

Study Number: R10997
Test Type: RACB
Route: Dosing in Feed
Species/Strain: Rat/Sprague-Dawley

PA46R: Summary of Gross Pathology with Litter Incidence
Test Compound: Diisobutyl Phthalate
CAS Number: 84-69-5

Date Report Requested: 03/18/2021
Time Report Requested: 14:18:36
Lab: RTI

Study Number: R10997
Study Gender: Both
PWG Approval Date: See web page for date of PWG Approval
Version: v1.1.8

F0 Male				
	Treatment Groups (ppm)			
	0	1000	5000	10000
Disposition Summary				
Animals Initially In Study	23	23	23	23
Censored				
Early Deaths				
Survivors				
Scheduled Sacrifice, Terminal	23	23	23	23
Number of Animals Examined	23	23	23	23
ALIMENTARY SYSTEM				
None				
CARDIOVASCULAR SYSTEM				
None				
ENDOCRINE SYSTEM				
None				
GENERAL BODY SYSTEM				
FAT	(23)	(23)	(23)	(23)
MESENTERY; DISCOLORATION; YELLOW; MODERATE				1 (4.3%)
MESENTERY; FIRM; MODERATE				1 (4.3%)

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F0 Male				
	Treatment Groups (ppm)			
	0	1000	5000	10000
GENITAL SYSTEM				
EPIDIDYMIS	(23)	(23)	(23)	(23)
CAUDA; DISCOLORATION; TRIANGULAR, YELLOW; MILD	1 (4.3%)			
CAUDA; DISCOLORATION; YELLOW; MODERATE	1 (4.3%)			
REDUCED IN SIZE; MARKED				1 (4.3%)
PREPUTIAL GLAND	(23)	(23)	(23)	(23)
DISCOLORATION; GREEN; ALL SEVERITIES	9 (39.1%)	8 (34.8%)	3 (13.0%)	8 (34.8%)
DISCOLORATION; GREEN; MILD	3 (13.0%)	4 (17.4%)	2 (8.7%)	6 (26.1%)
DISCOLORATION; GREEN; MINIMAL	4 (17.4%)	4 (17.4%)		1 (4.3%)
DISCOLORATION; GREEN; MODERATE	2 (8.7%)		1 (4.3%)	1 (4.3%)
DISCOLORATION; TAN; ALL SEVERITIES		2 (8.7%)	1 (4.3%)	1 (4.3%)
DISCOLORATION; TAN; MILD		1 (4.3%)	1 (4.3%)	1 (4.3%)
DISCOLORATION; TAN; MINIMAL		1 (4.3%)		
ENLARGED; MARKED				1 (4.3%)
TESTIS	(23)	(23)	(23)	(23)
FIRM; MODERATE				1 (4.3%)
REDUCED IN SIZE; MARKED				1 (4.3%)
HEMATOLYMPHOID SYSTEM				
None				
INTEGUMENTARY SYSTEM				
SKIN	(23)	(23)	(23)	(23)
ABDOMINAL; ALOPECIA; MINIMAL				1 (4.3%)
ALOPECIA; MILD			1 (4.3%)	
ABDOMINAL; CRUST; BROWN; MINIMAL				1 (4.3%)
CRUST; MINIMAL			1 (4.3%)	

F0 Male				
Treatment Groups (ppm)				
	0	1000	5000	10000
MUSCULOSKELETAL SYSTEM				
None				
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
None				
SPECIAL SENSES SYSTEM				
EYE	(23)	(23)	(23)	(23)
PERIORBITAL; DISCOLORATION; BROWN; MILD			1 (4.3%)	
URINARY SYSTEM				
KIDNEY	(23)	(23)	(23)	(23)
CORTEX; DEFORMITY; MODERATE	1 (4.3%)			

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F0 Female				
	Treatment Groups (ppm)			
	0	1000	5000	10000
Disposition Summary				
Animals Initially In Study	23	23	23	23
Censored				
Early Deaths				
Sacrificed, Moribund	2	2	2	1
Survivors				
Scheduled Sacrifice, Terminal	21	21	20	22
Number of Animals Examined	23	23	23	23
ALIMENTARY SYSTEM				
LIVER	(23)	(23)	(23)	(23)
DISCOLORATION; MOTTLED; MILD NODULE; TAN			1 (4.3%)	1 (4.3%)
SALIVARY GLAND	(23)	(23)	(23)	(23)
ENLARGED; SOFT; MILD		1 (4.3%)		
CARDIOVASCULAR SYSTEM				
None				
ENDOCRINE SYSTEM				
None				
GENERAL BODY SYSTEM				
FAT	(23)	(23)	(23)	(23)
MESENTERY; MASS; YELLOW	1 (4.3%)			

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F0 Female				
	Treatment Groups (ppm)			
	0	1000	5000	10000
GENITAL SYSTEM				
CLITORAL GLAND	(23)	(23)	(23)	(23)
ENLARGED; MARKED				1 (4.3%)
OVARY	(23)	(23)	(23)	(23)
CYST; CLEAR; MARKED				1 (4.3%)
CYST; CLEAR	1 (4.3%)			
CYST; CLEAR , SINGLE; MILD	1 (4.3%)			
UTERUS	(23)	(23)	(23)	(23)
DILATION; CLEAR; MODERATE	1 (4.3%)			
HEMATOLYMPHOID SYSTEM				
LYMPH NODE, MESENTERIC	(23)	(23)	(23)	(23)
ENLARGED; MODERATE			1 (4.3%)	
SPLEEN	(23)	(23)	(23)	(23)
ENLARGED; ALL SEVERITIES			2 (8.7%)	1 (4.3%)
ENLARGED; MARKED			1 (4.3%)	
ENLARGED; MILD			1 (4.3%)	1 (4.3%)

F0 Female				
	Treatment Groups (ppm)			
	0	1000	5000	10000
INTEGUMENTARY SYSTEM				
MAMMARY GLAND	(23)	(23)	(23)	(23)
ABDOMINAL; DISCOLORATION; RED; MILD		1 (4.3%)		
AXILLARY; ENLARGED; MODERATE		1 (4.3%)		
INGUINAL; ENLARGED; MULTIFOCAL; MARKED	1 (4.3%)			
CERVICAL; MASS; SOFT		1 (4.3%)		
INGUINAL; MASS; SOFT	1 (4.3%)			
SKIN	(23)	(23)	(23)	(23)
FORELIMB; ALOPECIA; MODERATE	1 (4.3%)			
SHOULDER; MASS; ULCERATED, RED			1 (4.3%)	
SKIN, ABDOMINAL	(23)	(23)	(23)	(23)
ULCER; MARKED				1 (4.3%)
SKIN, MAMMARY	(23)	(23)	(23)	(23)
MASS			1 (4.3%)	
MUSCULOSKELETAL SYSTEM				
None				
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
None				
SPECIAL SENSES SYSTEM				
None				

F0 Female				
Treatment Groups (ppm)				
	0	1000	5000	10000
URINARY SYSTEM				
KIDNEY	(23)	(23)	(23)	(23)
REDUCED IN SIZE; MODERATE			1 (4.3%)	
URETHRA	(23)	(23)	(23)	(23)
MASS; FIRM	1 (4.3%)			

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	Treatment Groups (ppm)			
	0	1000	5000	10000
Disposition Summary				
Animals Initially In Study	45	31	39	40
Censored				
Early Deaths				
Sacrificed, Moribund				1
Survivors				
Scheduled Sacrifice, Terminal	45	31	39	39
Number of Animals Examined	45	31	39	40
Total number litters	17	13	17	16
ALIMENTARY SYSTEM				
INTESTINES	(45)	(31)	(39)	(40)
SUBSTANCE; RED				1 (2.5%) [1]
LIVER	(45)	(31)	(39)	(40)
CAUDATE LOBE; DEFORMITY; YELLOW; MARKED		1 (3.2%) [1]		
CAUDATE LOBE; DEFORMITY; MODERATE				1 (2.5%) [1]
CAUDATE LOBE; DISCOLORATION; MOTTLED; ALL SEVERITIES			1 (2.6%) [1]	1 (2.5%) [1]
CAUDATE LOBE; DISCOLORATION; MOTTLED; MILD				1 (2.5%) [1]
CAUDATE LOBE; DISCOLORATION; MOTTLED; MODERATE			1 (2.6%) [1]	
CAUDATE LOBE; REDUCED IN SIZE; MARKED				1 (2.5%) [1]
CAUDATE LOBE; TORSION			1 (2.6%) [1]	
STOMACH	(45)	(31)	(39)	(40)
NO INGESTA				1 (2.5%) [1]
SUBSTANCE; RED				1 (2.5%) [1]
CARDIOVASCULAR SYSTEM				
None				

F1 Male: F1c NonParent Males				
	Treatment Groups (ppm)			
	0	1000	5000	10000
ENDOCRINE SYSTEM				
ADRENAL GLAND	(45)	(31)	(39)	(40)
ENLARGED; MODERATE			1 (2.6%) [1]	
REDUCED IN SIZE; MARKED		1 (3.2%) [1]		
GENERAL BODY SYSTEM				
None				

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F1 Male: F1c NonParent Males

	Treatment Groups (ppm)			
	0	1000	5000	10000
GENITAL SYSTEM				
COWPERS GLAND (BILATERAL)	(45)	(31)	(39)	(40)
REDUCED IN SIZE			3 (7.7%) [2]	1 (2.5%) [1]
COWPERS GLAND (UNILATERAL OR BILATERAL)	(45)	(31)	(39)	(40)
REDUCED IN SIZE			3 (7.7%) [2]	1 (2.5%) [1]
COWPERS GLAND, EPIDIDYMIS, LABC MUSCLE, PROSTATE, SEMINAL VESICLE, OR TESTIS	(45)	(31)	(39)	(40)
REDUCED IN SIZE, MALPOSITIONED, UNDESCENDED, OR MISSING	1 (2.2%) [1] **		6 (15.4%) [4]	9 (22.5%) [8] *
DORSAL PROSTATE	(45)	(31)	(39)	(40)
MISSING				1 (2.5%) [1]
REDUCED IN SIZE; ALL SEVERITIES			2 (5.1%) [2]	1 (2.5%) [1]
REDUCED IN SIZE; MARKED				1 (2.5%) [1]
REDUCED IN SIZE; MINIMAL			1 (2.6%) [1]	
REDUCED IN SIZE; MODERATE			1 (2.6%) [1]	
EPIDIDYMIS	(45)	(31)	(39)	(40)
CAUDA; DISCOLORATION; YELLOW; MILD			1 (2.6%) [1]	
CAUDA; NODULE			1 (2.6%) [1]	
EPIDIDYMIS (BILATERAL)	(45)	(31)	(39)	(40)
REDUCED IN SIZE				1 (2.5%) [1]
EPIDIDYMIS (UNILATERAL OR BILATERAL)	(45)	(31)	(39)	(40)
REDUCED IN SIZE	1 (2.2%) [1]		1 (2.6%) [1]	4 (10.0%) [3]
EPIDIDYMIS (UNILATERAL)	(45)	(31)	(39)	(40)
REDUCED IN SIZE	1 (2.2%) [1]		1 (2.6%) [1]	3 (7.5%) [3]
LEVATOR ANI PLUS BULBOCAVERNOSUS MUSCLE	(45)	(31)	(39)	(40)
REDUCED IN SIZE; ALL SEVERITIES			2 (5.1%) [1]	2 (5.0%) [1]
REDUCED IN SIZE; MILD				1 (2.5%) [1]
REDUCED IN SIZE; MODERATE			2 (5.1%) [1]	1 (2.5%) [1]
PENIS	(45)	(31)	(39)	(40)
FRENULUM PRESENT				1 (2.5%) [1]

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	Treatment Groups (ppm)			
	0	1000	5000	10000
PREPUTIAL GLAND	(45)	(31)	(39)	(40)
DISCOLORATION; BROWN; MODERATE			1 (2.6%) [1]	1 (2.5%) [1]
ENLARGED; MILD			1 (2.6%) [1]	
PREPUTIAL GLAND (UNILATERAL OR BILATERAL)	(45)	(31)	(39)	(40)
REDUCED IN SIZE			1 (2.6%) [1]	
PREPUTIAL GLAND (UNILATERAL)	(45)	(31)	(39)	(40)
REDUCED IN SIZE			1 (2.6%) [1]	
SEMINAL VESICLE	(45)	(31)	(39)	(40)
ADHESION; MARKED				1 (2.5%) [1]
DISCOLORATION; PINK; MODERATE			1 (2.6%) [1]	
SEMINAL VESICLE (UNILATERAL OR BILATERAL)	(45)	(31)	(39)	(40)
REDUCED IN SIZE			2 (5.1%) [2]	1 (2.5%) [1]
SEMINAL VESICLE (UNILATERAL)	(45)	(31)	(39)	(40)
REDUCED IN SIZE			2 (5.1%) [2]	1 (2.5%) [1]
TESTIS (BILATERAL)	(45)	(31)	(39)	(40)
REDUCED IN SIZE				1 (2.5%) [1]
TESTIS (UNILATERAL OR BILATERAL)	(45)	(31)	(39)	(40)
MALPOSITIONED				1 (2.5%) [1]
MALPOSITIONED OR UNDESCENDED				2 (5.0%) [1]
REDUCED IN SIZE	1 (2.2%) [1]		1 (2.6%) [1]	4 (10.0%) [3]
UNDESCENDED				2 (5.0%) [1]
TESTIS (UNILATERAL)	(45)	(31)	(39)	(40)
MALPOSITIONED				1 (2.5%) [1]
REDUCED IN SIZE	1 (2.2%) [1]		1 (2.6%) [1]	3 (7.5%) [3]
UNDESCENDED				2 (5.0%) [1]
VENTRAL PROSTATE	(45)	(31)	(39)	(40)
REDUCED IN SIZE; ALL SEVERITIES	0 *		2 (5.1%) [2]	4 (10.0%) [3]
REDUCED IN SIZE; MILD				1 (2.5%) [1]

F1 Male: F1c NonParent Males				
	Treatment Groups (ppm)			
	0	1000	5000	10000
REDUCED IN SIZE; MODERATE			2 (5.1%) [2]	3 (7.5%) [3]
HEMATOLYMPHOID SYSTEM				
SPLEEN	(45)	(31)	(39)	(40)
ENLARGED; MILD			1 (2.6%) [1]	
INTEGUMENTARY SYSTEM				
DIGIT	(45)	(31)	(39)	(40)
HINDFOOT; SHORT; THIRD				1 (2.5%) [1]
MUSCULOSKELETAL SYSTEM				
PAW	(45)	(31)	(39)	(40)
HINDFOOT; DEFORMITY; MODERATE				1 (2.5%) [1]
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
None				
SPECIAL SENSES SYSTEM				
EYE	(45)	(31)	(39)	(40)
DISCHARGE; BROWN; ALL SEVERITIES		1 (3.2%) [1]		1 (2.5%) [1]
DISCHARGE; BROWN; MINIMAL		1 (3.2%) [1]		
DISCHARGE; BROWN; MODERATE				1 (2.5%) [1]

F1 Male: F1c NonParent Males				
Treatment Groups (ppm)				
	0	1000	5000	10000
URINARY SYSTEM				
KIDNEY	(45)	(31)	(39)	(40)
PELVIS; DILATION; MILD	1 (2.2%) [1]			1 (2.5%) [1]
DILATION; ALL SEVERITIES	2 (4.4%) [1]	3 (9.7%) [3]	3 (7.7%) [3]	
DILATION; MINIMAL	2 (4.4%) [1]	2 (6.5%) [2]		
DILATION; MODERATE		1 (3.2%) [1]	3 (7.7%) [3]	
ENLARGED; MILD			1 (2.6%) [1]	

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F1 Female: F1c NonParent Female

	Treatment Groups (ppm)			
	0	1000	5000	10000
Disposition Summary				
Animals Initially In Study	28	32	40	32
Censored				
Early Deaths				
Survivors				
Scheduled Sacrifice, Terminal	28	32	40	32
Number of Animals Examined	28	32	40	32
Total number litters	15	12	17	13
ALIMENTARY SYSTEM				
LIVER	(28)	(32)	(40)	(32)
MEDIAN LOBE; NODULE			1 (2.5%) [1]	
MESENTERY	(28)	(32)	(40)	(32)
ADIPOSE; NODULE		1 (3.1%) [1]		
CARDIOVASCULAR SYSTEM				
None				
ENDOCRINE SYSTEM				
ADRENAL GLAND	(28)	(32)	(40)	(32)
DISCOLORATION; BROWN; MODERATE			1 (2.5%) [1]	
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
UTERUS	(28)	(32)	(40)	(32)
NODULE; FIRM	1 (3.6%) [1]	1 (3.1%) [1]		

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F1 Female: F1c NonParent Female

	Treatment Groups (ppm)			
	0	1000	5000	10000
HEMATOLYMPHOID SYSTEM				
SPLEEN	(28)	(32)	(40)	(32)
ENLARGED; MILD			1 (2.5%) [1]	
INTEGUMENTARY SYSTEM				
DIGIT	(28)	(32)	(40)	(32)
HINDFOOT; SHORT; THIRD		1 (3.1%) [1]		1 (3.1%) [1]
MUSCULOSKELETAL SYSTEM				
PAW	(28)	(32)	(40)	(32)
HINDFOOT; DEFORMITY; MODERATE		2 (6.3%) [1]		
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
None				
SPECIAL SENSES SYSTEM				
EYE	(28)	(32)	(40)	(32)
DISCHARGE; BROWN; MILD		1 (3.1%) [1]		
URINARY SYSTEM				
KIDNEY	(28)	(32)	(40)	(32)
DILATION; MINIMAL			1 (2.5%) [1]	
REDUCED IN SIZE; MINIMAL		1 (3.1%) [1]		

F1 Male: F1c Parental Males				
	Treatment Groups (ppm)			
	0	1000	5000	10000
Disposition Summary				
Animals Initially In Study	40	40	40	40
Censored				
Early Deaths				
Survivors				
Scheduled Sacrifice, Terminal	40	40	37	40
Number of Animals Examined	40	40	40	40
Total number litters	21	20	19	18
ALIMENTARY SYSTEM				
LIVER	(40)	(40)	(40)	(40)
DISCOLORATION; BROWN; MODERATE				1 (2.5%) [1]
CARDIOVASCULAR SYSTEM				
None				
ENDOCRINE SYSTEM				
None				
GENERAL BODY SYSTEM				
None				

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F1 Male: F1c Parental Males

	Treatment Groups (ppm)			
	0	1000	5000	10000
GENITAL SYSTEM				
COWPERS GLAND (BILATERAL)	(40)	(40)	(40)	(40)
REDUCED IN SIZE				1 (2.5%) [1]
COWPERS GLAND (UNILATERAL OR BILATERAL)	(40)	(40)	(40)	(40)
MISSING		1 (2.5%) [1]	1 (2.5%) [1]	3 (7.5%) [3]
REDUCED IN SIZE				2 (5.0%) [2]
COWPERS GLAND (UNILATERAL)	(40)	(40)	(40)	(40)
MISSING		1 (2.5%) [1]	1 (2.5%) [1]	3 (7.5%) [3]
REDUCED IN SIZE				1 (2.5%) [1]
COWPERS GLAND, EPIDIDYMIS, LABC MUSCLE, PROSTATE, SEMINAL VESICLE, OR TESTIS	(40)	(40)	(40)	(40)
REDUCED IN SIZE, MALPOSITIONED, UNDESCENDED, OR MISSING	0 **	2 (5.0%) [2]	4 (10.0%) [4]	11 (27.5%) [8] **
EPIDIDYMIS	(40)	(40)	(40)	(40)
DEFORMITY; MODERATE				1 (2.5%) [1]
EPIDIDYMIS (BILATERAL)	(40)	(40)	(40)	(40)
REDUCED IN SIZE	0 *		1 (2.5%) [1]	3 (7.5%) [3]
EPIDIDYMIS (UNILATERAL OR BILATERAL)	(40)	(40)	(40)	(40)
MISSING		1 (2.5%) [1]		
REDUCED IN SIZE	0 **		3 (7.5%) [3]	9 (22.5%) [7] *
EPIDIDYMIS (UNILATERAL)	(40)	(40)	(40)	(40)
MISSING		1 (2.5%) [1]		
REDUCED IN SIZE	0 **		2 (5.0%) [2]	6 (15.0%) [5]
PREPUTIAL GLAND	(40)	(40)	(40)	(40)
DISCHARGE; GREEN; MARKED				1 (2.5%) [1]
DISCOLORATION; BROWN; MODERATE				3 (7.5%) [3]
DISCOLORATION; GREEN; ALL SEVERITIES	0 *			4 (10.0%) [3]
DISCOLORATION; GREEN; MILD				1 (2.5%) [1]
DISCOLORATION; GREEN; MINIMAL				1 (2.5%) [1]
DISCOLORATION; GREEN; MODERATE				2 (5.0%) [2]

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Lab: RTI

F1 Male: F1c Parental Males

	Treatment Groups (ppm)			
	0	1000	5000	10000
ENLARGED; BROWN; MARKED				1 (2.5%) [1]
ENLARGED; GREEN; MILD				1 (2.5%) [1]
ENLARGED; ALL SEVERITIES			1 (2.5%) [1]	2 (5.0%) [2]
ENLARGED; MILD			1 (2.5%) [1]	
ENLARGED; MODERATE				2 (5.0%) [2]
NODULE; GREEN			1 (2.5%) [1]	
NODULE; YELLOW			1 (2.5%) [1]	
NODULE		1 (2.5%) [1]		1 (2.5%) [1]
PREPUTIAL GLAND (UNILATERAL OR BILATERAL)	(40)	(40)	(40)	(40)
REDUCED IN SIZE		1 (2.5%) [1]		
PREPUTIAL GLAND (UNILATERAL)	(40)	(40)	(40)	(40)
REDUCED IN SIZE		1 (2.5%) [1]		
SEMINAL VESICLE (BILATERAL)	(40)	(40)	(40)	(40)
REDUCED IN SIZE				1 (2.5%) [1]
SEMINAL VESICLE (UNILATERAL OR BILATERAL)	(40)	(40)	(40)	(40)
REDUCED IN SIZE				1 (2.5%) [1]
TESTIS (BILATERAL)	(40)	(40)	(40)	(40)
MALPOSITIONED				1 (2.5%) [1]
REDUCED IN SIZE	0 *		1 (2.5%) [1]	3 (7.5%) [3]
TESTIS (UNILATERAL OR BILATERAL)	(40)	(40)	(40)	(40)
MALPOSITIONED				3 (7.5%) [3]
MALPOSITIONED OR UNDESCENDED				3 (7.5%) [3]
MISSING		1 (2.5%) [1]		1 (2.5%) [1]
REDUCED IN SIZE	0 **		3 (7.5%) [3]	9 (22.5%) [7] *
TESTIS (UNILATERAL)	(40)	(40)	(40)	(40)
MALPOSITIONED				2 (5.0%) [2]
MISSING		1 (2.5%) [1]		1 (2.5%) [1]
REDUCED IN SIZE	0 **		2 (5.0%) [2]	6 (15.0%) [6] *

Study Number: R10997

Test Type: RACB

Route: Dosing in Feed

Species/Strain: Rat/Sprague-Dawley

PA46R: Summary of Gross Pathology with Litter Incidence

Test Compound: Diisobutyl Phthalate

CAS Number: 84-69-5

Date Report Requested: 03/18/2021

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Lab: RTI

F1 Male: F1c Parental Males

	Treatment Groups (ppm)			
	0	1000	5000	10000
VENTRAL PROSTATE REDUCED IN SIZE; MARKED	(40)	(40)	(40)	(40) 1 (2.5%) [1]
HEMATOLYMPHOID SYSTEM LYMPH NODE SUBMANDIBULAR; DISCOLORATION; BROWN; MODERATE	(40)	(40)	(40)	(40) 1 (2.5%) [1]
INTEGUMENTARY SYSTEM SKIN INGUINAL; DISCOLORATION; BROWN; MARKED	(40)	(40)	(40)	(40) 1 (2.5%) [1]
MUSCULOSKELETAL SYSTEM None				
NERVOUS SYSTEM None				
RESPIRATORY SYSTEM None				
SPECIAL SENSES SYSTEM None				
URINARY SYSTEM KIDNEY	(40)	(40)	(40)	(40)
PELVIS; DILATION; ALL SEVERITIES		1 (2.5%) [1]		3 (7.5%) [3]
PELVIS; DILATION; MILD				1 (2.5%) [1]
PELVIS; DILATION; MINIMAL		1 (2.5%) [1]		1 (2.5%) [1]
PELVIS; DILATION; MODERATE				1 (2.5%) [1]

Study Number: R10997

Test Type: RACB

Route: Dosing in Feed

Species/Strain: Rat/Sprague-Dawley

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Lab: RTI

F1 Female: F1c Parental Females

	Treatment Groups (ppm)			
	0	1000	5000	10000
Disposition Summary				
Animals Initially In Study	40	40	40	40
Censored				
Early Deaths				
Found Dead	1		1	
Sacrificed, Moribund	1		4	
Survivors				
Scheduled Sacrifice, Terminal	38	40	35	40
Number of Animals Examined	40	40	40	40
Total number litters	20	19	20	18
ALIMENTARY SYSTEM				
LIVER	(40)	(40)	(40)	(40)
MEDIAL LOBE; DEFORMITY; MILD		1 (2.5%) [1]		
CAUDATE LOBE; DISCOLORATION; RED; MODERATE		1 (2.5%) [1]		
DISCOLORATION; BROWN; MINIMAL				1 (2.5%) [1]
MESENTERY	(40)	(40)	(40)	(40)
NODULE			1 (2.5%) [1]	
CARDIOVASCULAR SYSTEM				
HEART	(40)	(40)	(40)	(40)
MISSHAPEN			1 (2.5%) [1]	
ENDOCRINE SYSTEM				
ADRENAL GLAND	(40)	(40)	(40)	(40)
ENLARGED; MILD			1 (2.5%) [1]	

Study Number: R10997

Test Type: RACB

Route: Dosing in Feed

Species/Strain: Rat/Sprague-Dawley

PA46R: Summary of Gross Pathology with Litter Incidence

Test Compound: Diisobutyl Phthalate

CAS Number: 84-69-5

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Lab: RTI

F1 Female: F1c Parental Females

	Treatment Groups (ppm)			
	0	1000	5000	10000
GENERAL BODY SYSTEM				
CAVITY, ABDOMINAL	(40)	(40)	(40)	(40)
FLUID			1 (2.5%) [1]	
FAT	(40)	(40)	(40)	(40)
MESENTERY; DISCOLORATION; MILD		1 (2.5%) [1]		
GENITAL SYSTEM				
CLITORAL GLAND	(40)	(40)	(40)	(40)
DISCOLORATION; GREEN; MILD	1 (2.5%) [1]	1 (2.5%) [1]	1 (2.5%) [1]	
ENLARGED; MILD	1 (2.5%) [1]	1 (2.5%) [1]	1 (2.5%) [1]	
OVARY	(40)	(40)	(40)	(40)
DISCOLORATION; PALE; MODERATE			1 (2.5%) [1]	
REDUCED IN SIZE; ALL SEVERITIES	2 (5.0%) [2]			1 (2.5%) [1]
REDUCED IN SIZE; MILD	2 (5.0%) [2]			
REDUCED IN SIZE; MODERATE				1 (2.5%) [1]
UTERUS	(40)	(40)	(40)	(40)
CYST; CLEAR		1 (2.5%) [1]		
ENLARGED; MARKED			1 (2.5%) [1]	

Study Number: R10997

Test Type: RACB

Route: Dosing in Feed

Species/Strain: Rat/Sprague-Dawley

PA46R: Summary of Gross Pathology with Litter Incidence

Test Compound: Diisobutyl Phthalate

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Lab: RTI

F1 Female: F1c Parental Females

	Treatment Groups (ppm)			
	0	1000	5000	10000
HEMATOLYMPHOID SYSTEM				
LYMPH NODE, AXILLARY	(40)	(40)	(40)	(40)
ENLARGED; PALE; MODERATE			1 (2.5%) [1]	
ENLARGED; MILD	1 (2.5%) [1]			
LYMPH NODE, INGUINAL	(40)	(40)	(40)	(40)
ENLARGED; PALE; MODERATE			1 (2.5%) [1]	
LYMPH NODE, MANDIBULAR	(40)	(40)	(40)	(40)
ENLARGED; PALE; MODERATE			1 (2.5%) [1]	
SPLEEN	(40)	(40)	(40)	(40)
ENLARGED; ALL SEVERITIES	1 (2.5%) [1]		1 (2.5%) [1]	
ENLARGED; MILD	1 (2.5%) [1]			
ENLARGED; MODERATE			1 (2.5%) [1]	
THYMUS	(40)	(40)	(40)	(40)
ENLARGED; MILD			1 (2.5%) [1]	
INTEGUMENTARY SYSTEM				
MAMMARY GLAND	(40)	(40)	(40)	(40)
AXILLARY; ENLARGED; MILD		1 (2.5%) [1]		
CERVICAL; ENLARGED; MILD	1 (2.5%) [1]			
AXILLARY; MASS; FIRM		1 (2.5%) [1]	2 (5.0%) [2]	1 (2.5%) [1]
SKIN	(40)	(40)	(40)	(40)
FORELIMB; ALOPECIA; MILD		1 (2.5%) [1]		
AXILLARY; ULCER; MARKED	1 (2.5%) [1]			
SKIN, ABDOMINAL	(40)	(40)	(40)	(40)
MASS; FIRM			1 (2.5%) [1]	

F1 Female: F1c Parental Females				
	Treatment Groups (ppm)			
	0	1000	5000	10000
MUSCULOSKELETAL SYSTEM				
DIAPHRAGM	(40)	(40)	(40)	(40)
MEDIAL LOBE; HERNIA; MILD			1 (2.5%) [1]	
PAW	(40)	(40)	(40)	(40)
FOREFOOT; DEFORMITY; MILD	1 (2.5%) [1]			
HINDFOOT; DEFORMITY; MILD	2 (5.0%) [2]			1 (2.5%) [1]
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
None				
SPECIAL SENSES SYSTEM				
None				
URINARY SYSTEM				
KIDNEY	(40)	(40)	(40)	(40)
DILATION; MILD			1 (2.5%) [1]	
MASS; PALE				1 (2.5%) [1]

F1 Male: F1c P+NP Males				
	Treatment Groups (ppm)			
	0	1000	5000	10000
Disposition Summary				
Animals Initially In Study	85	71	79	80
Censored				
Early Deaths				
Sacrificed, Moribund				1
Survivors				
Scheduled Sacrifice, Terminal	85	71	76	79
Number of Animals Examined	85	71	79	80
Total number litters	21	20	19	19
ALIMENTARY SYSTEM				
None				
CARDIOVASCULAR SYSTEM				
None				
ENDOCRINE SYSTEM				
None				
GENERAL BODY SYSTEM				
None				

Study Number: R10997

Test Type: RACB

Route: Dosing in Feed

Species/Strain: Rat/Sprague-Dawley

PA46R: Summary of Gross Pathology with Litter Incidence

Test Compound: Diisobutyl Phthalate

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Lab: RTI

F1 Male: F1c P+NP Males

	Treatment Groups (ppm)			
	0	1000	5000	10000
GENITAL SYSTEM				
COWPERS GLAND (BILATERAL)	(85)	(71)	(79)	(80)
REDUCED IN SIZE			3 (3.8%) [2]	2 (2.5%) [2]
COWPERS GLAND (UNILATERAL OR BILATERAL)	(85)	(71)	(79)	(80)
MISSING		1 (1.4%) [1]	1 (1.3%) [1]	3 (3.8%) [3]
REDUCED IN SIZE			3 (3.8%) [2]	3 (3.8%) [3]
COWPERS GLAND (UNILATERAL)	(85)	(71)	(79)	(80)
MISSING		1 (1.4%) [1]	1 (1.3%) [1]	3 (3.8%) [3]
REDUCED IN SIZE				1 (1.3%) [1]
COWPERS GLAND, EPIDIDYMIS, LABC MUSCLE, PROSTATE, SEMINAL VESICLE, OR TESTIS	(85)	(71)	(79)	(80)
REDUCED IN SIZE, MALPOSITIONED, UNDESCENDED, OR MISSING	1 (1.2%) [1] **	2 (2.8%) [2]	10 (12.7%) [7] *	20 (25.0%) [11] **
DORSAL PROSTATE	(85)	(71)	(79)	(80)
MISSING				1 (1.3%) [1]
REDUCED IN SIZE			2 (2.5%) [2]	1 (1.3%) [1]
EPIDIDYMIS (BILATERAL)	(85)	(71)	(79)	(80)
REDUCED IN SIZE	0 *		1 (1.3%) [1]	4 (5.0%) [4]
EPIDIDYMIS (UNILATERAL OR BILATERAL)	(85)	(71)	(79)	(80)
MISSING		1 (1.4%) [1]		
REDUCED IN SIZE	1 (1.2%) [1] **		4 (5.1%) [4]	13 (16.3%) [8] *
EPIDIDYMIS (UNILATERAL)	(85)	(71)	(79)	(80)
MISSING		1 (1.4%) [1]		
REDUCED IN SIZE	1 (1.2%) [1] **		3 (3.8%) [3]	9 (11.3%) [6] *
LEVATOR ANI PLUS BULBOCAVERNOSUS MUSCLE	(85)	(71)	(79)	(80)
REDUCED IN SIZE			2 (2.5%) [1]	2 (2.5%) [1]
PREPUTIAL GLAND (UNILATERAL OR BILATERAL)	(85)	(71)	(79)	(80)
REDUCED IN SIZE		1 (1.4%) [1]	1 (1.3%) [1]	
PREPUTIAL GLAND (UNILATERAL)	(85)	(71)	(79)	(80)
REDUCED IN SIZE		1 (1.4%) [1]	1 (1.3%) [1]	

Study Number: R10997

Test Type: RACB

Route: Dosing in Feed

Species/Strain: Rat/Sprague-Dawley

PA46R: Summary of Gross Pathology with Litter Incidence

Test Compound: Diisobutyl Phthalate

CAS Number: 84-69-5

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Lab: RTI

F1 Male: F1c P+NP Males

	Treatment Groups (ppm)			
	0	1000	5000	10000
SEMINAL VESICLE (BILATERAL)	(85)	(71)	(79)	(80)
REDUCED IN SIZE				1 (1.3%) [1]
SEMINAL VESICLE (UNILATERAL OR BILATERAL)	(85)	(71)	(79)	(80)
REDUCED IN SIZE			2 (2.5%) [2]	2 (2.5%) [2]
SEMINAL VESICLE (UNILATERAL)	(85)	(71)	(79)	(80)
REDUCED IN SIZE			2 (2.5%) [2]	1 (1.3%) [1]
TESTIS (BILATERAL)	(85)	(71)	(79)	(80)
MALPOSITIONED				1 (1.3%) [1]
REDUCED IN SIZE	0 *		1 (1.3%) [1]	4 (5.0%) [3]
TESTIS (UNILATERAL OR BILATERAL)	(85)	(71)	(79)	(80)
MALPOSITIONED				4 (5.0%) [3]
MALPOSITIONED OR UNDESCENDED				5 (6.3%) [3]
MISSING		1 (1.4%) [1]		1 (1.3%) [1]
REDUCED IN SIZE	1 (1.2%) [1] **		4 (5.1%) [4]	13 (16.3%) [8] *
UNDESCENDED				2 (2.5%) [1]
TESTIS (UNILATERAL)	(85)	(71)	(79)	(80)
MALPOSITIONED				3 (3.8%) [2]
MISSING		1 (1.4%) [1]		1 (1.3%) [1]
REDUCED IN SIZE	1 (1.2%) [1] **		3 (3.8%) [3]	9 (11.3%) [7] *
UNDESCENDED				2 (2.5%) [1]
VENTRAL PROSTATE	(85)	(71)	(79)	(80)
REDUCED IN SIZE	0 *		2 (2.5%) [2]	5 (6.3%) [4]
HEMATOLYMPHOID SYSTEM				
None				
INTEGUMENTARY SYSTEM				
None				

Study Number: R10997
Test Type: RACB
Route: Dosing in Feed
Species/Strain: Rat/Sprague-Dawley

PA46R: Summary of Gross Pathology with Litter Incidence
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F1 Male: F1c P+NP Males				
	Treatment Groups (ppm)			
	0	1000	5000	10000
MUSCULOSKELETAL SYSTEM	None			
NERVOUS SYSTEM	None			
RESPIRATORY SYSTEM	None			
SPECIAL SENSES SYSTEM	None			
URINARY SYSTEM	None			

F1 Male: F1c Extra Males			
	Treatment Groups (ppm)		
	0	1000	5000
Disposition Summary			
Animals Initially In Study	6	1	7
Censored			
Early Deaths			
Survivors			
Number of Animals Examined	2	1	2
Total number litters	2	1	1
ALIMENTARY SYSTEM			
None			
CARDIOVASCULAR SYSTEM			
None			
ENDOCRINE SYSTEM			
None			
GENERAL BODY SYSTEM			
None			

Study Number: R10997

Test Type: RACB

Route: Dosing in Feed

Species/Strain: Rat/Sprague-Dawley

PA46R: Summary of Gross Pathology with Litter Incidence

Test Compound: Diisobutyl Phthalate

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F1 Male: F1c Extra Males

	Treatment Groups (ppm)		
	0	1000	5000
GENITAL SYSTEM			
EPIDIDYMIS (LEFT)	(2)	(1)	(2)
DEFORMITY; MARKED	1 (50.0%) [1]		
DISCOLORATION; YELLOW; MARKED	1 (50.0%) [1]		
SEM VES W COAG GLANDS (PAIRED, EMPTY)	(2)	(1)	(2)
REDUCED IN SIZE			1 (50.0%) [1]
SEM VES W COAG GLANDS (PAIRED, FULL)	(2)	(1)	(2)
REDUCED IN SIZE			1 (50.0%) [1]
TESTIS (LEFT)	(2)	(1)	(2)
DISCOLORATION; TAN; MARKED	1 (50.0%) [1]		
REDUCED IN SIZE; MARKED	1 (50.0%) [1]		
HEMATOLYMPHOID SYSTEM			
None			
INTEGUMENTARY SYSTEM			
None			
MUSCULOSKELETAL SYSTEM			
None			
NERVOUS SYSTEM			
None			
RESPIRATORY SYSTEM			
LUNGS	(2)	(1)	(2)
DISCOLORATION; MOTTLED; MILD			1 (50.0%) [1]
SPECIAL SENSES SYSTEM			
None			

Study Number: R10997
Test Type: RACB
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Species/Strain: Rat/Sprague-Dawley

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F1 Male: F1c Extra Males			
	Treatment Groups (ppm)		
	0	1000	5000
URINARY SYSTEM			
KIDNEY (RIGHT)	(2)	(1)	(2)
DILATION; MILD			1 (50.0%) [1]

F1 Female: F1c Extra Females				
	Treatment Groups (ppm)			
	0	1000	5000	10000
Disposition Summary				
Animals Initially In Study	1	4	4	2
Censored				
Early Deaths				
Survivors				
Number of Animals Examined	1	2		2
Total number litters	1	2		2
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				

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F1 Female: F1c Extra Females				
Treatment Groups (ppm)				
	0	1000	5000	10000
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
None				
SPECIAL SENSES SYSTEM				
None				
URINARY SYSTEM				
None				

F2 Male				
	Treatment Groups (ppm)			
	0	1000	5000	10000
Disposition Summary				
Animals Initially In Study	160	161	135	122
Censored				
Early Deaths				
Survivors				
Scheduled Sacrifice, Terminal	160	161	135	122
Number of Animals Examined	160	161	135	122
Total number litters	31	35	27	33
ALIMENTARY SYSTEM				
None				
CARDIOVASCULAR SYSTEM				
None				
ENDOCRINE SYSTEM				
None				
GENERAL BODY SYSTEM				
FAT	(160)	(161)	(135)	(122)
DISCOLORATION; MILD		1 (0.6%) [1]		

Study Number: R10997

Test Type: RACB

Route: Dosing in Feed

Species/Strain: Rat/Sprague-Dawley

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F2 Male				
	Treatment Groups (ppm)			
	0	1000	5000	10000
GENITAL SYSTEM				
COWPERS GLAND, EPIDIDYMIS, LABC MUSCLE, PROSTATE, SEMINAL VESICLE, OR TESTIS	(160)	(161)	(135)	(122)
REDUCED IN SIZE, MALPOSITIONED, UNDESCENDED, OR MISSING	1 (0.6%) [1] **	2 (1.2%) [2]	10 (7.4%) [7] *	18 (14.8%) [13] **
TESTIS (BILATERAL)	(160)	(161)	(135)	(122)
REDUCED IN SIZE			1 (0.7%) [1]	
UNDESCENDED	0 *			4 (3.3%) [3]
TESTIS (UNILATERAL OR BILATERAL)	(160)	(161)	(135)	(122)
MALPOSITIONED			1 (0.7%) [1]	2 (1.6%) [2]
MALPOSITIONED OR UNDESCENDED	1 (0.6%) [1] **	2 (1.2%) [2]	8 (5.9%) [5]	17 (13.9%) [12] **
MISSING		1 (0.6%) [1]	2 (1.5%) [2]	
REDUCED IN SIZE			2 (1.5%) [2]	1 (0.8%) [1]
UNDESCENDED	1 (0.6%) [1] **	2 (1.2%) [2]	8 (5.9%) [5]	16 (13.1%) [11] **
TESTIS (UNILATERAL)	(160)	(161)	(135)	(122)
MALPOSITIONED			1 (0.7%) [1]	2 (1.6%) [2]
MISSING		1 (0.6%) [1]	2 (1.5%) [2]	
REDUCED IN SIZE			1 (0.7%) [1]	1 (0.8%) [1]
UNDESCENDED	1 (0.6%) [1] **	2 (1.2%) [2]	8 (5.9%) [5]	12 (9.8%) [10] **
HEMATOLYMPHOID SYSTEM				
None				
INTEGUMENTARY SYSTEM				
None				
MUSCULOSKELETAL SYSTEM				
None				
NERVOUS SYSTEM				
None				

F2 Male				
	Treatment Groups (ppm)			
	0	1000	5000	10000
RESPIRATORY SYSTEM				
None				
SPECIAL SENSES SYSTEM				
None				
URINARY SYSTEM				
KIDNEY	(160)	(161)	(135)	(122)
PELVIS; DILATION; ALL SEVERITIES	1 (0.6%) [1]	1 (0.6%) [1]	1 (0.7%) [1]	3 (2.5%) [3]
PELVIS; DILATION; MILD	1 (0.6%) [1]		1 (0.7%) [1]	1 (0.8%) [1]
PELVIS; DILATION; MINIMAL		1 (0.6%) [1]		2 (1.6%) [2]

F2 Female				
	Treatment Groups (ppm)			
	0	1000	5000	10000
Disposition Summary				
Animals Initially In Study	146	178	137	155
Censored				
Early Deaths				
Survivors				
Scheduled Sacrifice, Terminal	146	178	137	155
Number of Animals Examined	146	178	137	155
Total number litters	32	36	26	33
ALIMENTARY SYSTEM				
None				
CARDIOVASCULAR SYSTEM				
None				
ENDOCRINE SYSTEM				
None				
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
None				
HEMATOLYMPHOID SYSTEM				
None				
INTEGUMENTARY SYSTEM				
None				

F2 Female				
	Treatment Groups (ppm)			
	0	1000	5000	10000
MUSCULOSKELETAL SYSTEM				
PAW	(146)	(178)	(137)	(155)
HINDFOOT; DEFORMITY; MINIMAL				1 (0.6%) [1]
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
None				
SPECIAL SENSES SYSTEM				
None				
URINARY SYSTEM				
KIDNEY	(146)	(178)	(137)	(155)
PELVIS; DILATION; MILD		1 (0.6%) [1]		

Study Number: R10997

Test Type: RACB

Route: Dosing in Feed

Species/Strain: Rat/Sprague-Dawley

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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 and F2 animals. F1 litter incidence based on the number of F0 dams; F2 litter incidence based on number of F1 dams.

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

Non-pregnant females from the F0 and F1 generations are included in the analysis.

Statistical analysis for the F0 animals was performed by Cochran-Armitage (trend) and Fisher Exact (pairwise) tests.

Statistical analysis for all F1 and F2 cohorts was performed by Cochran-Armitage test with a Rao-Scott modification for the random effect due to litter.

If the same lesion is shown with multiple different severities, trend and pairwise statistical comparisons are performed only against the ALL SEVERITIES combination.

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 $P \leq 0.01$

The selection of F1c P+NP Males includes both the F1c Parental males and the F1c Nonparent males.

Animals that had both an undescended and malpositioned testis were only counted once in the "malpositioned or undescended" combination.

**** END OF REPORT ****