

Study Number: R88007B

Test Type: RACB

Route: Dosing in Feed

Species/Strain: Rat/Sprague-Dawley

C Number:

Study Gender:

PWG Approval Date

PA46R: Summary of Gross Pathology with Litter Incidence

Test Compound: Butyl Paraben

CAS Number: 94-26-8

R88007B

Both

See web page for date of PWG Approval

Date Report Requested: 12/04/2018

Time Report Requested: 13:23:30

Lab: RTI

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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
Number of Animals Examined	22	22	22	22
ALIMENTARY SYSTEM				
LIVER	(22)	(22)	(22)	(22)
CAUDATE LOBE; DEFORMITY; MODERATE		1 (4.5%)		
CAUDATE LOBE; DISCOLORATION; BROWN, MILD		1 (4.5%)		
MEDIAN LOBE; NODULE	1 (4.5%)			
CAUDATE LOBE; REDUCED IN SIZE; MODERATE		1 (4.5%)		
MESENTERY	(22)	(22)	(22)	(22)
ABDOMINAL; NODULE; RED			1 (4.5%)	1 (4.5%)
SALIVARY GLANDS	(22)	(22)	(22)	(22)
SUBMANDIBULAR; BILATERAL; FLUID; MILD	1 (4.5%)			
CARDIOVASCULAR SYSTEM				
HEART	(22)	(22)	(22)	(22)
ENLARGED; MILD	1 (4.5%)			
ENDOCRINE SYSTEM				
ADRENAL GLANDS	(22)	(22)	(22)	(22)
PITUITARY GLAND	(22)	(22)	(22)	(22)
THYROID GLANDS	(22)	(22)	(22)	(22)

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F0 Male				
	Treatment Groups (ppm)			
	0	5000	15000	40000
GENERAL BODY SYSTEM				
CAVITY, ABDOMINAL	(22)	(22)	(22)	(22)
FLUID; MODERATE, RED			1 (4.5%)	
FAT	(22)	(22)	(22)	(22)
ABDOMINAL; DISCOLORATION; MODERATE, WIDESPREAD, YELLOW			1 (4.5%)	

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F0 Male				
	Treatment Groups (ppm)			
	0	5000	15000	40000
GENITAL SYSTEM				
COAGULATING GLANDS	(22)	(22)	(22)	(22)
DORSAL PROSTATE	(22)	(22)	(22)	(22)
EPIDIDYMIDES	(22)	(22)	(22)	(22)
RIGHT; REDUCED IN SIZE; MODERATE				1 (4.5%)
PREPUTIAL GLANDS	(22)	(22)	(22)	(22)
BILATERAL; DISCOLORATION; BROWN, MILD		1 (4.5%)	1 (4.5%)	2 (9.1%)
BILATERAL; DISCOLORATION; GREEN, MILD	1 (4.5%)	1 (4.5%)		2 (9.1%)
LEFT; DISCOLORATION; BROWN, MILD				1 (4.5%)
LEFT; DISCOLORATION; BROWN, MODERATE	1 (4.5%)			2 (9.1%)
LEFT; DISCOLORATION; GREEN, MILD	1 (4.5%)	1 (4.5%)	2 (9.1%)	
LEFT; DISCOLORATION; GREEN, MODERATE	1 (4.5%)			
RIGHT; DISCOLORATION; BROWN, MINIMAL	1 (4.5%)			1 (4.5%)
RIGHT; DISCOLORATION; BROWN, MODERATE			1 (4.5%)	
RIGHT; DISCOLORATION; GREEN, MILD	1 (4.5%)		1 (4.5%)	1 (4.5%)
RIGHT; DISCOLORATION; GREEN, MODERATE		1 (4.5%)		
LEFT; ENLARGED; MARKED				1 (4.5%)
LEFT; ENLARGED; MODERATE	1 (4.5%)			
RIGHT; ENLARGED; MARKED		1 (4.5%)		
RIGHT; NODULE; TAN				1 (4.5%)
LEFT; REDUCED IN SIZE; MODERATE	1 (4.5%)	1 (4.5%)		
RIGHT; REDUCED IN SIZE; MARKED	1 (4.5%)			
SEMINAL VESICLES	(22)	(22)	(22)	(22)
TESTES	(22)	(22)	(22)	(22)
RIGHT; REDUCED IN SIZE; MODERATE				1 (4.5%)
VENTRAL PROSTATE	(22)	(22)	(22)	(22)

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F0 Male				
	Treatment Groups (ppm)			
	0	5000	15000	40000
HEMATOPOIETIC SYSTEM				
SPLEEN	(22)	(22)	(22)	(22)
DEFORMITY; MILD	1 (4.5%)			
REDUCED IN SIZE			1 (4.5%)	
THYMUS	(22)	(22)	(22)	(22)
DISCOLORATION; MINIMAL, RED		1 (4.5%)		
INTEGUMENTARY SYSTEM				
SKIN	(22)	(22)	(22)	(22)
INGUINAL; RIGHT; ALOPECIA; MILD				1 (4.5%)
SUBCUTANEOUS; INGUINAL; DISCOLORATION; BROWN, MILD, RIGHT				1 (4.5%)
HEAD; MASS; FIRM	1 (4.5%)			
SUBCUTANEOUS; MASS; GREEN	1 (4.5%)			
LYMPHOID SYSTEM				
None				
MUSCULOSKELETAL SYSTEM				
DIAPHRAGM	(22)	(22)	(22)	(22)
HERNIA; MODERATE	1 (4.5%)			
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
LUNGS	(22)	(22)	(22)	(22)
BILATERAL; DISCOLORATION; MODERATE, MOTTLED	1 (4.5%)			

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F0 Male				
	Treatment Groups (ppm)			
	0	5000	15000	40000
SPECIAL SENSES SYSTEM				
EYES	(22)	(22)	(22)	(22)
BILATERAL; DISCHARGE; BROWN, MARKED	1 (4.5%)			
URINARY SYSTEM				
KIDNEYS	(22)	(22)	(22)	(22)
CORTEX; BILATERAL; DISCOLORATION; MODERATE, MOTTLED		3 (13.6%)		

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Lab: RTI

F0 Female				
	Treatment Groups (ppm)			
	0	5000	15000	40000
Disposition Summary				
Animals Initially In Study	22	22	22	22
Early Deaths				
Euthanized, moribund		3	1	
Unscheduled Sacrifice	1	1		
Scheduled Deaths				
Scheduled sacrifice, terminal (LD 4, SD 32 - 219)	21	18	21	22
Number of Animals Examined	22	22	22	22
ALIMENTARY SYSTEM				
LIVER	(22)	(22)	(22)	(22)
DISCOLORATION; MILD, MOTTLED, WIDESPREAD		1 (4.5%)		
CARDIOVASCULAR SYSTEM				
None				
ENDOCRINE SYSTEM				
ADRENAL GLANDS	(22)	(22)	(22)	(22)
PITUITARY GLAND	(22)	(22)	(22)	(22)
THYROID GLANDS	(22)	(22)	(22)	(22)
GENERAL BODY SYSTEM				
None				

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Lab: RTI

F0 Female				
	Treatment Groups (ppm)			
	0	5000	15000	40000
GENITAL SYSTEM				
CERVIX	(22)	(22)	(22)	(22)
OVARIES	(22)	(22)	(22)	(22)
UTERUS	(22)	(22)	(22)	(22)
LEFT; CYST			1 (4.5%)	
VAGINA	(22)	(22)	(22)	(22)
FLUID; RED		1 (4.5%)		
HEMATOPOIETIC SYSTEM				
LYMPH NODE, AXILLARY	(22)	(22)	(22)	(22)
RIGHT; ENLARGED; MODERATE		1 (4.5%)		
SPLEEN	(22)	(22)	(22)	(22)
ENLARGED; MODERATE		1 (4.5%)		
THYMUS	(22)	(22)	(22)	(22)
DISCOLORATION; BROWN, MILD			1 (4.5%)	

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F0 Female				
	Treatment Groups (ppm)			
	0	5000	15000	40000
INTEGUMENTARY SYSTEM				
MAMMARY GLANDS	(22)	(22)	(22)	(22)
AXILLARY; ENLARGED; MODERATE		1 (4.5%)		
INGUINAL; LEFT; ENLARGED; DIFFUSE, MODERATE, RED	1 (4.5%)			
INGUINAL; LEFT; ENLARGED; MARKED, SOFT			1 (4.5%)	
INGUINAL; RIGHT; ENLARGED; DIFFUSE, MODERATE	1 (4.5%)			
AXILLARY; RIGHT; MASS; SOFT	1 (4.5%)			1 (4.5%)
INGUINAL; NODULE; SOFT	1 (4.5%)			
SKIN	(22)	(22)	(22)	(22)
DORSAL; CRUST; BROWN, MINIMAL, MULTIPLE				1 (4.5%)
FLANK; RIGHT; MASS; FIRM		1 (4.5%)		
INGUINAL; MASS; FIRM		1 (4.5%)		
SUBCUTANEOUS; LATERAL; MASS; FIRM		1 (4.5%)		
SUBCUTANEOUS; THICKENED; RED		1 (4.5%)		
SKIN, ABDOMINAL	(22)	(22)	(22)	(22)
INGUINAL; RIGHT; ULCER; MODERATE		1 (4.5%)		
LYMPHOID SYSTEM				
None				
MUSCULOSKELETAL SYSTEM				
None				
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
None				

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F0 Female				
	Treatment Groups (ppm)			
	0	5000	15000	40000
SPECIAL SENSES SYSTEM				
ZYMBALS GLANDS	(22)	(22)	(22)	(22)
LEFT; MASS; SOFT		1 (4.5%)		
URINARY SYSTEM				
KIDNEYS	(22)	(22)	(22)	(22)
RIGHT; DISCOLORATION; MILD, MOTTLED				1 (4.5%)
RIGHT; DISCOLORATION; MINIMAL, MOTTLED				1 (4.5%)

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
Number of Animals Examined	45	34	46	28
Total number litters	16	12	18	14

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Lab: RTI

F1 Male: F1c NonParent Males

	Treatment Groups (ppm)			
	0	5000	15000	40000
ALIMENTARY SYSTEM				
INTESTINE, COLON	(45)	(34)	(46)	(18)
DISCOLORATION; MODERATE, RED				1 (5.6%) [1]
PEYERS PATCH; ENLARGED; MILD	1 (2.2%) [1]			
INTESTINE, DUODENUM	(45)	(34)	(46)	(18)
DISCOLORATION; MARKED, RED				3 (16.7%) [2]
DISCOLORATION; MODERATE, RED				1 (5.6%) [1]
INTESTINE, ILEUM	(45)	(34)	(46)	(18)
DISCOLORATION; MODERATE, RED				1 (5.6%) [1]
INTESTINE, JEJUNUM	(45)	(34)	(46)	(18)
DISCOLORATION; MODERATE, RED				1 (5.6%) [1]
INTESTINE, RECTUM	(45)	(34)	(46)	(18)
PEYERS PATCH; ENLARGED; MARKED		1 (2.9%) [1]		
PEYERS PATCH; ENLARGED; MILD	1 (2.2%) [1]			
LIVER	(45)	(34)	(46)	(18)
CAUDATE LOBE; DEFORMITY; MODERATE			2 (4.3%) [2]	
CAUDATE LOBE; DISCOLORATION; MINIMAL, WHITE			1 (2.2%) [1]	
MEDIAN LOBE; NODULE	1 (2.2%) [1]	1 (2.9%) [1]		
CAUDATE LOBE; REDUCED IN SIZE; MODERATE			1 (2.2%) [1]	
STOMACH	(45)	(34)	(46)	(18)
DISCOLORATION; MARKED, RED				2 (11.1%) [2]
CARDIOVASCULAR SYSTEM				
None				

F1 Male: F1c NonParent Males				
	Treatment Groups (ppm)			
	0	5000	15000	40000
ENDOCRINE SYSTEM				
ADRENAL GLANDS	(45)	(34)	(46)	(18)
BILATERAL; DISCOLORATION; MILD, PALE				2 (11.1%) [1]
BILATERAL; DISCOLORATION; MODERATE, RED			1 (2.2%) [1]	
DISCOLORATION; MARKED, WHITE				2 (11.1%) [2]
DISCOLORATION; MILD, PALE	0 *			3 (16.7%) [3]
BILATERAL; ENLARGED; MARKED			1 (2.2%) [1]	
BILATERAL; ENLARGED; MODERATE			1 (2.2%) [1]	
PITUITARY GLAND	(45)	(34)	(46)	(18)
THYROID GLANDS	(45)	(34)	(46)	(18)
GENERAL BODY SYSTEM				
None				

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	Treatment Groups (ppm)			
	0	5000	15000	40000
GENITAL SYSTEM				
COAGULATING GLANDS	(45)	(34)	(46)	(18)
DORSAL PROSTATE	(45)	(34)	(46)	(18)
EPIDIDYMIDES	(45)	(34)	(46)	(18)
BILATERAL; REDUCED IN SIZE	1 (2.2%) [1]			
LEFT; REDUCED IN SIZE; MILD			1 (2.2%) [1]	
LEFT; REDUCED IN SIZE; MODERATE				1 (5.6%) [1]
SEMINAL VESICLES	(45)	(34)	(46)	(18)
BILATERAL; REDUCED IN SIZE; MINIMAL			1 (2.2%) [1]	
BILATERAL; REDUCED IN SIZE; MODERATE			1 (2.2%) [1]	
REDUCED IN SIZE	1 (2.2%) [1]			
TESTES	(45)	(34)	(46)	(18)
LEFT; REDUCED IN SIZE; MILD			1 (2.2%) [1]	
LEFT; REDUCED IN SIZE; MODERATE				1 (5.6%) [1]
LEFT; ROUND; MILD		1 (2.9%) [1]		
LEFT; SHORT; MILD		1 (2.9%) [1]		
VENTRAL PROSTATE	(45)	(34)	(46)	(18)
REDUCED IN SIZE; MODERATE			1 (2.2%) [1]	
REDUCED IN SIZE	1 (2.2%) [1]			
HEMATOPOIETIC SYSTEM				
SPLEEN	(45)	(34)	(46)	(18)
DEFORMITY; MILD				1 (5.6%) [1]
ENLARGED; MILD			1 (2.2%) [1]	
CAPSULE; NODULE; RED				1 (5.6%) [1]
THYMUS	(45)	(34)	(46)	(18)
DISCOLORATION; MODERATE, RED			1 (2.2%) [1]	

F1 Male: F1c NonParent Males				
	Treatment Groups (ppm)			
	0	5000	15000	40000
INTEGUMENTARY SYSTEM				
None				
LYMPHOID SYSTEM				
None				
MUSCULOSKELETAL SYSTEM				
DIAPHRAGM	(45)	(34)	(46)	(18)
HERNIA; MODERATE	1 (2.2%) [1]			
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
LUNGS	(45)	(34)	(46)	(18)
BILATERAL; DISCOLORATION; MILD, MOTTLED				1 (5.6%) [1]
DISCOLORATION; MARKED, MOTTLED				1 (5.6%) [1]
DISCOLORATION; MODERATE, MOTTLED	1 (2.2%) [1]			1 (5.6%) [1]
SPECIAL SENSES SYSTEM				
EYES	(45)	(34)	(46)	(18)
RIGHT; REDUCED IN SIZE	1 (2.2%) [1]			

F1 Male: F1c NonParent Males				
	Treatment Groups (ppm)			
	0	5000	15000	40000
URINARY SYSTEM				
KIDNEYS	(45)	(34)	(46)	(18)
CORTEX; RIGHT; CYST; FLUID-FILLED, MINIMAL	1 (2.2%) [1]			
PELVIS; RIGHT; DILATION; MILD	1 (2.2%) [1]	1 (2.9%) [1]	1 (2.2%) [1]	
PELVIS; RIGHT; DILATION; MINIMAL		3 (8.8%) [2]		
PELVIS; RIGHT; DILATION; MODERATE			3 (6.5%) [3]	
URINARY BLADDER	(45)	(34)	(46)	(18)
DISCOLORATION; MARKED, RED				1 (5.6%) [1]
FLUID				1 (5.6%) [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

Number of Animals Examined

40

35

41

24

Total number litters

17

14

15

7

ALIMENTARY SYSTEM

INTESTINE, DUODENUM

(40)

(35)

(41)

(9)

DISCOLORATION; MARKED, RED

4 (44.4%) [2]

DISCOLORATION; MODERATE, RED

2 (22.2%) [2]

INTESTINE, ILEUM

(40)

(35)

(41)

(9)

DISCOLORATION; MARKED, RED

1 (11.1%) [1]

INTESTINE, JEJUNUM

(40)

(35)

(41)

(9)

DISCOLORATION; MARKED, RED

1 (11.1%) [1]

LIVER

(40)

(35)

(41)

(9)

MEDIAL LOBE; CYST; FLUID-FILLED, MODERATE

1 (2.4%) [1]

MEDIAN LOBE; MISSHAPEN

1 (2.5%) [1]

STOMACH

(40)

(35)

(41)

(9)

DISCOLORATION; MARKED, RED

1 (11.1%) [1]

CARDIOVASCULAR SYSTEM

None

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F1 Female: F1c NonParent Female

	Treatment Groups (ppm)			
	0	5000	15000	40000
ENDOCRINE SYSTEM				
ADRENAL GLANDS	(40)	(35)	(41)	(9)
DISCOLORATION; MARKED, WHITE				1 (11.1%) [1]
DISCOLORATION; MODERATE				1 (11.1%) [1]
DISCOLORATION; MODERATE, RED			1 (2.4%) [1]	
BILATERAL; ENLARGED; MILD			1 (2.4%) [1]	
BILATERAL; ENLARGED; MODERATE			1 (2.4%) [1]	
PITUITARY GLAND	(40)	(35)	(41)	(9)
THYROID GLANDS	(40)	(35)	(41)	(9)
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
CERVIX	(40)	(35)	(41)	(9)
OVARIES	(40)	(35)	(41)	(9)
BILATERAL; REDUCED IN SIZE; MODERATE			1 (2.4%) [1]	
OVIDUCTS	(40)	(35)	(41)	(9)
RIGHT; CYST; FLUID-FILLED, MODERATE	1 (2.5%) [1]			
UTERUS	(40)	(35)	(41)	(9)
LEFT; CYST; FLUID-FILLED, MILD	1 (2.5%) [1]			
LEFT; CYST; FLUID-FILLED, MODERATE	1 (2.5%) [1]		1 (2.4%) [1]	
LEFT; CYST; MILD, PINK			1 (2.4%) [1]	
RIGHT; CYST; FLUID-FILLED, MILD		1 (2.9%) [1]		
LEFT; SEROSA; NODULE; PINK	1 (2.5%) [1]			
RIGHT; NODULE; PINK		1 (2.9%) [1]		
NODULE			1 (2.4%) [1]	
BILATERAL; REDUCED IN SIZE; MODERATE			1 (2.4%) [1]	
VAGINA	(40)	(35)	(41)	(9)

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F1 Female: F1c NonParent Female				
	Treatment Groups (ppm)			
	0	5000	15000	40000
HEMATOPOIETIC SYSTEM				
LYMPH NODE	(40)	(35)	(41)	(9)
LEFT; DISCOLORATION; BROWN, MILD			2 (4.9%) [2]	
LEFT; DISCOLORATION; BROWN, MODERATE	2 (5.0%) [2]		1 (2.4%) [1]	
SPLEEN	(40)	(35)	(41)	(9)
ENLARGED; MODERATE			2 (4.9%) [1]	
SEROSA; NODULE; PINK			1 (2.4%) [1]	
THYMUS	(40)	(35)	(41)	(9)
INTEGUMENTARY SYSTEM				
MAMMARY GLANDS	(40)	(35)	(41)	(9)
LYMPHOID SYSTEM				
None				
MUSCULOSKELETAL SYSTEM				
BONE, MAXILLA	(40)	(35)	(41)	(9)
MALOCCLUSION; MARKED			1 (2.4%) [1]	
DIAPHRAGM	(40)	(35)	(41)	(9)
HERNIA	1 (2.5%) [1]			
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
LUNGS	(40)	(35)	(41)	(9)
BILATERAL; DISCOLORATION; MODERATE, MOTTLED	1 (2.5%) [1]			
DISCOLORATION; MARKED, MOTTLED				1 (11.1%) [1]

F1 Female: F1c NonParent Female				
	Treatment Groups (ppm)			
	0	5000	15000	40000
SPECIAL SENSES SYSTEM				
EYES	(40)	(35)	(41)	(9)
BILATERAL; DISCHARGE; BROWN, MARKED			1 (2.4%) [1]	
BILATERAL; REDUCED IN SIZE; MARKED			1 (2.4%) [1]	
URINARY SYSTEM				
KIDNEYS	(40)	(35)	(41)	(9)
PELVIS; BILATERAL; DILATION; MILD		1 (2.9%) [1]		
BILATERAL; DISCOLORATION; BROWN, MILD			1 (2.4%) [1]	
BILATERAL; ENLARGED; MILD			2 (4.9%) [1]	
URINARY BLADDER	(40)	(35)	(41)	(9)
FLUID; MARKED, RED				2 (22.2%) [1]

Study Number: R88007B**Test Type:** RACB**Route:** Dosing in Feed**Species/Strain:** Rat/Sprague-Dawley**PA46R: Summary of Gross Pathology with Litter Incidence****Test Compound:** Butyl Paraben**CAS Number:** 94-26-8**Date Report Requested:** 12/04/2018**Time Report Requested:** 13:23:30**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
Number of Animals Examined	40	40	40	26
Total number litters	19	14	18	7
ALIMENTARY SYSTEM				
LIVER	(40)	(40)	(40)	(26)
MEDIAN LOBE; NODULE	1 (2.5%) [1]			
PANCREAS	(40)	(40)	(40)	(26)
DISCOLORATION; MODERATE, RED		1 (2.5%) [1]		
ENLARGED; MILD	1 (2.5%) [1]			
ENLARGED; MODERATE		1 (2.5%) [1]		
SALIVARY GLANDS	(40)	(40)	(40)	(26)
RIGHT; CERVICAL; FLUID; MILD			1 (2.5%) [1]	
STOMACH	(40)	(40)	(40)	(26)
CARDIOVASCULAR SYSTEM				
HEART	(40)	(40)	(40)	(26)
ATRIUM; RIGHT; ENLARGED; MARKED		2 (5.0%) [1]		
ATRIUM; LEFT; REDUCED IN SIZE; MARKED		1 (2.5%) [1]		

F1 Male: F1c Parental Males				
	Treatment Groups (ppm)			
	0	5000	15000	40000
ENDOCRINE SYSTEM				
ADRENAL GLANDS	(40)	(40)	(40)	(26)
PITUITARY GLAND	(40)	(40)	(40)	(26)
THYROID GLANDS	(40)	(40)	(40)	(26)
GENERAL BODY SYSTEM				
CAVITY, ABDOMINAL	(40)	(40)	(40)	(26)
LUMBAR; LEFT; MASS; DARK	1 (2.5%) [1]			
FAT	(40)	(40)	(40)	(26)
RIGHT; CERVICAL; FLUID; MILD			1 (2.5%) [1]	

Study Number: R88007B

Test Type: RACB

Route: Dosing in Feed

Species/Strain: Rat/Sprague-Dawley

PA46R: Summary of Gross Pathology with Litter Incidence

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Lab: RTI

F1 Male: F1c Parental Males

	Treatment Groups (ppm)			
	0	5000	15000	40000
GENITAL SYSTEM				
COAGULATING GLANDS	(40)	(40)	(40)	(26)
DORSAL PROSTATE	(40)	(40)	(40)	(26)
EPIDIDYMIDES	(40)	(40)	(40)	(26)
BILATERAL; REDUCED IN SIZE; MILD	1 (2.5%) [1]			
LEFT; REDUCED IN SIZE; MARKED			1 (2.5%) [1]	
PREPUTIAL GLANDS	(40)	(40)	(40)	(26)
BILATERAL; DISCOLORATION; GREEN, MILD	1 (2.5%) [1]	2 (5.0%) [2]		1 (3.8%) [1]
LEFT; DISCOLORATION; MILD, YELLOW			1 (2.5%) [1]	
BILATERAL; ENLARGED; MILD		1 (2.5%) [1]		1 (3.8%) [1]
LEFT; ENLARGED; MILD	1 (2.5%) [1]			
LEFT; MASS; SOFT			1 (2.5%) [1]	
PROSTATE GLAND	(40)	(40)	(40)	(26)
RIGHT; ADHESION; MODERATE				1 (3.8%) [1]
SEMINAL VESICLES	(40)	(40)	(40)	(26)
RIGHT; ADHESION; MODERATE				1 (3.8%) [1]
TESTES	(40)	(40)	(40)	(26)
RIGHT; DISCOLORATION; MILD, YELLOW	1 (2.5%) [1]			
LEFT; MISSING			1 (2.5%) [1]	
BILATERAL; REDUCED IN SIZE; MILD	1 (2.5%) [1]			
VENTRAL PROSTATE	(40)	(40)	(40)	(26)
RIGHT; REDUCED IN SIZE; MILD				1 (3.8%) [1]

Study Number: R88007B

Test Type: RACB

Route: Dosing in Feed

Species/Strain: Rat/Sprague-Dawley

PA46R: Summary of Gross Pathology with Litter Incidence

Test Compound: Butyl Paraben

CAS Number: 94-26-8

Date Report Requested: 12/04/2018

Time Report Requested: 13:23:30

Lab: RTI

F1 Male: F1c Parental Males

	Treatment Groups (ppm)			
	0	5000	15000	40000
HEMATOPOIETIC SYSTEM				
LYMPH NODE, CERVICAL	(40)	(40)	(40)	(26)
RIGHT; DISCOLORATION; MILD, YELLOW			1 (2.5%) [1]	
RIGHT; ENLARGED; FIRM, MODERATE			1 (2.5%) [1]	
SPLEEN	(40)	(40)	(40)	(26)
REDUCED IN SIZE	1 (2.5%) [1]			
THYMUS	(40)	(40)	(40)	(26)
DISCOLORATION; MARKED, RED		1 (2.5%) [1]		
INTEGUMENTARY SYSTEM				
MAMMARY GLANDS	(40)	(40)	(40)	(26)
INGUINAL; RIGHT; MASS; SOFT		1 (2.5%) [1]		
LYMPHOID SYSTEM				
None				
MUSCULOSKELETAL SYSTEM				
DIAPHRAGM	(40)	(40)	(40)	(26)
HERNIA; MODERATE	2 (5.0%) [1]			
NERVOUS SYSTEM				
BRAIN	(40)	(40)	(40)	(26)
BRAIN, FOREBRAIN	(40)	(40)	(40)	(26)
MISSHAPEN	1 (2.5%) [1]			
RESPIRATORY SYSTEM				
LUNGS	(40)	(40)	(40)	(26)
BILATERAL; DISCOLORATION; MILD, MOTTLED	1 (2.5%) [1]			

F1 Male: F1c Parental Males				
	Treatment Groups (ppm)			
	0	5000	15000	40000
SPECIAL SENSES SYSTEM				
EYES	(40)	(40)	(40)	(26)
LEFT; ALOPECIA; MINIMAL			1 (2.5%) [1]	
LEFT; DISCHARGE			1 (2.5%) [1]	
URINARY SYSTEM				
KIDNEYS	(40)	(40)	(40)	(26)
RIGHT; CYST; CLEAR	1 (2.5%) [1]			
PELVIS; RIGHT; DILATION; MILD		2 (5.0%) [2]		
PELVIS; RIGHT; DILATION; MINIMAL			1 (2.5%) [1]	
PELVIS; RIGHT; DILATION; MODERATE	2 (5.0%) [2]	1 (2.5%) [1]		
RIGHT; DILATION; MILD	1 (2.5%) [1]			

Study Number: R88007B**Test Type:** RACB**Route:** Dosing in Feed**Species/Strain:** Rat/Sprague-Dawley**PA46R: Summary of Gross Pathology with Litter Incidence****Test Compound:** Butyl Paraben**CAS Number:** 94-26-8**Date Report Requested:** 12/04/2018**Time Report Requested:** 13:23:30**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
Number of Animals Examined	40	40	40	26
Total number litters	20	14	18	8
ALIMENTARY SYSTEM				
LIVER	(40)	(40)	(40)	(26)
DISCOLORATION; MILD, MOTTLED	1 (2.5%) [1]			
MESENTERY	(40)	(40)	(40)	(26)
NODULE			2 (5.0%) [1]	
PANCREAS	(40)	(40)	(40)	(26)
DISCOLORATION; MODERATE, RED		1 (2.5%) [1]		
ENLARGED; MILD		1 (2.5%) [1]		
NODULE			1 (2.5%) [1]	
CARDIOVASCULAR SYSTEM				
HEART	(40)	(40)	(40)	(26)
ATRIUM; RIGHT; ENLARGED; MARKED		1 (2.5%) [1]		

F1 Female: F1c Parental Females				
	Treatment Groups (ppm)			
	0	5000	15000	40000
ENDOCRINE SYSTEM				
ADRENAL GLANDS	(40)	(40)	(40)	(26)
BILATERAL; DISCOLORATION; MODERATE, RED			1 (2.5%) [1]	
BILATERAL; ENLARGED; MODERATE			1 (2.5%) [1]	
ENLARGED; MODERATE			1 (2.5%) [1]	
PITUITARY GLAND	(40)	(40)	(40)	(26)
THYROID GLANDS	(40)	(40)	(40)	(26)
GENERAL BODY SYSTEM				
FAT	(40)	(40)	(40)	(26)
ABDOMINAL; RIGHT; MASS; DARK		1 (2.5%) [1]		

Study Number: R88007B

Test Type: RACB

Route: Dosing in Feed

Species/Strain: Rat/Sprague-Dawley

PA46R: Summary of Gross Pathology with Litter Incidence

Test Compound: Butyl Paraben

CAS Number: 94-26-8

Date Report Requested: 12/04/2018

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Lab: RTI

F1 Female: F1c Parental Females

	Treatment Groups (ppm)			
	0	5000	15000	40000
GENITAL SYSTEM				
CERVIX	(40)	(40)	(40)	(26)
CLITORAL GLANDS	(40)	(40)	(40)	(26)
BILATERAL; DISCOLORATION; GREEN, MILD		1 (2.5%) [1]		1 (3.8%) [1]
LEFT; DISCOLORATION; GREEN, MILD			1 (2.5%) [1]	
LEFT; DISCOLORATION; GREEN, MINIMAL				1 (3.8%) [1]
BILATERAL; ENLARGED; MILD		1 (2.5%) [1]		
BILATERAL; ENLARGED; MODERATE				1 (3.8%) [1]
LEFT; ENLARGED; MILD			1 (2.5%) [1]	
LEFT; ENLARGED; MINIMAL				1 (3.8%) [1]
OVARIES	(40)	(40)	(40)	(26)
LEFT; CYST; CLEAR, MILD	2 (5.0%) [2]	1 (2.5%) [1]		
BILATERAL; DISCOLORATION; BROWN, MODERATE			1 (2.5%) [1]	
BILATERAL; REDUCED IN SIZE; BROWN, MILD			1 (2.5%) [1]	
UTERUS	(40)	(40)	(40)	(26)
BILATERAL; DILATION; MILD			1 (2.5%) [1]	1 (3.8%) [1]
LEFT; DISCOLORATION; DARK, MILD	1 (2.5%) [1]			
BILATERAL; ENLARGED; MILD	1 (2.5%) [1]			
LEFT; NODULE; PALE		1 (2.5%) [1]		
VAGINA	(40)	(40)	(40)	(26)
HEMATOPOIETIC SYSTEM				
LYMPH NODE, MESENTERIC	(40)	(40)	(40)	(26)
ENLARGED; MARKED			1 (2.5%) [1]	
SPLEEN	(40)	(40)	(40)	(26)
ENLARGED; MODERATE			1 (2.5%) [1]	
NODULE			1 (2.5%) [1]	
THYMUS	(40)	(40)	(40)	(26)

Study Number: R88007B

Test Type: RACB

Route: Dosing in Feed

Species/Strain: Rat/Sprague-Dawley

PA46R: Summary of Gross Pathology with Litter Incidence

Test Compound: Butyl Paraben

CAS Number: 94-26-8

Date Report Requested: 12/04/2018

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Lab: RTI

F1 Female: F1c Parental Females

	Treatment Groups (ppm)			
	0	5000	15000	40000
INTEGUMENTARY SYSTEM				
MAMMARY GLANDS	(40)	(40)	(40)	(26)
AXILLARY; RIGHT; MASS; BROWN		1 (2.5%) [1]		
AXILLARY; RIGHT; MASS; FIRM		1 (2.5%) [1]		
AXILLARY; RIGHT; MASS			1 (2.5%) [1]	
CERVICAL; MASS			1 (2.5%) [1]	
RIGHT; INGUINAL; MASS; SOFT			1 (2.5%) [1]	
THORACIC; RIGHT; MASS; PINK		1 (2.5%) [1]		
SKIN	(40)	(40)	(40)	(26)
SUBCUTANEOUS; NECK; FLUID; MILD				1 (3.8%) [1]
MANDIBULAR; SUBCUTANEOUS; LESION; GREEN, MINIMAL		1 (2.5%) [1]		
SKIN, MAMMARY	(40)	(40)	(40)	(26)
ABDOMINAL; RIGHT; FIRM	1 (2.5%) [1]			
MASS	1 (2.5%) [1]			
INGUINAL; LEFT; THICKENED	1 (2.5%) [1]			
LYMPHOID SYSTEM				
None				
MUSCULOSKELETAL SYSTEM				
LIMB	(40)	(40)	(40)	(26)
FORELIMB; LEFT; SWELLING	1 (2.5%) [1]			
PAW	(40)	(40)	(40)	(26)
FORELIMB; LEFT; SWELLING	1 (2.5%) [1]			
NERVOUS SYSTEM				
BRAIN	(40)	(40)	(40)	(26)

F1 Female: F1c Parental Females				
	Treatment Groups (ppm)			
	0	5000	15000	40000
RESPIRATORY SYSTEM				
None				
SPECIAL SENSES SYSTEM				
EYES	(40)	(40)	(40)	(26)
BILATERAL; DISCHARGE; MINIMAL, RED	1 (2.5%) [1]			
URINARY SYSTEM				
KIDNEYS	(40)	(40)	(40)	(26)
RIGHT; DEFORMITY; MINIMAL		1 (2.5%) [1]	1 (2.5%) [1]	
RIGHT; PELVIS; DILATION; MILD			1 (2.5%) [1]	
NODULE			1 (2.5%) [1]	

F2 Male				
	Treatment Groups (ppm)			
	0	5000	15000	40000
Disposition Summary				
Animals Initially In Study	121	133	130	97
Early Deaths				
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 21)	121	133	130	97
Number of Animals Examined	121	133	130	97
Total number litters	27	30	29	24
ALIMENTARY SYSTEM				
None				
CARDIOVASCULAR SYSTEM				
None				
ENDOCRINE SYSTEM				
None				
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
TESTES	(121)	(133)	(130)	(97)
LEFT; MISSING; MARKED		1 (0.8%) [1]		
BILATERAL; REDUCED IN SIZE; MILD	1 (0.8%) [1]			
RIGHT; REDUCED IN SIZE; MODERATE		1 (0.8%) [1]		
LEFT; UNDESCENDED; MILD	2 (1.7%) [1]	1 (0.8%) [1]	1 (0.8%) [1]	2 (2.1%) [2]
LEFT; UNDESCENDED				1 (1.0%) [1]

F2 Male				
Treatment Groups (ppm)				
	0	5000	15000	40000
HEMATOPOIETIC SYSTEM				
None				
INTEGUMENTARY SYSTEM				
None				
LYMPHOID SYSTEM				
None				
MUSCULOSKELETAL SYSTEM				
None				
NERVOUS SYSTEM				
None				
RESPIRATORY SYSTEM				
None				
SPECIAL SENSES SYSTEM				
None				
URINARY SYSTEM				
None				

F2 Female				
	Treatment Groups (ppm)			
	0	5000	15000	40000
Disposition Summary				
Animals Initially In Study	117	132	114	79
Early Deaths				
Scheduled Deaths				
Scheduled sacrifice, terminal (PND 21)	117	132	114	79
Number of Animals Examined	117	132	114	79
Total number litters	25	28	29	22
ALIMENTARY SYSTEM				
None				
CARDIOVASCULAR SYSTEM				
None				
ENDOCRINE SYSTEM				
None				
GENERAL BODY SYSTEM				
None				
GENITAL SYSTEM				
None				
HEMATOPOIETIC SYSTEM				
None				
INTEGUMENTARY SYSTEM				
None				

F2 Female				
	Treatment Groups (ppm)			
	0	5000	15000	40000
LYMPHOID SYSTEM				
None				
MUSCULOSKELETAL SYSTEM				
None				
NERVOUS SYSTEM				
NERVE, OPTIC	(117)	(132)	(114)	(79)
REDUCED IN SIZE; MODERATE			1 (0.9%) [1]	
RESPIRATORY SYSTEM				
None				
SPECIAL SENSES SYSTEM				
EYES	(117)	(132)	(114)	(79)
BILATERAL; MISSING; MODERATE			1 (0.9%) [1]	
URINARY SYSTEM				
None				

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

PA46R: Summary of Gross Pathology with Litter Incidence
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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. The exception to this is if statistical analysis is performed for a lesion and the control group has no animals with the lesion then a 0 is included for the control group on the table for that lesion.

Number (percent) of animals affected given for each observation

Number of litters shown in square brackets for F1 and F2 animals

Statistical analysis for the F0 animals was performed by Cochran-Armitage test with poly-3 adjustment for both trend and pairwise tests.

Statistical analysis for the F1 Non-parental and F2 animals was performed by Cochran-Armitage test with a Rao-Scott modification for the random effect due to litter.

Statistical analysis for the F1 Parental animals was performed by Cochran-Armitage test with a poly-3 adjustment for age and a Rao-Scott modification for the random effect due to litter.

Statistical significance for the control group indicates a significant trend test

Statistical significance for a treatment group indicates a significant pairwise test compared to the vehicle control group

* Statistically significant at $P \leq 0.05$

** Statistically significant at $P \leq 0.01$

All trend and pairwise p-values are reported as one-sided.

Non-pregnant females from the F0 and F1 generations are included in the analysis.

SD – Study Day; GD – Gestation Day; LD – Lactation Day; PND – Postnatal Day, adults post-weaning

**** END OF REPORT ****