

Study Number: R10997

Test Type: RACB

Route: Dosing in Feed

Species/Strain: Rat/Sprague-Dawley

C Number:

Study Gender:

PWG Approval Date

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] 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: 13:38:21

Lab: RTI

Study Number: R10997

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence

Date Report Requested: 07/30/2019

Test Type: RACB

Test Compound: Diisobutyl Phthalate

Time Report Requested: 13:38:21

Route: Dosing in Feed

CAS Number: 84-69-5

Lab: RTI

Species/Strain: Rat/Sprague-Dawley

	F0 Male			
	Treatment Groups (ppm)			
	0	1000	5000	10000
Disposition Summary				
Animals Initially In Study	23	23	23	23
Early Deaths				
Scheduled Deaths				
Scheduled sacrifice, terminal (SD 139 - 141)	23	23	23	23
Animals Examined Microscopically	23	10	6	23
ALIMENTARY SYSTEM				
LIVER	(23)	(0)	(0)	(23)
BILE DUCT; HYPERPLASIA				1 [1.0]
INFLAMMATION; FOCAL				3 [1.0]
HEPATOCYTE; NECROSIS				1 [1.0]
CARDIOVASCULAR SYSTEM				
BLOOD VESSEL	(0)	(0)	(0)	(1)
ENDOCRINE SYSTEM				
ADRENAL GLAND	(23)	(0)	(0)	(23)
CORTEX; VACUOLATION; DIFFUSE				1 [2.0]
CORTEX; VACUOLATION; FOCAL	2 [1.0]			
PITUITARY GLAND	(22)	(0)	(0)	(22)
PARS DISTALIS; CYST				1
RATHKE'S CLEFT; DILATION				1 [2.0]
THYROID GLAND	(23)	(0)	(0)	(23)
GENERAL BODY SYSTEM				
FAT	(0)	(0)	(0)	(1)
INFLAMMATION, CHRONIC				1 [2.0]

Study Number: R10997

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence

Date Report Requested: 07/30/2019

Test Type: RACB

Test Compound: Diisobutyl Phthalate

Time Report Requested: 13:38:21

Route: Dosing in Feed

CAS Number: 84-69-5

Lab: RTI

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 [1.0]			
EPIDIDYMIS	(23)	(0)	(0)	(23)
DUCT; EXFOLIATED GERM CELL	3 [1.0]			2 [1.0]
MINERAL				1 [4.0]
NECROSIS				1 [4.0]
SPERM GRANULOMA	2 [2.5]			
PREPUTIAL GLAND	(10)	(10)	(4)	(9)
INFLAMMATION, CHRONIC	7 [1.6]	6 [1.2]	2 [1.5]	7 [1.7]
BILATERAL; INFLAMMATION, SUPPURATIVE	1 [2.0]	2 [2.5]	2 [3.0]	2 [3.0]
INFLAMMATION, SUPPURATIVE	2 [2.5]	1 [2.0]		
SEMINAL VESICLE	(23)	(0)	(0)	(23)
TESTIS	(23)	(0)	(0)	(23)
GERMINAL EPITHELIUM; DEGENERATION	4 [1.0]			5 [1.0]
SEMINIFEROUS TUBULE; MINERAL				1 [4.0]
SEMINIFEROUS TUBULE; NECROSIS				1 [4.0]
VENTRAL PROSTATE	(23)	(0)	(0)	(23)
INFILTRATION CELLULAR; LYMPHOCYTE	3 [1.0]			
INFLAMMATION, CHRONIC	2 [1.5]			2 [1.0]
INFLAMMATION, CHRONIC-ACTIVE	1 [1.0]			1 [1.0]
HEMATOLYMPHOID SYSTEM				
THYMUS	(23)	(0)	(0)	(23)
HYPERPLASIA; EPITHELIAL	2 [1.0]			1 [1.0]
INTEGUMENTARY SYSTEM				
SKIN	(0)	(0)	(1)	(1)
ULCERATION			1 [2.0]	1 [3.0]

Study Number: R10997

Test Type: RACB

Route: Dosing in Feed

Species/Strain: Rat/Sprague-Dawley

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence

Test Compound: Diisobutyl Phthalate

CAS Number: 84-69-5

Date Report Requested: 07/30/2019

Time Report Requested: 13:38:21

Lab: RTI

	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 [1.1]			22 [1.0]
DYSPLASIA	1 [2.0]			
INFARCT				1 [1.0]
INFLAMMATION; INTERSTITIAL				1 [1.0]
PAPILLA; MINERAL	2 [1.0]			
PELVIS; MINERAL				1 [1.0]

Study Number: R10997

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence

Date Report Requested: 07/30/2019

Test Type: RACB

Test Compound: Diisobutyl Phthalate

Time Report Requested: 13:38:21

Route: Dosing in Feed

CAS Number: 84-69-5

Lab: RTI

Species/Strain: Rat/Sprague-Dawley

	F0 Female			
	Treatment Groups (ppm)			
	0	1000	5000	10000
Disposition Summary				
Animals Initially In Study	23	23	23	23
Early Deaths				
Euthanized, moribund	2	2	2	1
Unscheduled Sacrifice			1	
Scheduled Deaths				
Scheduled sacrifice, terminal (SD 176 - 177)	21	21	20	22
Animals Examined Microscopically	23	3	4	23
ALIMENTARY SYSTEM				
LIVER	(23)	(0)	(1)	(23)
INFLAMMATION; FOCAL	1 [1.0]		1 [1.0]	1 [1.0]
SALIVARY GLAND	(0)	(1)	(0)	(0)
CARDIOVASCULAR SYSTEM				
No Tissues/Organs Examined				
ENDOCRINE SYSTEM				
ADRENAL GLAND	(23)	(0)	(0)	(23)
NECROSIS				1 [4.0]
CORTEX; VACUOLATION; FOCAL	1 [2.0]			1 [1.0]
PITUITARY GLAND	(23)	(0)	(0)	(23)
THYROID GLAND	(23)	(0)	(0)	(23)
C-CELL; HYPERPLASIA	1 [1.0]			1 [1.0]
GENERAL BODY SYSTEM				
FAT	(1)	(0)	(0)	(0)
NECROSIS	1 [2.0]			

Study Number: R10997

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence

Date Report Requested: 07/30/2019

Test Type: RACB

Test Compound: Diisobutyl Phthalate

Time Report Requested: 13:38:21

Route: Dosing in Feed

CAS Number: 84-69-5

Lab: RTI

Species/Strain: Rat/Sprague-Dawley

	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 [4.0]			1 [4.0]
OVARY	(23)	(0)	(0)	(23)
CORPUS LUTEUM; BILATERAL; CYST				2
CORPUS LUTEUM; CYST				1
CYST; EPITHELIAL				1
CYST	3			2
UTERUS	(21)	(0)	(0)	(23)
DILATION	1 [2.0]			1 [1.0]
ENDOMETRIUM; HYPERPLASIA; CYSTIC	2 [1.0]			
ENDOMETRIUM; METAPLASIA; SQUAMOUS	1 [1.0]			1 [1.0]
POLYP; STROMAL				2
VAGINA	(21)	(0)	(0)	(23)
MUCIFICATION				1 [2.0]
HEMATOLYMPHOID SYSTEM				
LYMPH NODE, MESENTERIC	(0)	(0)	(1)	(0)
SPLEEN	(0)	(0)	(2)	(1)
EXTRAMEDULLARY HEMATOPOIESIS			2 [2.5]	1 [2.0]
THYMUS	(23)	(0)	(0)	(23)
HYPERPLASIA; EPITHELIAL	3 [1.0]			

Study Number: R10997

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence

Date Report Requested: 07/30/2019

Test Type: RACB

Test Compound: Diisobutyl Phthalate

Time Report Requested: 13:38:21

Route: Dosing in Feed

CAS Number: 84-69-5

Lab: RTI

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 [2.0]		
INFLAMMATION, CHRONIC-ACTIVE		1 [3.0]		
SKIN	(1)	(0)	(0)	(0)
HAIR FOLLICLE; INFLAMMATION, CHRONIC	1 [1.0]			
SKIN, ABDOMINAL	(0)	(0)	(0)	(1)
ULCERATION				1 [4.0]
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 [1.1]		1 [3.0]	17 [1.1]
MEDULLA; BILATERAL; CYST				1
MEDULLA; CYST				4
CORTICOMEDULLARY JUNCTION; MINERAL	9 [1.1]		1 [1.0]	6 [1.0]
NEPHROBLASTEMATOSIS	1 [2.0]			

Study Number: R10997

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence

Date Report Requested: 07/30/2019

Test Type: RACB

Test Compound: Diisobutyl Phthalate

Time Report Requested: 13:38:21

Route: Dosing in Feed

CAS Number: 84-69-5

Lab: RTI

Species/Strain: Rat/Sprague-Dawley

F1 Male: F1c NonParent Males

	Treatment Groups (ppm)			
	0	1000	5000	10000
Disposition Summary				
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
ALIMENTARY SYSTEM				
LIVER	(45)	(1)	(2)	(40)
INFLAMMATION; CHRONIC		1 [3.0] (1)		1 [2.0] (1)
INFLAMMATION; FOCAL	32 [1.0] (15)			31 [1.0] (15)
HEPATOCYTE; NECROSIS			1 [4.0] (1)	
POLYARTERITIS NODOSA			1 [3.0] (1)	
CARDIOVASCULAR SYSTEM				
No Tissues/Organs Examined				
ENDOCRINE SYSTEM				
ADRENAL GLAND	(45)	(0)	(1)	(40)
CORTEX; HYPERPLASIA			1 [2.0] (1)	
POLYARTERITIS NODOSA			1 [1.0] (1)	
CORTEX; VACUOLATION; DIFFUSE				2 [1.0] (2)
PITUITARY GLAND	(45)	(31)	(39)	(40)
PARS DISTALIS; CYST; MULTIPLE			1 (1)	
PARS DISTALIS; CYST	3 (3)	1 (1)	2 (2)	1 (1)
PARS INTERMEDIA; CYST				1 (1)
PARS DISTALIS; HYPERTROPHY				3 [1.0] (2)
THYROID GLAND	(45)	(0)	(0)	(40)

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

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence
Test Compound: Diisobutyl Phthalate
CAS Number: 84-69-5

Date Report Requested: 07/30/2019
Time Report Requested: 13:38:21
Lab: RTI

F1 Male: F1c NonParent Males

Treatment Groups (ppm)

0 1000 5000 10000

GENERAL BODY SYSTEM
No Tissues/Organs Examined

Study Number: R10997

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence

Date Report Requested: 07/30/2019

Test Type: RACB

Test Compound: Diisobutyl Phthalate

Time Report Requested: 13:38:21

Route: Dosing in Feed

CAS Number: 84-69-5

Lab: RTI

Species/Strain: Rat/Sprague-Dawley

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 [3.0] (1)
DORSAL PROSTATE	(45)	(31)	(39)	(38)
INFLAMMATION, CHRONIC	1 [1.0] (1)			
EPIDIDYMIS	(45)	(31)	(39)	(40)
DUCT; ATROPHY			1 [2.0] (1)	3 [4.0] (2)
DUCT; EXFOLIATED GERM CELL	3 [1.7] (2)		5 [2.0] (4)	8 [1.8] (7)
HYOSPERMIA	1 [3.0] (1)		1 [2.0] (1)	4 [2.8] (3)
IMMATURE				1 (1)
SPERM GRANULOMA			1 [2.0] (1)	
LEVATOR ANI PLUS BULBOCAVERNOSUS MUSCLE	(45)	(0)	(2)	(39)
HYPOPLASIA				1 [3.0] (1)
PENIS	(2)	(0)	(0)	(1)
PREPUTIAL GLAND	(2)	(0)	(1)	(1)
DUCT; DILATION				1 [2.0] (1)
INFLAMMATION, CHRONIC	1 [1.0] (1)		1 [2.0] (1)	
SEMINAL VESICLE	(45)	(0)	(4)	(40)
TESTIS	(45)	(31)	(39)	(40)
GERMINAL EPITHELIUM; ATROPHY				1 [4.0] (1)
GERMINAL EPITHELIUM; DEGENERATION	3 [2.0] (2)	1 [1.0] (1)	8 [1.6] (6)	10 [1.8] (8)
SEMINIFEROUS TUBULE; DYSGENESIS	1 [1.0] (1)		2 [1.0] (1)	2 [1.5] (2)
EDEMA				2 [2.0] (1)
INTERSTITIAL CELL; HYPERPLASIA; DIFFUSE				2 [1.5] (1)
INTERSTITIAL CELL; HYPERPLASIA; FOCAL				2 [1.0] (2)
IMMATURE				1 (1)
VENTRAL PROSTATE	(45)	(31)	(39)	(40)

Study Number: R10997

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence

Date Report Requested: 07/30/2019

Test Type: RACB

Test Compound: Diisobutyl Phthalate

Time Report Requested: 13:38:21

Route: Dosing in Feed

CAS Number: 84-69-5

Lab: RTI

Species/Strain: Rat/Sprague-Dawley

F1 Male: F1c NonParent Males

	Treatment Groups (ppm)			
	0	1000	5000	10000
IMMATURE				1 (1)
INFILTRATION CELLULAR; LYMPHOCYTE	16 [1.1] (11)	12 [1.0] (10)	6 [1.2] (5)	17 [1.0] (9)
BILATERAL; INFLAMMATION, CHRONIC	14 [1.3] (8)	5 [1.8] (4)	6 [2.2] (5)	13 [1.8] (7)
INFLAMMATION, CHRONIC	2 [1.0] (2)	3 [1.3] (3)	9 [1.4] (7)	3 [1.3] (3)
HEMATOLYMPHOID SYSTEM				
SPLEEN	(45)	(0)	(1)	(40)
FOLLICLE; ATROPHY; LYMPHOID				1 [3.0] (1)
EXTRAMEDULLARY HEMATOPOIESIS			1 [1.0] (1)	
THYMUS	(45)	(0)	(0)	(40)
HYPERPLASIA; EPITHELIAL	1 [1.0] (1)			1 [1.0] (1)
NECROSIS; LYMPHOCYTIC				1 [4.0] (1)
INTEGUMENTARY SYSTEM				
DIGIT	(0)	(0)	(0)	(1)
HYPOPLASIA				1 [2.0] (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				

Study Number: R10997

Test Type: RACB

Route: Dosing in Feed

Species/Strain: Rat/Sprague-Dawley

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence

Test Compound: Diisobutyl Phthalate

CAS Number: 84-69-5

Date Report Requested: 07/30/2019

Time Report Requested: 13:38:21

Lab: RTI

F1 Male: F1c NonParent Males

	Treatment Groups (ppm)			
	0	1000	5000	10000
URINARY SYSTEM				
KIDNEY	(45)	(3)	(3)	(40)
CHRONIC PROGRESSIVE NEPHROPATHY	41 [1.0] (17)		1 [3.0] (1)	37 [1.2] (15)
MEDULLA; BILATERAL; CYST	1 (1)			
MEDULLA; CYST				5 (4)
PELVIS; DILATION	3 [1.3] (2)	3 [1.0] (3)	3 [1.7] (3)	2 [1.0] (2)
INFARCT	1 [2.0] (1)			
PAPILLA; MINERAL			1 [1.0] (1)	3 [1.0] (2)
NEPHROBLASTEMATOSIS				1 [1.0] (1)
POLYARTERITIS NODOSA			1 [2.0] (1)	

Study Number: R10997

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence

Date Report Requested: 07/30/2019

Test Type: RACB

Test Compound: Diisobutyl Phthalate

Time Report Requested: 13:38:21

Route: Dosing in Feed

CAS Number: 84-69-5

Lab: RTI

Species/Strain: Rat/Sprague-Dawley

F1 Female: F1c NonParent Female

	Treatment Groups (ppm)			
	0	1000	5000	10000
Disposition Summary				
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
ALIMENTARY SYSTEM				
LIVER	(28)	(0)	(1)	(32)
HEPATODIAPHRAGMATIC NODULE			1 (1)	
BILE DUCT; HYPERPLASIA				1 [1.0] (1)
INFLAMMATION; FOCAL	2 [1.0] (2)			4 [1.0] (4)
MINERAL; FOCAL				1 [1.0] (1)
MESENTERY	(2)	(1)	(0)	(0)
FAT; NECROSIS		1 [2.0] (1)		
CARDIOVASCULAR SYSTEM				
No Tissues/Organs Examined				
ENDOCRINE SYSTEM				
ADRENAL GLAND	(28)	(0)	(1)	(32)
POLYARTERITIS NODOSA			1 [2.0] (1)	
PITUITARY GLAND	(28)	(0)	(0)	(32)
PARS DISTALIS; CYST	2 (2)			
THYROID GLAND	(28)	(0)	(0)	(32)
GENERAL BODY SYSTEM				
No Tissues/Organs Examined				

Study Number: R10997

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence

Date Report Requested: 07/30/2019

Test Type: RACB

Test Compound: Diisobutyl Phthalate

Time Report Requested: 13:38:21

Route: Dosing in Feed

CAS Number: 84-69-5

Lab: RTI

Species/Strain: Rat/Sprague-Dawley

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 (1)			
INTERSTITIAL CELL; HYPERPLASIA				1 [1.0] (1)
UTERUS	(28)	(1)	(0)	(32)
CERVIX; CYST; SQUAMOUS	1 (1)			
CYST		1 (1)		
DILATION	2 [1.5] (2)			2 [1.5] (2)
ENDOMETRIUM; HYPERPLASIA; CYSTIC				2 [1.0] (2)
VAGINA	(28)	(0)	(0)	(32)
HEMATOLYMPHOID SYSTEM				
SPLEEN	(28)	(0)	(1)	(32)
EXTRAMEDULLARY HEMATOPOIESIS			1 [2.0] (1)	
THYMUS	(28)	(0)	(0)	(32)
HYPERPLASIA; EPITHELIAL	1 [1.0] (1)			1 [1.0] (1)
INTEGUMENTARY SYSTEM				
DIGIT	(0)	(1)	(0)	(1)
DEVELOPMENTAL MALFORMATION		1 (1)		1 (1)
MAMMARY GLAND	(28)	(0)	(0)	(32)
ACINUS; HYPERPLASIA	3 [1.0] (3)			5 [1.2] (4)
MUSCULOSKELETAL SYSTEM				
PAW	(0)	(2)	(0)	(0)
NERVOUS SYSTEM				
No Tissues/Organs Examined				
RESPIRATORY SYSTEM				
No Tissues/Organs Examined				

Study Number: R10997

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence

Date Report Requested: 07/30/2019

Test Type: RACB

Test Compound: Diisobutyl Phthalate

Time Report Requested: 13:38:21

Route: Dosing in Feed

CAS Number: 84-69-5

Lab: RTI

Species/Strain: Rat/Sprague-Dawley

F1 Female: F1c NonParent Female

Treatment Groups (ppm)

0

1000

5000

10000

SPECIAL SENSES SYSTEM

No Tissues/Organs Examined

URINARY SYSTEM

KIDNEY

(28)

(1)

(1)

(32)

CHRONIC PROGRESSIVE NEPHROPATHY

11 [1.0] (8)

19 [1.0] (10)

PELVIS; DILATION

1 [1.0] (1)

INFARCT

1 [1.0] (1)

CORTICOMEDULLARY JUNCTION; MINERAL

19 [1.1] (12)

15 [1.0] (7)

PAPILLA; MINERAL

2 [1.0] (1)

Study Number: R10997

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence

Date Report Requested: 07/30/2019

Test Type: RACB

Test Compound: Diisobutyl Phthalate

Time Report Requested: 13:38:21

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
Disposition Summary				
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
ALIMENTARY SYSTEM				
LIVER	(40)	(0)	(3)	(40)
BILE DUCT; HYPERPLASIA				1 [1.0] (1)
INFLAMMATION; FOCAL	5 [1.0] (5)			5 [1.0] (4)
HEPATOCYTE; NECROSIS				1 [3.0] (1)
CARDIOVASCULAR SYSTEM				
No Tissues/Organs Examined				
ENDOCRINE SYSTEM				
ADRENAL GLAND	(40)	(0)	(3)	(40)
CORTEX; HYPERTROPHY; FOCAL	2 [1.5] (2)			
CORTEX; VACUOLATION; DIFFUSE	2 [1.0] (2)			3 [1.0] (3)
CORTEX; VACUOLATION; FOCAL	3 [1.0] (3)			1 [1.0] (1)
PITUITARY GLAND	(40)	(40)	(40)	(40)
PARS DISTALIS; CYST	4 (4)	2 (2)	2 (2)	
PARS INTERMEDIA; CYST	1 (1)			
PARS DISTALIS; HYPERPLASIA				1 [1.0] (1)
PARS DISTALIS; HYPERTROPHY			1 [1.0] (1)	4 [1.5] (3)
THYROID GLAND	(40)	(0)	(3)	(40)
INFILTRATION; MONONUCLEAR CELL	1 [1.0] (1)			

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

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence
Test Compound: Diisobutyl Phthalate
CAS Number: 84-69-5

Date Report Requested: 07/30/2019
Time Report Requested: 13:38:21
Lab: RTI

F1 Male: F1c Parental Males

Treatment Groups (ppm)

0

1000

5000

10000

GENERAL BODY SYSTEM
No Tissues/Organs Examined

Study Number: R10997

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence

Date Report Requested: 07/30/2019

Test Type: RACB

Test Compound: Diisobutyl Phthalate

Time Report Requested: 13:38:21

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 [2.0] (1)
DORSAL PROSTATE	(40)	(0)	(3)	(40)
INFLAMMATION, ACUTE			1 [1.0] (1)	1 [2.0] (1)
EPIDIDYMIS	(40)	(40)	(40)	(40)
DUCT; ATROPHY			2 [3.5] (2)	5 [3.6] (5)
DUCT; EXFOLIATED GERM CELL	2 [1.0] (2)	1 [1.0] (1)	3 [1.7] (3)	6 [1.3] (5)
HYPOPLASIA			1 [4.0] (1)	3 [2.7] (3)
HYOSPERMIA			3 [3.7] (3)	8 [3.5] (6)
LEVATOR ANI PLUS BULBOCAVERNOSUS MUSCLE	(40)	(0)	(3)	(40)
PREPUTIAL GLAND	(2)	(1)	(2)	(8)
DUCT; DILATION				2 [2.0] (2)
BILATERAL; INFLAMMATION, CHRONIC	1 [2.0] (1)			
INFLAMMATION, CHRONIC	1 [1.0] (1)			
BILATERAL; INFLAMMATION, SUPPURATIVE			1 [4.0] (1)	2 [2.5] (2)
INFLAMMATION, SUPPURATIVE		1 [4.0] (1)	1 [4.0] (1)	4 [3.8] (3)
SEMINAL VESICLE	(40)	(0)	(3)	(40)
INFLAMMATION; ACUTE				1 [2.0] (1)
TESTIS	(40)	(40)	(40)	(40)
GERMINAL EPITHELIUM; ATROPHY				5 [4.0] (5)
GERMINAL EPITHELIUM; DEGENERATION	2 [1.0] (2)	3 [1.0] (3)	7 [1.9] (6)	13 [1.3] (10)
SEMINIFEROUS TUBULE; DYSGENESIS		1 [1.0] (1)	1 [1.0] (1)	1 [4.0] (1)
EDEMA			1 [4.0] (1)	4 [2.3] (4)
INTERSTITIAL CELL; HYPERPLASIA; DIFFUSE			1 [2.0] (1)	4 [2.5] (4)
INTERSTITIAL CELL; HYPERPLASIA; FOCAL				4 [1.0] (4)
HYPOPLASIA			1 [4.0] (1)	2 [4.0] (2)

Study Number: R10997

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence

Date Report Requested: 07/30/2019

Test Type: RACB

Test Compound: Diisobutyl Phthalate

Time Report Requested: 13:38:21

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 [1.0] (1)	
VENTRAL PROSTATE	(40)	(40)	(40)	(40)
INFILTRATION CELLULAR; LYMPHOCYTE	5 [1.0] (5)			8 [1.0] (7)
INFLAMMATION, CHRONIC	1 [1.0] (1)	5 [1.0] (5)	4 [1.3] (4)	3 [1.0] (3)
HEMATOLYMPHOID SYSTEM				
LYMPH NODE	(0)	(0)	(0)	(1)
HYPERPLASIA; PLASMA CELL				1 [2.0] (1)
LYMPH NODE, MANDIBULAR	(2)	(0)	(0)	(0)
SPLEEN	(0)	(0)	(3)	(0)
THYMUS	(40)	(0)	(3)	(39)
ATROPHY	1 [1.0] (1)			
HYPERPLASIA; EPITHELIAL	7 [1.0] (6)			3 [1.0] (3)
INTEGUMENTARY SYSTEM				
SKIN	(0)	(0)	(0)	(1)
INFLAMMATION, SUPPURATIVE				1 [4.0] (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

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence

Date Report Requested: 07/30/2019

Test Type: RACB

Test Compound: Diisobutyl Phthalate

Time Report Requested: 13:38:21

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
URINARY SYSTEM				
KIDNEY	(40)	(1)	(3)	(40)
PELVIS; CALCULUS	6 [1.3] (5)			
CHRONIC PROGRESSIVE NEPHROPATHY	39 [1.4] (21)	1 [1.0] (1)	3 [1.0] (3)	40 [1.2] (18)
MEDULLA; CYST	1 (1)			
PELVIS; DILATION	2 [1.0] (2)	1 [1.0] (1)		3 [1.7] (3)
CORTICOMEDULLARY JUNCTION; MINERAL				1 [1.0] (1)
PAPILLA; MINERAL	1 [1.0] (1)			5 [1.0] (4)
PELVIS; MINERAL	1 [1.0] (1)			

Study Number: R10997

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence

Date Report Requested: 07/30/2019

Test Type: RACB

Test Compound: Diisobutyl Phthalate

Time Report Requested: 13:38:21

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
Disposition Summary				
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
ALIMENTARY SYSTEM				
LIVER	(40)	(2)	(6)	(40)
HEPATODIAPHRAGMATIC NODULE		1 (1)	1 (1)	
BILE DUCT; HYPERPLASIA				1 [1.0] (1)
INFLAMMATION; FOCAL	2 [1.0] (2)		1 [1.0] (1)	
HEPATOCTE; NECROSIS		1 [4.0] (1)	1 [1.0] (1)	
MESENTERY	(0)	(1)	(1)	(0)
FAT; NECROSIS		1 [2.0] (1)		
PERIARTERITIS			1 [4.0] (1)	
CARDIOVASCULAR SYSTEM				
HEART	(0)	(0)	(1)	(0)
CARDIOMYOPATHY			1 [1.0] (1)	
POLYARTERITIS NODOSA			1 [2.0] (1)	

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

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence
Test Compound: Diisobutyl Phthalate
CAS Number: 84-69-5

Date Report Requested: 07/30/2019
Time Report Requested: 13:38:21
Lab: RTI

F1 Female: F1c Parental Females

	Treatment Groups (ppm)			
	0	1000	5000	10000
ENDOCRINE SYSTEM				
ADRENAL GLAND	(40)	(0)	(5)	(40)
CORTEX; HEMORRHAGE			1 [2.0] (1)	
CORTEX; HYPERPLASIA			1 [2.0] (1)	
PITUITARY GLAND	(40)	(0)	(5)	(40)
PARS DISTALIS; CYST	3 (2)			2 (2)
THYROID GLAND	(40)	(0)	(5)	(40)
FOLLICLE; CYST				1 (1)
C-CELL; HYPERPLASIA	1 [1.0] (1)			
GENERAL BODY SYSTEM				
No Tissues/Organs Examined				

Study Number: R10997

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence

Date Report Requested: 07/30/2019

Test Type: RACB

Test Compound: Diisobutyl Phthalate

Time Report Requested: 13:38:21

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 [3.0] (1)	
POLYARTERITIS NODOSA			1 [2.0] (1)	
CLITORAL GLAND	(3)	(1)	(1)	(0)
DUCT; DILATION	1 [2.0] (1)			
INFLAMMATION, SUPPURATIVE		1 [2.0] (1)	1 [4.0] (1)	
OVARY	(40)	(0)	(5)	(40)
CORPUS LUTEUM; BILATERAL; CYST	2 (2)			1 (1)
CORPUS LUTEUM; CYST	4 (4)			
CYST	1 (1)			1 (1)
POLYARTERITIS NODOSA			1 [3.0] (1)	
UTERUS	(39)	(1)	(5)	(40)
CERVIX; CYST; SQUAMOUS	1 (1)			
ENDOMETRIUM; CYST	2 (1)			
SUBSEROVA; CYST		1 (1)		
ENDOMETRIUM; DILATION; GLANDULAR, CYSTIC				2 [1.0] (1)
DILATION	1 [2.0] (1)			
INFLAMMATION; ACUTE			2 [2.0] (2)	
ENDOMETRIUM; METAPLASIA; SQUAMOUS	1 [1.0] (1)			
POLYARTERITIS NODOSA			1 [1.0] (1)	
POLYP; STROMAL	1 (1)			
VAGINA	(40)	(0)	(5)	(40)
CYST; SQUAMOUS	1 (1)			
INFLAMMATION; ACUTE			1 [4.0] (1)	1 [2.0] (1)
MUCIFICATION			1 [3.0] (1)	
POLYARTERITIS NODOSA			1 [2.0] (1)	

Study Number: R10997

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence

Date Report Requested: 07/30/2019

Test Type: RACB

Test Compound: Diisobutyl Phthalate

Time Report Requested: 13:38:21

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
HEMATOLYMPHOID SYSTEM				
LYMPH NODE	(0)	(0)	(1)	(0)
LYMPH NODE, AXILLARY	(1)	(0)	(1)	(0)
HYPERPLASIA; LYMPHOCYTE			1 [1.0] (1)	
HYPERPLASIA; PLASMA CELL	1 [3.0] (1)			
LYMPH NODE, MANDIBULAR	(0)	(0)	(1)	(0)
HYPERPLASIA; LYMPHOID			1 [2.0] (1)	
SPLEEN	(40)	(0)	(5)	(40)
EXTRAMEDULLARY HEMATOPOIESIS	1 [2.0] (1)		5 [1.8] (5)	
THYMUS	(39)	(0)	(4)	(40)
ATROPHY	10 [1.3] (8)			12 [1.3] (11)
CYST	1 (1)			
HYPERPLASIA; EPITHELIAL	3 [1.0] (3)			4 [1.0] (4)
INTEGUMENTARY SYSTEM				
MAMMARY GLAND	(38)	(2)	(6)	(40)
INFLAMMATION; ACUTE			1 [3.0] (1)	
SKIN	(1)	(0)	(0)	(0)
INFLAMMATION, SUPPURATIVE	1 [4.0] (1)			
SKIN, SUBCUTANEOUS TISSUE	(0)	(0)	(1)	(0)
INFLAMMATION, SUPPURATIVE			1 [4.0] (1)	
MUSCULOSKELETAL SYSTEM				
PAW	(2)	(0)	(0)	(0)
NERVOUS SYSTEM				
No Tissues/Organs Examined				
RESPIRATORY SYSTEM				
No Tissues/Organs Examined				

Study Number: R10997

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence

Date Report Requested: 07/30/2019

Test Type: RACB

Test Compound: Diisobutyl Phthalate

Time Report Requested: 13:38:21

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
SPECIAL SENSES SYSTEM				
No Tissues/Organs Examined				
URINARY SYSTEM				
KIDNEY	(40)	(0)	(6)	(40)
CHRONIC PROGRESSIVE NEPHROPATHY	30 [1.1] (17)		6 [1.0] (6)	34 [1.0] (17)
MEDULLA; CYST	1 (1)			
PAPILLA; DILATION; TUBULAR				1 [1.0] (1)
PELVIS; DILATION			1 [1.0] (1)	
CORTICOMEDULLARY JUNCTION; MINERAL	33 [1.1] (18)		3 [1.0] (3)	13 [1.0] (11)
PAPILLA; MINERAL	2 [1.0] (2)			3 [1.0] (3)
NEPHROBLASTEMATOSIS				1 [2.0] (1)
POLYARTERITIS NODOSA			1 [3.0] (1)	

Study Number: R10997

Test Type: RACB

Route: Dosing in Feed

Species/Strain: Rat/Sprague-Dawley

PA18R: Non-Neoplastic Lesions [a] with Mean Severity Grade [b] and Litter Incidence

Test Compound: Diisobutyl Phthalate

CAS Number: 84-69-5

Date Report Requested: 07/30/2019

Time Report Requested: 13:38:21

Lab: RTI

LEGEND

[a] 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 mean severity grade in square brackets

[b] Mean severity grade denoted by 1 - minimal, 2 - mild, 3 - moderate, 4 - marked

Number of litters shown in parentheses 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 ****