

Perfluorooctanesulfonate:

PK During Pregnancy and
Lactation + Analytical
Protocol

PROTOCOL 418-008: COMBINED ORAL (GAVAGE) FERTILITY, DEVELOPMENTAL AND PERINATAL/POSTNATAL REPRODUCTION TOXICITY STUDY OF PFOS IN RATS (SPONSOR'S STUDY NUMBER: 6295.9)

TABLE E20 (PAGE 1): LITTER OBSERVATIONS (NATURALLY DELIVERED PUPS) - SUMMARY - F2 GENERATION LITTERS

MATERNAL DOSAGE GROUP		I	II	III
MATERNAL DOSAGE (MG/KG/DAY)		0 (VEHICLE)	0.1	0.4
DELIVERED LITTERS WITH ONE OR MORE LIVEBORN PUPS				
	N	22	21	24
PUPS DELIVERED (TOTAL)	N	316	325	357
	MEAN±S.D.	14.4 ± 3.5	15.5 ± 2.5	14.9 ± 2.6
LIVEBORN	MEAN±S.D.	14.1 ± 3.5	15.1 ± 2.4	14.3 ± 2.5
	N(%)	310(98.1)	318(97.8)	344(96.4)
STILLBORN	MEAN±S.D.	0.3 ± 0.6	0.3 ± 1.1	0.5 ± 0.9
	N(%)	6(1.9)	7(2.2)	13(3.6)
PUPS FOUND DEAD OR PRESUMED CANNIBALIZED				
DAY 1	N/N(%)	2/310(0.6)	2/318(0.6)	2/344(0.6)
DAYS 2- 4	N/N(%)	7/308(2.3)	2/316(0.6)	11/342(3.2)
DAYS 5- 7	N/N(%)	0/171(0.0)	2/167(1.2)	5/191(2.6)
DAYS 8-14	N/N(%)	0/171(0.0)	1/165(0.6)	1/178(0.6)a
DAYS 15-21	N/N(%)	0/171(0.0)	0/164(0.0)	0/177(0.0)a
VIABILITY INDEX b	%	97.1	98.7	96.2
	N/N	301/310	314/318	331/344
LACTATION INDEX c	%	100.0	98.2	96.7
	N/N	171/171	164/167	177/183

DAY(S) = DAY(S) POSTPARTUM

- a. Excludes values for litter 13257; the dam was found dead on day 10 of lactation; eight pups were sacrificed.
b. Number of live pups on day 4 (preculling) postpartum/number of liveborn pups on day 1 postpartum.
c. Number of live pups on day 21 (weaning) postpartum/number of live pups on day 4 (postculling) postpartum.

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TABLE E20 (PAGE 2): LITTER OBSERVATIONS (NATURALLY DELIVERED PUPS) - SUMMARY - F2 GENERATION LITTERS

MATERNAL DOSAGE GROUP MATERNAL DOSAGE (MG/KG/DAY)		I 0 (VEHICLE)	II 0.1	III 0.4
DELIVERED LITTERS WITH ONE OR MORE LIVEBORN PUPS				
	N	22	21	24
SURVIVING PUPS/LITTER ^a				
DAY 1 b	MEAN±S.D.	14.1 ± 3.5	15.1 ± 2.4	14.3 ± 2.5
DAY 4 PRECULLING	MEAN±S.D.	13.7 ± 3.3	15.0 ± 2.8	13.8 ± 2.4
DAY 4 POSTCULLING	MEAN±S.D.	7.8 ± 0.8	8.0 ± 0.2	8.0 ± 0.2
DAY 7	MEAN±S.D.	7.8 ± 0.8	7.8 ± 0.5	7.8 ± 0.7
DAY 14	MEAN±S.D.	7.8 ± 0.8	7.8 ± 0.7	7.7 ± 0.8
DAY 21	MEAN±S.D.	7.8 ± 0.8	7.8 ± 0.7	[24]c 7.7 ± 0.8
PERCENT MALE PUPS PER NUMBER OF PUPS SEXED				
DAY 1 b	MEAN±S.D.	47.9 ± 15.2	52.1 ± 10.9	47.0 ± 13.3
DAY 4 PRECULLING	MEAN±S.D.	47.9 ± 15.1	51.5 ± 11.1	46.6 ± 13.4
DAY 4 POSTCULLING	MEAN±S.D.	47.0 ± 10.0	49.6 ± 1.6	49.1 ± 5.7
DAY 7	MEAN±S.D.	47.0 ± 10.0	48.9 ± 3.9	48.7 ± 6.4
DAY 14	MEAN±S.D.	47.0 ± 10.0	49.2 ± 2.6	48.3 ± 6.2
DAY 21	MEAN±S.D.	47.0 ± 10.0	49.2 ± 2.6	[24]c 48.3 ± 6.2

DAY = DAY POSTPARTUM

[] = NUMBER OF VALUES AVERAGED

a. Average number of live pups per litter, including litters with no surviving pups.

b. Includes pups born alive, found dead day 1 postpartum.

c. Excludes values for litter 13257; the dam was found dead on day 10 of lactation; eight pups were sacrificed.

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TABLE E20 (PAGE 3): LITTER OBSERVATIONS (NATURALLY DELIVERED PUPS) - SUMMARY - F2 GENERATION LITTERS

MATERNAL DOSAGE GROUP		I	II	III
MATERNAL DOSAGE (MG/KG/DAY)		0 (VEHICLE)	0.1	0.4
DELIVERED LITTERS WITH ONE OR MORE LIVEBORN PUPS	N	22	21	24
LIVE LITTER SIZE AT WEIGHING				
DAY 1	MEAN±S.D.	14.0 ± 3.5	15.0 ± 2.6	14.2 ± 2.5
DAY 4 PRECULLING	MEAN±S.D.	13.7 ± 3.3	15.0 ± 2.8	13.8 ± 2.4
DAY 4 POSTCULLING	MEAN±S.D.	7.8 ± 0.8	8.0 ± 0.2	7.9 ± 0.3
DAY 7	MEAN±S.D.	7.8 ± 0.8	7.8 ± 0.5	7.8 ± 0.7
DAY 14	MEAN±S.D.	7.8 ± 0.8	7.8 ± 0.7	7.7 ± 0.8 (23)a
DAY 21	MEAN±S.D.	7.8 ± 0.8	7.8 ± 0.7	7.7 ± 0.8 (23)a
PUP WEIGHT/LITTER (GRAMS)				
DAY 1	MEAN±S.D.	6.3 ± 0.8	6.1 ± 0.5	6.2 ± 0.5
DAY 4 PRECULLING	MEAN±S.D.	8.7 ± 1.6	8.2 ± 1.0	8.0 ± 1.3
DAY 4 POSTCULLING	MEAN±S.D.	8.8 ± 1.6	8.3 ± 1.0	8.0 ± 1.3
DAY 7	MEAN±S.D.	14.7 ± 2.4	13.9 ± 2.2	12.8 ± 2.6*
DAY 14	MEAN±S.D.	32.0 ± 3.5	31.8 ± 3.1	28.9 ± 4.7** (23)a
DAY 21	MEAN±S.D.	50.1 ± 5.1	49.2 ± 5.0	46.5 ± 6.3 (23)a

DAY = DAY POSTPARTUM

[] = NUMBER OF VALUES AVERAGED

a. Excludes values for litter 13257; the dam was found dead on day 10 of lactation; eight pups were sacrificed.

* Significantly different from the vehicle control group value ($p \leq 0.05$).

** Significantly different from the vehicle control group value ($p \leq 0.01$).