

Study Number: R88007B
Test Type: RACB
Route: Dosing in Feed
Species/Strain: Rat/Sprague-Dawley

PA18R: Non-Neoplastic Lesions with Mean Severity Grade and Litter Incidence

Test Compound: Butyl Paraben
CAS Number: 94-26-8

Date Report Requested: 11/20/2018
Time Report Requested: 07:22:55
Lab: RTI

C Number: R88007B
Study Gender: Both
PWG Approval Date See web page for date of PWG Approval

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	F0 Male			
	Treatment Groups (ppm)			
	0	5000	15000	40000
Disposition Summary				
Animals Initially In Study	22	22	22	22
Early Deaths				
Euthanized, moribund	2	1	1	
Scheduled Deaths				
Scheduled sacrifice, terminal (SD 224 - 226)	20	21	21	22
Animals Examined Microscopically	22	22	22	22
ALIMENTARY SYSTEM				
LIVER	(22)	(22)	(22)	(22)
ANGIECTASIS	1 [1.0]			
CLEAR CELL FOCUS	2	3	1	2
HEPATODIAPHRAGMATIC NODULE	1			
BILE DUCT; HYPERPLASIA		1 [1.0]	2 [1.0]	
INFILTRATION; MONONUCLEAR CELL	3 [1.0]	2 [1.0]	19 [1.0]	22 [1.0]
INFLAMMATION; FOCAL	3 [1.0]	2 [1.0]		3 [1.0]
HEPATOCYTE; MITOSIS, INCREASED				3 [1.0]
NECROSIS; FOCAL	1 [1.0]			
PIGMENT		1 [2.0]		
HEPATOCYTE; VACUOLATION; CYTOPLASMIC			11 [1.0]	22 [1.3]
MESENTERY	(0)	(0)	(1)	(1)
ACCESSORY SPLEEN				1
SALIVARY GLANDS	(1)	(0)	(0)	(0)
BILATERAL; EDEMA; PERIGLANDULAR	1 [2.0]			
CARDIOVASCULAR SYSTEM				
HEART	(1)	(0)	(0)	(0)

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	F0 Male			
	Treatment Groups (ppm)			
	0	5000	15000	40000
<hr/>				
ENDOCRINE SYSTEM				
ADRENAL CORTEX	(22)	(1)	(1)	(22)
UNILATERAL; HYPERTROPHY				1 [1.0]
UNILATERAL; VACUOLATION; CYTOPLASMIC, FOCAL		1 [1.0]		
ADRENAL MEDULLA	(22)	(1)	(1)	(22)
PITUITARY GLAND	(22)	(1)	(1)	(22)
PARS DISTALIS; CYST	1			
PARS NERVOSA; DEVELOPMENTAL MALFORMATION				1
PARS DISTALIS; HYPERPLASIA				1 [1.0]
THYROID GLANDS	(22)	(1)	(1)	(22)
C-CELL; UNILATERAL; HYPERPLASIA	1 [1.0]			1 [2.0]
<hr/>				
GENERAL BODY SYSTEM				
No Tissues/Organs Examined				

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Species/Strain: Rat/Sprague-Dawley

	F0 Male			
	Treatment Groups (ppm)			
	0	5000	15000	40000
GENITAL SYSTEM				
COAGULATING GLANDS	(22)	(1)	(1)	(22)
DORSAL PROSTATE	(22)	(1)	(1)	(22)
UNILATERAL; INFLAMMATION, ACUTE	1 [1.0]			1 [1.0]
EPIDIDYMIDES	(22)	(1)	(1)	(22)
HYOSPERMIA				1 [4.0]
PREPUTIAL GLANDS	(5)	(5)	(4)	(8)
BILATERAL; INFLAMMATION, CHRONIC; ACTIVE		2 [2.5]	1 [2.0]	
BILATERAL; INFLAMMATION, CHRONIC	2 [2.0]	1 [2.0]	1 [2.0]	4 [1.8]
UNILATERAL; INFLAMMATION, CHRONIC; ACTIVE		1 [2.0]		1 [2.0]
UNILATERAL; INFLAMMATION, CHRONIC	3 [1.7]		1 [1.0]	1 [2.0]
BILATERAL; INFLAMMATION, SUPPURATIVE				1 [3.0]
UNILATERAL; INFLAMMATION, SUPPURATIVE	1 [3.0]	1 [4.0]		1 [2.0]
SEMINAL VESICLES	(22)	(1)	(1)	(22)
TESTES	(22)	(1)	(1)	(22)
GERMINAL EPITHELIUM; ATROPHY				1 [4.0]
GERM CELL; DEGENERATION	1 [1.0]			
VENTRAL PROSTATE	(22)	(1)	(1)	(22)
UNILATERAL; INFLAMMATION, ACUTE	1 [1.0]			
BILATERAL; INFLAMMATION, CHRONIC	2 [1.5]	1 [1.0]		1 [1.0]
HEMATOPOIETIC SYSTEM				
SPLEEN	(22)	(1)	(1)	(22)
ACCESSORY NODULE	1			
FOLLICLE; ATROPHY; LYMPHOID			1 [2.0]	
THYMUS	(22)	(2)	(1)	(21)
HYPERPLASIA; EPITHELIAL	1 [1.0]			2 [1.0]

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	F0 Male			
	Treatment Groups (ppm)			
	0	5000	15000	40000
INTEGUMENTARY SYSTEM				
SKIN	(1)	(0)	(0)	(1)
INFLAMMATION, CHRONIC				1 [3.0]
LYMPHOID SYSTEM				
No Tissues/Organs Examined				
MUSCULOSKELETAL SYSTEM				
DIAPHRAGM	(1)	(0)	(0)	(0)
HEPATODIAPHRAGMATIC NODULE	1			
NERVOUS SYSTEM				
No Tissues/Organs Examined				
RESPIRATORY SYSTEM				
LUNGS	(1)	(0)	(0)	(0)
SPECIAL SENSES SYSTEM				
EYES	(1)	(0)	(0)	(0)
URINARY SYSTEM				
KIDNEYS	(22)	(4)	(1)	(22)
CHRONIC PROGRESSIVE NEPHROPATHY	21 [1.4]	4 [1.3]	1 [1.0]	22 [1.0]
RENAL TUBULE; BILATERAL; DILATION			1 [1.0]	
PELVIS; MINERAL; LINEAR	1 [1.0]			

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F0 Female					
	Treatment Groups (Females)				
	0	5000	15000	40000	
Disposition Summary					
Animals Initially In Study	22	22	22	22	22
Early Deaths					
Euthanized, moribund			3	1	
Unscheduled Sacrifice	1	1			
Scheduled Deaths					
Scheduled sacrifice, terminal (LD 4, SD 32 - 219)	22	21	18	21	22
Animals Examined Microscopically		22	22	22	22
ALIMENTARY SYSTEM					
LIVER	(0)	(22)	(22)	(22)	(22)
HEPATOCYTE; APOPTOSIS					1 [1.0]
CLEAR CELL FOCUS					2
EXTRAMEDULLARY HEMATOPOIESIS			1 [2.0]		
HEPATOCYTE; FATTY CHANGE; FOCAL					1 [1.0]
BILE DUCT; HYPERPLASIA					2 [1.0]
HEPATOCYTE; PERIportal; HYPERTROPHY			2 [1.0]	5 [1.0]	7 [1.0]
HEPATOCYTE; INCLUSION; CYTOPLASMIC					1 [1.0]
INFILTRATION; MONONUCLEAR CELL		1 [1.0]	1 [1.0]	11 [1.0]	15 [1.1]
HEPATOCYTE; MITOSIS; INCREASED					3 [1.0]
NECROSIS; FOCAL			2 [1.0]	1 [2.0]	
CARDIOVASCULAR SYSTEM					
No Tissues/Organs Examined					

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F0 Female

Treatment Groups (Females)

		0	5000	15000	40000
ENDOCRINE SYSTEM					
ADRENAL CORTEX	(0)	(22)	(4)	(1)	(22)
UNILATERAL; HYPERTROPHY; FOCAL		1 [1.0]			
ADRENAL MEDULLA	(0)	(22)	(4)	(1)	(22)
PITUITARY GLAND	(0)	(22)	(4)	(1)	(22)
PARS DISTALIS; CYST					1
THYROID GLANDS	(0)	(22)	(4)	(1)	(22)
C-CELL; UNILATERAL; HYPERPLASIA		1 [1.0]			
GENERAL BODY SYSTEM					
No Tissues/Organs Examined					

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F0 Female

Treatment Groups (Females)

	0	5000	15000	40000	
GENITAL SYSTEM					
CERVIX	(0)	(22)	(4)	(1)	(22)
CLITORAL GLANDS	(0)	(1)	(0)	(0)	(0)
UNILATERAL; INFLAMMATION, CHRONIC		1 [2.0]			
OVARIES	(0)	(22)	(22)	(22)	(22)
CORPUS LUTEUM; BILATERAL; CYST					1
CORPUS LUTEUM; UNILATERAL; CYST		2	3		3
FOLLICLE; BILATERAL; CYST				1	
FOLLICLE; UNILATERAL; CYST		4	3	3	2
UNILATERAL; CYST		2	1		
UTERUS	(0)	(22)	(22)	(22)	(22)
ENDOMETRIAL GLANDS; CYST		1	5	4	
DILATION			1 [2.0]		
ENDOMETRIUM; HYPERPLASIA; CYSTIC					1 [2.0]
HYPERPLASIA, ATYPICAL		1 [1.0]		1 [1.0]	
UNILATERAL; INFLAMMATION, ACUTE		1 [1.0]			
ENDOMETRIUM; METAPLASIA; SQUAMOUS		5 [1.4]	4 [1.5]	6 [1.3]	1 [2.0]
ENDOMETRIUM; POLYP; STROMAL				1	2
VAGINA	(0)	(22)	(4)	(1)	(22)
HEMATOPOIETIC SYSTEM					
LYMPH NODE	(0)	(0)	(1)	(0)	(0)
SPLEEN	(0)	(22)	(4)	(1)	(22)
EXTRAMEDULLARY HEMATOPOIESIS; INCREASED			1 [2.0]		
CAPSULE; FIBROSIS			1 [1.0]		
THYMUS	(0)	(22)	(4)	(1)	(22)
HYPERPLASIA; EPITHELIAL		3 [1.0]			1 [1.0]

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F0 Female					
Treatment Groups (Females)					
		0	5000	15000	40000
INTEGUMENTARY SYSTEM					
MAMMARY GLANDS	(0)	(2)	(3)	(1)	(1)
INFLAMMATION, ACUTE		1 [2.0]	1 [3.0]		
SKIN	(0)	(0)	(1)	(0)	(1)
ABSCESS; SUBCUTANEOUS			1 [4.0]		
INFLAMMATION, SUPPURATIVE			1 [4.0]		
ULCER					1 [2.0]
SKIN, ABDOMINAL	(0)	(0)	(1)	(0)	(0)
ULCER			1 [3.0]		
LYMPHOID SYSTEM					
No Tissues/Organs Examined					
MUSCULOSKELETAL SYSTEM					
No Tissues/Organs Examined					
NERVOUS SYSTEM					
No Tissues/Organs Examined					
RESPIRATORY SYSTEM					
No Tissues/Organs Examined					
SPECIAL SENSES SYSTEM					
ZYMBALS GLANDS	(0)	(0)	(1)	(0)	(0)

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F0 Female

Treatment Groups (Females)

	0	5000	15000	40000
URINARY SYSTEM				
KIDNEYS	(0)	(22)	(22)	(22)
CORTEX; ATROPHY				1 [1.0]
CHRONIC PROGRESSIVE NEPHROPATHY		21 [1.1]	19 [1.1]	20 [1.1]
RENAL TUBULE; BILATERAL; DILATION		1 [2.0]		
INFILTRATION; MONONUCLEAR CELL			1 [1.0]	
METAPLASIA; OSSEOUS			1 [1.0]	1 [1.0]
CORTICOMEDULLARY JUNCTION; MINERAL; FOCAL		8 [1.0]	8 [1.0]	13 [1.0]
PAPILLA; MINERAL; LINEAR			1 [1.0]	2 [1.0]
PELVIS; MINERAL		2 [1.0]		
RENAL TUBULE; REGENERATION			1 [1.0]	

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F1 Male: F1c NonParent Males

Treatment Groups (ppm)

	0	5000	15000	40000
Disposition Summary				
Animals Initially In Study	45	34	46	45
Early Deaths				
Euthanized, moribund	1			30
Found Dead	1			9
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 90 - 92)	43	34	46	6
Animals Examined Microscopically	45	34	46	6
Total number litters	16	12	18	5
ALIMENTARY SYSTEM				
INTESTINE, COLON	(1)	(1)	(0)	(0)
GALT; HYPERPLASIA; LYMPHOCYTE	1 [2.0] (1)	1 [2.0] (1)		
LIVER	(45)	(34)	(46)	(6)
DEFORMITY			2 (2)	
HEPATODIAPHRAGMATIC NODULE	1 (1)	1 (1)		
BILE DUCT; HYPERPLASIA			9 [1.0] (6)	4 [1.0] (4)
INFILTRATION; MONONUCLEAR CELL	1 [1.0] (1)	4 [1.0] (3)	29 [1.0] (14)	
INFLAMMATION; FOCAL	4 [1.0] (3)	2 [1.0] (2)	3 [1.0] (3)	
INFLAMMATION, GRANULOMATOUS; FOCAL			1 [1.0] (1)	
MINERAL; FOCAL			1 [2.0] (1)	
POLYARTERITIS, NODOSA			2 [1.0] (1)	
CARDIOVASCULAR SYSTEM				
No Tissues/Organs Examined				

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F1 Male: F1c NonParent Males

Treatment Groups (ppm)

	0	5000	15000	40000
ENDOCRINE SYSTEM				
ADRENAL CORTEX	(45)	(0)	(2)	(6)
BILATERAL; HYPERPLASIA			2 [2.5] (1)	
BILATERAL; POLYARTERITIS, NODOSA			2 [1.0] (1)	
ADRENAL MEDULLA	(45)	(0)	(2)	(6)
PITUITARY GLAND	(45)	(0)	(0)	(6)
PARS DISTALIS; CYST	1 (1)			
THYROID GLANDS	(44)	(0)	(0)	(6)
GENERAL BODY SYSTEM				
No Tissues/Organs Examined				

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F1 Male: F1c NonParent Males

	Treatment Groups (ppm)			
	0	5000	15000	40000
GENITAL SYSTEM				
COAGULATING GLANDS	(45)	(0)	(0)	(6)
BILATERAL; IMMATURE	1 [4.0] (1)			
DORSAL PROSTATE	(45)	(0)	(0)	(6)
BILATERAL; IMMATURE	1 [4.0] (1)			
UNILATERAL; INFLAMMATION, ACUTE	1 [1.0] (1)			
BILATERAL; INFLAMMATION, CHRONIC	1 [1.0] (1)			
EPIDIDYMIDES	(45)	(0)	(1)	(6)
DUCT; EXFOLIATED GERM CELL	3 [2.0] (1)		1 [1.0] (1)	1 [2.0] (1)
HYOSPERMIA	1 [4.0] (1)		1 [2.0] (1)	
IMMATURE	1 [4.0] (1)			
SEMINAL VESICLES	(45)	(0)	(2)	(6)
BILATERAL; IMMATURE	1 [4.0] (1)			
UNILATERAL; POLYARTERITIS, NODOSA			1 [1.0] (1)	
BILATERAL; SECRETORY MATERIAL DECREASED			1 [2.0] (1)	
TESTES	(45)	(1)	(1)	(6)
GERM CELL; DEGENERATION	3 [1.0] (1)		1 [2.0] (1)	1 [1.0] (1)
IMMATURE	1 [4.0] (1)			
VENTRAL PROSTATE	(45)	(0)	(1)	(6)
BILATERAL; IMMATURE	1 [4.0] (1)			
BILATERAL; INFLAMMATION, CHRONIC	29 [1.5] (15)			3 [1.0] (3)
HEMATOPOIETIC SYSTEM				
SPLEEN	(45)	(0)	(1)	(6)
ACCESSORY NODULE				1 (1)
EXTRAMEDULLARY HEMATOPOIESIS, INCREASED			1 [2.0] (1)	
THYMUS	(44)	(0)	(1)	(6)

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F1 Male: F1c NonParent Males

Treatment Groups (ppm)

	0	5000	15000	40000
INTEGUMENTARY SYSTEM				
No Tissues/Organs Examined				
LYMPHOID SYSTEM				
No Tissues/Organs Examined				
MUSCULOSKELETAL SYSTEM				
DIAPHRAGM	(1)	(0)	(0)	(0)
HERNIA	1 (1)			
NERVOUS SYSTEM				
No Tissues/Organs Examined				
RESPIRATORY SYSTEM				
LUNGS	(1)	(0)	(0)	(0)
HEMORRHAGE	1 [3.0] (1)			
SPECIAL SENSES SYSTEM				
EYES	(1)	(0)	(0)	(0)
RETINA; DYSPLASIA	1 [2.0] (1)			
URINARY SYSTEM				
KIDNEYS	(45)	(4)	(4)	(6)
CHRONIC PROGRESSIVE NEPHROPATHY	41 [1.1] (15)	4 [1.3] (3)	4 [1.0] (3)	1 [1.0] (1)
CORTEX; CYST	1 (1)			
MEDULLA; CYST	1 (1)			
PELVIS; DILATION	2 [2.0] (2)	4 [1.0] (3)	4 [1.3] (3)	
RENAL TUBULE; DILATION	1 [2.0] (1)			
PAPILLA; HYPERPLASIA; EPITHELIAL	1 [1.0] (1)			
INFLAMMATION, CHRONIC; INTERSTITIAL	1 [1.0] (1)			
CORTICOMEDULLARY JUNCTION; MINERAL; FOCAL	2 [1.0] (1)			
RENAL TUBULE; REGENERATION; FOCAL	1 [2.0] (1)			

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F1 Female: F1c NonParent Female

	Treatment Groups (ppm)			
	0	5000	15000	40000
Disposition Summary				
Animals Initially In Study	40	35	41	34
Early Deaths				
Euthanized, moribund	1			20
Found Dead				14
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 90 - 92)	39	35	41	
Animals Examined Microscopically	40	35	41	
Total number litters	17	14	15	
ALIMENTARY SYSTEM				
LIVER	(40)	(35)	(41)	(0)
CLEAR CELL FOCUS		1 (1)		
CYST; SQUAMOUS	1 (1)			
HEPATODIAPHRAGMATIC NODULE	1 (1)		1 (1)	
BILE DUCT; HYPERPLASIA		1 [1.0] (1)		
HEPATOCYTE; PERIportal; HYPERTROPHY		1 [1.0] (1)	6 [1.0] (5)	
INFILTRATION; MONONUCLEAR CELL		1 [1.0] (1)	27 [1.0] (12)	
INFLAMMATION; FOCAL	4 [1.0] (3)	6 [1.0] (5)	4 [1.0] (4)	
POLYARTERITIS; NODOSA			2 [1.0] (1)	
CARDIOVASCULAR SYSTEM				
No Tissues/Organs Examined				

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F1 Female: F1c NonParent Female

	Treatment Groups (ppm)			
	0	5000	15000	40000
ENDOCRINE SYSTEM				
ADRENAL CORTEX	(40)	(35)	(41)	(0)
BILATERAL; HYPERPLASIA			1 [2.0] (1)	
ADRENAL MEDULLA	(40)	(35)	(41)	(0)
PITUITARY GLAND	(40)	(0)	(0)	(0)
PARS DISTALIS; CYST	3 (3)			
THYROID GLANDS	(40)	(0)	(0)	(0)
GENERAL BODY SYSTEM				
No Tissues/Organs Examined				

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Species/Strain: Rat/Sprague-Dawley

F1 Female: F1c NonParent Female

	Treatment Groups (ppm)			
	0	5000	15000	40000
GENITAL SYSTEM				
CERVIX	(40)	(0)	(0)	(0)
HYPERPLASIA; MUCINOUS	1 [2.0] (1)			
CLITORAL GLANDS	(1)	(0)	(0)	(0)
BILATERAL; INFLAMMATION, CHRONIC	1 [1.0] (1)			
OVARIES	(39)	(0)	(1)	(0)
CORPUS LUTEUM; BILATERAL; CYST	2 (2)			
CORPUS LUTEUM; UNILATERAL; CYST	2 (2)			
BILATERAL; POLYARTERITIS; NODOSA			1 [1.0] (1)	
OVIDUCTS	(1)	(0)	(0)	(0)
UTERUS	(40)	(2)	(41)	(0)
ENDOMETRIAL GLANDS; CYST	1 (1)			
CYST	4 (4)	1 (1)	2 (2)	
DEVELOPMENTAL MALFORMATION	1 (1)			
HEMORRHAGE	1 [1.0] (1)			
ENDOMETRIUM; METAPLASIA; SQUAMOUS			1 [1.0] (1)	
POLYARTERITIS; NODOSA			2 [1.0] (1)	
VAGINA	(40)	(0)	(0)	(0)
HYPERPLASIA; MUCINOUS	1 [2.0] (1)			
HEMATOPOIETIC SYSTEM				
LYMPH NODE	(0)	(0)	(3)	(0)
SPLEEN	(40)	(0)	(2)	(0)
EXTRAMEDULLARY HEMATOPOIESIS; INCREASED			2 [2.0] (1)	
POLYARTERITIS; NODOSA			1 [3.0] (1)	
THYMUS	(39)	(35)	(41)	(0)
HYPERPLASIA; EPITHELIAL			1 [1.0] (1)	

Study Number: R88007B
 Test Type: RACB
 Route: Dosing in Feed
 Species/Strain: Rat/Sprague-Dawley

PA18R: Non-Neoplastic Lesions with Mean Severity Grade and Litter Incidence
 Test Compound: Butyl Paraben
 CAS Number: 94-26-8

Date Report Requested: 11/20/2018
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 Lab: RTI

F1 Female: F1c NonParent Female

	Treatment Groups (ppm)			
	0	5000	15000	40000
INTEGUMENTARY SYSTEM				
MAMMARY GLANDS	(39)	(0)	(41)	(0)
ACINUS; HYPERPLASIA	6 [1.2] (6)		4 [1.3] (4)	
LYMPHOID SYSTEM				
No Tissues/Organs Examined				
MUSCULOSKELETAL SYSTEM				
BONE, MAXILLA	(0)	(0)	(1)	(0)
DIAPHRAGM	(1)	(0)	(0)	(0)
NERVOUS SYSTEM				
No Tissues/Organs Examined				
RESPIRATORY SYSTEM				
LUNGS	(1)	(0)	(0)	(0)
SPECIAL SENSES SYSTEM				
EYES	(0)	(0)	(1)	(0)
URINARY SYSTEM				
KIDNEYS	(40)	(1)	(2)	(0)
CHRONIC PROGRESSIVE NEPHROPATHY	17 [1.0] (8)		2 [3.0] (1)	
CORTEX; CYST	1 [1.0] (1)			
PELVIS; DILATION		1 [1.0] (1)		
INFLAMMATION, CHRONIC; INTERSTITIAL	1 [1.0] (1)			
CORTICOMEDULLARY JUNCTION; MINERAL; FOCAL	24 [1.0] (14)	1 [1.0] (1)	2 [1.0] (1)	
PAPILLA; MINERAL; LINEAR			2 [1.0] (1)	
NEPHROBLASTEMATOSIS	1 [2.0] (1)			
POLYARTERITIS; NODOSA			2 [1.5] (1)	

Study Number: R88007B
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F1 Male: F1c Parental Males

	Treatment Groups (ppm)			
	0	5000	15000	40000
Disposition Summary				
Animals Initially In Study	40	40	40	26
Early Deaths				
Euthanized, moribund	1	3		
Unscheduled Sacrifice			1	
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 207 - 213)	39	37	39	26
Animals Examined Microscopically	40	40	40	26
Total number litters	19	14	18	7
ALIMENTARY SYSTEM				
LIVER	(40)	(40)	(40)	(26)
BASOPHILIC FOCUS				1 (1)
CHOLANGIOFIBROSIS	1 [1.0] (1)			
CLEAR CELL FOCUS	2 (2)	3 (3)	3 (3)	1 (1)
HEPATOCYTE; FATTY CHANGE; FOCAL			1 [1.0] (1)	
HEPATODIAPHRAGMATIC NODULE	3 (2)			
BILE DUCT; HYPERPLASIA	3 [1.0] (3)	2 [1.0] (2)	12 [1.0] (9)	19 [1.0] (7)
HEPATOCYTE; INCLUSION; CYTOPLASMIC				1 [1.0] (1)
INFILTRATION; MONONUCLEAR CELL		4 [1.0] (4)	32 [1.0] (18)	16 [1.0] (7)
INFLAMMATION; FOCAL	9 [1.0] (7)	7 [1.0] (6)	3 [1.0] (3)	2 [1.0] (1)
HEPATOCYTE; MITOSIS; INCREASED				5 [1.0] (4)
NECROSIS; FOCAL		1 [1.0] (1)	1 [1.0] (1)	
HEPATOCYTE; VACUOLATION; CYTOPLASMIC			9 [1.0] (7)	17 [1.2] (6)
PANCREAS	(1)	(1)	(0)	(0)
SALIVARY GLANDS	(2)	(0)	(1)	(0)
EDEMA; PERIGLANDULAR			1 [2.0] (1)	
STOMACH	(1)	(0)	(0)	(0)

Study Number: R88007B
Test Type: RACB
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Species/Strain: Rat/Sprague-Dawley

PA18R: Non-Neoplastic Lesions with Mean Severity Grade and Litter Incidence
Test Compound: Butyl Paraben
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Date Report Requested: 11/20/2018
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Lab: RTI

F1 Male: F1c Parental Males

	Treatment Groups (ppm)			
	0	5000	15000	40000
CARDIOVASCULAR SYSTEM				
HEART	(0)	(2)	(0)	(0)
AORTIC VALVE; VALVULOPATHY		1 [2.0] (1)		
ENDOCRINE SYSTEM				
ADRENAL CORTEX	(40)	(3)	(1)	(26)
BILATERAL; VACUOLIZATION CYTOPLASMIC; DIFFUSE		1 [2.0] (1)		
ADRENAL MEDULLA	(40)	(3)	(1)	(26)
PITUITARY GLAND	(40)	(3)	(1)	(25)
PARS DISTALIS; CYST	1 (1)			
THYROID GLANDS	(40)	(3)	(1)	(26)
GENERAL BODY SYSTEM				
FAT	(1)	(0)	(1)	(0)
NECROSIS	1 [2.0] (1)			

Study Number: R88007B

PA18R: Non-Neoplastic Lesions with Mean Severity Grade and Litter Incidence

Date Report Requested: 11/20/2018

Test Type: RACB

Test Compound: Butyl Paraben

Time Report Requested: 07:22:55

Route: Dosing in Feed

CAS Number: 94-26-8

Lab: RTI

Species/Strain: Rat/Sprague-Dawley

F1 Male: F1c Parental Males

	Treatment Groups (ppm)			
	0	5000	15000	40000
GENITAL SYSTEM				
COAGULATING GLANDS	(40)	(3)	(1)	(26)
DORSAL PROSTATE	(40)	(3)	(1)	(26)
UNILATERAL; INFLAMMATION, CHRONIC	1 [1.0] (1)			
EPIDIDYMIDES	(40)	(3)	(1)	(26)
DUCT; EXFOLIATED GERM CELL	1 [1.0] (1)			
HYOSPERMIA	1 [4.0] (1)		1 [4.0] (1)	
INFILTRATION; MONONUCLEAR CELL				1 [1.0] (1)
PREPUTIAL GLANDS	(2)	(2)	(1)	(1)
BILATERAL; INFLAMMATION, CHRONIC	2 [2.0] (2)	1 [2.0] (1)		
BILATERAL; INFLAMMATION, SUPPURATIVE		1 [3.0] (1)		1 [3.0] (1)
SEMINAL VESICLES	(40)	(3)	(1)	(26)
TESTES	(40)	(3)	(1)	(26)
GERMINAL EPITHELIUM; ATROPHY	1 [4.0] (1)			
GERM CELL; DEGENERATION	3 [1.0] (2)			1 [1.0] (1)
INTERSTITIAL CELL; HYPERPLASIA	1 [1.0] (1)			
VENTRAL PROSTATE	(40)	(3)	(1)	(26)
BILATERAL; INFLAMMATION, CHRONIC	8 [1.4] (6)			3 [1.0] (3)
UNILATERAL; INFLAMMATION, CHRONIC	1 [1.0] (1)			

Study Number: R88007B
Test Type: RACB
Route: Dosing in Feed
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Date Report Requested: 11/20/2018
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Lab: RTI

F1 Male: F1c Parental Males

	Treatment Groups (ppm)			
	0	5000	15000	40000
HEMATOPOIETIC SYSTEM				
LYMPH NODE	(1)	(0)	(0)	(0)
ABDOMINAL; PIGMENT	1 [2.0] (1)			
LYMPH NODE, CERVICAL	(2)	(0)	(1)	(0)
SPLEEN	(40)	(3)	(1)	(26)
LYMPHOCYTE; DEPLETION	1 [2.0] (1)			
THYMUS	(40)	(3)	(1)	(26)
APOPTOSIS; LYMPHOCYTE		1 [2.0] (1)		
ATROPHY	1 [2.0] (1)			
HEMORRHAGE		1 [2.0] (1)		
HYPERPLASIA; EPITHELIAL	2 [1.0] (2)			4 [1.0] (3)
INTEGUMENTARY SYSTEM				
MAMMARY GLANDS	(2)	(0)	(0)	(0)
SKIN	(0)	(1)	(1)	(0)
INFLAMMATION, SUPPURATIVE		1 [4.0] (1)		
EYELID; ULCER			1 [2.0] (1)	
LYMPHOID SYSTEM				
No Tissues/Organs Examined				
MUSCULOSKELETAL SYSTEM				
No Tissues/Organs Examined				
NERVOUS SYSTEM				
BRAIN	(0)	(2)	(0)	(0)
BRAIN, FOREBRAIN	(1)	(0)	(0)	(0)
RESPIRATORY SYSTEM				
LUNGS	(1)	(0)	(0)	(0)
CONGESTION	1 [2.0] (1)			

Study Number: R88007B
Test Type: RACB
Route: Dosing in Feed
Species/Strain: Rat/Sprague-Dawley

PA18R: Non-Neoplastic Lesions with Mean Severity Grade and Litter Incidence
Test Compound: Butyl Paraben
CAS Number: 94-26-8

Date Report Requested: 11/20/2018
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Lab: RTI

F1 Male: F1c Parental Males

	Treatment Groups (ppm)			
	0	5000	15000	40000
SPECIAL SENSES SYSTEM				
EYES	(0)	(0)	(1)	(0)
URINARY SYSTEM				
KIDNEYS	(40)	(6)	(2)	(26)
CHRONIC PROGRESSIVE NEPHROPATHY	40 [1.8] (19)	6 [1.8] (4)	2 [1.0] (2)	26 [1.0] (7)
MEDULLA; CYST	1 (1)			
PELVIS; DILATION	4 [1.3] (4)	3 [2.0] (3)	2 [1.5] (2)	
PELVIS; MINERAL	6 [1.5] (5)	1 [2.0] (1)		

Study Number: R88007B
 Test Type: RACB
 Route: Dosing in Feed
 Species/Strain: Rat/Sprague-Dawley

PA18R: Non-Neoplastic Lesions with Mean Severity Grade and Litter Incidence
 Test Compound: Butyl Paraben
 CAS Number: 94-26-8

Date Report Requested: 11/20/2018
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 Lab: RTI

F1 Female: F1c Parental Females

	Treatment Groups (ppm)			
	0	5000	15000	40000
Disposition Summary				
Animals Initially In Study	40	40	40	26
Early Deaths				
Euthanized, moribund	1	2	2	
Found Dead			1	
Unscheduled Sacrifice	2		2	
Scheduled Deaths				
Scheduled sacrifice, terminal (LD 21, PND 227 - 236)	37	38	35	26
Animals Examined Microscopically	40	40	40	26
Total number litters	20	14	18	8
ALIMENTARY SYSTEM				
LIVER	(40)	(40)	(40)	(26)
HEPATOCYTE; APOPTOSIS				1 [1.0] (1)
CLEAR CELL FOCUS				2 (2)
FATTY CHANGE; DIFFUSE	1 [2.0] (1)			
BILE DUCT; HYPERPLASIA	3 [1.0] (2)	3 [1.0] (2)	5 [1.0] (3)	11 [1.0] (7)
HEPATOCYTE; PERIPORTAL; HYPERTROPHY		22 [1.0] (11)	28 [1.1] (17)	24 [1.2] (8)
HEPATOCYTE; INCLUSION; CYTOPLASMIC				21 [1.0] (8)
INFILTRATION; MONONUCLEAR CELL	1 [1.0] (1)		10 [1.1] (8)	4 [1.0] (3)
INFLAMMATION; FOCAL	3 [1.0] (3)	3 [1.0] (3)		
NECROSIS	1 [1.0] (1)			
POLYARTERITIS; NODOSA			1 [1.0] (1)	
HEPATOCYTE; VACUOLIZATION; CYTOPLASMIC				6 [1.0] (3)
MESENTERY	(0)	(0)	(2)	(0)
POLYARTERITIS; NODOSA			2 [4.0] (1)	
PANCREAS	(0)	(1)	(1)	(0)

Study Number: R88007B
Test Type: RACB
Route: Dosing in Feed
Species/Strain: Rat/Sprague-Dawley

PA18R: Non-Neoplastic Lesions with Mean Severity Grade and Litter Incidence
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Date Report Requested: 11/20/2018
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Lab: RTI

F1 Female: F1c Parental Females

	Treatment Groups (ppm)			
	0	5000	15000	40000
CARDIOVASCULAR SYSTEM				
HEART	(0)	(1)	(0)	(0)
ENDOCRINE SYSTEM				
ADRENAL CORTEX	(40)	(40)	(40)	(26)
BILATERAL; DEGENERATION			1 [2.0] (1)	
BILATERAL; HYPERPLASIA; DIFFUSE			1 [2.0] (1)	
UNILATERAL; HYPERPLASIA; FOCAL		1 [1.0] (1)		
UNILATERAL; HYPERTROPHY; FOCAL			1 [1.0] (1)	
UNILATERAL; ; VACUOLIZATION CYTOPLASMIC; FOCAL	1 [1.0] (1)			
UNILATERAL; VACUOLIZATION CYTOPLASMIC; FOCAL		1 [1.0] (1)		
ZONA GLOMERULOSA; BILATERAL; VACUOLIZATION CYTOPLASMIC		2 [1.0] (2)	10 [1.0] (9)	23 [1.0] (8)
ADRENAL MEDULLA	(40)	(40)	(40)	(26)
PITUITARY GLAND	(40)	(2)	(5)	(26)
PARS DISTALIS; CYST	2 (2)			
THYROID GLANDS	(40)	(2)	(5)	(25)
C-CELL; UNILATERAL; HYPERPLASIA	1 [1.0] (1)			
GENERAL BODY SYSTEM				
FAT	(0)	(1)	(0)	(0)
NECROSIS		1 [2.0] (1)		

Study Number: R88007B
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 Lab: RTI

F1 Female: F1c Parental Females

	Treatment Groups (ppm)			
	0	5000	15000	40000
GENITAL SYSTEM				
CERVIX	(40)	(2)	(5)	(26)
CYST; SQUAMOUS	1 (1)			
POLYARTERITIS; NODOSA			2 [2.5] (1)	
CLITORAL GLANDS	(1)	(1)	(1)	(2)
DUCT; BILATERAL; ECTASIA		1 [2.0] (1)		1 [3.0] (1)
UNILATERAL; INFLAMMATION, CHRONIC, ACTIVE			1 [2.0] (1)	
OVARIES	(40)	(3)	(5)	(26)
CORPUS LUTEUM; BILATERAL; CYST	1 (1)	1 (1)		
CORPUS LUTEUM; UNILATERAL; CYST	5 (4)			1 (1)
FOLLICLE; BILATERAL; CYST	3 (3)			
FOLLICLE; UNILATERAL; CYST	6 (6)			2 (2)
OVIDUCT; UNILATERAL; CYST	1 (1)			
PARAOVARIAN TISSUE; UNILATERAL; CYST	1 (1)			
BILATERAL; POLYARTERITIS; NODOSA			2 [2.0] (1)	
UTERUS	(40)	(3)	(6)	(26)
ENDOMETRIAL GLANDS; CYST	1 (1)			
DILATION				1 [1.0] (1)
HEMATOCYST	1 (1)			
ENDOMETRIUM; METAPLASIA; SQUAMOUS	2 [1.0] (2)			
POLYARTERITIS; NODOSA			2 [2.0] (1)	
PLACENTA; RETENTION		1 (1)		
VAGINA	(40)	(2)	(5)	(26)
MUCIFICATION	1 [2.0] (1)			
POLYARTERITIS; NODOSA			1 [1.0] (1)	

Study Number: R88007B
Test Type: RACB
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Lab: RTI

F1 Female: F1c Parental Females

	Treatment Groups (ppm)			
	0	5000	15000	40000
HEMATOPOIETIC SYSTEM				
LYMPH NODE	(0)	(0)	(1)	(0)
SPLEEN	(40)	(2)	(5)	(26)
ACCESSORY SPLEEN			1 (1)	
EXTRAMEDULLARY HEMATOPOIESIS; INCREASED INFILTRATION, HISTIOCYTIC	1 [2.0] (1)	1 [2.0] (1)	1 [2.0] (1)	
THYMUS	(40)	(40)	(39)	(26)
ATROPHY	1 [1.0] (1)	1 [1.0] (1)	7 [1.0] (5)	13 [1.0] (6)
CYST			1 (1)	1 (1)
HYPERPLASIA; EPITHELIAL	3 [1.0] (3)			
INTEGUMENTARY SYSTEM				
MAMMARY GLANDS	(40)	(3)	(4)	(26)
INFLAMMATION, ACUTE	1 [3.0] (1)			
POLYARTERITIS; NODOSA			1 [1.0] (1)	
SKIN	(1)	(1)	(0)	(1)
EDEMA; SUBCUTANEOUS				1 [2.0] (1)
EPITHELIUM; HYPERPLASIA		1 [1.0] (1)		
DERMIS; INFLAMMATION, CHRONIC		1 [1.0] (1)		
LYMPHOID SYSTEM				
No Tissues/Organs Examined				
MUSCULOSKELETAL SYSTEM				
LIMB	(1)	(0)	(0)	(0)
PAW	(1)	(0)	(0)	(0)
NERVOUS SYSTEM				
BRAIN	(0)	(1)	(1)	(0)
RESPIRATORY SYSTEM				
No Tissues/Organs Examined				

Study Number: R88007B
Test Type: RACB
Route: Dosing in Feed
Species/Strain: Rat/Sprague-Dawley

PA18R: Non-Neoplastic Lesions with Mean Severity Grade and Litter Incidence
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CAS Number: 94-26-8

Date Report Requested: 11/20/2018
Time Report Requested: 07:22:55
Lab: RTI

F1 Female: F1c Parental Females

	Treatment Groups (ppm)			
	0	5000	15000	40000
SPECIAL SENSES SYSTEM				
EYES	(1)	(0)	(0)	(0)
URINARY SYSTEM				
KIDNEYS	(40)	(3)	(6)	(26)
CHRONIC PROGRESSIVE NEPHROPATHY	33 [1.1] (19)	2 [2.0] (2)	4 [3.0] (2)	8 [1.0] (5)
MEDULLA; CYST				1 [1.0] (1)
PELVIS; DILATION			1 [2.0] (1)	
RENAL TUBULE; PAPILLA; DILATION				2 [1.0] (2)
INFLAMMATION, CHRONIC; INTERSTITIAL	1 [1.0] (1)			2 [1.0] (2)
CORTICOMEDULLARY JUNCTION; MINERAL; FOCAL	22 [1.0] (14)	1 [1.0] (1)	2 [1.5] (2)	2 [1.0] (2)
PAPILLA; MINERAL; LINEAR	2 [1.0] (2)			
BILATERAL; POLYARTERITIS; NODOSA			2 [2.0] (1)	
RENAL TUBULE; REST				1 [1.0] (1)

Study Number: R88007B
Test Type: RACB
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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 ****