Makris, Susan

From: Susan Makris <Makris.Susan@epamail.epa.gov>
Sent: Thursday, June 06, 2013 5:42 PM
To: Makris, Susan
Subject: Fw: RE- TCE data - Johnson et al 2003
Attachments: EPA Requested Data 8-081.pdf

----- Forwarded by Susan Makris/DC/USEPA/US on 06/06/2013 05:41 PM -----

From: Paula Johnson <pauladj@email.arizona.edu>
To: Susan Makris/DC/USEPA/US@EPA
Date: 08/13/2008 08:55 PM
Subject: RE- TCE data - Johnson et al 2003

Susan,

Sorry for the delays ... I hope this will help. I've attached this as a pdf, so please let me know if this doesn't work for you.

Good luck in your assessments, Paula

At 07:12 PM 8/8/2008 -0400, you wrote:

> Dr. Johnson, I hope that you will be able to find some time to help us in this analysis, since the cardiac malformations that were identified in your laboratory are a very sensitive and important endpoint for consideration in the TCE human health risk assessment. We would like to be sure that we have clearly expressed our data needs. Specifically, we would like to have the following information: for each litter within each dose group, the number of pups/litter, and, for the litters with heart malformations, the incidence of malformations, i.e., the number of malformations/ the number of pups in the litter. We hope that you will be able to provide this data, and truly appreciate your efforts. Please contact me if you have any questions. Thanks so very much!
>
> Susan Makris
> USEPA/ORD/NCEA (8623P)
> 1200 Pennsylvania Ave., NW
> Washington, DC 20460
> makris.susan@epa.gov
> Office: 703-347-8522
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Paula Johnson
<pauladj@email.a
rizona.edu>

To

Susan Makris/DC/USEPA/US@EPA
07/11/2008 07:09 PM
cc
Subject
Re: Fw: TCE data - Johnson et al 2003

I am no longer involved in the research. It will take me a while to get to the data - it has been a long time! I'll see what I an do, but no promises. Paula

Paula D. Johnson, DVM, MS
Associate Veterinary Specialist, University Animal Care
The University of Arizona, Central Animal Facility
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"The opinions or statements expressed herein are my own and should not
be taken as a position, opinion, or endorsement of The University of Arizona."

At 05:19 PM 7/11/2008 -0400, you wrote:

----- Forwarded by Susan Makris/DC/USEPA/US on 07/11/2008 05:18 PM -----

Susan Makris/DC/USEPA/US
07/11/2008 04:51 PM

To
Paula Johnson <pdj@peds.arizona.edu>

cc
Jennifer Jinot/DC/USEPA/US@EPA,
John Fox/DC/USEPA/US@EPA

Subject

TCE data - Johnson et al

2003

Dr. Johnson, I am an EPA toxicologist working on the human health risk
assessment for TCE. In the process of considering the cardiac
malformation data from the Johnson et al 2003 publication for dose
response assessment, a data need was identified by our statisticians,
and we were hoping you could provide us with the necessary information.
The paper incudes group incidence data (in Table 2) expressed as number
of fetuses with abnormal hearts, and number and percent of litters with
fetuses with abnormal hearts. In order to perform an appropriate nested
analysis we would need to have information on the number of fetuses with
abnormal hearts in each individual litter. Thank you in advance for
your response to this request! Please feel free to call if you have any
questions.

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KEY:
S#,M# Gp# = code for blind treatments
TWtGN = Total Weight gain during pregnancy
#Fet = number of fetuses in the litter
#Res = number of resoprtion sites (no fetus) in the uterine horn
#Imp = number of implantation sites (no fetus)in the uterine horn
N Hrt = number of fetuses with Normal Hearts
AbnHrt = number of fetuses with Abnormal Hearts
Abnormalites = the type of cardiac defect seen

1100 ppm Trichloroethylene - Pregnancy Only Drinking water

S#	M#	Gp#	TWtGn	#Fet	#Res	#Imp	N Hrt	AbnHrt	Abnormalities
6	73	16	121	16	0	1	16	0	
6	74	16	106	8	2	0	7	1	1-ASD, VSD
6	75	16	139	14	0	0	13	1	1-ASD
6	76	16	158	20	1	0	17	3	1-A-V canal(VSD); 2-ASD; 3-ASD
6	77	16	120	10	2	1	10	0	
6	78	16	122	15	0	0	13	2	1-ASD; 2-AorticV-unicuspid, VSD
6	80	16	94	7	1	0	6	1	1-AorticV-fenestrated ant. leaflet
6	81	16	94	3	0	0	3	0	
6	82	16	134	12	5	0	9	3	1-ASD, VSD; 2-VSD-two muscular; 3-ASD
	Stats	9	121	105	11	2	94	11	

1.5 ppm Trichloroethylene - Pregnancy only Drinking water

S#	M#	Gp#	TWtGn	#Fet	#Res	#Imp	N Hrt	AbnHrt	Abnormalities
6	85	17	96	4	0	0	4	0	
6	86	17	154	14	1	0	14	0	
6	88	17	109	13	1	0	13	0	
6	89	17	143	14	0	0	14	0	
6	90	17	127	16	0	0	16	0	
6	92	17	158	15	0	0	13	2	1-L transposition; 2-VSD-subaortic
6	93	17	127	16	0	0	15	1	1-Absent RPA,PA and AO parallel,small PA
6	94	17	136	14	0	0	14	0	
6	96	17	183	17	0	0	14	3	1-ASD; 2-ASD; 3-VSD
6	97	17	116	11	1	0	9	2	1-VSD-apical and muscular; 2-ASD
9	4	17	135	13	3	0	13	0	
9	11	17	134	17	0	0	17	0	
9	33	17	142	17	0	0	16	1	1-ASD
	Stats	13	135	181	6	0	172	9	

250 ppb Trichloroethylene - Drinking water, Pregnancy Only

S#	M#	Gp#	TWtGn	#Fet	#Res	#Imp	N Hrt	AbnHrt	Abnormalities
20	1	53	124	15	1	0	14	1	1-TriV -small (R8 and R9 twinned-N Hrts)
20	5	53	128	10	1	0	10	0	
20	6	53	139	12	1	0	11	1	1-Huge Coronary Sinus
20	7	53	125	13	1	0	11	2	1-AoV-dysplastic, no coronary; 2-Tri/MitrV-abn
20	8	53	155	17	0	0	17	0	
20	11	53	166	14	6	0	14	0	
20	12	53	167	16	0	0	16	0	
20	13	53	61	1	0	0	1	0	
20	23	53							False pregnancy
20	19	53	116	12	1	0	11	1	1-ASD
	Stats	10	131.22	110	11	0	105	5	

2.5 ppb TCE in Pregnancy Only Drinking Water

S#	M#	Gp#	TWtGn	#Fet	#Res	#Imp	N Hrt	AbnHrt	Abnormalities
22	8	52	127	11	0	0	11	0	
22	10	52	140	13	2	0	13	0	
22	12	52	137	13	1	0	13	0	
22	13	52	115	10	2	0	10	0	
22	14	52	125	14	0	0	14	0	
22	15	52	134	13	1	0	13	0	
22	17	52	120	14	1	0	14	0	
22	20	52	108	12	1	0	12	0	
22	21	52	107	7	0	0	7	0	
22	40	52	127	13	0	0	13	0	
22	43	52	118	12	2	0	12	0	
22	45	52	128	12	0	0	12	0	
	Stats	12	123.83	144	10	0	144	0	

Maternal Statistics / Treatment Group

Control						
S#	M#	Gp#	#Fet	N Hrt	AbnHrt	Abnormalities
4	4	0.2	14	11	3	1- VSD, ECD-vent.attachmts, 2- D-loop in Rt Chest, 3- D-loop in Rt Chest
4	24	0.2	12	11	1	1- VSD
9	23	0.2	3	2	1	1- VSD-hi subAO
9	26	0.2	12	11	1	1- ASD
9	28	0.2	9	1	1	1- VSD lg muscular
17	16	0.2	13	12	1	1-ASD, Mitravl V-leaflet atresia
19	55	0.2	17	15	2	1-ASD, 2-ASD
20	15	0.2	14	12	2	1-ASD, 2-ASD, large
23	16	0.2	13	12	1	1-ASD
+ 46 Normal litters				506	0	
55 litters total			606 Fetuses total			
				9 litters with fetuses with abnormal hearts out of the 55 total litters		
					13 fetuses with abnormal hearts	
Control Summary (No statistical sign between groups over time, so controls were thus combined)						
606 fetuses /55 maternal rats total						
9 litters with fetuses with abnormal hearts out of the 55 total litters						
13/606 fetuses with abnormal hearts						