

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report Addendum

Table 1. Neoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Stop Dose Arm							
System and Neoplasm		Treatment (ug/kg)					
Lesion	Statistic	Control	2.5	25	250	2500	25000
Endocrine System							
Pituitary Gland * Adenoma,Pars Distalis	Simple Incidence	23/49 (46.9%)	16/50 (32.0%)	14/48 (29.2%)	20/50 (40.0%)	20/50 (40.0%)	20/46 (43.5%)
	Poly-K Incidence	23/38.5 (59.8%)	16/36.3 (44.1%)	14/33.5 (41.8%)	20/39.4 (50.8%)	20/38.5 (51.9%)	20/35.5 (56.3%)
	Terminal Incidence	7/11 (63.6%)	5/12 (41.7%)	8/13 (61.5%)	6/13 (46.2%)	9/17 (52.9%)	6/13 (46.2%)
	Time-to-First	502	397	442	448	520	445
	Poly-K P-Value	0.470	0.112N	0.081N	0.271N	0.308N	0.469N
Pituitary Gland * Carcinoma or Adenoma,Pars Distalis	Simple Incidence	23/49 (46.9%)	16/50 (32.0%)	14/48 (29.2%)	21/50 (42.0%)	20/50 (40.0%)	21/46 (45.7%)
	Poly-K Incidence	23/38.5 (59.8%)	16/36.3 (44.1%)	14/33.5 (41.8%)	21/39.7 (52.9%)	20/38.5 (51.9%)	21/35.5 (59.1%)
	Terminal Incidence	7/11 (63.6%)	5/12 (41.7%)	8/13 (61.5%)	6/13 (46.2%)	9/17 (52.9%)	7/13 (53.8%)
	Time-to-First	502	397	442	448	520	445
	Poly-K P-Value	0.373	0.112N	0.081N	0.340N	0.308N	0.574N

P-values for dose trend are presented in the "Control" column.

N indicates a negative trend or negative treatment comparison to control with corresponding lower-tail p-values.

Table 2. Neoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Stop Dose Arm							
System and Neoplasm		Treatment (ug/kg)					
Lesion	Statistic	Control	2.5	25	250	2500	25000
Endocrine System							
Pituitary Gland * Adenoma,Pars Distalis	Simple Incidence	29/46 (63.0%)	22/48 (45.8%)	19/48 (39.6%)	19/49 (38.8%)	19/50 (38.0%)	17/43 (39.5%)
	Poly-K Incidence	29/39.9 (72.7%)	22/38.4 (57.2%)	19/37.7 (50.4%)	19/34.3 (55.4%)	19/40.1 (47.4%)	17/30.8 (55.2%)
	Terminal Incidence	13/17 (76.5%)	8/16 (50.0%)	9/16 (56.3%)	9/13 (69.2%)	5/15 (33.3%)	5/9 (55.6%)
	Time-to-First	552	529	477	558	551	465
	Poly-K P-Value	0.023N*	0.098N	0.026N*	0.074N	0.012N*	0.082N
Pituitary Gland * Carcinoma or Adenoma,Pars Distalis	Simple Incidence	29/46 (63.0%)	22/48 (45.8%)	20/48 (41.7%)	19/49 (38.8%)	19/50 (38.0%)	17/43 (39.5%)
	Poly-K Incidence	29/39.9 (72.7%)	22/38.4 (57.2%)	20/38.0 (52.7%)	19/34.3 (55.4%)	19/40.1 (47.4%)	17/30.8 (55.2%)
	Terminal Incidence	13/17 (76.5%)	8/16 (50.0%)	9/16 (56.3%)	9/13 (69.2%)	5/15 (33.3%)	5/9 (55.6%)
	Time-to-First	552	529	477	558	551	465
	Poly-K P-Value	0.022N*	0.098N	0.042N*	0.074N	0.012N*	0.082N

P-values for dose trend are presented in the "Control" column.

N indicates a negative trend or negative treatment comparison to control with corresponding lower-tail p-values.

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<i>Table 3. Neoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Continuous Dose Arm</i>							
<i>System and Neoplasm</i>		<i>Treatment (ug/kg)</i>					
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Endocrine System							
Pituitary Gland * Adenoma, Pars Distalis	Simple Incidence	21/50 (42.0%)	22/48 (45.8%)	12/46 (26.1%)	20/49 (40.8%)	19/49 (38.8%)	21/46 (45.7%)
	Poly-K Incidence	21/39.9 (52.7%)	22/37.1 (59.2%)	12/31.4 (38.2%)	20/36.6 (54.7%)	19/34.1 (55.8%)	21/35.4 (59.3%)
	Terminal Incidence	7/16 (43.8%)	12/19 (63.2%)	4/14 (28.6%)	8/13 (61.5%)	5/10 (50.0%)	4/8 (50.0%)
	Time-to-First	477	497	434	561	456	510
	Poly-K P-Value	0.313	0.356	0.153N	0.523	0.487	0.356
Pituitary Gland * Carcinoma or Adenoma, Pars Distalis	Simple Incidence	22/50 (44.0%)	23/48 (47.9%)	12/46 (26.1%)	20/49 (40.8%)	19/49 (38.8%)	21/46 (45.7%)
	Poly-K Incidence	22/40.3 (54.6%)	23/37.7 (61.0%)	12/31.4 (38.2%)	20/36.6 (54.7%)	19/34.1 (55.8%)	21/35.4 (59.3%)
	Terminal Incidence	7/16 (43.8%)	12/19 (63.2%)	4/14 (28.6%)	8/13 (61.5%)	5/10 (50.0%)	4/8 (50.0%)
	Time-to-First	477	497	434	561	456	510
	Poly-K P-Value	0.408	0.361	0.115N	0.595	0.559	0.425

P-values for dose trend are presented in the "Control" column.

N indicates a negative trend or negative treatment comparison to control with corresponding lower-tail p-values.

<i>Table 4. Neoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Continuous Dose Arm</i>							
<i>System and Neoplasm</i>		<i>Treatment (ug/kg)</i>					
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Endocrine System							
Pituitary Gland * Adenoma, Pars Distalis	Simple Incidence	21/48 (43.8%)	25/48 (52.1%)	23/48 (47.9%)	21/50 (42.0%)	21/50 (42.0%)	17/45 (37.8%)
	Poly-K Incidence	21/36.9 (56.9%)	25/37.6 (66.6%)	23/38.4 (59.8%)	21/38.4 (54.7%)	21/38.0 (55.2%)	17/33.7 (50.5%)
	Terminal Incidence	7/14 (50.0%)	10/16 (62.5%)	8/17 (47.1%)	9/14 (64.3%)	8/16 (50.0%)	4/11 (36.4%)
	Time-to-First	494	613	412	460	546	386
	Poly-K P-Value	0.147N	0.254	0.490	0.515N	0.535N	0.374N
Pituitary Gland * Carcinoma or Adenoma, Pars Distalis	Simple Incidence	21/48 (43.8%)	25/48 (52.1%)	23/48 (47.9%)	21/50 (42.0%)	22/50 (44.0%)	17/45 (37.8%)
	Poly-K Incidence	21/36.9 (56.9%)	25/37.6 (66.6%)	23/38.4 (59.8%)	21/38.4 (54.7%)	22/38.4 (57.3%)	17/33.7 (50.5%)
	Terminal Incidence	7/14 (50.0%)	10/16 (62.5%)	8/17 (47.1%)	9/14 (64.3%)	8/16 (50.0%)	4/11 (36.4%)
	Time-to-First	494	613	412	460	546	386
	Poly-K P-Value	0.172N	0.254	0.490	0.515N	0.584	0.374N

P-values for dose trend are presented in the "Control" column.

N indicates a negative trend or negative treatment comparison to control with corresponding lower-tail p-values.

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<i>Table 5. Neoplasms by Body System for Terminal Sacrifice Females EE2 Continuous Dose Arm</i>				
<i>System and Neoplasm</i>	<i>Treatment (ug/kg)</i>			
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>0.05</i>	<i>0.50</i>
Endocrine System				
Pituitary Gland * Adenoma,Pars Distalis	Simple Incidence	21/50 (42.0%)	10/26 (38.5%)	17/26 (65.4%)
	Poly-K Incidence	21/39.9 (52.7%)	10/18.3 (54.6%)	17/23.2 (73.3%)
	Terminal Incidence	7/16 (43.8%)	4/7 (57.1%)	2/4 (50.0%)
	Time-to-First	477	484	360
	Poly-K P-Value	0.055	0.561	0.068
Pituitary Gland * Carcinoma or Adenoma,Pars Distalis	Simple Incidence	22/50 (44.0%)	10/26 (38.5%)	20/26 (76.9%)
	Poly-K Incidence	22/40.3 (54.6%)	10/18.3 (54.6%)	20/24.2 (82.8%)
	Terminal Incidence	7/16 (43.8%)	4/7 (57.1%)	2/4 (50.0%)
	Time-to-First	477	484	360
	Poly-K P-Value	0.009 **	0.615N	0.011 *
Pituitary Gland * Carcinoma,Pars Distalis	Simple Incidence	1/50 (2.0%)	0/26 (0.0%)	3/26 (11.5%)
	Poly-K Incidence	1/34.6 (2.9%)	0/15.9 (0.0%)	3/16.1 (18.7%)
	Terminal Incidence	0/16 (0.0%)	0/7 (0.0%)	0/4 (0.0%)
	Time-to-First	615	----	610
	Poly-K P-Value	0.053	0.652N	0.084

P-values for dose trend are presented in the "Control" column.

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<i>Table 6. Neoplasms by Body System for Terminal Sacrifice Males EE2 Continuous Dose Arm</i>				
<i>System and Neoplasm</i>		<i>Treatment (ug/kg)</i>		
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>0.05</i>	<i>0.50</i>
Endocrine System				
Pituitary Gland * Adenoma, Pars Distalis	Simple Incidence	21/48 (43.8%)	12/26 (46.2%)	6/26 (23.1%)
	Poly-K Incidence	21/36.9 (56.9%)	12/19.9 (60.2%)	6/20.8 (28.9%)
	Terminal Incidence	7/14 (50.0%)	6/9 (66.7%)	3/12 (25.0%)
	Time-to-First	494	543	518
	Poly-K P-Value	0.030N*	0.517	0.029N*
Pituitary Gland * Carcinoma or Adenoma, Pars Distalis	Simple Incidence	21/48 (43.8%)	12/26 (46.2%)	6/26 (23.1%)
	Poly-K Incidence	21/36.9 (56.9%)	12/19.9 (60.2%)	6/20.8 (28.9%)
	Terminal Incidence	7/14 (50.0%)	6/9 (66.7%)	3/12 (25.0%)
	Time-to-First	494	543	518
	Poly-K P-Value	0.030N*	0.517	0.029N*
Pituitary Gland * Lymphoma Malignant	Simple Incidence	2/48 (4.2%)	2/26 (7.7%)	1/26 (3.8%)
	Poly-K Incidence	2/33.7 (5.9%)	2/19.3 (10.4%)	1/20.3 (4.9%)
	Terminal Incidence	0/14 (0.0%)	0/9 (0.0%)	0/12 (0.0%)
	Time-to-First	486	369	473
	Poly-K P-Value	0.588N	0.482	0.676N

P-values for dose trend are presented in the "Control" column.

N indicates a negative trend or negative treatment comparison to control with corresponding lower-tail p-values.