

**Study Number:** R10997

**Test Type:** RACB

**Route:** Dosing in Feed

**Species/Strain:** Rat/Sprague-Dawley

**C Number:**

**Study Gender:**

**PWG Approval Date**

**PA03R: Non-Neoplastic Lesion Summary with Percent and Litter Incidence**

**Test Compound:** Diisobutyl Phthalate

**CAS Number:** 84-69-5

R10997

Both

See web page for date of PWG Approval

**Date Report Requested:** 07/30/2019

**Time Report Requested:** 13:35:02

**Lab:** RTI

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	F0 Male			
	Treatment Groups (ppm)			
	0	1000	5000	10000
<b>Disposition Summary</b>				
<b>Animals Initially In Study</b>	23	23	23	23
<b>Early Deaths</b>				
<b>Scheduled Deaths</b>				
<b>Scheduled sacrifice, terminal (SD 139 - 141)</b>	23	23	23	23
<b>Animals Examined Microscopically</b>	23	10	6	23
<b>ALIMENTARY SYSTEM</b>				
LIVER	(23)	(0)	(0)	(23)
BILE DUCT; HYPERPLASIA				1 (4%)
INFLAMMATION; FOCAL				3 (13%)
HEPATOCYTE; NECROSIS				1 (4%)
<b>CARDIOVASCULAR SYSTEM</b>				
BLOOD VESSEL	(0)	(0)	(0)	(1)
<b>ENDOCRINE SYSTEM</b>				
ADRENAL GLAND	(23)	(0)	(0)	(23)
CORTEX; VACUOLATION; DIFFUSE				1 (4%)
CORTEX; VACUOLATION; FOCAL	2 (9%)			
PITUITARY GLAND	(22)	(0)	(0)	(22)
PARS DISTALIS; CYST				1 (5%)
RATHKE'S CLEFT; DILATION				1 (5%)
THYROID GLAND	(23)	(0)	(0)	(23)
<b>GENERAL BODY SYSTEM</b>				
FAT	(0)	(0)	(0)	(1)
INFLAMMATION, CHRONIC				1 (100%)

Study Number: R10997

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Species/Strain: Rat/Sprague-Dawley

	F0 Male			
	Treatment Groups (ppm)			
	0	1000	5000	10000
GENITAL SYSTEM				
COAGULATING GLAND	(23)	(0)	(0)	(23)
DORSAL PROSTATE	(23)	(0)	(0)	(23)
INFLAMMATION, CHRONIC	1 (4%)			
EPIDIDYMIS	(23)	(0)	(0)	(23)
DUCT; EXFOLIATED GERM CELL	3 (13%)			2 (9%)
MINERAL				1 (4%)
NECROSIS				1 (4%)
SPERM GRANULOMA	2 (9%)			
PREPUTIAL GLAND	(10)	(10)	(4)	(9)
INFLAMMATION, CHRONIC	7 (70%)	6 (60%)	2 (50%)	7 (78%)
BILATERAL; INFLAMMATION, SUPPURATIVE	1 (10%)	2 (20%)	2 (50%)	2 (22%)
INFLAMMATION, SUPPURATIVE	2 (20%)	1 (10%)		
SEMINAL VESICLE	(23)	(0)	(0)	(23)
TESTIS	(23)	(0)	(0)	(23)
GERMINAL EPITHELIUM; DEGENERATION	4 (17%)			5 (22%)
SEMINIFEROUS TUBULE; MINERAL				1 (4%)
SEMINIFEROUS TUBULE; NECROSIS				1 (4%)
VENTRAL PROSTATE	(23)	(0)	(0)	(23)
INFILTRATION CELLULAR; LYMPHOCYTE	3 (13%)			
INFLAMMATION, CHRONIC	2 (9%)			2 (9%)
INFLAMMATION, CHRONIC-ACTIVE	1 (4%)			1 (4%)
HEMATOLYMPHOID SYSTEM				
THYMUS	(23)	(0)	(0)	(23)
HYPERPLASIA; EPITHELIAL	2 (9%)			1 (4%)
INTEGUMENTARY SYSTEM				
SKIN	(0)	(0)	(1)	(1)
ULCERATION			1 (100%)	1 (100%)

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	F0 Male			
	Treatment Groups (ppm)			
	0	1000	5000	10000
MUSCULOSKELETAL SYSTEM				
No Tissues/Organs Examined				
NERVOUS SYSTEM				
No Tissues/Organs Examined				
RESPIRATORY SYSTEM				
No Tissues/Organs Examined				
SPECIAL SENSES SYSTEM				
EYE	(0)	(0)	(1)	(0)
URINARY SYSTEM				
KIDNEY	(23)	(0)	(0)	(23)
CHRONIC PROGRESSIVE NEPHROPATHY	21 (91%)			22 (96%)
DYSPLASIA	1 (4%)			
INFARCT				1 (4%)
INFLAMMATION; INTERSTITIAL				1 (4%)
PAPILLA; MINERAL	2 (9%)			
PELVIS; MINERAL				1 (4%)

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	F0 Female			
	Treatment Groups (ppm)			
	0	1000	5000	10000
<b>Disposition Summary</b>				
<b>Animals Initially In Study</b>	23	23	23	23
<b>Early Deaths</b>				
<b>Euthanized, moribund</b>	2	2	2	1
<b>Unscheduled Sacrifice</b>			1	
<b>Scheduled Deaths</b>				
<b>Scheduled sacrifice, terminal (SD 176 - 177)</b>	21	21	20	22
<b>Animals Examined Microscopically</b>	23	3	4	23
<b>ALIMENTARY SYSTEM</b>				
LIVER	(23)	(0)	(1)	(23)
INFLAMMATION; FOCAL	1 (4%)		1 (100%)	1 (4%)
SALIVARY GLAND	(0)	(1)	(0)	(0)
<b>CARDIOVASCULAR SYSTEM</b>				
No Tissues/Organs Examined				
<b>ENDOCRINE SYSTEM</b>				
ADRENAL GLAND	(23)	(0)	(0)	(23)
NECROSIS				1 (4%)
CORTEX; VACUOLATION; FOCAL	1 (4%)			1 (4%)
PITUITARY GLAND	(23)	(0)	(0)	(23)
THYROID GLAND	(23)	(0)	(0)	(23)
C-CELL; HYPERPLASIA	1 (4%)			1 (4%)
<b>GENERAL BODY SYSTEM</b>				
FAT	(1)	(0)	(0)	(0)
NECROSIS	1 (100%)			

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	F0 Female			
	Treatment Groups (ppm)			
	0	1000	5000	10000
GENITAL SYSTEM				
CERVIX	(21)	(0)	(0)	(23)
CLITORAL GLAND	(1)	(0)	(0)	(1)
INFLAMMATION, SUPPURATIVE	1 (100%)			1 (100%)
OVARY	(23)	(0)	(0)	(23)
CORPUS LUTEUM; BILATERAL; CYST				2 (9%)
CORPUS LUTEUM; CYST				1 (4%)
CYST; EPITHELIAL				1 (4%)
CYST	3 (13%)			2 (9%)
UTERUS	(21)	(0)	(0)	(23)
DILATION	1 (5%)			1 (4%)
ENDOMETRIUM; HYPERPLASIA; CYSTIC	2 (10%)			
ENDOMETRIUM; METAPLASIA; SQUAMOUS	1 (5%)			1 (4%)
POLYP; STROMAL				2 (9%)
VAGINA	(21)	(0)	(0)	(23)
MUCIFICATION				1 (4%)
HEMATOLYMPHOID SYSTEM				
LYMPH NODE, MESENTERIC	(0)	(0)	(1)	(0)
SPLEEN	(0)	(0)	(2)	(1)
EXTRAMEDULLARY HEMATOPOIESIS			2 (100%)	1 (100%)
THYMUS	(23)	(0)	(0)	(23)
HYPERPLASIA; EPITHELIAL	3 (13%)			

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Species/Strain: Rat/Sprague-Dawley

	F0 Female			
	Treatment Groups (ppm)			
	0	1000	5000	10000
INTEGUMENTARY SYSTEM				
MAMMARY GLAND	(2)	(3)	(2)	(0)
INFLAMMATION, ACUTE		1 (33%)		
INFLAMMATION, CHRONIC-ACTIVE		1 (33%)		
SKIN	(1)	(0)	(0)	(0)
HAIR FOLLICLE; INFLAMMATION, CHRONIC	1 (100%)			
SKIN, ABDOMINAL	(0)	(0)	(0)	(1)
ULCERATION				1 (100%)
MUSCULOSKELETAL SYSTEM				
No Tissues/Organs Examined				
NERVOUS SYSTEM				
No Tissues/Organs Examined				
RESPIRATORY SYSTEM				
No Tissues/Organs Examined				
SPECIAL SENSES SYSTEM				
No Tissues/Organs Examined				
URINARY SYSTEM				
KIDNEY	(23)	(0)	(1)	(23)
CHRONIC PROGRESSIVE NEPHROPATHY	19 (83%)		1 (100%)	17 (74%)
MEDULLA; BILATERAL; CYST				1 (4%)
MEDULLA; CYST				4 (17%)
CORTICOMEDULLARY JUNCTION; MINERAL	9 (39%)		1 (100%)	6 (26%)
NEPHROBLASTEMATOSIS	1 (4%)			

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F1 Male: F1c NonParent Males

	Treatment Groups (ppm)			
	0	1000	5000	10000
<b>Disposition Summary</b>				
Animals Initially In Study	45	31	39	40
Early Deaths				
Euthanized, moribund				1
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 90 - 92)	45	31	39	39
Animals Examined Microscopically	45	31	39	40
Total number litters	17	13	17	16
<b>ALIMENTARY SYSTEM</b>				
LIVER	(45)	(1)	(2)	(40)
INFLAMMATION; CHRONIC		1 (100%) [1]		1 (3%) [1]
INFLAMMATION; FOCAL	32 (71%) [15]			31 (78%) [15]
HEPATOCYTE; NECROSIS			1 (50%) [1]	
POLYARTERITIS NODOSA			1 (50%) [1]	
<b>CARDIOVASCULAR SYSTEM</b>				
No Tissues/Organs Examined				
<b>ENDOCRINE SYSTEM</b>				
ADRENAL GLAND	(45)	(0)	(1)	(40)
CORTEX; HYPERPLASIA			1 (100%) [1]	
POLYARTERITIS NODOSA			1 (100%) [1]	
CORTEX; VACUOLATION; DIFFUSE				2 (5%) [2]
PITUITARY GLAND	(45)	(31)	(39)	(40)
PARS DISTALIS; CYST; MULTIPLE			1 (3%) [1]	
PARS DISTALIS; CYST	3 (7%) [3]	1 (3%) [1]	2 (5%) [2]	1 (3%) [1]
PARS INTERMEDIA; CYST				1 (3%) [1]
PARS DISTALIS; HYPERTROPHY				3 (8%) [2]
THYROID GLAND	(45)	(0)	(0)	(40)

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**F1 Male: F1c NonParent Males**

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**Treatment Groups (ppm)**

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**0**

**1000**

**5000**

**10000**

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GENERAL BODY SYSTEM  
No Tissues/Organs Examined

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F1 Male: F1c NonParent Males

	Treatment Groups (ppm)			
	0	1000	5000	10000
GENITAL SYSTEM				
COAGULATING GLAND	(45)	(0)	(3)	(40)
COWPERS GLAND	(44)	(31)	(39)	(39)
HYPOPLASIA				1 (3%) [1]
DORSAL PROSTATE	(45)	(31)	(39)	(38)
INFLAMMATION, CHRONIC	1 (2%) [1]			
EPIDIDYMIS	(45)	(31)	(39)	(40)
DUCT; ATROPHY			1 (3%) [1]	3 (8%) [2]
DUCT; EXFOLIATED GERM CELL	3 (7%) [2]		5 (13%) [4]	8 (20%) [7]
HYOSPERMIA	1 (2%) [1]		1 (3%) [1]	4 (10%) [3]
IMMATURE				1 (3%) [1]
SPERM GRANULOMA			1 (3%) [1]	
LEVATOR ANI PLUS BULBOCAVERNOSUS MUSCLE	(45)	(0)	(2)	(39)
HYPOPLASIA				1 (3%) [1]
PENIS	(2)	(0)	(0)	(1)
PREPUTIAL GLAND	(2)	(0)	(1)	(1)
DUCT; DILATION				1 (100%) [1]
INFLAMMATION, CHRONIC	1 (50%) [1]		1 (100%) [1]	
SEMINAL VESICLE	(45)	(0)	(4)	(40)
TESTIS	(45)	(31)	(39)	(40)
GERMINAL EPITHELIUM; ATROPHY				1 (3%) [1]
GERMINAL EPITHELIUM; DEGENERATION	3 (7%) [2]	1 (3%) [1]	8 (21%) [6]	10 (25%) [8]
SEMINIFEROUS TUBULE; DYSGENESIS	1 (2%) [1]		2 (5%) [1]	2 (5%) [2]
EDEMA				2 (5%) [1]
INTERSTITIAL CELL; HYPERPLASIA; DIFFUSE				2 (5%) [1]
INTERSTITIAL CELL; HYPERPLASIA; FOCAL				2 (5%) [2]
IMMATURE				1 (3%) [1]
VENTRAL PROSTATE	(45)	(31)	(39)	(40)

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F1 Male: F1c NonParent Males

	Treatment Groups (ppm)			
	0	1000	5000	10000
IMMATURE				1 (3%) [1]
INFILTRATION CELLULAR; LYMPHOCYTE	16 (36%) [11]	12 (39%) [10]	6 (15%) [5]	17 (43%) [9]
BILATERAL; INFLAMMATION, CHRONIC	14 (31%) [8]	5 (16%) [4]	6 (15%) [5]	13 (33%) [7]
INFLAMMATION, CHRONIC	2 (4%) [2]	3 (10%) [3]	9 (23%) [7]	3 (8%) [3]
HEMATOLYMPHOID SYSTEM				
SPLEEN	(45)	(0)	(1)	(40)
FOLLICLE; ATROPHY; LYMPHOID				1 (3%) [1]
EXTRAMEDULLARY HEMATOPOIESIS			1 (100%) [1]	
THYMUS	(45)	(0)	(0)	(40)
HYPERPLASIA; EPITHELIAL	1 (2%) [1]			1 (3%) [1]
NECROSIS; LYMPHOCYTIC				1 (3%) [1]
INTEGUMENTARY SYSTEM				
DIGIT	(0)	(0)	(0)	(1)
HYPOPLASIA				1 (100%) [1]
MUSCULOSKELETAL SYSTEM				
PAW	(0)	(0)	(0)	(1)
NERVOUS SYSTEM				
No Tissues/Organs Examined				
RESPIRATORY SYSTEM				
No Tissues/Organs Examined				
SPECIAL SENSES SYSTEM				
No Tissues/Organs Examined				

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**F1 Male: F1c NonParent Males**

	Treatment Groups (ppm)			
	0	1000	5000	10000
URINARY SYSTEM				
KIDNEY	(45)	(3)	(3)	(40)
CHRONIC PROGRESSIVE NEPHROPATHY	41 (91%) [17]		1 (33%) [1]	37 (93%) [15]
MEDULLA; BILATERAL; CYST	1 (2%) [1]			
MEDULLA; CYST				5 (13%) [4]
PELVIS; DILATION	3 (7%) [2]	3 (100%) [3]	3 (100%) [3]	2 (5%) [2]
INFARCT	1 (2%) [1]			
PAPILLA; MINERAL			1 (33%) [1]	3 (8%) [2]
NEPHROBLASTEMATOSIS				1 (3%) [1]
POLYARTERITIS NODOSA			1 (33%) [1]	

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F1 Female: F1c NonParent Female

	Treatment Groups (ppm)			
	0	1000	5000	10000
<b>Disposition Summary</b>				
Animals Initially In Study	28	32	40	32
Early Deaths				
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 90 - 92)	28	32	40	32
Animals Examined Microscopically	28	5	3	32
Total number litters	15	4	3	13
<b>ALIMENTARY SYSTEM</b>				
LIVER	(28)	(0)	(1)	(32)
HEPATODIAPHRAGMATIC NODULE			1 (100%) [1]	
BILE DUCT; HYPERPLASIA				1 (3%) [1]
INFLAMMATION; FOCAL	2 (7%) [2]			4 (13%) [4]
MINERAL; FOCAL				1 (3%) [1]
MESENTERY	(2)	(1)	(0)	(0)
FAT; NECROSIS		1 (100%) [1]		
<b>CARDIOVASCULAR SYSTEM</b>				
No Tissues/Organs Examined				
<b>ENDOCRINE SYSTEM</b>				
ADRENAL GLAND	(28)	(0)	(1)	(32)
POLYARTERITIS NODOSA			1 (100%) [1]	
PITUITARY GLAND	(28)	(0)	(0)	(32)
PARS DISTALIS; CYST	2 (7%) [2]			
THYROID GLAND	(28)	(0)	(0)	(32)
<b>GENERAL BODY SYSTEM</b>				
No Tissues/Organs Examined				

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F1 Female: F1c NonParent Female

	Treatment Groups (ppm)			
	0	1000	5000	10000
GENITAL SYSTEM				
CERVIX	(28)	(0)	(0)	(32)
OVARY	(28)	(0)	(0)	(32)
CORPUS LUTEUM; CYST	1 (4%) [1]			
INTERSTITIAL CELL; HYPERPLASIA				1 (3%) [1]
UTERUS	(28)	(1)	(0)	(32)
CERVIX; CYST; SQUAMOUS	1 (4%) [1]			
CYST		1 (100%) [1]		
DILATION	2 (7%) [2]			2 (6%) [2]
ENDOMETRIUM; HYPERPLASIA; CYSTIC				2 (6%) [2]
VAGINA	(28)	(0)	(0)	(32)
HEMATOLYMPHOID SYSTEM				
SPLEEN	(28)	(0)	(1)	(32)
EXTRAMEDULLARY HEMATOPOIESIS			1 (100%) [1]	
THYMUS	(28)	(0)	(0)	(32)
HYPERPLASIA; EPITHELIAL	1 (4%) [1]			1 (3%) [1]
INTEGUMENTARY SYSTEM				
DIGIT	(0)	(1)	(0)	(1)
DEVELOPMENTAL MALFORMATION		1 (100%) [1]		1 (100%) [1]
MAMMARY GLAND	(28)	(0)	(0)	(32)
ACINUS; HYPERPLASIA	3 (11%) [3]			5 (16%) [4]
MUSCULOSKELETAL SYSTEM				
PAW	(0)	(2)	(0)	(0)
NERVOUS SYSTEM				
No Tissues/Organs Examined				
RESPIRATORY SYSTEM				
No Tissues/Organs Examined				



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F1 Male: F1c Parental Males

	Treatment Groups (ppm)			
	0	1000	5000	10000
<b>Disposition Summary</b>				
Animals Initially In Study	40	40	40	40
Early Deaths				
Unscheduled Sacrifice			3	
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 213 - 223)	40	40	37	40
Animals Examined Microscopically	40	40	40	40
Total number litters	21	20	19	18
<b>ALIMENTARY SYSTEM</b>				
LIVER	(40)	(0)	(3)	(40)
BILE DUCT; HYPERPLASIA INFLAMMATION; FOCAL HEPATOCTE; NECROSIS	5 (13%) [5]			1 (3%) [1] 5 (13%) [4] 1 (3%) [1]
<b>CARDIOVASCULAR SYSTEM</b>				
No Tissues/Organs Examined				
<b>ENDOCRINE SYSTEM</b>				
ADRENAL GLAND	(40)	(0)	(3)	(40)
CORTEX; HYPERTROPHY; FOCAL CORTEX; VACUOLATION; DIFFUSE CORTEX; VACUOLATION; FOCAL	2 (5%) [2] 2 (5%) [2] 3 (8%) [3]			3 (8%) [3] 1 (3%) [1]
PITUITARY GLAND	(40)	(40)	(40)	(40)
PARS DISTALIS; CYST PARS INTERMEDIA; CYST PARS DISTALIS; HYPERPLASIA PARS DISTALIS; HYPERTROPHY	4 (10%) [4] 1 (3%) [1]  	2 (5%) [2]	2 (5%) [2]	1 (3%) [1] 4 (10%) [3]
THYROID GLAND	(40)	(0)	(3)	(40)
INFILTRATION; MONONUCLEAR CELL	1 (3%) [1]			

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**Test Compound:** Diisobutyl Phthalate  
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**Date Report Requested:** 07/30/2019  
**Time Report Requested:** 13:35:02  
**Lab:** RTI

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**F1 Male: F1c Parental Males**

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**Treatment Groups (ppm)**

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**0**

**1000**

**5000**

**10000**

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GENERAL BODY SYSTEM

No Tissues/Organs Examined

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Study Number: R10997

PA03R: Non-Neoplastic Lesion Summary with Percent and Litter Incidence

Date Report Requested: 07/30/2019

Test Type: RACB

Test Compound: Diisobutyl Phthalate

Time Report Requested: 13:35:02

Route: Dosing in Feed

CAS Number: 84-69-5

Lab: RTI

Species/Strain: Rat/Sprague-Dawley

F1 Male: F1c Parental Males

	Treatment Groups (ppm)			
	0	1000	5000	10000
GENITAL SYSTEM				
COAGULATING GLAND	(40)	(0)	(3)	(40)
COWPERS GLAND	(40)	(40)	(40)	(40)
HYPOPLASIA				1 (3%) [1]
DORSAL PROSTATE	(40)	(0)	(3)	(40)
INFLAMMATION, ACUTE			1 (33%) [1]	1 (3%) [1]
EPIDIDYMIS	(40)	(40)	(40)	(40)
DUCT; ATROPHY			2 (5%) [2]	5 (13%) [5]
DUCT; EXFOLIATED GERM CELL	2 (5%) [2]	1 (3%) [1]	3 (8%) [3]	6 (15%) [5]
HYPOPLASIA			1 (3%) [1]	3 (8%) [3]
HYOSPERMIA			3 (8%) [3]	8 (20%) [6]
LEVATOR ANI PLUS BULBOCAVERNOSUS MUSCLE	(40)	(0)	(3)	(40)
PREPUTIAL GLAND	(2)	(1)	(2)	(8)
DUCT; DILATION				2 (25%) [2]
BILATERAL; INFLAMMATION, CHRONIC	1 (50%) [1]			
INFLAMMATION, CHRONIC	1 (50%) [1]			
BILATERAL; INFLAMMATION, SUPPURATIVE			1 (50%) [1]	2 (25%) [2]
INFLAMMATION, SUPPURATIVE		1 (100%) [1]	1 (50%) [1]	4 (50%) [3]
SEMINAL VESICLE	(40)	(0)	(3)	(40)
INFLAMMATION; ACUTE				1 (3%) [1]
TESTIS	(40)	(40)	(40)	(40)
GERMINAL EPITHELIUM; ATROPHY				5 (13%) [5]
GERMINAL EPITHELIUM; DEGENERATION	2 (5%) [2]	3 (8%) [3]	7 (18%) [6]	13 (33%) [10]
SEMINIFEROUS TUBULE; DYSGENESIS		1 (3%) [1]	1 (3%) [1]	1 (3%) [1]
EDEMA			1 (3%) [1]	4 (10%) [4]
INTERSTITIAL CELL; HYPERPLASIA; DIFFUSE			1 (3%) [1]	4 (10%) [4]
INTERSTITIAL CELL; HYPERPLASIA; FOCAL				4 (10%) [4]
HYPOPLASIA			1 (3%) [1]	2 (5%) [2]

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Route: Dosing in Feed

CAS Number: 84-69-5

Lab: RTI

Species/Strain: Rat/Sprague-Dawley

F1 Male: F1c Parental Males

	Treatment Groups (ppm)			
	0	1000	5000	10000
MINERAL			1 (3%) [1]	
VENTRAL PROSTATE	(40)	(40)	(40)	(40)
INFILTRATION CELLULAR; LYMPHOCYTE	5 (13%) [5]			8 (20%) [7]
INFLAMMATION, CHRONIC	1 (3%) [1]	5 (13%) [5]	4 (10%) [4]	3 (8%) [3]
HEMATOLYMPHOID SYSTEM				
LYMPH NODE	(0)	(0)	(0)	(1)
HYPERPLASIA; PLASMA CELL				1 (100%) [1]
LYMPH NODE, MANDIBULAR	(2)	(0)	(0)	(0)
SPLEEN	(0)	(0)	(3)	(0)
THYMUS	(40)	(0)	(3)	(39)
ATROPHY	1 (3%) [1]			
HYPERPLASIA; EPITHELIAL	7 (18%) [6]			3 (8%) [3]
INTEGUMENTARY SYSTEM				
SKIN	(0)	(0)	(0)	(1)
INFLAMMATION, SUPPURATIVE				1 (100%) [1]
MUSCULOSKELETAL SYSTEM				
No Tissues/Organs Examined				
NERVOUS SYSTEM				
No Tissues/Organs Examined				
RESPIRATORY SYSTEM				
No Tissues/Organs Examined				
SPECIAL SENSES SYSTEM				
No Tissues/Organs Examined				

Study Number: R10997

Test Type: RACB

Route: Dosing in Feed

Species/Strain: Rat/Sprague-Dawley

PA03R: Non-Neoplastic Lesion Summary with Percent and Litter Incidence

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CAS Number: 84-69-5

Date Report Requested: 07/30/2019

Time Report Requested: 13:35:02

Lab: RTI

F1 Male: F1c Parental Males

	Treatment Groups (ppm)			
	0	1000	5000	10000
URINARY SYSTEM				
KIDNEY	(40)	(1)	(3)	(40)
PELVIS; CALCULUS	6 (15%) [5]			
CHRONIC PROGRESSIVE NEPHROPATHY	39 (98%) [21]	1 (100%) [1]	3 (100%) [3]	40 (100%) [18]
MEDULLA; CYST	1 (3%) [1]			
PELVIS; DILATION	2 (5%) [2]	1 (100%) [1]		3 (8%) [3]
CORTICOMEDULLARY JUNCTION; MINERAL				1 (3%) [1]
PAPILLA; MINERAL	1 (3%) [1]			5 (13%) [4]
PELVIS; MINERAL	1 (3%) [1]			

Study Number: R10997  
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Date Report Requested: 07/30/2019  
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 Lab: RTI

F1 Female: F1c Parental Females

	Treatment Groups (ppm)			
	0	1000	5000	10000
<b>Disposition Summary</b>				
Animals Initially In Study	40	40	40	40
Early Deaths				
Euthanized, moribund	1		4	
Found Dead	1		1	
Scheduled Deaths				
Scheduled sacrifice, terminal (LD 21, PND 232 - 237)	38	40	35	40
Animals Examined Microscopically	40	7	9	40
Total number litters	20	7	9	18
<b>ALIMENTARY SYSTEM</b>				
LIVER	(40)	(2)	(6)	(40)
HEPATODIAPHRAGMATIC NODULE		1 (50%) [1]	1 (17%) [1]	
BILE DUCT; HYPERPLASIA				1 (3%) [1]
INFLAMMATION; FOCAL	2 (5%) [2]		1 (17%) [1]	
HEPATOCYTE; NECROSIS		1 (50%) [1]	1 (17%) [1]	
MESENTERY	(0)	(1)	(1)	(0)
FAT; NECROSIS		1 (100%) [1]		
PERIARTERITIS			1 (100%) [1]	
<b>CARDIOVASCULAR SYSTEM</b>				
HEART	(0)	(0)	(1)	(0)
CARDIOMYOPATHY			1 (100%) [1]	
POLYARTERITIS NODOSA			1 (100%) [1]	

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

**PA03R: Non-Neoplastic Lesion Summary with Percent and Litter Incidence**  
**Test Compound:** Diisobutyl Phthalate  
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**Date Report Requested:** 07/30/2019  
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**F1 Female: F1c Parental Females**

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	<b>Treatment Groups (ppm)</b>			
	<b>0</b>	<b>1000</b>	<b>5000</b>	<b>10000</b>
<b>ENDOCRINE SYSTEM</b>				
ADRENAL GLAND	(40)	(0)	(5)	(40)
CORTEX; HEMORRHAGE			1 (20%) [1]	
CORTEX; HYPERPLASIA			1 (20%) [1]	
PITUITARY GLAND	(40)	(0)	(5)	(40)
PARS DISTALIS; CYST	3 (8%) [2]			2 (5%) [2]
THYROID GLAND	(40)	(0)	(5)	(40)
FOLLICLE; CYST				1 (3%) [1]
C-CELL; HYPERPLASIA	1 (3%) [1]			
<b>GENERAL BODY SYSTEM</b>				
No Tissues/Organs Examined				

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Study Number: R10997

PA03R: Non-Neoplastic Lesion Summary with Percent and Litter Incidence

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Test Type: RACB

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Route: Dosing in Feed

CAS Number: 84-69-5

Lab: RTI

Species/Strain: Rat/Sprague-Dawley

F1 Female: F1c Parental Females

	Treatment Groups (ppm)			
	0	1000	5000	10000
GENITAL SYSTEM				
CERVIX	(40)	(0)	(5)	(40)
INFLAMMATION; ACUTE			1 (20%) [1]	
POLYARTERITIS NODOSA			1 (20%) [1]	
CLITORAL GLAND	(3)	(1)	(1)	(0)
DUCT; DILATION	1 (33%) [1]			
INFLAMMATION, SUPPURATIVE		1 (100%) [1]	1 (100%) [1]	
OVARY	(40)	(0)	(5)	(40)
CORPUS LUTEUM; BILATERAL; CYST	2 (5%) [2]			1 (3%) [1]
CORPUS LUTEUM; CYST	4 (10%) [4]			
CYST	1 (3%) [1]			1 (3%) [1]
POLYARTERITIS NODOSA			1 (20%) [1]	
UTERUS	(39)	(1)	(5)	(40)
CERVIX; CYST; SQUAMOUS	1 (3%) [1]			
ENDOMETRIUM; CYST	2 (5%) [1]			
SUBSEROA; CYST		1 (100%) [1]		
ENDOMETRIUM; DILATION; GLANDULAR, CYSTIC				2 (5%) [1]
DILATION	1 (3%) [1]			
INFLAMMATION; ACUTE			2 (40%) [2]	
ENDOMETRIUM; METAPLASIA; SQUAMOUS	1 (3%) [1]			
POLYARTERITIS NODOSA			1 (20%) [1]	
POLYP; STROMAL	1 (3%) [1]			
VAGINA	(40)	(0)	(5)	(40)
CYST; SQUAMOUS	1 (3%) [1]			
INFLAMMATION; ACUTE			1 (20%) [1]	1 (3%) [1]
MUCIFICATION			1 (20%) [1]	
POLYARTERITIS NODOSA			1 (20%) [1]	

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PA03R: Non-Neoplastic Lesion Summary with Percent and Litter Incidence

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Lab: RTI

Species/Strain: Rat/Sprague-Dawley

F1 Female: F1c Parental Females

	Treatment Groups (ppm)			
	0	1000	5000	10000
<b>HEMATOLYMPHOID SYSTEM</b>				
LYMPH NODE	(0)	(0)	(1)	(0)
LYMPH NODE, AXILLARY	(1)	(0)	(1)	(0)
HYPERPLASIA; LYMPHOCYTE			1 (100%) [1]	
HYPERPLASIA; PLASMA CELL	1 (100%) [1]			
LYMPH NODE, MANDIBULAR	(0)	(0)	(1)	(0)
HYPERPLASIA; LYMPHOID			1 (100%) [1]	
SPLEEN	(40)	(0)	(5)	(40)
EXTRAMEDULLARY HEMATOPOIESIS	1 (3%) [1]		5 (100%) [5]	
THYMUS	(39)	(0)	(4)	(40)
ATROPHY	10 (26%) [8]			12 (30%) [11]
CYST	1 (3%) [1]			
HYPERPLASIA; EPITHELIAL	3 (8%) [3]			4 (10%) [4]
<b>INTEGUMENTARY SYSTEM</b>				
MAMMARY GLAND	(38)	(2)	(6)	(40)
INFLAMMATION; ACUTE			1 (17%) [1]	
SKIN	(1)	(0)	(0)	(0)
INFLAMMATION, SUPPURATIVE	1 (100%) [1]			
SKIN, SUBCUTANEOUS TISSUE	(0)	(0)	(1)	(0)
INFLAMMATION, SUPPURATIVE			1 (100%) [1]	
<b>MUSCULOSKELETAL SYSTEM</b>				
PAW	(2)	(0)	(0)	(0)
<b>NERVOUS SYSTEM</b>				
No Tissues/Organs Examined				
<b>RESPIRATORY SYSTEM</b>				
No Tissues/Organs Examined				

**Study Number:** R10997  
**Test Type:** RACB  
**Route:** Dosing in Feed  
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**PA03R: Non-Neoplastic Lesion Summary with Percent and Litter Incidence**  
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**F1 Female: F1c Parental Females**

	Treatment Groups (ppm)			
	0	1000	5000	10000
SPECIAL SENSES SYSTEM				
No Tissues/Organs Examined				
URINARY SYSTEM				
KIDNEY	(40)	(0)	(6)	(40)
CHRONIC PROGRESSIVE NEPHROPATHY	30 (75%) [17]		6 (100%) [6]	34 (85%) [17]
MEDULLA; CYST	1 (3%) [1]			
PAPILLA; DILATION; TUBULAR				1 (3%) [1]
PELVIS; DILATION			1 (17%) [1]	
CORTICOMEDULLARY JUNCTION; MINERAL	33 (83%) [18]		3 (50%) [3]	13 (33%) [11]
PAPILLA; MINERAL	2 (5%) [2]			3 (8%) [3]
NEPHROBLASTEMATOSIS				1 (3%) [1]
POLYARTERITIS NODOSA			1 (17%) [1]	

**Study Number:** R10997  
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#### LEGEND

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Number of animals examined given for each tissue. If none of the animals examined have the specific lesion then there is a blank for that dose group for that specific lesion.

Number of animals with observation reported with percent incidence in parentheses

Number of litters shown in square brackets for F1 and F2 animals

Phase day range of terminal sacrifice shown in parentheses in disposition summary

SD – Study Day; GD – Gestation Day; LD – Lactation Day; PND – Postnatal Day, adults post-weaning

**\*\* END OF REPORT \*\***