

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

PA02R: 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: 07:22:47

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
Scheduled Sacrifice				
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)
MESENTERY	(0)	(0)	(1)	(1)
SALIVARY GLANDS	(1)	(0)	(0)	(0)
CARDIOVASCULAR SYSTEM				
HEART	(1)	(0)	(0)	(0)
ENDOCRINE SYSTEM				
ADRENAL CORTEX	(22)	(1)	(1)	(22)
ADRENAL MEDULLA	(22)	(1)	(1)	(22)
PITUITARY GLAND	(22)	(1)	(1)	(22)
THYROID GLANDS	(22)	(1)	(1)	(22)
GENERAL BODY SYSTEM				
No Tissues/Organs Examined				

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	F0 Male			
	Treatment Groups (ppm)			
	0	5000	15000	40000
GENITAL SYSTEM				
COAGULATING GLANDS	(22)	(1)	(1)	(22)
DORSAL PROSTATE	(22)	(1)	(1)	(22)
EPIDIDYMIDES	(22)	(1)	(1)	(22)
PREPUTIAL GLANDS	(5)	(5)	(4)	(8)
SEMINAL VESICLES	(22)	(1)	(1)	(22)
TESTES	(22)	(1)	(1)	(22)
VENTRAL PROSTATE	(22)	(1)	(1)	(22)
HEMATOPOIETIC SYSTEM				
SPLEEN	(22)	(1)	(1)	(22)
THYMUS	(22)	(2)	(1)	(21)
INTEGUMENTARY SYSTEM				
SKIN	(1)	(0)	(0)	(1)
NEURAL CREST TUMOR; MALIGNANT	1 (100%)			
LYMPHOID SYSTEM				
No Tissues/Organs Examined				
MUSCULOSKELETAL SYSTEM				
DIAPHRAGM	(1)	(0)	(0)	(0)
NERVOUS SYSTEM				
No Tissues/Organs Examined				
RESPIRATORY SYSTEM				
LUNGS	(1)	(0)	(0)	(0)
SPECIAL SENSES SYSTEM				
EYES	(1)	(0)	(0)	(0)

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	F0 Male			
	Treatment Groups (ppm)			
	0	5000	15000	40000
URINARY SYSTEM				
KIDNEYS	(22)	(4)	(1)	(22)
No Systemic Lesions				

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Tumor Summary Data for F0 Male	Treatment Groups (ppm)			
	0	5000	15000	40000
Total Animals with Primary Neoplasms	0	0	0	0
Total Primary Neoplasms	0	0	0	0
Total Animals with Benign Neoplasms	1	0	0	0
Total Benign Neoplasms	1	0	0	0
Total Animals with Malignant Neoplasms	1	0	0	0
Total Malignant Neoplasms	1	0	0	0
Total Animals with Metastatic Neoplasms	0	0	0	0
Total Metastatic Neoplasms	0	0	0	0
Total Animals with Malignant Neoplasms Uncertain Primary Site	0	0	0	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
Scheduled Sacrifice					
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)
CARDIOVASCULAR SYSTEM					
No Tissues/Organs Examined					
ENDOCRINE SYSTEM					
ADRENAL CORTEX	(0)	(22)	(4)	(1)	(22)
ADRENAL MEDULLA	(0)	(22)	(4)	(1)	(22)
PITUITARY GLAND	(0)	(22)	(4)	(1)	(22)
THYROID GLANDS	(0)	(22)	(4)	(1)	(22)
GENERAL BODY SYSTEM					
No Tissues/Organs Examined					
GENITAL SYSTEM					
CERVIX	(0)	(22)	(4)	(1)	(22)
CLITORAL GLANDS	(0)	(1)	(0)	(0)	(0)
OVARIES	(0)	(22)	(22)	(22)	(22)
UTERUS	(0)	(22)	(22)	(22)	(22)
VAGINA	(0)	(22)	(4)	(1)	(22)

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F0 Female					
Treatment Groups (Females)					
		0	5000	15000	40000
HEMATOPOIETIC SYSTEM					
LYMPH NODE	(0)	(0)	(1)	(0)	(0)
SPLEEN	(0)	(22)	(4)	(1)	(22)
THYMUS	(0)	(22)	(4)	(1)	(22)
INTEGUMENTARY SYSTEM					
MAMMARY GLANDS	(0)	(2)	(3)	(1)	(1)
ADENOCARCINOMA			1 (33%)		
FIBROADENOMA		1 (50%)	1 (33%)	1 (100%)	1 (100%)
SKIN	(0)	(0)	(1)	(0)	(1)
SKIN, ABDOMINAL	(0)	(0)	(1)	(0)	(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)
ADENOMA			1 (100%)		
URINARY SYSTEM					
KIDNEYS	(0)	(22)	(22)	(22)	(22)
No Systemic Lesions					

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Tumor Summary Data for F0 Female	Treatment Groups (Females)			
	0	5000	15000	40000
Total Animals with Primary Neoplasms	0	0	0	0
Total Primary Neoplasms	0	0	0	0
Total Animals with Benign Neoplasms	0	1	2	1
Total Benign Neoplasms	0	1	2	1
Total Animals with Malignant Neoplasms	0	0	1	0
Total Malignant Neoplasms	0	0	1	0
Total Animals with Metastatic Neoplasms	0	0	0	0
Total Metastatic Neoplasms	0	0	0	0
Total Animals with Malignant Neoplasms Uncertain Primary Site	0	0	0	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
Scheduled Sacrifice				
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)
LIVER	(45)	(34)	(46)	(6)
CARDIOVASCULAR SYSTEM				
No Tissues/Organs Examined				
ENDOCRINE SYSTEM				
ADRENAL CORTEX	(45)	(0)	(2)	(6)
ADRENAL MEDULLA	(45)	(0)	(2)	(6)
PITUITARY GLAND	(45)	(0)	(0)	(6)
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)
DORSAL PROSTATE	(45)	(0)	(0)	(6)
EPIDIDYMIDES	(45)	(0)	(1)	(6)
SEMINAL VESICLES	(45)	(0)	(2)	(6)
TESTES	(45)	(1)	(1)	(6)
VENTRAL PROSTATE	(45)	(0)	(1)	(6)
HEMATOPOIETIC SYSTEM				
SPLEEN	(45)	(0)	(1)	(6)
THYMUS	(44)	(0)	(1)	(6)
INTEGUMENTARY SYSTEM				
No Tissues/Organs Examined				
LYMPHOID SYSTEM				
No Tissues/Organs Examined				
MUSCULOSKELETAL SYSTEM				
DIAPHRAGM	(1)	(0)	(0)	(0)
NERVOUS SYSTEM				
No Tissues/Organs Examined				
RESPIRATORY SYSTEM				
LUNGS	(1)	(0)	(0)	(0)
SPECIAL SENSES SYSTEM				
EYES	(1)	(0)	(0)	(0)
URINARY SYSTEM				
KIDNEYS	(45)	(4)	(4)	(6)
No Systemic Lesions				

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Tumor Summary Data for F1 Male F1c NonParent Males

	Treatment Groups (ppm)			
	0	5000	15000	40000
Total Animals with Primary Neoplasms	0	0	0	0
Total Primary Neoplasms	0	0	0	0
Total Animals with Benign Neoplasms	0	0	0	0
Total Benign Neoplasms	0	0	0	0
Total Animals with Malignant Neoplasms	0	0	0	0
Total Malignant Neoplasms	0	0	0	0
Total Animals with Metastatic Neoplasms	0	0	0	0
Total Metastatic Neoplasms	0	0	0	0
Total Animals with Malignant Neoplasms Uncertain Primary Site	0	0	0	0

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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
Scheduled Sacrifice				
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)
CARDIOVASCULAR SYSTEM				
No Tissues/Organs Examined				
ENDOCRINE SYSTEM				
ADRENAL CORTEX	(40)	(35)	(41)	(0)
ADRENAL MEDULLA	(40)	(35)	(41)	(0)
PITUITARY GLAND	(40)	(0)	(0)	(0)
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)
CLITORAL GLANDS	(1)	(0)	(0)	(0)
OVARIES	(39)	(0)	(1)	(0)
OVIDUCTS	(1)	(0)	(0)	(0)
UTERUS	(40)	(2)	(41)	(0)
VAGINA	(40)	(0)	(0)	(0)
HEMATOPOIETIC SYSTEM				
LYMPH NODE	(0)	(0)	(3)	(0)
SPLEEN	(40)	(0)	(2)	(0)
THYMUS	(39)	(35)	(41)	(0)
INTEGUMENTARY SYSTEM				
MAMMARY GLANDS	(39)	(0)	(41)	(0)
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)

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F1 Female: F1c NonParent Female

Treatment Groups (ppm)

	0	5000	15000	40000
URINARY SYSTEM				
KIDNEYS	(40)	(1)	(2)	(0)
No Systemic Lesions				

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Tumor Summary Data for F1 Female F1c NonParent Female	Treatment Groups (ppm)			
	0	5000	15000	40000
Total Animals with Primary Neoplasms	0	0	0	0
Total Primary Neoplasms	0	0	0	0
Total Animals with Benign Neoplasms	0	0	0	0
Total Benign Neoplasms	0	0	0	0
Total Animals with Malignant Neoplasms	0	0	0	0
Total Malignant Neoplasms	0	0	0	0
Total Animals with Metastatic Neoplasms	0	0	0	0
Total Metastatic Neoplasms	0	0	0	0
Total Animals with Malignant Neoplasms Uncertain Primary Site	0	0	0	0

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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
Scheduled Sacrifice				
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)
PANCREAS	(1)	(1)	(0)	(0)
SALIVARY GLANDS	(2)	(0)	(1)	(0)
STOMACH	(1)	(0)	(0)	(0)
CARDIOVASCULAR SYSTEM				
HEART	(0)	(2)	(0)	(0)
ENDOCRINE SYSTEM				
ADRENAL CORTEX	(40)	(3)	(1)	(26)
ADRENAL MEDULLA	(40)	(3)	(1)	(26)
PITUITARY GLAND	(40)	(3)	(1)	(25)
THYROID GLANDS	(40)	(3)	(1)	(26)
GENERAL BODY SYSTEM				
FAT	(1)	(0)	(1)	(0)

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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)
EPIDIDYMIDES	(40)	(3)	(1)	(26)
PREPUTIAL GLANDS	(2)	(2)	(1)	(1)
SEMINAL VESICLES	(40)	(3)	(1)	(26)
TESTES	(40)	(3)	(1)	(26)
VENTRAL PROSTATE	(40)	(3)	(1)	(26)
HEMATOPOIETIC SYSTEM				
LYMPH NODE	(1)	(0)	(0)	(0)
LYMPH NODE, CERVICAL	(2)	(0)	(1)	(0)
SPLEEN	(40)	(3)	(1)	(26)
THYMUS	(40)	(3)	(1)	(26)
INTEGUMENTARY SYSTEM				
MAMMARY GLANDS	(2)	(0)	(0)	(0)
SKIN	(0)	(1)	(1)	(0)
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)
SCHWANNOMA; MALIGNANT	1 (100%) [1]			
RESPIRATORY SYSTEM				
LUNGS	(1)	(0)	(0)	(0)

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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)
No Systemic Lesions				

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Tumor Summary Data for F1 Male F1c Parental Males

	Treatment Groups (ppm)			
	0	5000	15000	40000
Total Animals with Primary Neoplasms	0	0	0	0
Total Primary Neoplasms	0	0	0	0
Total Animals with Benign Neoplasms	0	0	0	0
Total Benign Neoplasms	0	0	0	0
Total Animals with Malignant Neoplasms	1	0	0	0
Total Malignant Neoplasms	1	0	0	0
Total Animals with Metastatic Neoplasms	0	0	0	0
Total Metastatic Neoplasms	0	0	0	0
Total Animals with Malignant Neoplasms Uncertain Primary Site	0	0	0	0

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F1 Female: F1c Parental Females

	Treatment Groups (ppm)			
	0	5000	15000	40000
Disposition Summary				
Animals Initially In Study	40	40	40	26
Scheduled Sacrifice				
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)
MESENTERY	(0)	(0)	(2)	(0)
PANCREAS	(0)	(1)	(1)	(0)
CARDIOVASCULAR SYSTEM				
HEART	(0)	(1)	(0)	(0)
ENDOCRINE SYSTEM				
ADRENAL CORTEX	(40)	(40)	(40)	(26)
ADRENAL MEDULLA	(40)	(40)	(40)	(26)
PITUITARY GLAND	(40)	(2)	(5)	(26)
THYROID GLANDS	(40)	(2)	(5)	(25)
GENERAL BODY SYSTEM				
FAT	(0)	(1)	(0)	(0)

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F1 Female: F1c Parental Females

	Treatment Groups (ppm)			
	0	5000	15000	40000
GENITAL SYSTEM				
CERVIX	(40)	(2)	(5)	(26)
CLITORAL GLANDS	(1)	(1)	(1)	(2)
OVARIES	(40)	(3)	(5)	(26)
UTERUS	(40)	(3)	(6)	(26)
VAGINA	(40)	(2)	(5)	(26)
HEMATOPOIETIC SYSTEM				
LYMPH NODE	(0)	(0)	(1)	(0)
SPLEEN	(40)	(2)	(5)	(26)
THYMUS	(40)	(40)	(39)	(26)
INTEGUMENTARY SYSTEM				
MAMMARY GLANDS	(40)	(3)	(4)	(26)
ADENOCARCINOMA		2 (67%) [2]	1 (25%) [1]	
FIBROADENOMA			2 (50%) [2]	
SKIN	(1)	(1)	(0)	(1)
LYMPHOID SYSTEM				
No Tissues/Organs Examined				
MUSCULOSKELETAL SYSTEM				
LIMB	(1)	(0)	(0)	(0)
NOT OTHERWISE SPECIFIED; SARCOMA	1 (100%) [1]			
PAW	(1)	(0)	(0)	(0)
SARCOMA	1 (100%) [1]			
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

PA02R: 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: 07:22:47
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)
No Systemic Lesions				

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

PA02R: 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: 07:22:47
Lab: RTI

Tumor Summary Data for F1 Female F1c Parental Females

	Treatment Groups (ppm)			
	0	5000	15000	40000
Total Animals with Primary Neoplasms	0	0	0	0
Total Primary Neoplasms	0	0	0	0
Total Animals with Benign Neoplasms	0	0	2	0
Total Benign Neoplasms	0	0	2	0
Total Animals with Malignant Neoplasms	1	2	1	0
Total Malignant Neoplasms	2	2	1	0
Total Animals with Metastatic Neoplasms	0	0	0	0
Total Metastatic Neoplasms	0	0	0	0
Total Animals with Malignant Neoplasms Uncertain Primary Site	0	0	0	0

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

PA02R: Neoplastic Lesion Summary with Percent and Litter Incidence
Test Compound: Butyl Paraben
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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 ****