

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

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

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

Date Report Requested: 11/20/2018
Time Report Requested: 07:22:46
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 (5%)			
CLEAR CELL FOCUS	2 (9%)	3 (14%)	1 (5%)	2 (9%)
HEPATODIAPHRAGMATIC NODULE	1 (5%)			
BILE DUCT; HYPERPLASIA		1 (5%)	2 (9%)	
INFILTRATION; MONONUCLEAR CELL	3 (14%)	2 (9%)	19 (86%)	22 (100%)
INFLAMMATION; FOCAL	3 (14%)	2 (9%)		3 (14%)
HEPATOCYTE; MITOSIS, INCREASED				3 (14%)
NECROSIS; FOCAL	1 (5%)			
PIGMENT		1 (5%)		
HEPATOCYTE; VACUOLATION; CYTOPLASMIC			11 (50%)	22 (100%)
MESENTERY	(0)	(0)	(1)	(1)
ACCESSORY SPLEEN				1 (100%)
SALIVARY GLANDS	(1)	(0)	(0)	(0)
BILATERAL; EDEMA; PERIGLANDULAR	1 (100%)			
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 (5%)
UNILATERAL; VACUOLATION; CYTOPLASMIC, FOCAL		1 (100%)		
ADRENAL MEDULLA	(22)	(1)	(1)	(22)
PITUITARY GLAND	(22)	(1)	(1)	(22)
PARS DISTALIS; CYST	1 (5%)			
PARS NERVOSA; DEVELOPMENTAL MALFORMATION				1 (5%)
PARS DISTALIS; HYPERPLASIA				1 (5%)
THYROID GLANDS	(22)	(1)	(1)	(22)
C-CELL; UNILATERAL; HYPERPLASIA	1 (5%)			1 (5%)
<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 (5%)			1 (5%)
EPIDIDYMIDES	(22)	(1)	(1)	(22)
HYOSPERMIA				1 (5%)
PREPUTIAL GLANDS	(5)	(5)	(4)	(8)
BILATERAL; INFLAMMATION, CHRONIC; ACTIVE		2 (40%)	1 (25%)	
BILATERAL; INFLAMMATION, CHRONIC	2 (40%)	1 (20%)	1 (25%)	4 (50%)
UNILATERAL; INFLAMMATION, CHRONIC; ACTIVE		1 (20%)		1 (13%)
UNILATERAL; INFLAMMATION, CHRONIC	3 (60%)		1 (25%)	1 (13%)
BILATERAL; INFLAMMATION, SUPPURATIVE				1 (13%)
UNILATERAL; INFLAMMATION, SUPPURATIVE	1 (20%)	1 (20%)		1 (13%)
SEMINAL VESICLES	(22)	(1)	(1)	(22)
TESTES	(22)	(1)	(1)	(22)
GERMINAL EPITHELIUM; ATROPHY				1 (5%)
GERM CELL; DEGENERATION	1 (5%)			
VENTRAL PROSTATE	(22)	(1)	(1)	(22)
UNILATERAL; INFLAMMATION, ACUTE	1 (5%)			
BILATERAL; INFLAMMATION, CHRONIC	2 (9%)	1 (100%)		1 (5%)
HEMATOPOIETIC SYSTEM				
SPLEEN	(22)	(1)	(1)	(22)
ACCESSORY NODULE	1 (5%)			
FOLLICLE; ATROPHY; LYMPHOID			1 (100%)	
THYMUS	(22)	(2)	(1)	(21)
HYPERPLASIA; EPITHELIAL	1 (5%)			2 (10%)

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	F0 Male			
	Treatment Groups (ppm)			
	0	5000	15000	40000
INTEGUMENTARY SYSTEM				
SKIN	(1)	(0)	(0)	(1)
INFLAMMATION, CHRONIC				1 (100%)
LYMPHOID SYSTEM				
No Tissues/Organs Examined				
MUSCULOSKELETAL SYSTEM				
DIAPHRAGM	(1)	(0)	(0)	(0)
HEPATODIAPHRAGMATIC NODULE	1 (100%)			
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 (95%)	4 (100%)	1 (100%)	22 (100%)
RENAL TUBULE; BILATERAL; DILATION			1 (100%)	
PELVIS; MINERAL; LINEAR	1 (5%)			

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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 (5%)
CLEAR CELL FOCUS					2 (9%)
EXTRAMEDULLARY HEMATOPOIESIS			1 (5%)		
HEPATOCYTE; FATTY CHANGE; FOCAL					1 (5%)
BILE DUCT; HYPERPLASIA					2 (9%)
HEPATOCYTE; PERIportal; HYPERTROPHY			2 (9%)	5 (23%)	7 (32%)
HEPATOCYTE; INCLUSION; CYTOPLASMIC					1 (5%)
INFILTRATION; MONONUCLEAR CELL		1 (5%)	1 (5%)	11 (50%)	15 (68%)
HEPATOCYTE; MITOSIS; INCREASED					3 (14%)
NECROSIS; FOCAL			2 (9%)	1 (5%)	
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 (5%)			
ADRENAL MEDULLA	(0)	(22)	(4)	(1)	(22)
PITUITARY GLAND	(0)	(22)	(4)	(1)	(22)
PARS DISTALIS; CYST					1 (5%)
THYROID GLANDS	(0)	(22)	(4)	(1)	(22)
C-CELL; UNILATERAL; HYPERPLASIA		1 (5%)			
GENERAL BODY SYSTEM					
No Tissues/Organs Examined					

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Lab: RTI

Species/Strain: Rat/Sprague-Dawley

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 (100%)			
OVARIES	(0)	(22)	(22)	(22)	(22)
CORPUS LUTEUM; BILATERAL; CYST					1 (5%)
CORPUS LUTEUM; UNILATERAL; CYST		2 (9%)	3 (14%)		3 (14%)
FOLLICLE; BILATERAL; CYST				1 (5%)	
FOLLICLE; UNILATERAL; CYST		4 (18%)	3 (14%)	3 (14%)	2 (9%)
UNILATERAL; CYST		2 (9%)	1 (5%)		
UTERUS	(0)	(22)	(22)	(22)	(22)
ENDOMETRIAL GLANDS; CYST		1 (5%)	5 (23%)	4 (18%)	
DILATION			1 (5%)		
ENDOMETRIUM; HYPERPLASIA; CYSTIC					1 (5%)
HYPERPLASIA, ATYPICAL		1 (5%)		1 (5%)	
UNILATERAL; INFLAMMATION, ACUTE		1 (5%)			
ENDOMETRIUM; METAPLASIA; SQUAMOUS		5 (23%)	4 (18%)	6 (27%)	1 (5%)
ENDOMETRIUM; POLYP; STROMAL				1 (5%)	2 (9%)
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 (25%)		
CAPSULE; FIBROSIS			1 (25%)		
THYMUS	(0)	(22)	(4)	(1)	(22)
HYPERPLASIA; EPITHELIAL		3 (14%)			1 (5%)

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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 (50%)	1 (33%)		
SKIN	(0)	(0)	(1)	(0)	(1)
ABSCESS; SUBCUTANEOUS			1 (100%)		
INFLAMMATION, SUPPURATIVE			1 (100%)		
ULCER					1 (100%)
SKIN, ABDOMINAL	(0)	(0)	(1)	(0)	(0)
ULCER			1 (100%)		
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 (5%)
CHRONIC PROGRESSIVE NEPHROPATHY		21 (95%)	19 (86%)	20 (91%)
RENAL TUBULE; BILATERAL; DILATION		1 (5%)		
INFILTRATION; MONONUCLEAR CELL			1 (5%)	
METAPLASIA; OSSEOUS			1 (5%)	1 (5%)
CORTICOMEDULLARY JUNCTION; MINERAL; FOCAL		8 (36%)	8 (36%)	13 (59%)
PAPILLA; MINERAL; LINEAR			1 (5%)	2 (9%)
PELVIS; MINERAL		2 (9%)		
RENAL TUBULE; REGENERATION			1 (5%)	

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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 (100%) [1]	1 (100%) [1]		
LIVER	(45)	(34)	(46)	(6)
DEFORMITY			2 (4%) [2]	
HEPATODIAPHRAGMATIC NODULE	1 (2%) [1]	1 (3%) [1]		
BILE DUCT; HYPERPLASIA			9 (20%) [6]	4 (67%) [4]
INFILTRATION; MONONUCLEAR CELL	1 (2%) [1]	4 (12%) [3]	29 (63%) [14]	
INFLAMMATION; FOCAL	4 (9%) [3]	2 (6%) [2]	3 (7%) [3]	
INFLAMMATION, GRANULOMATOUS; FOCAL			1 (2%) [1]	
MINERAL; FOCAL			1 (2%) [1]	
POLYARTERITIS, NODOSA			2 (4%) [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 (100%) [1]	
BILATERAL; POLYARTERITIS, NODOSA			2 (100%) [1]	
ADRENAL MEDULLA	(45)	(0)	(2)	(6)
PITUITARY GLAND	(45)	(0)	(0)	(6)
PARS DISTALIS; CYST	1 (2%) [1]			
THYROID GLANDS	(44)	(0)	(0)	(6)
GENERAL BODY SYSTEM				
No Tissues/Organs Examined				

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Test Compound: Butyl Paraben

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Route: Dosing in Feed

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Lab: RTI

Species/Strain: Rat/Sprague-Dawley

F1 Male: F1c NonParent Males

Treatment Groups (ppm)

	0	5000	15000	40000
GENITAL SYSTEM				
COAGULATING GLANDS	(45)	(0)	(0)	(6)
BILATERAL; IMMATURE	1 (2%) [1]			
DORSAL PROSTATE	(45)	(0)	(0)	(6)
BILATERAL; IMMATURE	1 (2%) [1]			
UNILATERAL; INFLAMMATION, ACUTE	1 (2%) [1]			
BILATERAL; INFLAMMATION, CHRONIC	1 (2%) [1]			
EPIDIDYMIDES	(45)	(0)	(1)	(6)
DUCT; EXFOLIATED GERM CELL	3 (7%) [1]		1 (100%) [1]	1 (17%) [1]
HYOSPERMIA	1 (2%) [1]		1 (100%) [1]	
IMMATURE	1 (2%) [1]			
SEMINAL VESICLES	(45)	(0)	(2)	(6)
BILATERAL; IMMATURE	1 (2%) [1]			
UNILATERAL; POLYARTERITIS, NODOSA			1 (50%) [1]	
BILATERAL; SECRETORY MATERIAL DECREASED			1 (50%) [1]	
TESTES	(45)	(1)	(1)	(6)
GERM CELL; DEGENERATION	3 (7%) [1]		1 (100%) [1]	1 (17%) [1]
IMMATURE	1 (2%) [1]			
VENTRAL PROSTATE	(45)	(0)	(1)	(6)
BILATERAL; IMMATURE	1 (2%) [1]			
BILATERAL; INFLAMMATION, CHRONIC	29 (64%) [15]			3 (50%) [3]
HEMATOPOIETIC SYSTEM				
SPLEEN	(45)	(0)	(1)	(6)
ACCESSORY NODULE				1 (17%) [1]
EXTRAMEDULLARY HEMATOPOIESIS, INCREASED			1 (100%) [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 (100%) [1]			
NERVOUS SYSTEM				
No Tissues/Organs Examined				
RESPIRATORY SYSTEM				
LUNGS	(1)	(0)	(0)	(0)
HEMORRHAGE	1 (100%) [1]			
SPECIAL SENSES SYSTEM				
EYES	(1)	(0)	(0)	(0)
RETINA; DYSPLASIA	1 (100%) [1]			
URINARY SYSTEM				
KIDNEYS	(45)	(4)	(4)	(6)
CHRONIC PROGRESSIVE NEPHROPATHY	41 (91%) [15]	4 (100%) [3]	4 (100%) [3]	1 (17%) [1]
CORTEX; CYST	1 (2%) [1]			
MEDULLA; CYST	1 (2%) [1]			
PELVIS; DILATION	2 (4%) [2]	4 (100%) [3]	4 (100%) [3]	
RENAL TUBULE; DILATION	1 (2%) [1]			
PAPILLA; HYPERPLASIA; EPITHELIAL	1 (2%) [1]			
INFLAMMATION, CHRONIC; INTERSTITIAL	1 (2%) [1]			
CORTICOMEDULLARY JUNCTION; MINERAL; FOCAL	2 (4%) [1]			
RENAL TUBULE; REGENERATION; FOCAL	1 (2%) [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 (3%) [1]		
CYST; SQUAMOUS	1 (3%) [1]			
HEPATODIAPHRAGMATIC NODULE	1 (3%) [1]		1 (2%) [1]	
BILE DUCT; HYPERPLASIA		1 (3%) [1]		
HEPATOCYTE; PERIportal; HYPERTROPHY		1 (3%) [1]	6 (15%) [5]	
INFILTRATION; MONONUCLEAR CELL		1 (3%) [1]	27 (66%) [12]	
INFLAMMATION; FOCAL	4 (10%) [3]	6 (17%) [5]	4 (10%) [4]	
POLYARTERITIS; NODOSA			2 (5%) [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%) [1]	
ADRENAL MEDULLA	(40)	(35)	(41)	(0)
PITUITARY GLAND	(40)	(0)	(0)	(0)
PARS DISTALIS; CYST	3 (8%) [3]			
THYROID GLANDS	(40)	(0)	(0)	(0)
GENERAL BODY SYSTEM				
No Tissues/Organs Examined				

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F1 Female: F1c NonParent Female

	Treatment Groups (ppm)			
	0	5000	15000	40000
GENITAL SYSTEM				
CERVIX	(40)	(0)	(0)	(0)
HYPERPLASIA; MUCINOUS	1 (3%) [1]			
CLITORAL GLANDS	(1)	(0)	(0)	(0)
BILATERAL; INFLAMMATION, CHRONIC	1 (100%) [1]			
OVARIES	(39)	(0)	(1)	(0)
CORPUS LUTEUM; BILATERAL; CYST	2 (5%) [2]			
CORPUS LUTEUM; UNILATERAL; CYST	2 (5%) [2]			
BILATERAL; POLYARTERITIS; NODOSA			1 (100%) [1]	
OVIDUCTS	(1)	(0)	(0)	(0)
UTERUS	(40)	(2)	(41)	(0)
ENDOMETRIAL GLANDS; CYST	1 (3%) [1]			
CYST	4 (10%) [4]	1 (50%) [1]	2 (5%) [2]	
DEVELOPMENTAL MALFORMATION	1 (3%) [1]			
HEMORRHAGE	1 (3%) [1]			
ENDOMETRIUM; METAPLASIA; SQUAMOUS			1 (2%) [1]	
POLYARTERITIS; NODOSA			2 (5%) [1]	
VAGINA	(40)	(0)	(0)	(0)
HYPERPLASIA; MUCINOUS	1 (3%) [1]			
HEMATOPOIETIC SYSTEM				
LYMPH NODE	(0)	(0)	(3)	(0)
SPLEEN	(40)	(0)	(2)	(0)
EXTRAMEDULLARY HEMATOPOIESIS; INCREASED			2 (100%) [1]	
POLYARTERITIS; NODOSA			1 (50%) [1]	
THYMUS	(39)	(35)	(41)	(0)
HYPERPLASIA; EPITHELIAL			1 (2%) [1]	

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

PA03R: Non-Neoplastic Lesion Summary with Percent and Litter Incidence
Test Compound: Butyl Paraben
CAS Number: 94-26-8

Date Report Requested: 11/20/2018
Time Report Requested: 07:22:46
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 (15%) [6]		4 (10%) [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 (43%) [8]		2 (100%) [1]	
CORTEX; CYST	1 (3%) [1]			
PELVIS; DILATION		1 (100%) [1]		
INFLAMMATION, CHRONIC; INTERSTITIAL	1 (3%) [1]			
CORTICOMEDULLARY JUNCTION; MINERAL; FOCAL	24 (60%) [14]	1 (100%) [1]	2 (100%) [1]	
PAPILLA; MINERAL; LINEAR			2 (100%) [1]	
NEPHROBLASTEMATOSIS	1 (3%) [1]			
POLYARTERITIS; NODOSA			2 (100%) [1]	

Study Number: R88007B
 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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Date Report Requested: 11/20/2018
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 Lab: RTI

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 (4%) [1]
CHOLANGIOFIBROSIS	1 (3%) [1]			
CLEAR CELL FOCUS	2 (5%) [2]	3 (8%) [3]	3 (8%) [3]	1 (4%) [1]
HEPATOCYTE; FATTY CHANGE; FOCAL			1 (3%) [1]	
HEPATODIAPHRAGMATIC NODULE	3 (8%) [2]			
BILE DUCT; HYPERPLASIA	3 (8%) [3]	2 (5%) [2]	12 (30%) [9]	19 (73%) [7]
HEPATOCYTE; INCLUSION; CYTOPLASMIC				1 (4%) [1]
INFILTRATION; MONONUCLEAR CELL		4 (10%) [4]	32 (80%) [18]	16 (62%) [7]
INFLAMMATION; FOCAL	9 (23%) [7]	7 (18%) [6]	3 (8%) [3]	2 (8%) [1]
HEPATOCYTE; MITOSIS; INCREASED				5 (19%) [4]
NECROSIS; FOCAL		1 (3%) [1]	1 (3%) [1]	
HEPATOCYTE; VACUOLATION; CYTOPLASMIC			9 (23%) [7]	17 (65%) [6]
PANCREAS	(1)	(1)	(0)	(0)
SALIVARY GLANDS	(2)	(0)	(1)	(0)
EDEMA; PERIGLANDULAR			1 (100%) [1]	
STOMACH	(1)	(0)	(0)	(0)

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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 (50%) [1]		
ENDOCRINE SYSTEM				
ADRENAL CORTEX	(40)	(3)	(1)	(26)
BILATERAL; VACUOLIZATION CYTOPLASMIC; DIFFUSE		1 (33%) [1]		
ADRENAL MEDULLA	(40)	(3)	(1)	(26)
PITUITARY GLAND	(40)	(3)	(1)	(25)
PARS DISTALIS; CYST	1 (3%) [1]			
THYROID GLANDS	(40)	(3)	(1)	(26)
GENERAL BODY SYSTEM				
FAT	(1)	(0)	(1)	(0)
NECROSIS	1 (100%) [1]			

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

PA03R: Non-Neoplastic Lesion Summary with Percent 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
GENITAL SYSTEM				
COAGULATING GLANDS	(40)	(3)	(1)	(26)
DORSAL PROSTATE	(40)	(3)	(1)	(26)
UNILATERAL; INFLAMMATION, CHRONIC	1 (3%) [1]			
EPIDIDYMIDES	(40)	(3)	(1)	(26)
DUCT; EXFOLIATED GERM CELL	1 (3%) [1]			
HYOSPERMIA	1 (3%) [1]		1 (100%) [1]	
INFILTRATION; MONONUCLEAR CELL				1 (4%) [1]
PREPUTIAL GLANDS	(2)	(2)	(1)	(1)
BILATERAL; INFLAMMATION, CHRONIC	2 (100%) [2]	1 (50%) [1]		
BILATERAL; INFLAMMATION, SUPPURATIVE		1 (50%) [1]		1 (100%) [1]
SEMINAL VESICLES	(40)	(3)	(1)	(26)
TESTES	(40)	(3)	(1)	(26)
GERMINAL EPITHELIUM; ATROPHY	1 (3%) [1]			
GERM CELL; DEGENERATION	3 (8%) [2]			1 (4%) [1]
INTERSTITIAL CELL; HYPERPLASIA	1 (3%) [1]			
VENTRAL PROSTATE	(40)	(3)	(1)	(26)
BILATERAL; INFLAMMATION, CHRONIC	8 (20%) [6]			3 (12%) [3]
UNILATERAL; INFLAMMATION, CHRONIC	1 (3%) [1]			

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

PA03R: Non-Neoplastic Lesion Summary with Percent 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
HEMATOPOIETIC SYSTEM				
LYMPH NODE	(1)	(0)	(0)	(0)
ABDOMINAL; PIGMENT	1 (100%) [1]			
LYMPH NODE, CERVICAL	(2)	(0)	(1)	(0)
SPLEEN	(40)	(3)	(1)	(26)
LYMPHOCYTE; DEPLETION	1 (3%) [1]			
THYMUS	(40)	(3)	(1)	(26)
APOPTOSIS; LYMPHOCYTE		1 (33%) [1]		
ATROPHY	1 (3%) [1]			
HEMORRHAGE		1 (33%) [1]		
HYPERPLASIA; EPITHELIAL	2 (5%) [2]			4 (15%) [3]
INTEGUMENTARY SYSTEM				
MAMMARY GLANDS	(2)	(0)	(0)	(0)
SKIN	(0)	(1)	(1)	(0)
INFLAMMATION, SUPPURATIVE		1 (100%) [1]		
EYELID; ULCER			1 (100%) [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 (100%) [1]			

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

PA03R: Non-Neoplastic Lesion Summary with Percent and Litter Incidence
Test Compound: Butyl Paraben
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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 (100%) [19]	6 (100%) [4]	2 (100%) [2]	26 (100%) [7]
MEDULLA; CYST	1 (3%) [1]			
PELVIS; DILATION	4 (10%) [4]	3 (50%) [3]	2 (100%) [2]	
PELVIS; MINERAL	6 (15%) [5]	1 (17%) [1]		

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

PA03R: Non-Neoplastic Lesion Summary with Percent 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 (4%) [1]
CLEAR CELL FOCUS				2 (8%) [2]
FATTY CHANGE; DIFFUSE	1 (3%) [1]			
BILE DUCT; HYPERPLASIA	3 (8%) [2]	3 (8%) [2]	5 (13%) [3]	11 (42%) [7]
HEPATOCYTE; PERIPORTAL; HYPERTROPHY		22 (55%) [11]	28 (70%) [17]	24 (92%) [8]
HEPATOCYTE; INCLUSION; CYTOPLASMIC				21 (81%) [8]
INFILTRATION; MONONUCLEAR CELL	1 (3%) [1]		10 (25%) [8]	4 (15%) [3]
INFLAMMATION; FOCAL	3 (8%) [3]	3 (8%) [3]		
NECROSIS	1 (3%) [1]			
POLYARTERITIS; NODOSA			1 (3%) [1]	
HEPATOCYTE; VACUOLIZATION; CYTOPLASMIC				6 (23%) [3]
MESENTERY	(0)	(0)	(2)	(0)
POLYARTERITIS; NODOSA			2 (100%) [1]	
PANCREAS	(0)	(1)	(1)	(0)

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

PA03R: Non-Neoplastic Lesion Summary with Percent and Litter Incidence
Test Compound: Butyl Paraben
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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 (3%) [1]	
BILATERAL; HYPERPLASIA; DIFFUSE			1 (3%) [1]	
UNILATERAL; HYPERPLASIA; FOCAL		1 (3%) [1]		
UNILATERAL; HYPERTROPHY; FOCAL			1 (3%) [1]	
UNILATERAL; ; VACUOLIZATION CYTOPLASMIC; FOCAL	1 (3%) [1]			
UNILATERAL; VACUOLIZATION CYTOPLASMIC; FOCAL		1 (3%) [1]		
ZONA GLOMERULOSA; BILATERAL; VACUOLIZATION CYTOPLASMIC		2 (5%) [2]	10 (25%) [9]	23 (88%) [8]
ADRENAL MEDULLA	(40)	(40)	(40)	(26)
PITUITARY GLAND	(40)	(2)	(5)	(26)
PARS DISTALIS; CYST	2 (5%) [2]			
THYROID GLANDS	(40)	(2)	(5)	(25)
C-CELL; UNILATERAL; HYPERPLASIA	1 (3%) [1]			
GENERAL BODY SYSTEM				
FAT	(0)	(1)	(0)	(0)
NECROSIS		1 (100%) [1]		

Study Number: R88007B

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

Date Report Requested: 11/20/2018

Test Type: RACB

Test Compound: Butyl Paraben

Time Report Requested: 07:22:46

Route: Dosing in Feed

CAS Number: 94-26-8

Lab: RTI

Species/Strain: Rat/Sprague-Dawley

F1 Female: F1c Parental Females

	Treatment Groups (ppm)			
	0	5000	15000	40000
GENITAL SYSTEM				
CERVIX	(40)	(2)	(5)	(26)
CYST; SQUAMOUS	1 (3%) [1]			
POLYARTERITIS; NODOSA			2 (40%) [1]	
CLITORAL GLANDS	(1)	(1)	(1)	(2)
DUCT; BILATERAL; ECTASIA		1 (100%) [1]		1 (50%) [1]
UNILATERAL; INFLAMMATION, CHRONIC, ACTIVE			1 (100%) [1]	
OVARIES	(40)	(3)	(5)	(26)
CORPUS LUTEUM; BILATERAL; CYST	1 (3%) [1]	1 (33%) [1]		
CORPUS LUTEUM; UNILATERAL; CYST	5 (13%) [4]			1 (4%) [1]
FOLLICLE; BILATERAL; CYST	3 (8%) [3]			
FOLLICLE; UNILATERAL; CYST	6 (15%) [6]			2 (8%) [2]
OVIDUCT; UNILATERAL; CYST	1 (3%) [1]			
PARAOVARIAN TISSUE; UNILATERAL; CYST	1 (3%) [1]			
BILATERAL; POLYARTERITIS; NODOSA			2 (40%) [1]	
UTERUS	(40)	(3)	(6)	(26)
ENDOMETRIAL GLANDS; CYST	1 (3%) [1]			
DILATION				1 (4%) [1]
HEMATOCYST	1 (3%) [1]			
ENDOMETRIUM; METAPLASIA; SQUAMOUS	2 (5%) [2]			
POLYARTERITIS; NODOSA			2 (33%) [1]	
PLACENTA; RETENTION		1 (33%) [1]		
VAGINA	(40)	(2)	(5)	(26)
MUCIFICATION	1 (3%) [1]			
POLYARTERITIS; NODOSA			1 (20%) [1]	

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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 (20%) [1]	
EXTRAMEDULLARY HEMATOPOIESIS; INCREASED INFILTRATION, HISTIOCYTIC	1 (3%) [1]	1 (50%) [1]	1 (20%) [1]	
THYMUS	(40)	(40)	(39)	(26)
ATROPHY	1 (3%) [1]	1 (3%) [1]	7 (18%) [5]	13 (50%) [6]
CYST			1 (3%) [1]	1 (4%) [1]
HYPERPLASIA; EPITHELIAL	3 (8%) [3]			
INTEGUMENTARY SYSTEM				
MAMMARY GLANDS	(40)	(3)	(4)	(26)
INFLAMMATION, ACUTE	1 (3%) [1]			
POLYARTERITIS; NODOSA			1 (25%) [1]	
SKIN	(1)	(1)	(0)	(1)
EDEMA; SUBCUTANEOUS				1 (100%) [1]
EPITHELIUM; HYPERPLASIA		1 (100%) [1]		
DERMIS; INFLAMMATION, CHRONIC		1 (100%) [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
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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 (83%) [19]	2 (67%) [2]	4 (67%) [2]	8 (31%) [5]
MEDULLA; CYST				1 (4%) [1]
PELVIS; DILATION			1 (17%) [1]	
RENAL TUBULE; PAPILLA; DILATION				2 (8%) [2]
INFLAMMATION, CHRONIC; INTERSTITIAL	1 (3%) [1]			2 (8%) [2]
CORTICOMEDULLARY JUNCTION; MINERAL; FOCAL	22 (55%) [14]	1 (33%) [1]	2 (33%) [2]	2 (8%) [2]
PAPILLA; MINERAL; LINEAR	2 (5%) [2]			
BILATERAL; POLYARTERITIS; NODOSA			2 (33%) [1]	
RENAL TUBULE; REST				1 (4%) [1]

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LEGEND

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 ****