

Study Number: C10188-02

Test Type: TOX

Route: Dosing in Feed

Species/Strain: Rat/Harlan Sprague Dawley

Study Number:

Study Gender:

PWG Approval Date

PA46R: Summary of Gross Pathology with Litter Incidence

Test Compound: Di(2-Ethylhexyl) Phthalate

CAS Number: 117-81-7

C10188-02

Both

See web page for date of PWG Approval

Date Report Requested: 07/31/2020

Time Report Requested: 11:24:41

Lab: NTP

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Lab: NTP

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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Treatment Groups (ppm)

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	(50)	(49)	(50)	(50)	(47)
Left; Size, Small					1 (2.1%) [1]
Right; Size, Small					1 (2.1%) [1]
Epididymis	(49)	(49)	(50)	(50)	(49)
Fluid or Blood Filled				1 (2.0%) [1]	
Size, Small	0 **		2 (4.0%) [2]		14 (28.6%) [12] **
Epididymis, Left	(49)	(49)	(50)	(50)	(49)
Caput; Agenesis					1 (2.0%) [1]
Corpus; Agenesis					1 (2.0%) [1]
Corpus, Cauda, or Caput; Agenesis/Not Present					1 (2.0%) [1]
Epididymis, Right	(49)	(49)	(49)	(50)	(49)
Caput; Agenesis	0 **				4 (8.2%) [4]
Cauda; Agenesis					2 (4.1%) [2]
Corpus; Agenesis					2 (4.1%) [2]
Corpus, Cauda, or Caput; Agenesis/Not Present	0 **				6 (12.2%) [5]
Not Present					1 (2.0%) [1]
Epididymis, Right or Left	(49)	(49)	(50)	(50)	(49)
Caput; Agenesis	0 **				4 (8.2%) [4]
Cauda; Agenesis					2 (4.1%) [2]
Corpus; Agenesis	0 *				3 (6.1%) [3]
Corpus, Cauda, or Caput; Agenesis/Not Present	0 **				6 (12.2%) [5]
Gubernaculum, Left	(47)	(49)	(49)	(50)	(41)
Not Present	0 **				15 (36.6%) [12] **
Gubernaculum, Right	(47)	(49)	(48)	(50)	(41)
Not Present	0 **				15 (36.6%) [12] **
Gubernaculum, Right or Left	(47)	(49)	(49)	(50)	(41)
Not Present	0 **				18 (43.9%) [14] **

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Lab: NTP

Species/Strain: Rat/Harlan Sprague Dawley

F1 Male

	Treatment Groups (ppm)				
	0	300	1000	3000	10000
LABC Muscle	(50)	(49)	(50)	(50)	(48)
Size, Small					2 (4.2%) [2]
Phallus	(50)	(49)	(49)	(50)	(49)
Cleft	0 *				3 (6.1%) [3]
Size, Small	0 *				3 (6.1%) [3]
Prepuce	(50)	(49)	(50)	(50)	(49)
Cleft					1 (2.0%) [1]
Incomplete Preputial Separation	0 **				7 (14.3%) [7] *
Prostate	(50)	(49)	(50)	(50)	(47)
Misshapen					1 (2.1%) [1]
Size, Enlarged (or swelling)		1 (2.0%) [1]			1 (2.1%) [1]
Size, Small					1 (2.1%) [1]
Seminal Vesicles/Coagulating Glands	(50)	(49)	(50)	(50)	(47)
Size, Small	1 (2.0%) [1] **		1 (2.0%) [1]	1 (2.0%) [1]	8 (17.0%) [7]
Testis	(49)	(49)	(50)	(50)	(49)
Crainial Suspensory Ligament	0 **				5 (10.2%) [4]
Fluid or Blood Filled		1 (2.0%) [1]	1 (2.0%) [1]	1 (2.0%) [1]	1 (2.0%) [1]
Size, Enlarged (or swelling)					1 (2.0%) [1]
Size, Small	2 (4.1%) [2] **	2 (4.1%) [2]	4 (8.0%) [4]	2 (4.0%) [2]	45 (91.8%) [23] **
Testis, Left	(49)	(49)	(50)	(50)	(49)
Abdominal; Undescended	1 (2.0%) [1] **				13 (26.5%) [10] *
Inguinal; Undescended	0 *	1 (2.0%) [1]	1 (2.0%) [1]		4 (8.2%) [4]
Inguinal or Abdominal; Undescended	1 (2.0%) [1] **	1 (2.0%) [1]	1 (2.0%) [1]		17 (34.7%) [12] **
Testis, Right	(49)	(49)	(49)	(50)	(49)
Not Present					1 (2.0%) [1]
Abdominal; Undescended	1 (2.0%) [1] **				18 (36.7%) [14] **
Inguinal; Undescended		1 (2.0%) [1]	1 (2.0%) [1]		3 (6.1%) [3]
Inguinal or Abdominal; Undescended	1 (2.0%) [1] **	1 (2.0%) [1]	1 (2.0%) [1]		21 (42.9%) [15] **

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F1 Male

Treatment Groups (ppm)

	0	300	1000	3000	10000
Testis, Right or Left	(49)	(49)	(50)	(50)	(49)
Abdominal; Undescended	1 (2.0%) [1] **				19 (38.8%) [14] **
Inguinal; Undescended	0 *	1 (2.0%) [1]	1 (2.0%) [1]		4 (8.2%) [4]
Inguinal or Abdominal; Undescended	1 (2.0%) [1] **	1 (2.0%) [1]	1 (2.0%) [1]		23 (46.9%) [16] **
Urinary Tract	(50)	(49)	(50)	(50)	(48)
Hematuria or Discolored Urine		1 (2.0%) [1]			1 (2.1%) [1]

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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	(50)	(50)	(50)	(50)	(48)
Follicular Cysts	4 (8.0%) [4]	4 (8.0%) [4]	6 (12.0%) [6]	1 (2.0%) [1]	3 (6.3%) [3]
Right; Misshapen		1 (2.0%) [1]			
Size, Enlarged (or swelling)		2 (4.0%) [2]		1 (2.0%) [1]	
Phallus	(50)	(50)	(50)	(50)	(48)
Cleft				2 (4.0%) [1]	1 (2.1%) [1]
Uterus	(50)	(50)	(50)	(50)	(48)
Hydrometrocolpus	2 (4.0%) [2]				1 (2.1%) [1]
Size, Enlarged (or swelling)	4 (8.0%) [4] *	3 (6.0%) [3]	2 (4.0%) [2]	1 (2.0%) [1]	8 (16.7%) [7]
Size, Small			1 (2.0%) [1]		
Vagina	(50)	(50)	(50)	(50)	(48)
Not Patent	0 *				5 (10.4%) [3]

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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 ****