 ± 0.6	4.1 ± 0.8

	Aberrant Cycles ^b				
	<i>Parental</i>				
≥ 4 Days Diest.	2	1	1	4	1
≥ 3 Days Est.	17	13	15	16	13
	<i>F1</i>				
≥ 4 Days Diest.	5	3	3	5	3
≥ 3 Days Est.	25	25	29	11	14

Distribution of Cycle Status at Start of 21-Day Evaluation Period, F1					
P	1	4	1	2	5
E	8	10	11	14	11
M	6	2	2	0	2
D	15	13	16	13	12
Distribution Rats in Estrous at End of 21-Day Evaluation Period, F1					
End in Estrous	13	17	18	19	19

Mean Implantations, Liveborn, and Stillborn ± S.D. per Litter by Group ^c					
	<i>Parental Litters</i>				
Implantations	15.3 ± 1.9	15.6 ± 2.1	15.2 ± 2.3	15.6 ± 2.0	15.3 ± 2.0
Liveborn	14.2 ± 2.2	14.2 ± 2.6	13.4 ± 3.6	13.8 ± 3.0	13.4 ± 3.3
Stillborn	0.1 ± 0.3	0.4 ± 1.4	0.2 ± 0.4	0.1 ± 0.4	0.2 ± 0.6
	<i>F1 Litters</i>				
Implantations	14.8 ± 3.0	15.8 ± 2.1	14.7 ± 2.8	15.0 ± 2.9	14.5 ± 2.9
Liveborn	13.6 ± 2.9	13.7 ± 2.4	13.8 ± 3.0	13.5 ± 3.1	13.3 ± 2.8
Stillborn	0.2 ± 0.5	0.2 ± 0.5	0.2 ± 0.6	0.2 ± 0.5	0.1 ± 0.2

^aOriginal analysis counted cycles from the day following estrous (or proestrous if diestrus followed proestrous without observation of estrous) to the day following the end of the next estrous. The numbers in this table have been reduced by one day to correspond to the new analysis presented in this submission, in which cycles were counted from the day following estrous to the last day of the next estrous.

- ^b The definitions of aberrant cycles come from Daston, G. and Kimmel, C. (Eds), 1998. An Evaluation of Reproductive Endpoints for Human Health Risk Assessment. ILSI (November, 1998). Data presented is from evaluation of raw cycling data from ARGUS Research study 418-020, submitted with this table.
- ^c This data was not discussed on August 30, 2002; however, it was agreed to represent these data in this submission. The data are from Tables C19, C20, E20, and E21 of the final report on the APFO multi-generation reproduction/developmental study which has been previously submitted to AR-226.