

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

**PA05R: Incidence Rates of Neoplastic Lesions with Litter Incidence (Systemic Lesions Abridged) (a)**

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

**Date Report Requested:** 11/20/2018  
**Time Report Requested:** 07:22:53  
**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
<b>Disposition Summary</b>				
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
<b>ALIMENTARY SYSTEM</b>				
LIVER	(22)	(22)	(22)	(22)
MESENTERY	(0)	(0)	(1)	(1)
SALIVARY GLANDS	(1)	(0)	(0)	(0)
<b>CARDIOVASCULAR SYSTEM</b>				
HEART	(1)	(0)	(0)	(0)
<b>ENDOCRINE SYSTEM</b>				
ADRENAL CORTEX	(22)	(1)	(1)	(22)
ADRENAL MEDULLA	(22)	(1)	(1)	(22)
PITUITARY GLAND	(22)	(1)	(1)	(22)
THYROID GLANDS	(22)	(1)	(1)	(22)
<b>GENERAL BODY SYSTEM</b>				
No Tissues/Organs Examined				

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	F0 Male			
	Treatment Groups (ppm)			
	0	5000	15000	40000
<b>GENITAL SYSTEM</b>				
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)
<b>HEMATOPOIETIC SYSTEM</b>				
SPLEEN	(22)	(1)	(1)	(22)
THYMUS	(22)	(2)	(1)	(21)
<b>INTEGUMENTARY SYSTEM</b>				
SKIN	(1)	(0)	(0)	(1)
NEURAL CREST TUMOR; MALIGNANT	1 (100%)			
<b>LYMPHOID SYSTEM</b>				
No Tissues/Organs Examined				
<b>MUSCULOSKELETAL SYSTEM</b>				
DIAPHRAGM	(1)	(0)	(0)	(0)
<b>NERVOUS SYSTEM</b>				
No Tissues/Organs Examined				
<b>RESPIRATORY SYSTEM</b>				
LUNGS	(1)	(0)	(0)	(0)
<b>SPECIAL SENSES SYSTEM</b>				
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
<b>Disposition Summary</b>					
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
<b>HEMATOPOIETIC SYSTEM</b>					
LYMPH NODE	(0)	(0)	(1)	(0)	(0)
SPLEEN	(0)	(22)	(4)	(1)	(22)
THYMUS	(0)	(22)	(4)	(1)	(22)
<b>INTEGUMENTARY SYSTEM</b>					
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)
<b>LYMPHOID SYSTEM</b>					
No Tissues/Organs Examined					
<b>MUSCULOSKELETAL SYSTEM</b>					
No Tissues/Organs Examined					
<b>NERVOUS SYSTEM</b>					
No Tissues/Organs Examined					
<b>RESPIRATORY SYSTEM</b>					
No Tissues/Organs Examined					
<b>SPECIAL SENSES SYSTEM</b>					
ZYMBALS GLANDS	(0)	(0)	(1)	(0)	(0)
ADENOMA			1 (100%)		
<b>URINARY SYSTEM</b>					
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
<b>Disposition Summary</b>				
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
<b>GENITAL SYSTEM</b>				
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)
<b>HEMATOPOIETIC SYSTEM</b>				
SPLEEN	(45)	(0)	(1)	(6)
THYMUS	(44)	(0)	(1)	(6)
<b>INTEGUMENTARY SYSTEM</b>				
No Tissues/Organs Examined				
<b>LYMPHOID SYSTEM</b>				
No Tissues/Organs Examined				
<b>MUSCULOSKELETAL SYSTEM</b>				
DIAPHRAGM	(1)	(0)	(0)	(0)
<b>NERVOUS SYSTEM</b>				
No Tissues/Organs Examined				
<b>RESPIRATORY SYSTEM</b>				
LUNGS	(1)	(0)	(0)	(0)
<b>SPECIAL SENSES SYSTEM</b>				
EYES	(1)	(0)	(0)	(0)
<b>URINARY SYSTEM</b>				
KIDNEYS	(45)	(4)	(4)	(6)
No Systemic Lesions				

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**Tumor Summary Data for F1 Male F1c NonParent Males**

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

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**F1 Female: F1c NonParent Female**

	Treatment Groups (ppm)			
	0	5000	15000	40000
<b>Disposition Summary</b>				
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
<b>GENITAL SYSTEM</b>				
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)
<b>HEMATOPOIETIC SYSTEM</b>				
LYMPH NODE	(0)	(0)	(3)	(0)
SPLEEN	(40)	(0)	(2)	(0)
THYMUS	(39)	(35)	(41)	(0)
<b>INTEGUMENTARY SYSTEM</b>				
MAMMARY GLANDS	(39)	(0)	(41)	(0)
<b>LYMPHOID SYSTEM</b>				
No Tissues/Organs Examined				
<b>MUSCULOSKELETAL SYSTEM</b>				
BONE, MAXILLA	(0)	(0)	(1)	(0)
DIAPHRAGM	(1)	(0)	(0)	(0)
<b>NERVOUS SYSTEM</b>				
No Tissues/Organs Examined				
<b>RESPIRATORY SYSTEM</b>				
LUNGS	(1)	(0)	(0)	(0)
<b>SPECIAL SENSES SYSTEM</b>				
EYES	(0)	(0)	(1)	(0)

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**F1 Female: F1c NonParent Female**

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**Treatment Groups (ppm)**

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	<b>0</b>	<b>5000</b>	<b>15000</b>	<b>40000</b>
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
<b>Disposition Summary</b>				
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
<b>ALIMENTARY SYSTEM</b>				
LIVER	(40)	(40)	(40)	(26)
PANCREAS	(1)	(1)	(0)	(0)
SALIVARY GLANDS	(2)	(0)	(1)	(0)
STOMACH	(1)	(0)	(0)	(0)
<b>CARDIOVASCULAR SYSTEM</b>				
HEART	(0)	(2)	(0)	(0)
<b>ENDOCRINE SYSTEM</b>				
ADRENAL CORTEX	(40)	(3)	(1)	(26)
ADRENAL MEDULLA	(40)	(3)	(1)	(26)
PITUITARY GLAND	(40)	(3)	(1)	(25)
THYROID GLANDS	(40)	(3)	(1)	(26)
<b>GENERAL BODY SYSTEM</b>				
FAT	(1)	(0)	(1)	(0)



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F1 Male: F1c Parental Males

	Treatment Groups (ppm)			
	0	5000	15000	40000
<b>GENITAL SYSTEM</b>				
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)
<b>HEMATOPOIETIC SYSTEM</b>				
LYMPH NODE	(1)	(0)	(0)	(0)
LYMPH NODE, CERVICAL	(2)	(0)	(1)	(0)
SPLEEN	(40)	(3)	(1)	(26)
THYMUS	(40)	(3)	(1)	(26)
<b>INTEGUMENTARY SYSTEM</b>				
MAMMARY GLANDS	(2)	(0)	(0)	(0)
SKIN	(0)	(1)	(1)	(0)
<b>LYMPHOID SYSTEM</b>				
No Tissues/Organs Examined				
<b>MUSCULOSKELETAL SYSTEM</b>				
No Tissues/Organs Examined				
<b>NERVOUS SYSTEM</b>				
BRAIN	(0)	(2)	(0)	(0)
BRAIN, FOREBRAIN	(1)	(0)	(0)	(0)
SCHWANNOMA; MALIGNANT	1 (100%) [1]			
<b>RESPIRATORY SYSTEM</b>				
LUNGS	(1)	(0)	(0)	(0)

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**Lab:** RTI

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**F1 Male: F1c Parental Males**

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

**PA05R: Incidence Rates of Neoplastic Lesions with Litter Incidence (Systemic Lesions Abridged) (a)**  
**Test Compound:** Butyl Paraben  
**CAS Number:** 94-26-8

**Date Report Requested:** 11/20/2018  
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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

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

PA05R: Incidence Rates of Neoplastic Lesions with Litter Incidence (Systemic Lesions  
 Abridged) (a)  
 Test Compound: Butyl Paraben  
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Date Report Requested: 11/20/2018  
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F1 Female: F1c Parental Females

	Treatment Groups (ppm)			
	0	5000	15000	40000
<b>Disposition Summary</b>				
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
<b>GENITAL SYSTEM</b>				
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)
<b>HEMATOPOIETIC SYSTEM</b>				
LYMPH NODE	(0)	(0)	(1)	(0)
SPLEEN	(40)	(2)	(5)	(26)
THYMUS	(40)	(40)	(39)	(26)
<b>INTEGUMENTARY SYSTEM</b>				
MAMMARY GLANDS	(40)	(3)	(4)	(26)
ADENOCARCINOMA		2 (67%) [2]	1 (25%) [1]	
FIBROADENOMA			2 (50%) [2]	
SKIN	(1)	(1)	(0)	(1)
<b>LYMPHOID SYSTEM</b>				
No Tissues/Organs Examined				
<b>MUSCULOSKELETAL SYSTEM</b>				
LIMB	(1)	(0)	(0)	(0)
NOT OTHERWISE SPECIFIED; SARCOMA	1 (100%) [1]			
PAW	(1)	(0)	(0)	(0)
SARCOMA	1 (100%) [1]			
<b>NERVOUS SYSTEM</b>				
BRAIN	(0)	(1)	(1)	(0)
<b>RESPIRATORY SYSTEM</b>				
No Tissues/Organs Examined				

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

**PA05R: Incidence Rates of Neoplastic Lesions with Litter Incidence (Systemic Lesions Abridged) (a)**  
**Test Compound:** Butyl Paraben  
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**F1 Female: F1c Parental Females**

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	<b>Treatment Groups (ppm)</b>			
	<b>0</b>	<b>5000</b>	<b>15000</b>	<b>40000</b>
SPECIAL SENSES SYSTEM				
EYES	(1)	(0)	(0)	(0)
URINARY SYSTEM				
KIDNEYS	(40)	(3)	(6)	(26)
No Systemic Lesions				

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

**PA05R: Incidence Rates of Neoplastic Lesions with Litter Incidence (Systemic Lesions Abridged) (a)**  
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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

**PA05R: Incidence Rates of Neoplastic Lesions with Litter Incidence (Systemic Lesions Abridged) (a)**  
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#### LEGEND

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

Number of animals with observation reported with percent incidence in parentheses

(a) Systemic lesions are included once in the total lesion count regardless of how many times they occurred in a single animal

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 \*\***