

Study Number: C10987
Test Type: TOX
Route: Dosing in Feed
Species/Strain: Rat/Harlan Sprague Dawley

PA46R: Summary of Gross Pathology with Litter Incidence
Test Compound: Dibutyl Phthalate
CAS Number: 84-74-2

Date Report Requested: 07/27/2020
Time Report Requested: 10:25:16
Lab: NTP

Study Number:

C10987

Study Gender:

Both

PWG Approval Date

See web page for date of PWG Approval

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F1 Male

Treatment Groups (ppm)

0

300

1000

3000

10000

Disposition Summary

Animals Initially In Study

Early Deaths

Scheduled Deaths

Number of Animals Examined

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

None

HEMATOLYMPHOID SYSTEM

None

INTEGUMENTARY SYSTEM

None

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

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0

300

1000

3000

10000

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

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Treatment Groups (ppm)

	0	300	1000	3000	10000
GENITOURINARY SYSTEM					
Cowper's Glands	(48)	(49)	(48)	(49)	(46)
Size, Enlarged (or swelling)	1 (2.1%) [1]				
Epididymis	(48)	(49)	(48)	(49)	(46)
Right; Caput; Agenesis					2 (4.3%) [2]
Right; Cauda; Agenesis					2 (4.3%) [2]
Right; Corpus; Agenesis					2 (4.3%) [2]
Right; Corpus, Cauda, or Caput; Agenesis					2 (4.3%) [2]
Size, Enlarged (or swelling)		2 (4.1%) [2]			
Size, Small	0 **		3 (6.3%) [3]		27 (58.7%) [19] **
Gubernaculum	(46)	(48)	(47)	(46)	(38)
Right; Not Present					1 (2.6%) [1]
Phallus	(48)	(49)	(48)	(49)	(45)
Not Present			1 (2.1%) [1]		
Prepuce	(48)	(49)	(48)	(49)	(45)
Incomplete Preputial Separation	1 (2.1%) [1]				
Prostate	(48)	(49)	(48)	(49)	(46)
Size, Enlarged (or swelling)		2 (4.1%) [2]			
Size, Small	0 *		1 (2.1%) [1]	2 (4.1%) [2]	4 (8.7%) [4]
Prostate, Left	(47)	(49)	(48)	(49)	(46)
Ventral; Agenesis					2 (4.3%) [2]
Ventral, Dorsal, or Lateral; Agenesis					2 (4.3%) [2]
Prostate, Right	(48)	(49)	(48)	(49)	(46)
Dorsal; Agenesis				1 (2.0%) [1]	
Lateral; Agenesis				1 (2.0%) [1]	
Ventral; Agenesis				1 (2.0%) [1]	2 (4.3%) [2]
Ventral, Dorsal, or Lateral; Agenesis				1 (2.0%) [1]	2 (4.3%) [2]
Prostate, Right or Left	(48)	(49)	(48)	(49)	(46)

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	0	300	1000	3000	10000
Dorsal; Agenesis				1 (2.0%) [1]	
Lateral; Agenesis				1 (2.0%) [1]	
Ventral; Agenesis				1 (2.0%) [1]	2 (4.3%) [2]
Ventral, Dorsal, or Lateral; Agenesis				1 (2.0%) [1]	2 (4.3%) [2]
Seminal Vesicles/Coagulating Glands	(48)	(49)	(48)	(49)	(46)
Size, Small	1 (2.1%) [1] *	2 (4.1%) [2]	2 (4.2%) [2]	1 (2.0%) [1]	7 (15.2%) [6]
Testis	(48)	(49)	(48)	(49)	(46)
Fluid or Blood Filled	1 (2.1%) [1]			1 (2.0%) [1]	3 (6.5%) [3]
Right; Not Present					2 (4.3%) [2]
Size, Enlarged (or swelling)			1 (2.1%) [1]	1 (2.0%) [1]	1 (2.2%) [1]
Size, Small	1 (2.1%) [1] **		4 (8.3%) [4]	2 (4.1%) [2]	36 (78.3%) [23] **
Left; Abdominal; Undescended	1 (2.1%) [1] **	2 (4.1%) [2]	1 (2.1%) [1]	2 (4.1%) [2]	20 (43.5%) [14] **
Left; Inguinal; Undescended	1 (2.1%) [1] *				4 (8.7%) [4]
Left; Inguinal or Abdominal; Undescended	2 (4.2%) [2] **	2 (4.1%) [2]	1 (2.1%) [1]	2 (4.1%) [2]	24 (52.2%) [17] **
Right; Abdominal; Undescended	1 (2.1%) [1] **	3 (6.1%) [3]	1 (2.1%) [1]	2 (4.1%) [2]	20 (43.5%) [16] **
Right; Inguinal; Undescended	1 (2.1%) [1]				3 (6.5%) [3]
Right; Inguinal or Abdominal; Undescended	2 (4.2%) [2] **	3 (6.1%) [3]	1 (2.1%) [1]	2 (4.1%) [2]	23 (50.0%) [17] **
Right or Left; Abdominal; Undescended	1 (2.1%) [1] **	3 (6.1%) [3]	2 (4.2%) [2]	2 (4.1%) [2]	29 (63.0%) [21] **
Right or Left; Inguinal; Undescended	1 (2.1%) [1] **				7 (15.2%) [7]
Right or Left; Inguinal or Abdominal; Undescended	2 (4.2%) [2] **	3 (6.1%) [3]	2 (4.2%) [2]	2 (4.1%) [2]	32 (69.6%) [23] **
Urinary Tract	(48)	(49)	(48)	(49)	(46)
Hematuria or Discolored Urine	1 (2.1%) [1]				
Left; Hydronephrosis					1 (2.2%) [1]
Right; Hydronephrosis					1 (2.2%) [1]
Right or Left; Hydronephrosis					1 (2.2%) [1]
Left; Hydroureter				1 (2.0%) [1]	
Right; Hydroureter				1 (2.0%) [1]	
Right or Left; Hydroureter				1 (2.0%) [1]	

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F1 Male

Treatment Groups (ppm)

	0	300	1000	3000	10000
Vas Deferens Right; Not Present	(48)	(49)	(48)	(49)	(46) 2 (4.3%) [2]

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F1 Female

Treatment Groups (ppm)

0

300

1000

3000

10000

Disposition Summary

Animals Initially In Study

Early Deaths

Scheduled Deaths

Number of Animals Examined

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

None

HEMATOLYMPHOID SYSTEM

None

INTEGUMENTARY SYSTEM

None

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

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F1 Female

Treatment Groups (ppm)

0

300

1000

3000

10000

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

GENITOURINARY SYSTEM

Ovaries	(49)	(47)	(48)	(48)	(48)
Left; Corpora Albicans	1 (2.0%) [1]				1 (2.1%) [1]
Right; Corpora Albicans	1 (2.0%) [1]				1 (2.1%) [1]
Follicular Cysts	1 (2.0%) [1]	3 (6.4%) [3]	3 (6.3%) [3]	3 (6.3%) [3]	5 (10.4%) [5]
Left; Not Present		1 (2.1%) [1]			
Size, Enlarged (or swelling)	2 (4.1%) [2]	1 (2.1%) [1]	1 (2.1%) [1]	1 (2.1%) [1]	
Uterus	(49)	(47)	(48)	(48)	(48)
Hydrometrocolpus	2 (4.1%) [1]	1 (2.1%) [1]		1 (2.1%) [1]	3 (6.3%) [3]
Size, Enlarged (or swelling)	4 (8.2%) [4]	2 (4.3%) [2]	4 (8.3%) [4]	2 (4.2%) [2]	4 (8.3%) [3]
Vagina	(49)	(47)	(48)	(48)	(48)
Not Patent			1 (2.1%) [1]		

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LEGEND

Number of animals examined for each tissue shown in parentheses. If none of the animals examined have the specific lesion then there is a blank for that dose group for that specific lesion. The exception to this is if statistical significance is found for a lesion and the control group has no animals with the lesion then a 0 is included for the control group on the table for that lesion.

Number (percent) of animals affected given for each observation

Number of litters with observations shown in square brackets for F1 animals. F1 litter incidence based on the number of F0 dams.

All trend and pairwise p-values are reported as one-sided.

Statistical analysis performed by Cochran-Armitage test with a Rao-Scott modification for the random effect due to litter.

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 $P \leq 0.05$

** Statistically significant at $P \leq 0.01$

"None" under a system heading means that no data were collected for that system.

**** END OF REPORT ****